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# federal register



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# Rules and Regulations

Federal Register

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

## FEDERAL RESERVE SYSTEM

### 12 CFR Part 265

[Docket No. R-0746]

#### Delegation of Authority to the General Counsel and Director of the Board's Division of Banking Supervision and Regulation

**AGENCY:** Board of Governors of the Federal Reserve System.

**ACTION:** Final rule.

**SUMMARY:** Pursuant to sections 11(i) and (k) of the Federal Reserve Act (12 U.S.C. 248(i) and (k)), the Board is amending its Rules Regarding Delegation of Authority (12 CFR part 265). The amendment expands the duties delegated to the General Counsel and the Director of the Board's Division of Banking Supervision and Regulation to include the authority to enter into, stay, modify, terminate or suspend a cease-and-desist order, removal and prohibition order, or civil money penalty assessment order, when the order has been consented to by the institution or individual subject to the order. The Board believes that the Federal Reserve's enforcement functions can be made more efficient and responsive by delegating this authority.

**EFFECTIVE DATE:** February 28, 1992.

**FOR FURTHER INFORMATION CONTACT:** Gregory A. Baer, Attorney (202/452-3236), Legal Division, Board of Governors of the Federal Reserve System. For the hearing impaired *only*, Telecommunication Device for the Deaf (TDD), Dorothea Thompson (202/452-3544), Board of Governors of the Federal Reserve System, 20th and C Streets, NW., Washington, DC 20551.

**SUPPLEMENTARY INFORMATION:** Section 11(k) of the Federal Reserve Act provides that the Board may delegate any of its functions, other than those related to rulemaking or pertaining

principally to monetary and credit policies. Section 11(i) authorizes the Board to make regulations necessary to enable the Board to perform its duties effectively. Pursuant to this authority, the Board is amending its Rules Regarding Delegation of Authority (12 CFR part 265).

In order to address unsafe and unsound banking practices and violations of the statutes, rules and regulations under its jurisdiction, the Federal Reserve undertakes formal enforcement actions against financial institutions and the individuals associated with them. Over the past two years, the Federal Reserve has issued or executed approximately 150 enforcement orders and written agreements, the great majority of which were consented to by the person subject to the order or agreement. The number of such actions is expected to grow in the future.

The Board is proposing an expansion of the powers delegated to the General Counsel and the Director of the Division of Banking Supervision and Regulation. Specifically, the Board is proposing to grant joint authority to the General Counsel and the Director to enter into, stay, modify, terminate or suspend cease-and-desist, removal and prohibition, and civil money penalty assessment orders when they have been consented to by the institutions or individuals subject to the orders. The Board believes that the Federal Reserve's enforcement functions can be made more efficient and responsive by delegating this authority. The Board would retain its approval authority over all contested enforcement actions and enforcement actions involving the issuance of temporary cease-and-desist orders and suspension orders.

The provisions of section 553 of title 5, United States Code, relating to notice, public participation, and deferred effective date have not been followed in connection with the adoption of this amendment because the change to be effected is procedural in nature and does not constitute a substantive rule subject to the requirements of that section. The Board's expanded rulemaking procedures have not been followed because the amendment is a technical, procedural one.

## List of Subjects in 12 CFR Part 265

Authority delegations (Government agencies), Federal Reserve System.

For the reasons outlined above, the Board of Governors is amending 12 CFR part 265 as set forth below:

### PART 265—RULES REGARDING DELEGATION OF AUTHORITY

1. The authority citation for 12 CFR part 265 continues to read as follows:

**Authority:** Section 11 (i) and (k) of the Federal Reserve Act (12 U.S.C. 248 (i) and (k)).

2. Section 265.6 is amended by republishing the introductory text and adding paragraph (e) to read as follows:

#### § 265.6 Functions delegated to General Counsel.

The Board's general counsel (or the general counsel's delegee) is authorized:

\* \* \* \* \*

(e) *Consent enforcement orders.* With the concurrence of the director of the Board's Division of Banking Supervision and Regulation (or the Director's delegee):

(1) To enter into a cease-and-desist order, removal and prohibition order, or civil money penalty assessment order with a bank holding company or any nonbanking subsidiary thereof, with a state member bank, or with any other person or entity subject to the Board's jurisdiction, when the order has been consented to by the institution or individual subject to the order;

(2) To stay, modify, terminate, or suspend an order issued pursuant to paragraph (e)(1) of this section.

By order of the Board of Governors of the Federal Reserve System, February 14, 1992.

Jennifer J. Johnson,

*Associate Secretary of the Board.*

[FR Doc. 92-4546 Filed 2-27-92; 8:45 am]

BILLING CODE 6210-01-M

## DEPARTMENT OF TRANSPORTATION

### Coast Guard

#### 33 CFR Part 165

[CGD1 92-008]

**Safety Zone Regulations: Kill Van Kull, New York and New Jersey**

**AGENCY:** Coast Guard, DOT.

**ACTION:** Temporary Final Rule.

**SUMMARY:** The Coast Guard is establishing a safety zone in the waters of Bergen Point West Reach in the Kill Van Kull of New York and New Jersey. This zone will divide a portion of the channel at Bergen Point West Reach into two sections, a northern half and a southern half. In the northern half, concentrated drilling and blasting will be conducted and no vessel is permitted to transit that section. In the southern half, vessel passage is permitted under the criteria set forth in this regulation. This action is necessary to protect the maritime community from the possible dangers and hazards to navigation associated with the extensive blasting and dredging operations which are being conducted in the northern half of this section of the channel.

**EFFECTIVE DATE:** This regulation becomes effective at 6 a.m., February 13, 1992. It terminates at 12 a.m., August 10, 1992, unless terminated sooner by Captain of the Port NY (COTP NY).

**FOR FURTHER INFORMATION CONTACT:** MST1 S. Whinham of Captain of the Port, New York (212) 668-7934.

**SUPPLEMENTARY INFORMATION:****Drafting Information**

The drafters of this notice are LTJG J.E. Peschel, Project Officer, Captain of the Port, New York and LCDR J. Astley, Project Attorney, First Coast Guard District, Legal Office.

**Regulatory History**

Pursuant to 5 U.S.C. 553, a notice of proposed rulemaking was not published for this regulation and good cause exists for making it effective in less than 30 days after Federal Register publication. Publishing an NPRM and delaying its effective date would be contrary to the public interest since immediate action is needed to respond to any potential hazards. The request for this zone was not received until February 12, 1992. Therefore, there was not sufficient time to publish proposed rules in advance of the event or to provide for a delayed effective date.

On August 8, 1991 this office submitted for publication a final rule which would impose a regulated navigation area (RNA) over the entire Kill Van Kull for the duration of a three year deepening project which is occurring throughout the Kill. When that rule is published it will appear as Part 165.165 of this Title (CGD1 89-085). As that rule has not been made effective yet this action is necessary to safeguard users of this waterway from the hazards involved with this ongoing project. This regulation is necessary, as an interim

measure, to adequately ensure vessel safety in the affected area until the RNA is published and becomes effective.

**Background and Purpose**

In August 1991, the Army Corps of Engineers (A.C.O.E.) and the Port Authorities of New York and New Jersey commenced an extensive channel deepening project in the Kill Van Kull and the Bergen Point area. This project reduces the available channel width by one half in the area of the worksite, from approximately 800 feet to 400 feet for the duration of the project.

In order to minimize the burden on the maritime community during this important and necessary dredging operation, the project is divided into phases. During each phase, blasting and dredging operations occur in only a small portion of the navigable channel. Limiting the size of the work area allows vessels to continue navigating the waterway with few, if any, restrictions, while providing the necessary level of safety and allowing the A.C.O.E. to complete the project without undue delay.

Since August, the work area has shifted westward along Bergen Point Reach toward Shooters Island. Each time the work area moved, the Coast Guard established a safety zone around the work site. These safety zones were narrowly tailored to provide an adequate level of safety to vessels transiting the area while minimizing the restrictions imposed on vessel operations. In addition, throughout the blasting and dredging project the Coast Guard has consulted with the port community and kept them apprised of developments.

On February 12, 1992 the A.C.O.E. advised COTP NY that the previous work area as published in the Federal Register of January 10, 1991 had been completed and that the depths had been certified. The safety zone around that area is cancelled upon the effective date and time of this new regulation. The new safety zone is temporary in nature, and will be in effect less than six months. It provides the minimum level of safety needed to protect users of the waterway from the dangers and hazards associated with the dredging and blasting operation while navigating in a heavily trafficked area.

This regulation is issued pursuant to 33 U.S.C. 1225 and 1231 as set out in the authority citation for all of Part 165.

**Regulatory Evaluation**

These regulations are not major under Executive Order 12291 and not significant under Department of Transportation Regulatory Policies and

Procedures (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this proposal to be so minimal that a Regulatory Evaluation is unnecessary.

**Small Entities**

Because it expects the impact of this regulation to be minimal, the Coast Guard certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that this final rule will not have a significant economic impact on a substantial number of small entities.

**Collection of Information**

This rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

**Federalism**

The Coast Guard has analyzed this action in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that these regulations do not raise sufficient federalism implications to warrant the preparation of a Federalism Assessment.

**Environment**

The Coast Guard has considered the environmental impact of these regulations and concluded that under section 2.B.2.c. of Commandant Instruction M16475.1B, they will have no significant impact and they are categorically excluded from further environmental documentation.

**List of Subjects in 33 CFR Part 165**

Harbors, Marine safety, Navigation (water), Security measures, Vessels, Waterways.

**Regulation**

In consideration of the foregoing, part 165 of title 33, Code of Federal Regulations, is amended as follows:

**PART 165—[AMENDED]**

1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 USC 1225 and 1231; 50 USC 191; 49 CFR 1.46 and 33 CFR 1.05-1(g), 6.04-1, 6.04-6 and 33 CFR 160.5.

2. A new 165.T 01-008 is added to read as follows:

**§ 165.T 01-008 Safety Zone: Bergen Point West Reach, Kill Van Kull—New York and New Jersey.**

(a) *Location.* The following area has been declared a Safety Zone: All waters of Bergen Point West Reach in the Kill Van Kull Channel, west of a line drawn shore to shore along the 074°08'41.8"W

line of longitude, and east of a line drawn north from Staten Island along the 074°08'56.6"W line of longitude to a point at 40°38'39"N 074°08'56.6"W and thence east to shore at Bergen Point at 40°38'39"N 074°08'41.8"W. KVK Channel Light Buoy 14 (LLNR 34565) has been initially relocated in approximate position 40°38'28.99"N 074°08'42.22"W, and KVK Channel Light Buoy 14A (NO LLNR) will initially be located in approximate position 40°38'30.342"N 074°08'56.197"W to indicate the eastern and western boundaries, respectively, of this zone.

(b) *Effective date.* This regulation becomes effective at 6 a.m., February 13, 1992. It terminates at 12 a.m., August 10, 1992, unless terminated sooner by COTP NY.

(c) *Regulations.* (1) Northern half of channel: No vessel may operate in the northern half of the channel within this

zone. In accordance with the general regulations in § 165.23 of this part, entry into or movement within this area of the safety zone is prohibited unless authorized by the Captain of the Port.

(2) Southern half of channel: (i) Each vessel transiting the southern half of the channel in this zone is required to do so at minimum wake speed.

(ii) No vessel shall enter this zone when they are advised by the drilling barge or Vessel Traffic Service New York (VTSNY) that a misfire or hangfire has occurred. Vessels already underway in the zone shall proceed to clear the area immediately.

(iii) Vessels, 300 gross tons or greater and tugs with tows, are prohibited from meeting or overtaking in this portion of the channel.

(iv) Vessels, 300 gross tons or greater and tugs with tows, transiting with the

prevailing current are regarded as the stand-on vessel.

(v) Prior to entering this safety zone, the master, pilot or operator of each vessel, 300 gross tons or greater and tugs with tows, shall notify VTSNY as to their decision regarding the employment of assist tugs and intentions while transiting the safety zone.

(vi) For vessels towing astern, hawser or wire length must not exceed 100 feet for that tow. This length is measured from the towing bit on the towing vessel to the point where the hawser or wire connects with the vessel being towed.

Dated: February 12, 1992.

R.M. Larrabee,

*Captain, U.S. Coast Guard, Captain of the Port, New York.*

[FR Doc. 92-4642 Filed 2-27-92; 8:45 am]

BILLING CODE 4910-14-M

# Proposed Rules

Federal Register

Vol. 57, No. 40

Friday, February 28, 1992

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## DEPARTMENT OF TRANSPORTATION

### Coast Guard

#### 33 CFR Part 155

[CGD 91-034/90-068]

RIN 2115-AE81 and 66

### Vessel Response Plans and Carriage and Inspection of Discharge-Removal Equipment

AGENCY: Coast Guard, DOT.

ACTION: Notice of meetings of the Oil Spill Response Plan Negotiated Rulemaking Committee; correction.

**SUMMARY:** The Coast Guard is correcting the schedule of meeting dates for the Oil Spill Response Plan Negotiated Rulemaking Committee published January 16, 1992. The committee has decided to cancel the meeting previously scheduled for February 27, 1992 and schedule a new meeting on March 10, 1992.

**DATES:** The corrected schedule of meetings of the negotiated rulemaking committee is as follows: February 28, 1992 and March 10, 1992 as well as March 11-13 if the workload requires. The meetings will be held between 8:30 a.m. and 5 p.m., except the March 10th meeting will begin at 9 a.m.

**ADDRESSES:** The meetings will be held in room 8236 on February 28, 1992 and in room 4234 on March 10-13, 1992 at DOT Headquarters, 400 Seventh Street SW., Washington, DC 20590.

**FOR FURTHER INFORMATION CONTACT:** For information contact Lieutenant Commander Glenn Wiltshire, OPA 90 Staff (G-MS-1), at (202) 267-6739 between 7 a.m. and 3:30 p.m., Monday through Friday, except federal holidays.

**SUPPLEMENTARY INFORMATION:** In a previous notice in the Federal Register (57 FR 1890, January 16, 1992), the Coast Guard announced a meeting schedule for the Oil Spill Response Plan Negotiated Rulemaking Committee. At their last meeting on February 13, 1992, the committee decided to cancel the

meeting scheduled for February 27th and to meet on March 10th and, if necessary, on March 11th, 12th, and 13th. The next meeting of the committee is being held on February 28, 1992. All committee meetings will be open to the public, subject to space availability.

Dated: February 24, 1992.

R.C. North,

*Captain, U.S. Coast Guard, Acting Chief, Office of Marine Safety, Security and Environmental Protection.*

[FR Doc. 92-4643 Filed 2-27-92; 8:45 am]

BILLING CODE 4910-14-M

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 76

[MM Docket No. 82-434, DA 92-218]

### Network-Cable Cross-Ownership

AGENCY: Federal Communications Commission.

ACTION: Proposed rule, Order extending time.

**SUMMARY:** By this action, the Commission extends the deadlines for filing comments and reply comments to the *Second Further Notice of Proposed Rulemaking* in MM Docket No. 82-434, 57 FR 868 (January 9, 1992). This *Notice* seeks to update the record on our proposal to eliminate § 76.501(a)(1) of the Commission's rules, which prohibits common ownership of cable television systems and national television networks. Capital Cities/ABC, Inc. (Capital Cities/ABC) requested a 30-day extension of time to file comments and reply comments in this proceeding. The Commission is not persuaded that 30 additional days are required, although we do agree that some additional time should be allowed. Therefore, we will grant the motion in part and extend the deadlines for filing initial and reply comments by 20 days.

**DATES:** Comments are due on or before March 23, 1992 and reply comments are due on or before April 7, 1992.

**FOR FURTHER INFORMATION CONTACT:** James Coltharp, Policy and Rules Division, Mass Media Bureau, (202) 632-6302.

#### SUPPLEMENTARY INFORMATION:

In the Matter of Amendment of Part 76, Subpart J, Section 76.501 of the Commission's

Rules and Regulations to Eliminate the Prohibition on Common Ownership of Cable Television Systems and National Television Networks.

#### Order Granting Extension of Time

Adopted: February 21, 1992. Released: February 21, 1992.

By the Chief, Mass Media Bureau: 1. On December 30, 1991, the Commission released a Second Further Notice of Proposed Rulemaking in MM Docket No. 82-434, 7 FCC Rcd 586 (1991) (Second FNPRM), in order to seek further comment on our proposal to eliminate Section 76.501(a)(1) of our rules, which prohibits common ownership of cable television systems and national television networks. The Second FNPRM sought to update the record in this proceeding and also invited comment on options that would permit network ownership of cable systems subject to safeguards that address competition and diversity concerns. Accordingly, we established a deadline of March 2, 1992, for filing comments and a deadline of March 17, 1992, for filing reply comments.

2. Before the Commission is a motion for extension of time filed by Capital Cities/ABC, Inc. (Capital Cities/ABC) on February 18, 1992. The motion requests an extension of time to file comments until April 1, 1992, and reply comments until April 16, 1992.

3. Capital Cities/ABC requests an extension to permit Capital Cities/ABC, CBS, Inc., National Broadcasting Company, Inc., the Network Affiliated Stations Alliance, and the Association of Independent Television Stations to engage in further discussions to reach agreement about appropriate safeguards if networks are allowed to own local cable systems. All of the above-mentioned parties have agreed that a 30-day postponement in the comment dates for this proceeding would provide the needed opportunity for further discussion, and join in the motion.

4. As set forth in § 1.46 of our rules, 47 CFR 1.46, it is our policy that extensions of time not be routinely granted. In this case, however, some additional time will allow the interested parties to continue a constructive discussion of the possible safeguards pertaining to network-cable cross-ownership, which may encourage an agreement that could assist us in resolving several concerns raised by interested parties. At the same

time, we seek to proceed with this matter as expeditiously as possible, and are not persuaded that 30 additional days should be required for parties to conclude their discussions. Therefore, we will grant the motion in part and extend the deadlines for filing initial and reply comments by 20 days, respectively, to March 23, 1992, and April 7, 1992. We also note that we do not contemplate granting further extensions of time.

5. Accordingly, *It is Ordered* That the Motion for Extension of Time filed by Capital Cities/ABC IS GRANTED in Part, and the deadlines for filing comments and reply comments in this proceeding ARE EXTENDED to March 23, 1992, and April 7, 1992, respectively.

6. This action is taken pursuant to authority found in Sections 4(i) and 303(r) of the Communications Act of 1934, as amended, and Sections 0.204(b), 0.283, and 1.46 of the Commission's Rules.

7. For further information on this proceeding, contact James Coltharp, Policy and Rules Division, Mass Media Bureau, (202) 632-6302.

Federal Communications Commission.

Roy J. Stewart,

Chief, Mass Media Bureau.

[FR Doc. 92-4641 Filed 2-27-92; 8:45 am]

BILLING CODE 6712-01-M

## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

#### 49 CFR Part 391

[FHWA Docket No. MC-91-1]

RIN 2125-AC62

#### Qualifications of Drivers; Vision

**AGENCY:** Federal Highway Administration (FHWA), DOT.

**ACTION:** Advance notice of proposed rulemaking (ANPRM).

**SUMMARY:** The FHWA is requesting comments from interested parties on the need, if any, to amend its driver qualification requirements relating to the vision standard found at 49 CFR 391.41(b)(10). The vision standard sets forth minimum vision requirements for drivers of commercial motor vehicles (CMV) operating in interstate commerce. The FHWA believes that a review of the standard is necessary to assess the effect advances in medical science and technology may have on the standard. These advances may lead to amending the current standard, including the possibility of individual waivers, and

the accompanying examination guides that are provided to medical examiners.

**DATES:** Written comments must be received on or before April 28, 1992.

**ADDRESSES:** Submit written, signed comments to FHWA Docket No. MC-91-1, room 4232, HCC-10, Office of the Chief Counsel, Federal Highway Administration, 400 Seventh Street SW., Washington, DC 20590. Commenters may, in addition to submitting "hard copies" of their comments, submit a floppy disk in standard or high density formats containing data compatible with either WordPerfect or WordStar for IBM systems or Microsoft Word or WordPerfect or WordStar for Apple Macintosh systems. Commenters should clearly label submitted disks with the software format used (e.g., WordPerfect 5.0 [IBM] or Microsoft Word 4.0 [Mac]). All comments received will be available for examination at the above address from 8:30 a.m. to 3:30 p.m., e.t., Monday through Friday, except legal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard.

**FOR FURTHER INFORMATION CONTACT:** Ms. Eliane Viner, (202) 366-2981, Office of Motor Carrier Standards, or Mr. Raymond W. Cuprill, Office of the Chief Counsel (202) 366-0834, Federal Highway Administration, Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except legal holidays.

#### SUPPLEMENTARY INFORMATION:

##### Background—Authority

The FHWA is authorized by statute to establish minimum driver qualification requirements for drivers of commercial motor vehicles in interstate commerce. This authority was originally granted to the Interstate Commerce Commission in the Motor Carrier Act of 1935, now codified in relevant part at 49 U.S.C. 3102 (1988). The authority was transferred to the DOT in 1966 with enactment of the Department of Transportation Act.

In 1984, the Congress further directed the Secretary to establish minimum safety standards to ensure that "the physical condition of operators of commercial motor vehicles is adequate to enable them to operate such vehicles safely \* \* \*." 49 U.S.C. App. 2505 (1988).

The FHWA's first concern is to enhance safety on the Nation's highways. The FHWA's rules are designed to protect the general public. However, it is not FHWA's policy to unnecessarily limit the employment opportunities of individuals with disabilities. The FHWA is concerned

that its physical qualification requirements be based on sound medical, scientific, and technological grounds, and that individual determination be made to the maximum extent possible consistent with the FHWA's responsibility to ensure commercial motor vehicles are operated safely.

Several congressional committee reports accompanying the Americans with Disabilities Act of 1990 (42 U.S.C. 12101, Pub. L. 101-336, 104 Stat. 327) expressly state that, while the committees expect persons who wish to drive CMVs to meet FHWA's minimum physical qualification standards, the committees also expect the FHWA to review its standards in light of the ADA within 2 years. See H. Rep. 101-596, 101st Cong., 2d Sess. 60-61 (1990) (conference report); H. Rep. 101-485, Part 2, 101st Cong., 2d Sess. 57 (1990) (House Committee on Education and Labor); H. Rep. 101-458, Part 3, 101st Cong., 2d Sess. 34 (1990) (House Committee on the Judiciary); S. Rep. 101-116, 101st Cong., 1st Sess. 27-28 (1989) (Senate Committee on Labor and Human Resources). This ANPRM is part of that review with respect to the vision standard. This review also is being conducted in light of Section 504 of the Rehabilitation Act of 1973, as amended.

#### Current Standard

The current vision standard is found at 49 CFR 391.41(b)(10) and provides:

A person is physically qualified to drive a [commercial] motor vehicle if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of at least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing standard red, green, and amber.

#### Regulatory History

The first Federal vision standard appeared in 1937 when the Federal Motor Carrier Safety Regulations (FMCSRs) required "good eyesight in both eyes (either without glasses or by correction with glasses), including adequate perception of red and green colors."

In 1939, the vision standard was changed to require "visual acuity (either without glasses or by correction with glasses) of not less than 20/40 (Snellen) in one eye, and 20/100 (Snellen) in the other eye; form field of not less than 45 degrees in all meridians from the point

of fixation; ability to distinguish red, green, and yellow."

In 1952, the vision standard was strengthened to require "visual acuity of not less than 20/40 (Snellen) in each eye, whether without glasses or by correction."

In 1964, the vision standard was revised to add "form field of vision in the horizontal meridian shall not be less than a total of 140 degrees; ability to distinguish colors red, green and yellow; drivers requiring glasses shall wear properly-prescribed glasses at all times when driving."

Effective January 1, 1971, physical qualifications for drivers in § 391.41 were "revised in the light of discussions with the Administration's medical advisers." 35 FR 78. Among the amendments, a provision under § 391.41(b)(10) required a driver to have distant binocular acuity of not less than 20/40 (Snellen) with or without corrective lenses; field of vision of at least 70 degrees in the horizontal meridian in each eye; ability to recognize the colors of traffic signals and devices showing standard red, green, and amber.

The current rule has remained unchanged since 1971. Since that time, several studies have been conducted addressing the role vision plays in driving motor vehicles, including commercial motor vehicles. The following studies have been reviewed by the FHWA and copies have been placed in the docket for public review.

1. Henderson, R. L., and Burg, Albert. Published by System Development Corp., Santa Monica, CA. "The Role of Vision and Audition in Truck and Bus Driving." Dec. 1973, TM-(L)-5260/000/00. A systematic analysis was made of the visual requirements of CMV driving, based upon a review of the scientific literature, a detailed examination of the driving task, and observations of and interviews with qualified drivers. As a result of this analysis, new visual performance measures dealing with perception of motion and dynamic performance of the total visual system were identified as important to driving. A device was designed and constructed that provided the capability of testing performance on these new visual performance parameters as well as on selected conventional measures.

Performance on these vision tests was measured on 236 CMV drivers and compared with past accident records. The results show that visual performance measures identified analytically were also shown experimentally to be related to accident involvement. However, the limited size of the sample of truck and bus drivers

on which experimental data were collected prevents generalization of the findings to the entire population of commercial carrier drivers and precludes the generation of qualification standards. Moreover, the term "poor driving record" is used in this study to denote an accident rate higher than that experienced by other drivers. Again, the study does not distinguish at-fault from other accidents, or accidents in which limited vision may have played a role from others.

2. Bartow Associates, Inc., "The Monocular Driver: A Review of Distant Visual Acuity Risk Analysis Data," Sept. 1982, DTFH61-82-F-30050. This study concludes that there is no positive relationship between accident rate and static visual acuity for drivers under age 54 and only a weak relationship for those over 60. The empirical support for the importance of visual field for safe driving is tenuous at best. Drivers with visual disabilities appear to have a higher proportion of side accidents. Whether the apparent blind side risk for the monocular driver is substantially higher than that of the general population is not conclusively shown. Potentially spurious relationships, small sample sizes, lack of controls, and the potential dominance of other variables reduces the validity of much of the past research. No correlation exists between defective stereoscopic vision and accident rates. Adequate monocular cues appear to exist for depth perception by an attentive driver during the day. Little research has been done on depth perception at night. The oscillatory nature of eye movement while driving and the attendant head and vehicle motion preclude consideration of a blind spot as an important issue in monocular driving. Early allegations that one-eyed drivers are unable to grasp an emergency situation quickly are not founded based on any measures of the probable increment in perception time needed by the monocular driver.

In several studies, including one on 14,000 drivers, the most consistent result was a failure to find a direct relationship between poor static visual acuity performance and high accident rates for young and middle-aged drivers. There appeared to be no consistent relationship between glare sensitivity or glare recovery time and measures of accident involvement. There also did not appear to be any difference in the glare recovery ability between monocular and binocular conditions. No substantive research was found comparing the night driving ability of monocular to binocular drivers.

3. McKnight, A. J., Shinar, D., Hilburn, B., National Public Services Research Institute, 1985, DTFH61-83-C-00134. "Visual Tasks Driving Analysis of Monocular Versus Binocular Heavy Duty Truckers." This study compared the performance of 40 monocular and 40 binocular tractor-trailer drivers on measures of both visual and driving performance. On the visual measures, the monocular drivers were deficient in contrast sensitivity, visual acuity under low illumination and glare, and binocular depth perception. They were not deficient in static or dynamic visual acuity, visual field or individual eye, or glare recovery.

Measures of visual search, lane keeping, clearance judgment, gap judgment, hazard detection, and information interpretation showed no differences between monocular and binocular drivers. The only driving measure in which monocular drivers showed evidence of decrement was the distance at which signs could be read in both daytime and nighttime driving. This decrement correlated significantly with the binocular depth perception measure.

It was concluded that monocular and binocular drivers show significant differences in the ability to see clearly and certain driving functions dependent on this ability, and do not show differences in the safety of day-to-day driving.

4. Janke, M.K., California Dept. of Motor Vehicles, 1986. "The Relation Between Vision Test Performance and Accidents." This study states that "evidence continues to accumulate that there is a weak, but statistically significant, relationship between vision measures and accident involvement. A study of 10,000 volunteer subjects "found that drivers showing visual field loss in both eyes had three-year prior accident and conviction rates (per 100,000 miles) that were twice as high as those of age- and sex-matched control group with normal visual fields. This finding was highly significant statistically."

The study suggests that a special battery of vision tests could be used as a diagnostic tool in the case of drivers whose record indicates the possible existence of a vision problem. Vision tests can be used as feedback mechanisms rather than, or as well as, licensure screening devices. Thus they can alert drivers to visual deficiencies they are not aware of, and motivate them to seek correction of their defects. No known attempt has ever been made rigorously to establish the existence of this possible beneficial effect. The State

of California continues to grant waivers to drivers with visual impairment.

5. Rogers, Partrice N., Ratz, Michael, and Janke, Mary K., "Accident and Conviction Rates of Visually Impaired Heavy-Duty Operators," Jan. 1987, DTFH-81-85-00114. This study compared two-year accident and conviction rates of visually impaired heavy-vehicle operators (with class 1 and 2 licensure) to those of a sample of visually non-impaired heavy-vehicle operators. Non-impaired drivers met current federal acuity standards (corrected acuity of 20/40 or better in both eyes) while impaired drivers had substandard static acuity and were assessed within either moderately (corrected acuity between 20/40 and 20/200 in the worse eye, 20/40 or better in the other) or severely (corrected acuity worse than 20/200 Snellen in the worse eye) impaired subgroups. Total mileage estimates for Class 1 and Class 2 drivers obtained in a mailed questionnaire did not differ significantly between impairment groups. However, other potential bias issues remained and are discussed. "Visually impaired drivers had a significantly higher incidence of total accidents (37.15% more) \* \* \* and \* \* \* convictions (48.38% more) \* \* \* than did the non-impaired drivers." The severely impaired drivers had directionally worse records than did the moderately impaired drivers on three of the four traffic safety measures. These findings lead to qualified support for the current federal standard, particularly regarding the severely impaired, with less support of its application regarding the moderately impaired heavy-vehicle operator.

This study does not distinguish between accidents in which the driver was at fault and others or between accidents in which a vision impairment may be relevant and those in which surely an impairment is not. Nor does the study provide a rationale for the relevance of conviction rates. These factors may limit the study's usefulness in resolving questions raised in the rulemaking.

As a concurrent effort with this ANPRM, the FHWA has awarded a research contract to Ketron, Inc., to study visual disorders and commercial motor vehicle drivers. The objectives of this study are to (1) reassess the basis for the visual disorder standards; (2) revise testing procedures, if necessary; (3) define what is an acceptable level of vision for CMV drivers; and (4) determine the risk associated with defining "acceptable" levels for visual capabilities such as visual acuity, field of vision, central vision, horizontal field

of vision, and color perception. On June 24, 1991, the contractor held a conference with vision experts from the visual sciences community, occupational health care professionals, motor carrier safety experts, and other representatives from the motor carrier industry to obtain their views on the vision standard for CMV drivers. A copy of the final report will be placed in the docket once the contractor submits it to the FHWA. Disability groups and others are invited to comment on this report. The FHWA may undertake additional studies and analyses based on the information received in response to this ANPRM and the Ketron study.

The FHWA has received and denied numerous requests for waivers of the vision standard. Recently, the FHWA has received petitions for rulemaking to revise § 391.41(b)(10) and for waivers from this requirement. The FHWA has denied the petitions for individual waivers and accepted them as petitions for rulemaking.<sup>1</sup> The FHWA believes that rulemaking to review the vision standard and the possibility of individual waivers, generally, will better serve all affected persons.

#### *Request for Comments*

The FHWA requests comments from individuals, medical specialists, motor carriers, unions, driver organizations, motor carrier associations and all other interested parties. The FHWA is seeking technical and medical details on existing vision requirements for drivers, especially CMVs. The information should include, but not be limited to, recommended minimum standards, examination procedures (including who should be qualified to perform the examination), ophthalmological conditions which would adversely affect a person's ability to safely operate a CMV, potential criteria for individual waivers, and possible restrictions on driving (but not total prohibition) for persons with certain visual defects. The FHWA is also seeking information on advances made in the treatment and accommodation of individuals with vision impairment and/or loss, especially as it relates to the safe operation of a CMV. We are interested in receiving information on all aspects of the vision standard for CMV drivers (i.e., examination procedures, guidelines, consultations, documentation, limitations/restrictions, etc.). Additionally, information is requested concerning the potential costs, benefits and safety risks associated with

allowing persons with a vision impairment to drive CMVs. The FHWA is particularly interested in receiving responses to the following questions, although comments need not be limited to these questions. Commenters are urged to include scientific and medical data to support their comments.

1. Do the current standards reflect the current state of the art or knowledge in the visual sciences both in terms of methods of treatment/correction and public safety? Please explain.

2. If FHWA were to implement a vision waiver program what should be the minimum preconditions required of the driver, such as a physician's (ophthalmologist's) recommendation, driving experience, driving history and accident involvement, additional training, over-the-road driving test, and degree of vision deficiency (corrected)?

3. Should a driver who does not meet the 20/40 visual acuity standard in one eye (e.g., a monocular driver) be allowed to operate a CMV in interstate commerce? If "yes," should restrictions be placed upon such an individual? Should such a driver be allowed to operate a CMV laden with hazardous materials or transport passengers?

4. What diagnostic tests and/or evaluation procedures should be required? What are the most appropriate measuring and screening methods (e.g., Snellen test)?

5. Should the visual acuity standard of 20/40 be maintained for each eye separately, or should it be required for binocular acuity of at least 20/40 only?

6. The current standard calls for a field of vision of at least 70 degrees in each eye. Expert medical opinion states that the horizontal field of vision should be 120 degrees in each eye. The FHWA is interested in comments on the field of vision standard. Of particular interest is the effect such devices as mirrors would have on assisting persons with restricted field of vision.

7. What level of depth perception, if any, should be required for driving CMVs? When can a CMV driver no longer compensate for lack of "normal" depth perception?

8. What would be an acceptable level for visual acuity, field of vision, central vision, horizontal field of vision (including blind spots and missed points), and color perception for a CMV driver? Please address each item separately.

9. What vision-related medical evaluation procedures should be implemented and who should make the decision as to a CMV driver's medical qualification with regard to the vision standard? Should the examining

<sup>1</sup> Vision Petitions: Mr. Walter C. Boyles of Auburn, IN in August, 1990. Mr. Charles A. Smart of Worcester, MA in May, 1990.

physician make the certification decision based on the recommendation of an ophthalmologist or an optometrist? Should vision screening be conducted through the state driver license application programs?

10. What modifications can be made to CMVs to accommodate persons with impaired vision? How will such modifications help and what are their costs and effectiveness, and what are the risks?

11. Should an individual who has recently become monocular but has previously driven a CMV and has demonstrated safe operation of a CMV on the highway be allowed to continue operating a CMV? What criteria should be used to demonstrate safe operation? Does it make a difference whether the driver has been monocular from birth?

12. Are there mitigating factors that may reduce the risk associated with vision impairment?

13. What other medical conditions affecting vision or types of vision impairments should the FHWA vision standard address and what additional requirements, if any, should be incorporated?

14. Medical examinations are required to be performed at least every 24 months. Should there be a different time frame for recertification of a particular vision condition (e.g., glaucoma)? Should this recertification time requirement be set by the medical examiner or be specified by the FHWA in the regulation?

Commenters are not limited to responding to the above questions. They are encouraged to submit any facts or views relevant to the role of vision in the safe operation of CMVs.

#### **Rulemaking Analyses and Notices Executive Order 12291 (Federal Regulation) and DOT Regulatory Policies and Procedures**

The action being considered by the FHWA in this document would amend the physical qualification requirements for commercial motor vehicle drivers subject to the FMCSRs. The FHWA has not yet determined whether this document contains a major rule under Executive Order 12291. However, the FHWA considers this to be a significant regulation under the regulatory policies and procedures of the DOT because of the substantial public interest anticipated in this action. The potential economic impact of this rulemaking is not known at this stage. Therefore, a full regulatory evaluation has not yet been prepared.

#### **Regulatory Flexibility Act**

In compliance with the Regulatory Flexibility Act (Pub. L. 96-354), the agency will evaluate the effects of this proposal on small entities. Following the agency's evaluation, the FHWA will certify whether this proposed action will have a significant economic impact on a substantial number of small entities.

#### **Executive Order 12612 (Federalism Assessment)**

This action will be analyzed in accordance with the principles and criteria contained in Executive Order 12612 to determine whether it has sufficient federalism implications to warrant the preparation of a Federalism Assessment.

#### **Executive Order 12372 (Intergovernmental Review)**

Catalog of Federal Domestic Assistance Program Number 20.217,

Motor Carrier Safety. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.

#### **Paperwork Reduction Act**

This rule does not contain a collection of information requirement for purposes of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*

#### **National Environmental Policy Act**

The agency will analyze this action for the purpose of the National Environmental Policy Act of 1969 to determine whether this action will have any effect on the quality of the environment.

#### **Regulation Identification Number**

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

#### **List of Subjects in 49 CFR Part 391**

Driver qualifications, Highways and roads, Highway safety, Motor carriers, Motor vehicle safety.

**Authority:** 49 U.S.C. 3102; 49 U.S.C. App. 2505; 49 CFR 1.48.

**Issued on:** February 21, 1992.

**T.D. Larson,**  
*Administrator.*

[FR Doc. 92-4606 Filed 2-27-92; 8:45 am]

**BILLING CODE 4910-22-M**

# Notices

Federal Register

Vol. 57, No. 40

Friday, February 28, 1992

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

## DEPARTMENT OF AGRICULTURE

### Food Safety and Inspection Service

[Docket No. 92-004N]

#### National Advisory Committee on Microbiological Criteria for Foods; Meetings

Pursuant to the Federal Advisory Committee Act (5 U.S.C., appendix I), notice is hereby given that Subcommittee meetings of the National Advisory Committee on Microbiological Criteria for Foods, will be held on Monday through Thursday, March 16-19, 1992, and a plenary session of the Committee will be held on Friday, March 20, 1992, in Orlando, Florida, at the Orlando Airport Marriott Hotel, 7499 Augusta National Drive, Orlando, Florida, telephone (407) 851-9000. The Committee provides advice and recommendations to the Secretaries of Agriculture and Health and Human Services concerning the development of microbiological criteria by which the safety and wholesomeness of food can be assessed, including criteria for microorganisms that indicate whether foods have been produced using good manufacturing practices.

Scheduled sessions are as follows:

1. Monday, March 16, 1 p.m. to 4:30 p.m.—HACCP Subcommittee;
2. Tuesday and Wednesday, March 17-18, 8:30 a.m. to 4:30 p.m.—Concurrent sessions of the Meat and Poultry and Seafood Subcommittees;
3. Thursday, March 18, 8:30 a.m. to 4:30 p.m.—Open agenda; and
4. Friday, March 20, 8:30 a.m. to 4:30 p.m.—Plenary session of the National Advisory Committee on Microbiological Criteria for Foods.

The Committee meetings are open to the public on a space available basis. Comments of interested persons may be filed prior to the meeting in order that they may be considered and should be addressed to Ms. Linda Hayden,

Executive Secretariat, U.S. Department of Agriculture, Food Safety and Inspection Service, room 3175, South Agriculture Building, 14th and Independence Avenue SW., Washington, DC 20250. In submitting comments, please reference the docket number appearing in the heading of this notice. Background materials and copies of the agenda are available for inspection by contacting Ms. Hayden on (202) 720-9150.

Done at Washington, DC, on February 25, 1992.

H. Russell Cross,

Administrator, Food Safety and Inspection Service.

{FR Doc. 92-4703 Filed 2-27-92; 8:45 am}

BILLING CODE 3410-DM-M

### Forest Service

#### Wall Wolf/Indian Henry Timber Sale; Clearwater National Forest, Clearwater County, ID

AGENCY: Forest Service, USDA.

ACTION: Notice; Intent to prepare an environmental impact statement.

**SUMMARY:** The Forest Service will prepare an Environmental Impact Statement (EIS) to document the analysis and disclose the environmental impacts of proposed actions to harvest timber, build roads, and regenerate new stands of trees in the Upper Quartz Creek drainage, a tributary to the North Fork of the Clearwater River. The analysis area consists of approximately 16,670 acres. It is located approximately 50 air miles from Orofino, Idaho. Portions of the proposed action are located in the proposed Mallard-Larkins Roadless Area (#1300) and the Citizens Proposal for Roadless Areas.

The northern boundary of the study area follows Indian Henry Ridge from the ridge west of Wall Creek east to its junction with Pot Mountain Ridge. Pot Mountain Ridge forms the east and south boundary. The west boundary extends from the ridge west of Wolf Creek and Pot Mountain Ridge north to Quartz Creek, west down Quartz Creek and then north, up the ridge to the west of Wall Creek to its junction with Indian Henry Ridge.

**DATES:** Written comments concerning the scope of the analysis should be received within 45 days of the date of

publication of the Notice in the Federal Register. The Draft Environmental Impact Statement is expected to be filed with the Environmental Protection Agency in December 1992. The Final Environmental Impact Statement (EIS) and Record of Decision are expected to be completed in December 1993.

**ADDRESSES:** Written comments should be sent to Arthur S. Bourassa, District Ranger, North Fork Ranger District, P.O. Box 2139, Orofino, Idaho 83544.

**FOR FURTHER INFORMATION CONTACT:** Specific questions about the proposed action, analysis and EIS should be directed to Jennefer Waggoner, North Fork Ranger District, Phone: (208) 476-3775.

**SUPPLEMENTARY INFORMATION:** These management activities would be administered by the North Fork Ranger District, Clearwater National Forest, Clearwater County, Idaho. Because of the potential for significant impacts resulting from the proposed action (as defined by 40 CFR 1508.27) an Environmental Impact Statement will be prepared.

The proposed actions are consistent with the Forest Plan (September 1987) which provides the overall guidance (Goals, Standards and Guidelines, and Management Area direction) in achieving the desired future condition for this area. There are six management areas located within the study area. The purpose and goals for the proposed actions are specifically defined by these management areas and include:

**Management Area E1**—Provide an optimum, sustained production of wood products through harvests that fully realize site potential and result in healthy, vigorous stands.

**Management Area C3**—Provide winter range and thermal cover for elk on steep breaklands with south exposures supporting suitable browse stands.

**Management Area C4**—Provide sufficient winter forage and thermal cover for existing and projected big game populations while achieving timber production outputs.

**Management Area A4**—Travel corridors along designated roads and trails. Maintain or enhance natural scenic qualities and dispersed recreation. Modify big-game summer range and timber management to meet key values.

**Management Area M2**—Provide for the protection and enhancement of riparian dependent resources. Management activities can include timber harvest, grazing and recreation as long as these practices enhance and protect the riparian values.

**Management Area US**—Unsuitable for timber management. Includes nonforest and low productive forest lands incapable of producing crops of industrial wood and lands with apparent regeneration limitations. Manage for soil and watershed protection.

The analysis area encompasses the entire Upper Quartz Creek drainage. It includes all or part of sections 1, 12, and 13, T40N, R8E, BM; sections 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 14, 15, 16, 17, 21, 22, and 27 T40N, R9E, BM; sections 6 and 7, T40N, R10E; sections 24, 25, 26, 27, 28, 29, 31, 32, 33, 34, 35, and 36, T41N, R9E, BM; and sections 19, 30, and 31, T41N, R10E, BM. All but approximately 200 acres meets the RARE II criteria for roadless areas.

There are several smaller drainages in the upper Quartz Creek watershed. These are Wall Creek, Wolf Creek, Saddle Creek, Twin Cabin Creek, Indian Creek, Henry Creek and several unnamed drainages.

The North Fork Ranger District proposes to initiate regeneration harvest on approximately 1602 acres and construct approximately 10 miles of road. Specifically, the proposal includes 19 acres of seed tree harvest, 279 acres of shelterwood harvest, and 1304 acres of group selection harvest. Approximately 54% of the area to be harvested would require a skyline yarding system, and the other 46% would require helicopter yarding systems. The proposal also includes the construction of a connector road (3 miles) on Indian Henry ridge. The proposed harvest would generate approximately 10 million board feet of wood products.

Preliminary issues and concerns identified as a result of internal scoping and public comments received on the Integrated Resource Analysis include:

- The efficiency and cost-effectiveness of the timber sale.
- The need for alternative yarding procedures to effectively harvest on steep slopes.
- The effect of any management activity on the roadless character of the proposed Mallard-Larkins Roadless Area.
- Potential effect on threatened, endangered or sensitive species.
- The protection of watershed values—especially as this is a "Stream

Segment of Concern"—as they relate to fish productivity and riparian zones.

- The effect of any management activity on elk security.
- The effect of any management activity on dispersed recreation.
- The protection and continuity of old growth stands for viable populations of dependent species.
- The effect any management activity would have on the outfitter/guide.
- The cumulative effect of this activity and other activities in the area.
- Protection/enhancement of the visual resources.
- The ability to regenerate high elevation (> 5000') sites.
- The effect a connector road on Indian Henry Ridge would have on the roadless/wilderness charter, wildlife movement and security, and economics.

No meetings are scheduled, but letters, phone calls, or personal visits are invited for the purpose of providing information related to this proposal. This additional information will be used to prepare a Draft Environmental Impact Statement. This process will include:

1. Determination of significant issues.
2. Determination of potential cooperating agencies.
3. Identification and elimination from detailed study of nonsignificant issues, or issues that have been covered by previous environmental review.
4. Identification of reasonable alternatives to the proposed action.
5. Identification of potential environmental effects of the alternatives.

The analysis will consider a range of alternatives developed from the key issues. One of these will be the "No Action" alternative, in which all harvest and regeneration activities are deferred. Other alternatives will consider various levels and location of harvest and regeneration activities in response to issues and non-timber objectives.

Public participation is important all through the analysis process. Agencies and other interested publics are invited to visit with Forest Service officials at any time during the process. However, two specific time periods are identified for the receipt of formal comments on the analysis. They are: (1) during the scoping process (the next 45 days) and, (2) during the formal review period of the Draft EIS.

The comment period on the draft environmental impact statement will be 45 days from the date the Environmental Protection Agency publishes the notice of availability in the **Federal Register**.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the draft environmental

impact statement should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement.

Comments may also address the adequacy of the draft environmental impact statement or the merits of the alternatives formulated and discussed in the statement. (Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.)

The Forest Service believes it is important to give reviewers notice at this early stage of several court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 553 (1978). Also, environmental objections that could be raised at the draft environmental impact statement stage but that are not raised until after completion of the final environmental impact statement may be waived or dismissed by the courts. *Wisconsin Heritages, Inc. v. Harris*, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45-day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the final environmental impact statement.

The Final EIS is expected to be released December 31, 1993. The Forest Supervisor for the Clearwater National Forest who is the responsible official for the EIS will make a decision regarding this proposal considering the comments, responses, and environmental consequences discussed in the Final Environmental Impact Statement, and applicable laws regulations and policies. The reasons for the decision will be documented in a Record of Decision.

Dated: February 18, 1992.

**Bert Kulesza,**

*Deputy Forest Supervisor, Clearwater National Forest.*

[FR Doc. 92-4549 Filed 2-27-92; 8:45 am]

BILLING CODE 3410-11-M

**Fern Star Timber Sale; Clearwater National Forest, Clearwater County, ID****AGENCY:** Forest Service, USDA.**ACTION:** Notice; intent to prepare an environmental impact statement.

**SUMMARY:** The Forest Service will prepare an Environmental Impact Statement (EIS) to document the analysis and disclose the environmental impacts of proposed actions to harvest timber, build roads, and regenerate new stands of trees in the Isabella, Fern, Twin, and Nub Creek drainages, which are tributary to the North Fork of the Clearwater River. The analysis area is located approximately 50 air miles from Orofino, Idaho. The majority of the analysis area is located in the RARE II Mallard-Larkins Roadless Area (#1300) and in various citizens wilderness proposals.

The Fern Star analysis area is located east and north of the confluence of Isabella Creek and the North Fork of the Clearwater River. The analysis is comprised of 14,723 contiguous acres of public land administered by the North Fork Ranger District of the Clearwater National Forest. The analysis area is bounded on the north by the Mallard-Larkins Pioneer Area, on the south by the North Fork of the Clearwater River, on the west by Isabella Creek and Goat Ridge, and on the east by Skull Creek.

**DATES:** Written comments concerning the scope of the analysis should be received within 45 days of the date of publication of the Notice in the *Federal Register*. The Draft Environmental Impact Statement is expected to be filed with the Environmental Protection Agency in October, 1992. The Final Environmental Impact Statement (EIS) and Record of Decision are expected to be completed in June 1993.

**ADDRESSES:** Send written comments to Arthur S. Bourassa, District Ranger, North Fork Ranger District, P.O. Box 2139, Orofino, ID 83544.

**FOR FURTHER INFORMATION CONTACT:** Specific questions about the proposed action, analysis, and EIS should be directed to Jennefer Waggoner, Resource Analyst, or Arthur S. Bourassa, District Ranger, North Fork Ranger District, Clearwater National Forest, (208) 476-3775.

**SUPPLEMENTARY INFORMATION:** All management activities would be administered by the North Fork Ranger District of the Clearwater National Forest, Clearwater County, Idaho. Because of the potential for significant impacts resulting from the proposed action (as defined by 40 CFR 1508.27) an

Environmental Impact Statement will be prepared.

The proposed actions are consistent with the Forest Plan (September 1987) which provides the overall guidance (Goals, Standards and Guidelines, and Management Area direction) in achieving the desired future condition for this area. There are six management areas located within the study area. The purpose and goals for the proposed actions are specifically defined by these management areas and include:

**Management Area A4—Travel corridors** along designated roads and trails. Maintain or enhance natural scenic qualities and dispersed recreation. Modify big-game summer range and timber management to meet key values.

**Management Area C4—Provide** sufficient winter forage and thermal cover for existing and projected big game populations while achieving timber production outputs.

**Management Area E1—Provide** an optimum, sustained production of wood products through harvests that fully realize site potential and result in healthy, vigorous stands.

**Management Area E3—Manage** timber without or with very few limited and restricted roads utilizing long-line and aerial harvest methods. Develop trail systems for dispersed recreation where compatible with timber management. Provide maximum protection of soil and water values.

**Management Area M2—Provide** for the protection and enhancement of riparian dependent resources. Management activities can include timber harvest, grazing, and recreation as long as these practices enhance and protect the riparian values.

**Management Area U5—Unsuitable** for timber management. Includes nonforest and low productive forest lands incapable of producing crops of industrial wood and lands with apparent regeneration limitations. Manage for soil and watershed protection.

The analysis area encompasses all or portions of sections 1, 2, 3, 4, 5, and 6, T40N, R7E, BM; sections 4, 5, 6, 7, and 8, T40N, R8E, BM; sections 15, 16, 17, 18, 19, 20, 21, 22, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, and 36, T41N, R7E, BM; and sections 29, 30, 31, 32, 33, and 34, T41N, R8E, BM.

The North Fork Ranger District proposes to initiate regeneration harvest on approximately 2550 acres and construct approximately 11.2 miles of new road. Specifically, the proposal includes 1800 acres of clearcut harvest and 690 acres of shelterwood harvest. Approximately 53% of the area to be

harvested would require use of cable yarding systems and the other 47% would utilize helicopter yarding systems. The proposed harvest would generate approximately 87 million board feet of wood products.

Preliminary issues and concerns identified as a result scoping include:

- The effect of any management activities on the roadless character of the proposed Mallard-Larkins Roadless Area.
- Protection of the visual resources.
- The effects of the proposed activities on the outfitter/guide in the area.
- The protection and continuity of old growth stands for viable populations of dependent species.
- The effect of proposed activities on recreation users of the area.
- The effects of management practices on elk security.
- The protection of watershed values, fish productivity, and riparian zones.
- Potential effect on threatened, endangered, and sensitive species.
- The efficiency and cost-effectiveness of the timber sale.
- The effect of proposed practices on the stability of the steep slopes that characterize the area.

No meetings are scheduled, but letters, phone calls, or personal visits are invited for the purpose of providing information related to this proposal. This additional information will be used to prepare a Draft Environmental Impact Statement. This process will include:

1. Determination of significant issues.
2. Determination of potential cooperating agencies.
3. Identification and elimination from detailed study of nonsignificant issues, or issues that have been covered by previous environmental review.
4. Identification of reasonable alternatives to the proposed action.
5. Identification of potential environmental effects of the alternatives.

The analysis will consider a range of alternatives developed from the key issues. One of these will be the "No Action" alternative, in which all harvest and regeneration activities are deferred. Other alternatives will consider various levels and location of harvest and regeneration activities in response to issues and non-timber objectives.

Public participation is important all through the analysis process. Agencies and other interested publics are invited to visit with Forest Service officials at any time during the process. However, two specific time periods are identified for the receipt of formal comments on the analysis. They are: (1) During the

scoping process (the next 45 days) and, (2) During the formal review period of the Draft EIS.

The comment period on the draft environmental impact statement will be 45 days from date the Environmental Protection Agency publishes the notice of availability in the *Federal Register*.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the draft environmental impact statement should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement.

Comments may also address the adequacy of the draft environmental impact statement or the merits of the alternatives formulated and discussed in the statement. (Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.)

The Forest Service believes it is important to give reviewers notice at this early stage of several court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 553 (1978). Also, environmental objections that could be raised at the draft environmental impact statement stage but that are not raised until after completion of the final environmental impact statement may be waived or dismissed by the courts. *Wisconsin Heritages, Inc. v. Harris*, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45-day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the final environmental impact statement.

The Final EIS is expected to be released June 30, 1993. The Forest Supervisor for the Clearwater National Forest who is the responsible official for the EIS will make a decision regarding this proposal considering the comments, responses, and environmental consequences discussed in the Final Environmental Impact Statement, and applicable laws, regulations and policies. The reasons for the decision

will be documented in a Record of Decision.

Dated: February 18, 1992.

Bert Kulesza,  
Deputy Forest Supervisor, Clearwater  
National Forest.

[FR Doc. 92-4550 Filed 2-27-92; 8:45 am]

BILLING CODE 3410-11-M

### Stalf and Erskine Helicopter Sales; Sequoia National Forest, Kern County, CA; Intent To Prepare an Environmental Impact Statement

The Department of Agriculture, Forest Service will prepare an environmental impact statement for a proposal to harvest and regenerate timber on the Stalf and Erskine Helicopter Sales within the Greenhorn Ranger District. The Sequoia National Forest Land and Resource Management Plan has been prepared. One of the management emphases in the Plan is to manage for timber harvest and production on lands within the Piute East and West Compartments.

The alternatives to be considered will range from "No Action" to harvesting up to approximately 16 million board feet. The quantity of timber cut, road construction and reconstruction, as well as the physical, biological, economic, and social effects of project implementation will be analyzed within the context of the alternatives. Potential resource issues which may affect alternative development are clearcutting, visual quality, spotted owl habitat, maintaining biodiversity, reforestation, and furbearer habitat.

The U.S. Fish and Wildlife Service will be invited to participate as a cooperating agency to evaluate potential impacts on threatened and endangered species habitat if any such species are found to exist in the proposed timber sale areas. Federal, State, and local agencies, as well as industry; and other individuals or organizations who may be interested in or affected by the decision, will be invited to participate in the scoping process. This process will include:

1. Identification of potential issues and/or concerns.
2. Identification of issues to be analyzed in depth.
3. Elimination of insignificant issues or those which have been covered by a previous environmental review.

Scoping will be initiated during the winter of 1992, and will continue into the spring of 1992.

The analysis is expected to take approximately 9 months to complete. The draft EIS is expected to be filed with the Environmental Protection

Agency (EPA) and available for public review and comment by November 1992. EPA will publish a notice of availability for the draft EIS in the *Federal Register*. The comment period will be 45 days from the date of the EPA's published notice of availability. All persons interested in the proposed projects are urged to participate at that time. Comments on the draft EIS should be as specific as possible and may address the adequacy of the EIS or the merits of the alternatives considered. (See the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3.) In addition, Federal court decisions have established that reviewers of a draft EIS must structure their participation in the environmental review so that it is meaningful and alerts an agency to the reviewer's positions and contentions. *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 553 (1978). Environmental objections that could have been raised at the draft EIS review stage, but are not raised until after completion of the final EIS may be waived or dismissed by the courts. *City of Argoon v. Hodel*, 803 F. 2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc. v. Harris*, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in these proposed actions participate by the close of the 45-day comment period so that substantive comments and objections are made available to the Forest Service in a timely manner so the agency can respond to them in the final EIS. To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the draft EIS should be as specific as possible.

The final EIS is scheduled to be completed by February 1993. In the final EIS, the Forest Service is required to respond to comments received from the public and consulted agencies. The responsible official will consider the comments, responses, laws, regulations, and policies in making a decision regarding these project proposals. The responsible official will document the decision and reasons for the decision in the Record of Decision. That decision will be subject to appeal.

Philip H. Bayles, Acting Forest Supervisor, Sequoia National Forest, Porterville, CA, is the responsible official. Written comments, questions, and suggestions concerning the analysis should be sent to Linda Brett, District Ranger, Greenhorn Ranger District, P.O.

Box 6129, Bakersfield, California 93386  
(phone 805-871-2223).

Dated: February 21, 1992.

Philip H. Bayles,

Acting Forest Supervisor.

[FR Doc. 92-4548 Filed 2-27-92; 8:45 am]

BILLING CODE 3410-11-M

## DEPARTMENT OF COMMERCE

### International Trade Administration

[A-570-813]

#### Final Determination of Sales at Less Than Fair Value: Refined Antimony Trioxide From the People's Republic of China

**AGENCY:** Import Administration, International Trade Administration, Department of Commerce.

**EFFECTIVE DATE:** February 28, 1992.

**FOR FURTHER INFORMATION CONTACT:** Susan M. Strumbel or Carole Showers, Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 377-1442 and 377-3217, respectively.

#### Final Determination

The Department determines that refined antimony trioxide from the People's Republic of China ("PRC") is being, or is likely to be, sold in the United States at less than fair value, as provided in section 735 of the Tariff Act of 1930, as amended ("the Act") (19 U.S.C. 1673d). The estimated margin is shown in the "Suspension of Liquidation" section of this notice.

#### Case History

Since the publication of our preliminary determination on October 9, 1991 (56 FR 50849), and its reprint on November 5, 1991 (56 FR 56496), the following events have occurred.

On October 25, 1991, respondents withdrew their request, submitted on September 13, 1991, that the Department use domestic Chinese input prices to value the factors of production.

On November 6, 1991, we published a notice postponing the final determination until no later than February 21, 1992 (56 FR 56631). We verified the responses of China National Nonferrous Metals Import and Export Corporation ("CNIEC"), China National Metals and Minerals Import and Export Corporation ("China Minmetals"), Xikouangshan Antimony Trioxide Refinery ("Xikouangshan") and Stibium Products Refinery ("Stibium") in Hunan Province and in Beijing, PRC, from

November 18 through November 30, 1991. We also verified certain U.S. subsidiaries of respondents in Houston, Texas and Duarte, California from January 13 through January 18, 1992. A public hearing was held on February 14, 1992.

#### Separate Rates

In our preliminary determination, we stated that we were seeking additional information from respondents on the issue of whether they should receive company-specific rates. Based on that information, we determine that company-specific rates are appropriate for CNIEC and China Minmetals. (For further discussion, see DOC Postion to Comment 6 below).

#### Scope of the Investigation

The product covered by this investigation is refined antimony trioxide (also known as antimony oxide) from the PRC. Antimony trioxide is a crystalline powder of the chemical formula Sb<sub>2</sub>O<sub>3</sub>, currently classified under subheading 2825.80.00 of the Harmonized Tariff Schedule ("HTS"). Refined antimony trioxide includes blends with organic or inorganic additives comprising up to and including 20 percent of the blend by volume or weight. Crude antimony trioxide (antimony trioxide having less than 98 percent Sb<sub>2</sub>O<sub>3</sub>) is excluded. Although the HTS subheading is provided for convenience and customs purposes, our written description of the scope of this proceeding is dispositive.

#### Period of Investigation

The period of investigation ("POI") is November 1, 1990 through April 30, 1991.

#### Fair Value Comparisons

To determine whether sales of refined antimony trioxide from the PRC to the United States were made at less than fair value, we compared the United States price to the foreign market value ("FMV"), as specified in the "United States Price" and "Foreign Market Value" sections of this notice.

#### United States Price

For both respondents, we based United States price on purchase price where sales were made directly to unrelated parties prior to the date of importation into the United States, in accordance with section 772(b) of the Act. We used purchase price as defined in section 772 of the Act, both because refined antimony trioxide was sold to unrelated purchasers in the United States prior to importation into the United States, and because exporter's sales price ("ESP") methodology was

not indicated by other circumstances. Where sales to the first unrelated purchasers took place after importation into the United States, we based United States price on ESP, in accordance with section 772(c) of the Act.

As in our preliminary determination, we have made no adjustments to United States price or FMV for selling expenses. (For further discussion, see DOC Postion to Comment 21).

#### A. China Minmetals

For China Minmetals, we calculated both purchase price and ESP based on packed, FOB, CIF or Ex-Dock prices to unrelated customers in the United States. We made deductions, where appropriate, for foreign inland freight, ocean freight, marine insurance, U.S. brokerage and handling, U.S. duty and U.S. terminal charges.

At the time of our preliminary determination, we stated that we did not make an adjustment for foreign inland insurance, as reported by respondent, because we were unable to obtain a value for this factor from either surrogate country. Since that time, we have received no information from any party, and have no information from the surrogate countries, concerning this valuation. Therefore, we are still unable to make this adjustment.

#### B. CNIEC

For CNIEC, we calculated both purchase price and ESP based on packed, ex-warehouse, FOB, or delivered prices to unrelated customers in the United States. We made deductions, where appropriate, for foreign inland freight, ocean freight, marine insurance, U.S. duty, U.S. inland freight, U.S. drayage, U.S. handling, dock discharge and U.S. port charges. We did not make an adjustment for foreign inland insurance for the reason discussed above. For certain sales, CNIEC did not report U.S. inland freight. For those sales, we used average inland freight as best information available ("BIA").

We have included in CNIEC's U.S. sales one transaction that was discovered at verification (see Comment 18 below). We have also included a second transaction which was not treated as a sale made by CNIEC in the preliminary determination.

#### Foreign Market Value

As in our preliminary determination, we are treating the PRC as a nonmarket economy country ("NME") for the purposes of the final determination. As a result, section 773(c) of the Act directs

the Department to base FMV on the NME producers' factors of production.

For one refinery, Stibium, we were not able to verify the conversion factor for the blast furnace of the production process. Therefore, we used information from the petition as BIA for the factors of production this stage of Stibium's production process. (For further discussion, see DOC Position to Comment 12.) Those factors were valued in the surrogate country.

#### *Surrogate Country*

Section 773(c) of the Act requires the Department to value the factors of production, to the extent possible, in one or more market economy countries that are at a level of economic development comparable to that of the nonmarket economy country, and that are significant producers of comparable merchandise. Based on these criteria, we have determined that Bolivia is the most appropriate surrogate country within which to value the PRC factors of production. (See, DOC Position to Comments 1 and 2 for a complete discussion of this issue.)

With the exception of the blast furnace stage of Stibium's production process, we calculated FMV based on the PRC producers' factors of production. Refined antimony trioxide factors of production include materials, labor, and energy. To value antimony concentrate, we used the London Metal Bulletin ("LMB") prices for Bolivian-origin antimony concentrate. (For further discussion, see DOC Position to Comment 4.) For other materials, labor, and energy, we used Bolivian values where they were available. Where Bolivian values were not available, *i.e.* for coke, soft coal, and inland freight, we used Thai values. Where appropriate, the factor values were inflated to POI levels using wholesale price indices published by the International Monetary Fund.

We added to materials, labor, and energy, amounts for selling, general and administrative expenses ("SG&A"), factory overhead, profit, and packing. The factory overhead, SG&A, and packing expenses were based on the experience of a Bolivian producer. For profit, we used the statutory minimum of eight percent of the sum of production costs and general expenses. (For further discussion, see DOC Position to Comment 3.)

For the factors of production reported for the Xikuangshan factory, adjustments were made as follows: (1) For the reduction and oxidation furnaces, we revised the reported yield for all non-antimony materials, labor, and energy to include the factors that

had been assigned to scrap, (2) for the blast furnace, we included a limestone factor, (3) we recalculated labor to include down days and days off due to illness, travel, etc., (4) we did not make an adjustment to the cost of manufacture for the two by-products created from producing refined antimony trioxide because we were unable to verify the quantities, and (5) we corrected minor clerical errors.

For the factors of production reported for the Stibium factory, adjustments were made as follows: (1) We relied on BIA for all factors related to the blast furnace (as discussed above and in DOC Position to Comment 12), (2) for the reduction furnace, we recalculated the factors reported for soft coal, soda ash, and electricity, (3) for the oxidation furnace, we recalculated the factors reported for soft coal and electricity, (4) for the reduction and oxidation furnaces, we revised the reported yield for all non-antimony materials, labor, and energy to include the factors which had been assigned to scrap, (5) we accepted respondent's revised labor calculation methodology, and (6) we eliminated our adjustment for byproducts because the adjustment was already included in the respondent's calculations.

We made currency conversions in accordance with 19 CFR 353.60(a).

#### *Verification*

Pursuant to section 776(b) of the Act, we verified information used in reaching our final determination. We used standard verification procedures, including examination of relevant accounting records and original source documents provided by respondents.

#### *Interested Party Comments*

*Comment 1:* Petitioners assert that the Department should choose Bolivia as the surrogate, free market economy for valuing PRC production because, both in terms of economic development and in significant production of a comparable product, Bolivia is more similar to the PRC than is Thailand. With respect to economic comparability, petitioners argue that per capita gross national product ("GNP"), the distribution of gross domestic product, and the distribution of labor between agricultural and non-agricultural sectors all reflect that Bolivia is clearly at a level of economic development far more comparable to the PRC than is Thailand.

Further, petitioners assert that Bolivia produces crude antimony trioxide, a product which is more comparable to the subject merchandise than is antimony metal produced in Thailand. Unlike Thailand, Bolivia has produced

refined antimony trioxide in the past. Bolivia is currently a significant producer and exporter of crude antimony trioxide and, unlike Thailand, its production is for commercial sales as opposed to captive consumption. In Thailand, crude antimony trioxide is produced only as an intermediate product to be used in the production of antimony metal. Petitioners assert that antimony metal differs significantly from refined antimony trioxide in composition, physical properties and applications. Petitioners state that, most importantly, the products have entirely different applications. Antimony metal is used for a variety of industrial uses including starting-lighting-ignition, batteries, ammunition, corrosion resistant pumps and pipes, tank linings, roofing sheets, solder, cable sheaths, and antifriction bearings. Refined antimony trioxide, in contrast, is used as a flame-retardant synergist or catalyst in glass or ceramic production, and as a chemical intermediate. Thus, based on production of a comparable product, Bolivia is clearly a more suitable surrogate than Thailand for valuing the PRC factors of production.

Respondents dispute petitioners' assertion that Bolivia is a more appropriate surrogate country than Thailand in which to value the factors of production. Respondents state that the Department has often used Thailand to value factors of production in cases involving the PRC. Furthermore, respondents assert that, in terms of economic comparability, Bolivia has experienced a negative growth rate and hyperinflation, unlike the PRC. Respondents claim that if the hyperinflationary Bolivian experience is used for surrogate purposes, it will be impossible for Chinese producers to determine whether they are selling at a dumped price.

Respondents also assert that antimony metal is a more comparable product to the subject merchandise than is crude antimony trioxide. As seen at verification, the Chinese production process has three stages—ore to crude, crude to metal, metal to refined. Therefore, because antimony metal is one step away from the production of refined antimony trioxide, it is more similar than crude antimony trioxide, which is produced two steps prior to producing refined antimony trioxide. In addition, respondents add that a substantial number of U.S. antimony trioxide producers import antimony metal from the PRC to produce refined antimony trioxide. Finally, respondents state that Thailand is a significant producer/exporter of antimony metal.

*DOC Position:* In our preliminary determination, we stated that in economic terms, Bolivia and Thailand were equally comparable to the PRC for purposes of selecting a surrogate country within which to value PRC factors of production. Nonetheless, the Department strives, where possible, to select one surrogate country for purposes of factor valuation. In making this determination and consistent with 19 CFR 353.52(b), the Department has traditionally considered GNP, per capita GNP, the distribution of labor within the economy, and the rate of economic growth. While all these factors are important, the disparity in the per capita GNP figures between Thailand and Bolivia has persuaded us that Bolivia is the more comparable economy for purposes of this investigation.

With respect to the significant production of a comparable product, based on an analysis of information gathered throughout this investigation, we have determined that antimony metal is more comparable to refined antimony trioxide than is crude antimony. Refined antimony trioxide is produced in three stages—ore to crude, crude to metal, and metal to refined. Because antimony metal is at an intermediate stage of processing in the spectrum from ore to refined, it is more comparable to the end product. The mere fact that antimony metal is also used to produce other products does not detract from its greater comparability to refined antimony, particularly since crude antimony is two production steps away from refined antimony and the metal production stage immediately precedes the production of refined antimony trioxide, the subject merchandise.

Therefore, because Bolivia is a significant producer of antimony metal, a comparable product, and we find it to be more comparable economically, we determine that Bolivia is the appropriate surrogate country within which to value PRC factors of production. In those few instances where values were unobtainable from Bolivia, we have used values from Thailand.

*Comment 2:* Respondents argue that, if the Department continues to believe that Bolivia and Thailand are equally comparable to the PRC, as a "tie-breaker" the Department should consider the similarity of the production processes in the various countries. Respondents contend that the production process utilized in Thailand is more comparable to that used in the PRC, indicating that Thailand may be the better surrogate.

*DOC Position:* The Department has concluded that, based on the statutory

criteria for surrogate selection, Bolivia is more comparable than Thailand for purposes of this investigation (see DOC Position to Comment 1 above.)

Consequently, we need not consider whether the production process for refined antimony trioxide in Thailand or Bolivia is more similar to that of the PRC.

*Comment 3:* Respondents argue that since Laurel Industries, a petitioner, is related to and controls Empresa Metalurgica Vinto ("Vinto"), the Department should disregard the profit and SG&A obtained from this Bolivian company for purposes of calculation constructed value. Respondents contend that information provided by Vinto does not fairly reflect the profit or SG&A of antimony producers in the United States, worldwide, or in the PRC. Consequently, respondents suggest that the Department use the statutory minimum of eight percent profit and ten percent SG&A as BIA in constructing FMV for the product under investigation.

Petitioners contend that since a Bolivian firm producing crude antimony trioxide has supplied GS&A and profit data to the Department, the Department should continue using these actual data for its final determination. Petitioners state that respondents' claim that Vinto is related to Laurel Industries is incorrect. Vinto and Laurel signed a joint cooperation and technology transfer agreement but the two firms are not related. Neither has any ownership interest in the other, nor does any relationship exist through either company's employees. Vinto, in fact, is a government-owned entity. Vinto and Laurel trade under an arms-length toll contract and are in no way related.

Petitioners further contend that respondents' claim that Vinto's profits are too high is erroneous. Laurel has other source of supply besides Vinto. If Vinto's prices were not competitive, Laurel would stop purchasing from this firm because Laurel is in no way bound to Vinto as a supplier.

*DOC Position:* We have determined that it is appropriate to use Vinto's actual SG&A figures for purposes of this final determination. No evidence has been provided to demonstrate that this amount is atypically high by industry-wide standards, or that it is tainted by virtue of Laurel's association with Vinto. Where we are using a surrogate producer's expenses, there is no evidence on the record which persuades the Department that a relationship with this petitioner can, or has, affected those expenses.

We are concerned, however, that Laurel's relationship to this Bolivian producer raises reasonable suspicions

concerning Vinto's profitability. Laurel is Vinto's only customer, so Vinto's revenues are determined entirely by the price paid by Laurel. Moreover, in discussing why an LMB price differential exists, between Bolivian and Chinese concentrate, petitioners have pointed to their willingness to pay a premium for the Bolivian product so as to diversify their sources of supply. These factors lead us to conclude that use of Vinto's profit rate would mean that petitioners effectively control this aspect of the calculations, an outcome which we cannot accept. For these reasons, the Department has used as profit the statutory minimum of eight percent of general expenses and cost, pursuant to section 773(e)(1)(B)(ii) of the Act, for the final determination.

*Comment 4:* Petitioners claim that the Department should base its valuation of antimony concentrate on the price for Bolivian-origin concentrate tracked by the LMB rather than on the export price of Chinese-origin antimony concentrate tracked by the LMB. In the PRC, refined antimony trioxide is a class-one product subject to special state controls and the entire antimony sector which produces it is an integral part of the PRC's command economy. Section 773 of the Act does not permit the Department to base its valuation of the antimony concentrate factor on the export price of the PRC product. In fact, the Act precludes the Department from valuing it in this manner. Section 773 allows the Department to use NME cost data only when the entire firm or sector, even though it operates within an NME, is subject to market forces. Otherwise, the statute requires the Department to use cost data from a comparable market economy country. In addition, petitioners assert that the Chinese export price of antimony concentrate is subsidized and, therefore, cannot be used. Further, petitioners claim that the Department's decision in the preliminary determination that the LMB price for Chinese antimony concentrate most accurately reflects the actual impurity levels of the concentrate used by respondents is in error. In fact, 60 percent antimony concentrate of Chinese and Bolivian origin are completely competitive and fungible. The LMB tracks the market price for the best 60 percent concentrate of Chinese origin, which is comparable in quality to the only other major source—60 percent concentrate of Bolivian origin. Petitioners purchase antimony concentrate from both sources and comparative assays show the difference to be insignificant.

Respondents assert that the LMB price for Chinese concentrate is not the Chinese market price but a world market price. Respondents argue that Chinese concentrate has a lower price than Bolivian concentrate because of differences in impurity levels, as the Department noted in its preliminary determination.

*DOC Position:* We agree, in part, with petitioners. For the final determination, the Department has determined that Bolivia is the appropriate surrogate country by which to value factors of production. (See, *DOC Position to Comment 1.*) There are three LMB prices listed for antimony concentrate, one for Chinese-origin concentrate and two for non-Chinese-origin concentrate. Based upon conversations with experts in the field, we have determined that the two prices for non-Chinese-origin concentrate are actually prices for Bolivian-origin concentrate. (See, February 19 and 21, 1992 memoranda to file re: conversations with Metal Bulletin experts.) The Department has determined that an average of the prices for Bolivian-origin concentrate is the most appropriate valuation of the antimony concentrate factor.

Evidence on the record suggests that the LMB prices for Bolivian-origin concentrate are internationally-traded prices for lump and clean sulfid concentrates. Both of these types of ore are used by the respondents in their production of the product under investigation. Therefore, an average of these two LMB prices, results in a valuation of the factor for antimony concentrate which most accurately reflects respondents' production experience.

Section 773(c)(4) of the Act, mandates the valuation of factors of production "to the extent possible" on the basis of prices or costs of such factors "in one or more market economy countries \* \* \*." Since the Department has available to it prices of products produced in a market economy (the LMB prices for Bolivian-origin concentrate) by which to value this factor, it must use them over the LMB price for Chinese-origin concentrate.

Respondents argue that the LMB price for Chinese-origin concentrate is not an internal Chinese price but, instead, an internationally-quoted price for Chinese antimony concentrate. The Department, however, cannot ignore the fact that the PRC is an NME country which is the major exporter of antimony concentrate on the world market. Accordingly, distortion caused by the nonmarket nature of the Chinese economy will affect subsequent transactions involving the product, as reflected in the LMB.

With regard to purported differences in impurity levels, current evidence on the record is conflicting, rather than conclusive. The same experts who informed the Department at the time of the preliminary determination that the price discrepancy between the Chinese- and Bolivian-origin concentrate was due to the difference in impurity levels now inform the Department that the discrepancy could also be accounted for by a premium which buyers are willing to pay for a second source of supply. Thus, the information on the record does not establish the reason for the difference in price.

*Comment 5:* Respondents request that for values other than the antimony concentrate, the Department use the information provided in a facsimile transmission from the U.S. Embassy in Thailand rather than the import prices used in the preliminary determination, since the Embassy information more accurately reflects the actual experience of local producers during the POI.

Petitioners state that the Department's practice demonstrates a preference for valuing all of the factors of production in a single surrogate country. Since Bolivia is the most appropriate surrogate, the Department should follow this practice in its final determination by valuing in Bolivia all of the factors of production, including those valued in Thailand for the preliminary determination. Petitioners' case brief contains values for fluorespar, soft coal, and coke, the only factors not already valued in Bolivia. The Department should use these factors in its final determination.

*DOC Position:* We agree with petitioners that it is the Department's preference to value factors of production in one surrogate country, if possible. Therefore, we have valued the PRC factors of production in Bolivia where public information from independent sources was available. We did not accept petitioners' values for fluorespar, soft coal, or coke, as we were able to obtain values for these inputs from independent sources in Thailand. The Thai values were (i) based on input values or (ii) taken from the information submitted by the U.S. Embassy.

*Comment 6:* Petitioners claim that CNIEC and Minmetals are government-controlled entities whose exports are strictly regulated. Therefore, the Department should assign a single, country-wide antidumping duty rate to their exports. CNIEC is a subsidiary of CNNC, which is a "nationally integrated enterprise" directly under the leadership of the State Council of the PRC. The corporate charter for the Ministry of Foreign Economic Relations and Trade ("MOFERT") spells out the extent of

central government control over its export activities. MOFERT controls both the quantity and price of exports of refined antimony trioxide, a class-one product.

Respondents argue that each trading company should be given a separate antidumping duty margin because the companies vigorously compete with each other, MOFERT sets only export quotas, not prices, and the companies have proven both *de jure* and *de facto* absence of central control over export prices. *DOC Position:* We have determined that exporters in nonmarket economy countries are entitled to separate, company-specific rates when they can demonstrate an absence of central government control, both in law and in fact, with respect to exports. (See Final Determination of Sales at Less Than Fair Value: Sparklers from the People's Republic of China, 56 FR 20588, May 6, 1991.) Evidence supporting, though not requiring, a finding of *de jure* absence of central control includes: (1) Absence of restrictive stipulations associated with an individual exporter's business and export licenses; (2) any legislative enactments decentralizing control of companies; or (3) any other formal measures by the government decentralizing control of companies. A finding of *de facto* absence of central government control with respect to exports is based on two prerequisites: (1) Whether each exporter sets its own export prices independently of the government and other exporters; and (2) whether each exporter can keep the proceeds from its sales.

The evidence on the record demonstrates that each exporter of refined antimony trioxide sets its own prices for export. At verification, MOFERT officials stated that it did not set prices of refined antimony trioxide and we saw no evidence at the trading companies to contradict this. Officials from each of the two companies explained that export prices were established independently on the basis of monthly LMB price quotes. In addition, we observed different prices being charged by the two companies at or about the same time period.

At verification, we also noted that CNIEC's sales proceeds were deposited to its own account and that CNIEC bank records revealed no payments to the PRC government, CNIEC Beijing, or CNNC. Nor was there evidence of any control exercised by these entities over CNIEC's accounts. At Minmetals Hunan, we also traced proceeds from sales of refined antimony trioxide to that company's bank accounts and general ledger. We found no evidence of

payments to the PRC government, China Minmetals Beijing, or MOFERT, or of control exercised by any of these agencies over Minmetals' receipts.

Our examination of the business and export licenses of these companies revealed no restrictive stipulations on the export of various antimony products, including refined antimony trioxide. While at MOFERT, we received excerpts from the State Council Directive No. 12 of 1988, on the deregulation of the branches of foreign trade corporations. This directive made the branches financially independent from their former headquarters.

In view of the ample evidence on the record, as noted above, we have assigned separate, company-specific rates for purposes of our final determination.

*Comment 7:* Petitioners assert that respondents deliberately withheld and misreported key information with respect to their factors of production. For example, verification demonstrated that respondents understated the antimony content of their raw material by at least two-to-one. In addition, petitioners assert that respondents withheld information on the antimony content of blast furnace slag. Petitioners state that this information, critical to determining the blast furnace conversion rate, was neither reported by respondents nor verified by the Department. Therefore, the Department should use BIA.

Respondents claim that the verified concentrate percentage was different than that provided in the questionnaire response because of a simple communication problem between counsel and respondents, and that the Department should use the information collected at verification.

*DOC Position:* The Department does not believe that respondents deliberately withheld or misreported key information with respect to the factors of production. Except as identified in other sections of this notice, we have accepted respondents' information as verified. Therefore, with the exception of the blast furnace stage of Stibium's production process, we have used respondents' data for the final determination.

*Comment 8:* Petitioners claim that the Department may have verified the antimony content of the antimony concentrate on a dry basis, when the assay was actually taken on a wet basis. The water content of the antimony quoted on a wet basis is about eight percent. Thus, the assay of concentrate on a wet basis will be significantly less than the assay on a dry basis. In support of its assertion,

petitioners cite an article written about the production of antimony oxide in Xikuangshan which suggests that the assay verified by the Department was taken on a wet basis.

*DOC Position:* We disagree with petitioners. There is no evidence on the record to support this assumption for the companies under investigation.

*Comment 9:* Petitioners argue that the Department cannot accept Xikuangshan's blast furnace factors of production because the factors were based on theoretical, formula-based output of crude antimony rather than actual output. Additionally, the antimony content of blast furnace slag is not known, and the Department was unable to reconcile the production of crude antimony with the consumption of crude antimony in the reduction furnace. Petitioners further claim that this calculation rate is excessively high when compared to a state of the art facility like that owned by a petitioner using a far superior concentrate.

Petitioners additionally contend that in calculating the blast furnace conversion rate, Xikuangshan assumed a fixed loss-of-antimony-in-process rate and a fixed loss-to-slag rate. Petitioners contend that these loss rates are never fixed but vary considerably over time. Therefore, the Department should not accept these unverified loss rates for purposes of establishing a blast furnace conversion rate.

Xikuangshan suggests that the Department must base its judgments upon the production process and the records it observed at verification. Xikuangshan claims that, since it uses a continuous flow process, the Department must rely on the veracity of the formula provided by it to calculate the standard output of crude antimony rather than weighing the actual output of crude antimony, disagreeing the petitioners' claim that crude antimony is an output. Rather, Xikuangshan asserts that crude antimony trioxide is an intermediate process stage in the continuous production process and suggests that petitioners' objection to the verification of the standard output of crude antimony boils down to the fact that Xikuangshan uses a continuous production process and, therefore, does not weigh crude antimony oxide when it comes out of the blast furnace. Xikuangshan argues that the blast furnace factor was based on actual raw materials input into the production process, and actual output of the reduction furnace and oxidation furnace. Since the Department was able to verify the inputs and the outputs of the reduction and oxidation furnaces,

the Department was able to verify the output of the blast furnace.

*DOC Position:* We disagree with petitioners. Respondents' production process does not allow the type of verification suggested by petitioners. Nevertheless, we are able to verify the factors of production of the Xikuangshan blast furnace. We verified that Xikuangshan weighs work-in-process crude inventory at the end of each month. At verification, the Department was able to reconcile monthly reported output crude antimony from the blast furnace with monthly recorded input crude antimony into the reduction furnace with recorded weighed work-in-process crude antimony inventory for each month. Thus, the Department was satisfied that Xikuangshan accounted for all the actual inputs and outputs of the blast and reduction furnaces during the POI.

*Comment 10:* Petitioners claim that Xikuangshan's calculation of its blast furnace conversion rate is significantly flawed because it takes into account antimony-containing scrap recycled from the blast furnace. Petitioners argue that the use of the reported conversion rate would significantly understate the consumption of antimony concentrates in the production of the subject merchandise.

Xikuangshan claims that the amount of scrap and its antimony content were verified. Further, it asserts that the antimony is not underquantified and the cost of recycling the scrap is captured in the cost.

*DOC Position:* We disagree with petitioners. Antimony scrap with a higher concentration than the lump/concentrate is recycled into the blast furnace. The Department verified that the antimony contained in the scrap was included in the calculation of the total antimony input into the furnace. Therefore, the antimony contained in the scrap is included in the factors of production.

However, the Department noted that Xikuangshan's methodology allocated fabrication expenses to antimony contained in the output of the furnaces that was eventually recycled as scrap. These fabrication expenses were not included in the submitted factors of production. Therefore, the Department adjusted the conversion rates to properly charge all fabrication costs to finished output only.

*Comment 11:* Petitioners claim that the Xikuangshan verification should have established that the quantity of crude produced in the blast furnace equalled the quantity of crude used by the reduction furnace, and that the

quantity of antimony metal produced in the reduction furnace equalled the quantity of antimony metal used by the oxidation furnace. Otherwise, Xikuangshan cannot demonstrate that the quantities of these intermediate products produced at prior stages were actually used in their entirety to produce refined antimony trioxide. If these quantities cannot be reconciled from one stage to the next, the Department should draw no inference regarding production factors from the actual output of refined antimony trioxide over the POI. In support of their argument, petitioners state that the Department's verification report does not establish that the quantity output from one stage equalled the quantity input to the next stage.

Xikuangshan argues that the Department's verification reports do not indicate that it failed to account for work-in-process and that, in fact, the reports state that consumption included beginning inventory and inputs added, less inventory.

*DOC Position:* We disagree with petitioners. Xikuangshan's methodology calculates the factors of production in three stages, one for each furnace used in production. The calculation accounts for work-in-process between the processing stages. Because the Department verified that the quantities were reconciled from one stage to the next, we consider this calculation to be a reasonable method for determining usage, and an accurate reflection thereof, during the POI.

*Comment 12:* Petitioners claim that Stibium calculated a blast furnace conversion rate rather than establish a rate based on actual consumption of inputs over the POI. Further, the method of calculating the conversion rate is inherently faulty because it does not account for the fact that Stibium recycled large amounts of antimony-containing scrap back to the blast furnace from the reduction furnace. Thus, Stibium's conversion rate is not a rate for converting antimony concentrate to crude antimony trioxide but a rate for converting the combined input of concentrate and recycled scrap to crude antimony trioxide. The conversion rate of the combined input seriously understates the antimony concentrate factor of production. Petitioners cite the verification report which states that the quantity of crude antimony trioxide produced by the blast furnace could not be verified. Thus, it was not possible to determine whether the total amount of crude produced over the POI was used in the reduction furnace over the same period. This lapse

in record-keeping undermines any attempt to verify Stibium's factors of production.

Stibium argues that its blast furnace factor was based on actual raw material input into the production process and actual output of the reduction and oxidation furnaces. Since the Department was able to verify the blast furnace input and the reduction and oxidation furnaces' outputs, the Department was able to verify the output of the blast furnace.

*DOC Position:* We agree with petitioners. Stibium's blast furnace conversion factor was based on a calculation with unsupported ratios for loss in process and slag rate. Additionally, the Stibium Refinery did not provide any documentation to support that it weighed crude work-in-process inventory at the end of each month of the POI. Thus, the Department was unable to reconcile the calculated crude antimony output from the blast furnace with crude antimony input into the reduction furnace. As a result, the Department used, as BIA, the factors of production information for the blast furnace as reported in the petition, valued using surrogate country prices.

*Comment 13:* Petitioners claim that the verification of Stibium's factors of production assumes that the quality of antimony metal produced in the reduction furnace exactly equals the quantity of antimony metal used in the oxidation furnace. Since this equality was never established from Stibium's production records, verification of these factors is seriously flawed.

*DOC Position:* We disagree with petitioners. Stibium's revised methodology calculates factors of production for the reduction furnace and the oxidation furnace by dividing total weighed input by total weighed output for each furnace. Any differences between output from the reduction furnace and input into the oxidation furnace are included in work-in-process. Thus, it is not relevant whether the quantity of antimony metal produced in the reduction furnace exactly equals the quantity of antimony metal used in the oxidation furnace.

*Comment 14:* Petitioners claim that the straight-line proportionality method is not valid for deriving a value for less than 60 percent antimony concentrate based on the price of 60 percent antimony concentrate. The Department admitted that this method could result in as much as ten percent error. Petitioners have supplied a valuation chart based on one petitioner's experience indicating the value to a refined antimony trioxide

producer of antimony concentrate of various percentages of antimony content.

*DOC Position:* Based on information from an independent source, we have reason to believe that the straight-line proportionality method may, in fact, overstate the price of less than 60 percent antimony concentrate. (See Memorandum from Susan Kubbach to Francis J. Sailer, dated February 21, 1992, on file in the Central Records Unit.) However, lacking actual prices for the lower concentrate levels, we have no means of adjusting the straight-line proportionality formula. Therefore, we have used this formula as best available information.

*Comment 15:* Respondents state that the LMB price is a quote for one metric ton of concentrate containing 600 kilograms of antimony. Therefore, the Department must first multiply the LMB price by 60 percent to arrive at the price for the antimony content without any impurities. The resulting price should then be multiplied by the percentage of antimony contained in the respondents' antimony input in order to arrive at the surrogate value. Then, because the LMB price is CIF, respondents assert that the Department should subtract ocean freight charges. To this end, respondents have provided an invoice showing actual ocean freight expenses incurred.

Petitioners claim that respondents are mistaken in their method of evaluating antimony concentrate. They assert that the LMB price is actually for one metric ton of contained antimony. Thus, because respondents reported the quantity of their concentrate on an antimony-contained basis, the Department need only multiply the LMB price by this quantity to arrive at the surrogate value.

In addition, petitioners claim that the Department should not accept the ocean freight invoice provided by respondents because the information was submitted only 24 hours prior to the due date for rebuttal briefs. Furthermore, the invoice was not verified, does not indicate the quantity shipped, and the carrier appears to be from a nonmarket economy.

*DOC Position:* We agree with petitioners regarding the LMB quotation. The LMB quote is based on a per metric ton unit of antimony contained. (See, "February 19, 1992 Memo to File, RE: Conversation with LMB Specialist" on file in the Central Records unit.) Respondents also reported their antimony input factor on an antimony-contained basis. Therefore, our calculations are made on an antimony-contained basis.

In addition, we have made further adjustment to the LMB price to account for ocean freight and marine insurance. The LMB quotation is on a CIF basis. Petitioners, in exhibit 16 of their petition, provided information with which we were able to make this adjustment.

*Comment 16:* Petitioners state that since respondents failed to report all U.S. sales and to report accurately all movement expenses, the Department must use BIA for U.S. price as set forth in the petition.

*DOC Position:* We disagree with petitioners. The discrepancies found at verification for the U.S. sales listing were minor. Therefore, the Department believes it would be inappropriate to use BIA for U.S. price.

*Comment 17:* Petitioners state that, in reviewing the completeness of China Minmetals' U.S. sales list, the verification team discovered invoices for shipments from Minmetals Hunan to a related U.S. company not previously mentioned in respondent's questionnaire response. Furthermore, petitioners noted that after the Department returned from verification in the PRC, China Minmetals provided inadequate documentation supporting that these two entities were related.

China Minmetals states that while the Department was at China Minmetals Hunan for verification, it suggested to the Department that a U.S. sales verification at the U.S. company could take place in the United States. China Minmetals further states that after the home market verification, the Department decided not to visit this company. Therefore, China Minmetals provided a copy of the original stock certificate of this company to prove the relationship with China Minmetals.

Furthermore, China Minmetals states that the sales made by this company were outside the period of investigation.

*DOC Position:* Based on documentation provided at verification, we are satisfied that the two companies are related. Moreover, because the sales to the first unrelated customer occurred outside the POI, there was no need to report it.

*Comment 18:* Petitioners state that CNIEC's failure to report a large U.S. sale should result in the use of BIA for U.S. price. Even if the Department were to accept this sale, it did not verify the amount paid for the merchandise, nor other charges such as discharge, drayage, brokerage, handling, duty and U.S. inland freight and insurance.

CNIEC argues that with the exception of one contract, the Department verified that CNIEC reported all sales. Respondents further argue that a March 7, 1991, contract discovered at CNIEC's

Hunan Branch was not a sale during the POI because CNIEC breached the contract when it did not make the agreed upon shipment of the refined antimony trioxide. CNIEC further claims that even if the Department determines that this sale should have been included, the Department verified all of the information about the sale at verification and it should use this information for the final determination.

*DOC Position:* According to the documents supplied at verification, CNIEC and its customer never formally canceled the contract and the merchandise was eventually shipped, on the terms agreed upon in the contract. Therefore, the Department is including this sale for purposes of its final determination. Furthermore, the sale terms of this contract were CIF. The Department has verified all the information required to make all of its adjustment to U.S. price. We disagree with petitioners that omission of this sale requires the application of BIA.

There were rather unusual circumstances surrounding the transaction and we believe the omission was inadvertent.

*Comment 19:* Petitioners state that since CNIEC failed to report certain movement expenses, significantly understated certain expenses, or was unable to document other movement expenses, the Department should use the net U.S. price reported in the petition as BIA for its final determination. However, the petitioners assert that if the Department decides to reconstruct and supplement CNIEC's sales data bases, then the Department must use as BIA the highest movement expenses verified by the Department or reported by CNIEC for each movement category.

CNIEC maintains that the Department should accept the movement charges for Metaland, CNIEC's subsidiary, because the average allocation methodology used to report them has been accepted by the Department in prior cases.

*DOC Position:* The Department prefers shipment-specific movement expenses and for those sales where shipment-specific information was available, we used it. Where shipment-specific data were not available, we accepted CNIEC's average values as there is no evidence that they systematically over- or understate actual movement charges. However, we have adjusted these average figures, where appropriate, to include inland freight.

*Comment 20:* Petitioners claim that the Department's investigation accounted for only 25 percent of exports of the subject merchandise from the PRC during the POI. Petitioners state that the

Department should not have excluded the other sales based on respondents' claims that certain exporters did not know, at the time of sale, that shipment were destined for the United States. Petitioners also state that the Department did not adequately verify respondents' claim that 75 percent of shipments during the period were made pursuant to contracts signed prior to the POI. Consequently, the Department should use BIA in establishing United States price.

Respondents claim that the Department verified the universe of sales of Newmet Inc. ("Newmet"), a related party of China Minmetals, through Newmet and MOFERT. Furthermore, respondents assert that the Department verified, through MOFERT and the respective companies' sales ledgers, that CNIEC and China Minmetals account for over 60 percent of the sales during the POI.

*DOC Position:* We agree with respondents. At verification, we verified that respondents reported all sales of refined antimony trioxide made to the United States during the POI except for the one missing sale discussed in Comment 17 above. Moreover, as discussed in a September 11, 1991 memo to the file (on file in the Central Records Unit), there were allegations that other exporters of refined antimony trioxide existed. Based on information on the record at that time, we determined that the PRC exporters being investigated accounted for most if not all of the imports during the POI. Therefore, we decided not to include the other possible exporters in our investigation. During verification, we found no evidence that the two exporters investigated did not account for all sales to the United States during the POI. Thus, we are confident that our investigation was comprehensive.

*Comment 21:* Petitioners assert that the Department should adjust for warehousing, credit, packing, and commission expenses incurred on U.S. sales, regardless of whether similar expenses could be identified or quantified in the surrogate country. The U.S. Court of International Trade in *Funai Electric Company, Ltd., v. United States*, 713 F. Supp. 420 (CIT) (1989), ruled that the Department could adjust constructed value for circumstances of sale in the United States in the absence of specific evidence that these expenses were incorporated within the statutory minimum of ten percent for SG&A.

Respondents disagree with petitioners' request that the Department reduce the U.S. price for indirect selling expenses but not make a corresponding

adjustment to the foreign market value to account for indirect selling expenses.

**DOC Position:** As in our preliminary determination, we have made no adjustments to United States price or FMV for selling expenses. To have made such an adjustment to FMV would have required an arbitrary division of the surrogate country producer's selling expenses into amounts for direct, indirect, and other general and administrative expenses. Alternatively, to reduce ESP for selling expenses without making corresponding adjustments to FMV would have resulted in an unfair and unreasonable inflation of any differences between ESP and FMV. See, Final Determination of Sales at Less than Fair Value:

Oscillating fans and Ceiling Fans from the People's Republic of China, (56 FR 55271, October 25, 1991) and Final Results of Antidumping Duty Administrative Review: Tapered Roller Bearings and Parts Thereof, Finished and Unfinished, from the Republic of Hungary, (55 FR 48146, November 19, 1990).

**Comment 22:** Petitioners claim that technical matters raised in respondents' briefs may not be considered by the Department because respondents' case briefs were not certified by competent authorities from the responding firms but only by respondents' counsel who is not qualified to certify to these factors.

**DOC Position:** We disagree with petitioners. Section 353.31(i) of the Commerce regulations (19 CFR 353.31(i)) requires proper certification of factual information submitted to the Department for consideration in the proceeding. Any technical matters raised in respondents' case briefs were raised in the context of argument based upon factual information properly certified, and earlier submitted, to the Department. Contrary to petitioners' assertion, § 353.38(c) of the regulations addressing case briefs, as opposed to the submission of factual information, states that the purpose of the case brief is to separately present in full all arguments which the submitter continues to view as relevant to the Department's final determination. There is no statutory or regulatory requirement that an authority from a responding firm certify a case brief submitted in an administrative proceeding.

#### *Suspension of Liquidation*

We are directing the U.S. Customs Service to continue suspension of liquidation of all entries of refined antimony trioxide from the PRC, as defined in the "Scope of Investigation" section of this notice that are entered, or withdrawn from warehouse, for

consumption on or after the date of publication of this notice in the **Federal Register**. The U.S. Customs Service shall require a cash deposit or bond equal to the estimated weighted-average amount by which the foreign market value of the subject merchandise exceeds the United States price as shown below. The suspension of liquidation will remain in effect until further notice.

The weighted-average dumping margins are as follows:

Weighted-average manufacturer/ producer/exported	Margin percent
China Minmetals .....	80.64
CNIEC .....	13.05
All others .....	33.10

#### *ITC Notification*

In accordance with section 735(d) of the Act, we have notified the ITC of our determination.

This determination is published pursuant to section 735(d) of the Act (19 U.S.C. 1673d(d)) and (19 CFR 353.20(a)(4)).

Dated: February 21, 1992.

Marjorie A. Chorlins,

Acting Assistant Secretary for Import  
Administration.

[FR Doc. 92-4635 Filed 2-27-92; 8:45 am]

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[A-588-028]

#### **Final Results of Antidumping Duty Administrative Review and Partial Termination: Roller Chain, Other Than Bicycle, From Japan**

**AGENCY:** International Trade Administration, Import Administration, Department of Commerce.

**EFFECTIVE DATE:** February 28, 1992.

#### **FOR FURTHER INFORMATION**

**CONTACT:** Mark Wells, Office of Antidumping Investigations, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230; telephone (202) 377-3003.

#### **FINAL RESULTS**

##### **Background**

On December 5, 1991, the Department of Commerce (the Department) published in the **Federal Register** the preliminary results of this administrative review of the antidumping duty order on roller chain, other than bicycle ("roller chain"), from Japan (56 FR 63708). The Department

has now completed this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

The review covers five manufacturers/exporters of roller chain for the period April 1, 1989 through March 31, 1990. They are: Hitachi Metals Techno, Ltd., Izumi Chain Manufacturing Co., Ltd., Kaga Kogyo, K.K. (Kaga Industries Co., Ltd.), Pulton Chain Company, and RK Excel, Ltd. Additionally, the Department has determined that one firm that was listed in the notice of initiation, Kaga Koken, no longer exists. Counsel for the petitioner, the American Chain Association, presented evidence that Kaga Koken was "dissolved by resolution at a shareholders' meeting on May 13, 1987" nearly two years before the period of review. Accordingly, and with the consent of the petitioner, we are terminating the review of Kaga Koken, in accordance with 19 CFR 353.22(a)(5), and because no party to the proceeding is prejudiced by the termination, we are waiving the 90 day requirement.

The period of review (POR) is April 1, 1989 through March 31, 1990. Administrative reviews of several other firms are being conducted separately.

#### *Scope of the Review*

Imports covered by the review are shipments of roller chain, other than bicycle, ("roller chain") from Japan. The term "roller chain, other than bicycle" includes chain, with or without attachments, whether or not plated or coated, and whether or not manufactured to American or British standards, which is used for power transmission and/or conveyance. Such chain consists of a series of alternately-assembled roller links and pin links in which the pins articulate inside the bushings and the rollers are free to turn on the bushings. Pins and bushings are press fit in their respective link plates. Chain may be single strand, having one row of roller links, or multiple strand, having more than one row of roller links. The center plates are located between the strands of roller links. Such chain may be either single or double pitch and may be used as power transmission or conveyor chain.

The review also covers leaf chain, which consists of a series of link plates alternately assembled with pins in such a way that the joint is free to articulate between adjoining pitches. The review further covers chain model numbers 25 and 35. Roller chain is currently classifiable under Harmonized Tariff Schedule (HTS) subheadings 7315.11.00

through 7616.90.00. Although the HTS subheadings are provided for convenience and customs purposes, the written description of the scope of this proceeding is dispositive.

#### *Use of Best Information Available*

As provided for in section 776(c) of the Act, the Department has determined that use of best information available (BIA) is appropriate for all sales of roller chain from Izumi and Pulton, to calculate the margin on Hitachi sales requiring a difference in merchandise adjustment (difmer), and for RK Excel U.S. sales with a reported gross unit price of zero.

Our decision to use BIA for Izumi and Pulton is based on the Magnitude of the omissions and deficiencies in their responses. Izumi failed to provide the Department with information necessary to calculate constructed value (CV). Pulton failed to provide the information necessary to select comparison products or calculate a CV.

Hitachi reported that it purchased some roller chain from related parties in the home market. The Department requested that for purposes of the difmer calculation, Hitachi provide the cost of manufacture (COM) of these products. Hitachi responded that it was unable to obtain the cost information because of its limited relationship with the supplier. Instead, it supplied the weighted-average acquisition price to be used as the basis for the difmer calculation. The acquisition price from a related supplier does not provide a reliable basis upon which to calculate the cost attributable to the physical differences in the merchandise.

Section 776(c) of the Act requires the Department to use the best information available "whenever a party or any other person refuses or is unable to produce information requested in a timely manner and in the form required, or otherwise significantly impedes an investigation." In deciding what to use as best information available, the Department may take into account whether a party refuses to provide requested information (19 CFR 353.37(b)). Thus, the Department may determine, on a case-by-case basis, what the best information available is.

In selecting a BIA rate, the statute and the implementing regulation direct the Department to evaluate the nature of the information on the record, as well as the respondent's actions during the administrative proceeding. When a company refuses to cooperate with the Department or otherwise significantly impedes the proceedings, as BIA we generally assign the higher of: (a) the highest rate for any firm for any

previous review or the original less-than-fair-value investigation, or (b) the highest rate found for any firm in this review. When a company is considered by the Department to be cooperative because it substantially responds to the Department's requests, we generally assign to that company the higher of: (a) The highest rate calculated for a responding firm with shipments during the period, or (b) the highest rate for that company for any previous review or the original investigation, which may include a prior rate based on BIA. See, e.g., Final Results of Antidumping Duty Administrative Review: Antifriction Bearings (Other Than Tapered Roller Bearings) and Parts Thereof from the Federal Republic of Germany (56 FR 31692, July 11, 1991); Final Results of Antidumping Duty Administrative Review: Portable Electric Typewriters from Japan (56 FR 56394, November 4, 1991).

Following this hierarchy, as BIA for Izumi and Pulton we assigned the highest rate for each company from any previous review or the original investigation. For Izumi that is the 17.57 percent rate from the 1987-88 review period (55 FR 42602, October 22, 1990), and for Pulton that is the 15.92 percent rate from the 1981-83 review periods (56 FR 32175, July 15, 1991).

For Hitachi's U.S. sales where it was unable to provide cost of production information to calculate difmers, as BIA, we have used the weighted-average margin found on all other Hitachi sales.

Similarly, for RK Excel's few sales with a gross unit price of zero, as BIA, we have used the weighted-average margin found on all other RK Excel sales.

#### *United States Price*

For Hitachi, Kaga, and RK Excel, we based United States Price on purchase price or exporter's sales price methodology, as set forth in the preliminary results.

#### *Foreign Market Value*

In calculating foreign market value, the Department used home market prices or constructed value, as set forth in the preliminary results.

#### *Analysis of Comments Received*

We gave interested parties an opportunity to comment on the preliminary results. We received comments from petitioner, Hitachi, and Izumi.

#### *Comment 1*

Petitioner states that the BIA margins applied to Izumi and Pulton should be modified to reflect the highest individual

rate, including BIA rates, assigned for any previous review. In this case, petitioner contends that the BIA rates assigned to Izumi and Pulton should be 17.57 percent and 15.92 percent, respectively, both of which were based on BIA.

Citing the Final Results of Antidumping Duty Administrative Review: Fishnetting of Man-Made Fibers from Japan, (56 FR 49456, September 30, 1991) ("*Fishnetting*"), petitioner claims that when determining the "highest rate for [a] company for any previous review," the Department does not restrict itself to calculated margins, but includes BIA rates previously assigned to the party in question, even when it concludes that the companies have been "substantially cooperative."

#### *Department Position*

We agree with petitioner. As noted in the preliminary results of this review, the Department determined that both Izumi and Pulton were cooperative parties. As such, the Department's selection of BIA is based on the criteria established in the second tier described in the Use of Best Information Available section of this notice. The reason for this is that although rates selected under the second tier are still adverse, they are generally less punitive than those in the first tier reserved for uncooperative firms, and thus encourage cooperation.

As petitioner correctly noted, the Department does not draw any distinction between a firm's prior calculated and prior BIA rates in selecting BIA for a cooperative firm. The cooperative firm is still at an advantage vis-a-vis uncooperative firms because selection of BIA is restricted to the firm's own prior rates, or to a calculated rate from that review period.

Applying the second tier of the hierarchy, as BIA for Izumi we are using the 17.57 percent rate from the 1987-88 review period (55 FR 42602, October 22, 1990), and as BIA for Pulton we are using the 15.92 percent rate from the 1981-83 review periods (56 FR 32175, July 15, 1991).

#### *Comment 2*

Petitioner contends that the Department's BIA methodology, as applied in the preliminary results, provides a BIA floor equal to the "highest rate for a responding firm with shipments during the period." Petitioner notes that for the preliminary results the Department published a BIA rate for Izumi that was lower than the highest calculated rate for this review (the 4.12 percent rate calculated for Hitachi) and

lower than Izumi's own highest previous rate (17.57 percent).

Izumi maintains that the Department's use of BIA was not justified, since there was substantial information on the record to allow the Department to calculate a margin for Izumi. Izumi asserts that its methodology of reporting CV was reasonable and should be used to calculate CV. If the Department rejects Izumi's CV data, Izumi suggests several alternatives for the Department to calculate its margin: (1) Using only Izumi's identical matches (*i.e.*, less than 10 percent of Izumi's sales); (2) making difference of merchandise adjustments for non-identical matches, although the differences in merchandise exceed 20 percent; (3) using third country sales data reported by Izumi, although Izumi's home market is viable; and (4) accepting Izumi's identical matches, while using BIA for the rest of Izumi's sales.

#### *Department Position*

We agree with petitioner that the highest rate for a responding firm with shipments during the period forms a BIA floor for substantially cooperative respondents for the results of this review. For these final results, we have assigned to Izumi its highest rate from a previous review, which is higher.

We disagree with Izumi that its CV data should be used. The Department's decision to use BIA for Izumi was based on the magnitude of the omissions and deficiencies in its responses. Izumi's proposed options for calculating its margin are not acceptable. Izumi's home market is viable, but in most cases, the difference in merchandise between the U.S. product and the most similar home market product is greater than 20 percent. Therefore, it would be necessary to use CV to calculate FMV for all but a small number of sales. In Izumi's case, it failed to provide the Department with adequate CV information.

#### *Comment 3*

Petitioner requests that the Department modify its calculation of the value-added tax (VATR) for all respondents. Petitioner claims that, under the approach required by the statute and by judicial precedent, the Department should add a VAT amount to home market price. The Department should then increase U.S. price by the lesser of the VAT amount applicable to the home market sale or the amount that would have been assessed, but was forgiven on exportation.

In the preliminary results, petitioner contends that the Department essentially performed a circumstance of sale adjustment for VAT. Citing *Daewoo*

*Electronics Co., Ltd. Co., v. United States*, 760 F. Supp. 200, 208 (CIT 1991) ("*Daewoo*"), petitioner asserts that such an adjustment is contrary to law.

#### *Department Position*

We disagree with petitioner. As this issue is presently before the Court of Appeals for the Federal Circuit, the Department is not applying the *Daewoo* decision. The methodology used to adjust for VAT for the preliminary results, and in these final results, is consistent with the Department's practice.

#### *Comment 4*

Petitioner states that Hitachi's claimed inventory carrying costs account only for inventory time in the United States, improperly excluding costs for "time on the water."

Hitachi rebuts that costs for "time on the water" were included, with other inventory carrying costs, in its indirect selling expenses.

#### *Department Position*

We agree with Hitachi. Costs for "time on the water" are included in its indirect selling expense calculation.

#### *Comment 5*

Petitioner disputes the BIA methodology used by the Department to calculate FMVs for Kaga's sales without contemporaneous matches, and for which we have no CV information. As BIA for these sales for the preliminary results, we calculated a weighted-average FMV for each product based on all reported sales. There was an identical weighted-average FMV for each U.S. model. Petitioner maintains that this methodology is not appropriate because it rewards Kaga for failing to meet its minimum reporting obligations. For the final results, petitioner recommends that the Department assign to Kaga's unmatched sales the highest rate found for the company in any prior review.

#### *Department Position*

We disagree with petitioner. No use of punitive BIA is warranted in this situation. The Department's use of FMV averaging was an appropriate means of filling the gaps where contemporaneous model matches did not exist. However, Section 777A of the Act requires the Department to ensure that samples and averages shall be representative of the transactions under review. Therefore, before adopting for these final results the use of weighted-average FMVs for the unmatched sales, we conducted two studies on prices to ensure that the

transactions, and thus the results produced, would be representative.

First, we compared the monthly weighted-average price to the annual weighted-average price. We found that the annual weighted-average price for more than 90 percent of the products sold was within 10 percent of the monthly weighted-average price. Second, we tested whether home market prices of the subject merchandise consistently rose or fell during the POR. We found that no significant correlation existed between price and time. That is, prices did not consistently rise or fall so as to make annual weighted-average prices unrepresentative of home market prices.

The results of these test demonstrate that Kaga's pricing practices remained stable during the review period, thus ensuring that an annual weighted-average FMV is as representative of home market prices as the traditional monthly weighted-average FMV. We are satisfied that, if the weighted-average FMV is representative of the home market prices for the POR, then the margins calculated using the weighted-average prices are accurate. See, *Final Results of Antidumping Duty Administrative Review: Tapered Roller Bearings, Four Inches or Less in Outside Diameter, and Certain Components Thereof, from Japan*, (56 FR 65228, December 16, 1991).

#### *Comment 6*

Petitioner states that the Department should disallow RK Excel's claimed adjustment to FMV for technical services. Petitioner argues that we should treat RK Excel's technical services expenses as indirect expenses, rather than direct expenses.

The bulk of the expenses in question consist of the salary, fringe benefit, travel and automobile depreciation expenses of a single employee whose sole duty is to provide after-sale technical service to OEM customers. The remainder of the expenses consists of travel expenses of the R & D Department associated with performing technical services for OEMs.

#### *Department Position*

We agree with petitioner in part. For the preliminary results, we disallowed the portion of this claimed adjustment which consists of salary and benefits, because we consider them fixed expenses which would have been incurred whether or not any sales occurred. We would also normally disallow the automobile depreciation portion of the claim for the same reason. In this case, however, we have not done

so because the amount involved is insignificant. We have continued to allow the travel expense portion of the claim because we consider respondent's methodology—dividing expense incurred during the period by sales during the same period—reasonable.

#### Final Results of the Review

Based on our final analysis, we determine that the following weighted-average margins exist for the period April 1, 1989, through March 31, 1990:

Manufacturer/Exporter	Margin (Percent)
Hitachi Metals Tochno, Ltd. ....	3.50
Izumi Chain Co., Ltd. ....	17.57
Kaga Industries Co., Ltd. ....	0.00
Pulton Chain Co., Inc.: .....	
Pulton Chain/HIC: .....	
Pulton Chain/I & OC .....	15.92
RK Excel Co., Ltd. ....	0.34
All others .....	3.50

The Department shall determine, and the Customs Service shall assess, antidumping duties on all appropriate entries. Individual differences between United States price and foreign market value may vary from the percentage stated above. The Department will issue appraisement instructions directly to the Customs Service.

Furthermore, the following deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise, entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(1) of the Act: (1) The cash deposit rate for the reviewed companies will be as outlined above; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original less-than-fair-value investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will be 3.50 percent. This rate represents the highest rate for any firm with shipments in the administrative review, other than those firms receiving a rate based entirely on best information available.

These deposit requirements, when imposed, shall remain in effect until publication of the final results of the next administrative review.

This notice also serves as a final reminder to importers of their

responsibility under 19 CFR 353.26 to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This administrative review and notice are in accordance with section 751(a)(1) of the Act (19 U.S.C. 1675(a)(1)) and 19 CFR 353.22(c)(5).

Dated: February 21, 1992.

Majorie A. Chorlins,  
Acting Assistant Secretary for Import Administration.  
[FR Doc. 92-4636 Filed 2-27-92; 8:45 am]  
BILLING CODE 3510-DS-M

#### Export Trade Certificate of Review

**ACTION:** Notice of application for an amendment to an export trade certificate of review.

**SUMMARY:** The Office of Export Trading Company Affairs ("OETCA"), International Trade Administration, Department of Commerce, has received an application for an amendment to an Export Trade Certificate of Review. This notice summarizes the amendment and requests comments relevant to whether the certificate should be amended.

**FOR FURTHER INFORMATION CONTACT:** George Muller, Director, Office of Export Trading Company Affairs, International Trade Administration, 202/377-5131. This is not a toll-free number.

**SUPPLEMENTARY INFORMATION:** Title III of the Export Trading Company Act of 1982 (15 U.S.C. 4001-21) authorizes the Secretary of Commerce to issue Export Trade Certificates of Review. A Certificate of Review protects the holder and the members identified in the Certificate from state and federal government antitrust actions and from private, treble damage antitrust actions for the export conduct specified in the Certificate and carried out in compliance with its terms and conditions. Section 302(b)(1) of the Act and 15 CFR 325.6(a) require the Secretary to publish a notice in the *Federal Register* identifying the applicant and summarizing its proposed export conduct.

#### Request for Public Comments

Interested parties may submit written comments relevant to the determination whether the Certificate should be amended. An original and five (5) copies should be submitted no later than 20

days after the date of this notice to: Office of Export Trading Company Affairs, International Trade Administration, Department of Commerce, Room 1800H, Washington, DC 20230. Information submitted by any person is exempt from disclosure under the Freedom of Information Act (5 U.S.C. 552). Comments should refer to this application as "Export Trade Certificate of Review, application number 90-3A007."

OETCA has received the following application for an amendment to Export Trade Certificate of Review No. 90-00007, which was issued on August 22, 1990 (55 FR 35445, August 30, 1990) and previously amended on December 12, 1990 (55 FR 53031, December 26, 1990) and June 11, 1991 (56 FR 27946, June 18, 1991). The applicant has requested expedited review of the application pursuant to 15 CFR 325.8. A summary of the application follows.

#### Summary of the Application

**Applicant:** United States Surimi Commission ("USSC") 4200 First Interstate Center, Seattle, Washington 98104-4082, Contact: Mr. Wm. Paul MacGregor, Legal Counsel, Telephone: 206/624-5950.

**Application No.:** 90-3A007.

**Date Deemed Submitted:** February 25, 1992.

#### Request for Amended Conduct

USSC seeks to amend its Certificate to:

1. add Premier Pacific Seafoods, Inc. of Seattle, WA (controlling entities: Dave Galloway (74%) and Doug Forsythe (26%)) as a "Member" within the meaning of section 325.2(a) of the Regulations (15 CFR 325.2 (1)); and
2. delete ProFish International, Inc., Seattle, WA (controlling entity: none); and Golden Age Fisheries, Seattle, WA (controlling entities: BTI, Inc., Seattle, WA (50%) and Simonson Investments, Inc., Seattle, WA (50%)) as "Members" of the Certificate.

Dated: February 25, 1992.

George Muller,  
Director, Office of Export Trading, Company Affairs.

[FR Doc. 92-4637 Filed 2-27-92; 8:45 am]

BILLING CODE 3510-DR-M

#### Short-Supply Determination: Certain Hexagonal Steel Tubes and Trilobe Steel Tubes

**AGENCY:** Import Administration/ International Trade Administration, Commerce.

**ACTION:** Notice of short-supply determination on certain hexagonal steel tubes and trilobe steel tubes.

**SHORT-SUPPLY REVIEW NUMBER:** 65.

**SUMMARY:** The Secretary of Commerce ("Secretary") hereby grants a short-supply allowance for 28 metric tons of certain hexagonal steel tubes and trilobe steel tubes through March 31, 1992, under Article 7 of the Arrangement Between the European Economic Community and the Government of the United States of America Concerning Trade in Certain Steel Pipes and Tubes ("the U.S.-EC Arrangement").

**EFFECTIVE DATE:** February 19, 1992.

**FOR FURTHER INFORMATION CONTACT:**

Marissa A. Rauch or Kathy McNamara, Office of Agreements Compliance, Import Administration, U.S. Department of Commerce, room 7866, 14th Street and Constitution Avenue, NW., Washington, DC 20230 (202) 377-1382 or (202) 377-3793.

**SUPPLEMENTARY INFORMATION:** On February 4, 1992, the Secretary received an adequate petition from AL-KO Kober Corporation ("AL-KO Kober"), requesting a short-supply allowance for 28 metric tons of this product through March 31, 1992, under Article 7 of the U.S.-EC Arrangement. AL-KO Kober requested short supply because this product is not available in the United States and because its foreign supplier has insufficient quota available. The Secretary conducted this short-supply review pursuant to section 4(b)(4)(A) of the Steel Trade Liberalization Program Implementation Act, Public Law 101-221, 103 Stat. 1886 (1989) ("the Act"), the § 357.102 of the Department of Commerce's Short-Supply Procedures, 19 CFR 357.102 ("Commerce's Short-Supply Procedures").

#### Specifications

The requested material consists of one size of custom-shaped asymmetrical hexagonal tubes and one size of trilobe tubes. The two shapes of tubing are complimentary and used together to form a unified axle.

The exact sizes, grades and quantity requested of each tube are as follows:

Size	Steel grade	Quantity (metric tons)
80×3.....	SAE 1012 or 1020 ..... Trilobe Tubes	21
56×5.7.....	QSTE 460 TM.....	7

The hexagonal tubes are welded, but have smoothed outer seams. The cross-section of the 80×3 mm hexagonal tube

consists of three 96 degree angles between which are three 144 degree angles in alternating order. The 144 degree angles tend to be sharper than the other angles, which are more rounded.

The trilobe tubes are welded, but have smoothed outer seams. The cross-section of the trilobe tubes are essentially rounded equiangular, equilateral triangles comprised of three equiangular lobes. Each of the three lobes is a bell-shaped, rounded curve, the sides of which form a 60 degree angle. Between the bell-shaped lobes are shallow, U-shaped curves, and the sides of each form a 120 degree angle.

#### Action

On February 4, 1992, the Secretary established an official record on this short-supply request (Case Number 65) in the Central Records Unit, room B-099, Import Administration, U.S. Department of Commerce at the above address. Section 4(b)(4)(B) of the Act and § 357.106(b)(1) of Commerce's Short-Supply Procedures require the Secretary to apply a rebuttable presumption that a product is in short supply and to make a determination with respect to a short-supply petition not later than the 15th day after the petition is filed if the Secretary finds that one of the following conditions exists: (1) The raw steelmaking capacity utilization in the United States equals or exceeds 90 percent; (2) the importation of additional quantities of the requested steel product was authorized by the Secretary during each of the two immediately preceding years; or (3) the requested steel product is not currently produced in the United States. The Secretary finds that the requested product is not produced in the United States. Therefore, the Secretary has applied a rebuttable presumption that this product is presently in short supply in accordance with section 4(b)(4)(B)(i) of the Act and § 357.106(b)(1) of Commerce's Short-Supply Procedures.

Unless domestic steel producers provided proof that they could and would produce the requested quantity of this product within the desired period of time, provided it represented a normal order-to-delivery period, the Secretary would issue a short-supply allowance not later than February 19, 1992. On February 10, 1992, the Secretary published a notice in the *Federal Register* announcing a review of this request and providing domestic steel producers an opportunity to rebut the presumption of short supply. All comments were required to be received no later than February 18, 1991. No comments were received.

#### Conclusion

Since the Secretary received no comments to the *Federal Register* notice by potential suppliers to rebut the Secretary's presumption of short supply for the requested product, the Secretary hereby grants, pursuant to section 4(b)(4)(A) of the Act and § 357.102 of Commerce's Short-Supply Procedures, a short-supply allowance for 28 metric tons of the requested steel tubes in the sizes and quantities noted above, under the U.S.-EC Arrangement. This material must be exported no later than March 31, 1992.

Dated: February 19, 1992.

Marjorie A. Chorlins,

Acting Assistant Secretary for Import Administration.

[FR Doc. 92-4638 Filed 2-27-92; 8:45 am]

BILLING CODE 3510-DS-M

#### COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

##### Adjustment of Import Limits for Certain Cotton and Man-Made Fiber Textile Products Produced or Manufactured in Costa Rica

February 24, 1992.

**AGENCY:** Committee for the Implementation of Textile Agreements (CITA).

**ACTION:** Issuing a directive to the Commissioner of Customs adjusting limits.

**EFFECTIVE DATE:** March 2, 1992.

**FOR FURTHER INFORMATION CONTACT:** Nicole Bivens Collinson, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 377-4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 566-5810. For information on embargoes and quota re-openings, call (202) 377-3715.

#### SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1654).

The current limit for Categories 347/348 is being increased by application of swing and carryover. The limit for Categories 340/640 is being reduced to account for the swing being applied.

A description of the textile and apparel categories in terms of HTS numbers is available in the **CORRELATION:** Textile and Apparel Categories with the Harmonized Tariff

Schedule of the United States (see Federal Register notice 56 FR 60101, published on November 27, 1991). Also see 56 FR 22157, published on May 14, 1991.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the Memorandum of Understanding dated February 14, 1989, but are designed to assist only in the implementation of certain of its provisions.

**Auggie D. Tantillo,**  
Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements  
February 24, 1992.

Commissioner of Customs,  
Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on May 8, 1991, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton and man-made fiber textile products, produced or manufactured in Costa Rica and exported during the twelve-month period which began on June 1, 1991 and extends through May 31, 1992.

Effective on March 2, 1992, you are directed to amend the directive dated May 8, 1991, to adjust the limits for the following categories, as provided under the terms of the Memorandum of Understanding dated February 14, 1989:

Category	Adjusted twelve-month limit <sup>1</sup>
340/640 .....	592,971 dozen.
347/348 .....	1,060,420 dozen.

<sup>1</sup> The limits have not been adjusted to account for any imports exported after May 31, 1991.

The Committee for the Implementation of Textile Agreements has determined that these actions fall within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,  
**Auggie D. Tantillo,**  
Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 92-4598 Filed 2-27-92; 8:45 am]  
BILLING CODE 3510-DR-F

**COMMITTEE FOR PURCHASE FROM THE BLIND AND OTHER SEVERELY HANDICAPPED**

**Procurement List Addition**

**AGENCY:** Committee for Purchase from the Blind and Other Severely Handicapped.

**ACTION:** Addition to procurement list.

**SUMMARY:** This action adds to the Procurement List a commodity to be furnished by a nonprofit agency employing persons who are blind.

**EFFECTIVE DATE:** March 30, 1992.

**ADDRESSES:** Committee for Purchase from the Blind and Other Severely Handicapped, Crystal Square 5, suite 1107, 1755 Jefferson Davis Highway, Arlington, Virginia 22202-3509.

**FOR FURTHER INFORMATION CONTACT:** Beverly Milkman (703) 557-1145.

**SUPPLEMENTARY INFORMATION:** On November 8, 1991, the Committee for Purchase from the Blind and Other Severely Handicapped published a notice (56 FR 57323) of proposed addition to the Procurement List.

Comments were received on this proposed addition from the current contractors for the containers and other interested parties, expressing concern about delays and disruptions in service to blind persons if the containers were supplied by a single source. Both current contractors also indicated that the proposed addition would adversely affect their business.

By placing only one-third of the annual requirement for the containers on the Procurement List, the Committee has eliminated the sole source concerns. In addition, the annual value of the amount placed on the Procurement List constitutes only a small percentage of each of the current contractors' total sales. Thus, the Committee has concluded that there will not be a severe adverse impact on either firm as a result of adding one-third of the annual requirement for the containers to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to produce the commodity at a fair market price and impact of the addition on the current or most recent contractors, the Committee has determined that the commodity listed below is suitable for procurement by the Federal Government under 41 U.S.C. 46-48c and 41 CFR 51-2.4.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodity to the Government.
2. The action will not have a severe economic impact on current contractors for the commodity.

3. The action will result in authorizing small entities to furnish the commodity to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46-48c) in connection with the commodity proposed for addition to the Procurement List.

Accordingly, the following commodity is hereby added to the Procurement List:

Cassette Mailing Containers  
8115-00-NIB-0001

(One-third of the requirement for the Library of Congress, National Library Services for the Blind and Physically Handicapped)

This action does not affect contracts awarded prior to the effective date of this addition or options exercised under those contracts.

**Beverly L. Milkman,**  
Executive Director.

[FR Doc. 92-4649 Filed 2-27-92; 8:45]

BILLING CODE 6620-33-M

**Procurement List; Additions**

**AGENCY:** Committee for Purchase from the Blind and Other Severely Handicapped.

**ACTION:** Addition to procurement list.

**SUMMARY:** This action adds to the Procurement List services to be furnished by a nonprofit agency employing persons with severe disabilities.

**EFFECTIVE DATE:** March 30, 1992.

**ADDRESSES:** Committee for Purchase from the Blind and Other Severely Handicapped, Crystal Square 5, suite 1107, 1755 Jefferson Davis Highway, Arlington, Virginia 22202-3509.

**FOR FURTHER INFORMATION CONTACT:** Beverly Milkman (703) 557-1145.

**SUPPLEMENTARY INFORMATION:** On December 13, 1991 and January 6, 1992, the Committee for Purchase from the Blind and Other Severely Handicapped published notices (56 FR 65047 and 57 FR 400) of proposed additions to the Procurement List.

After consideration of the material presented to it concerning the capability of a qualified nonprofit agency to provide the services at a fair market price and the impact of the addition on the current or most recent contractor, the Committee has determined that the services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46-48c and 41 CFR 51-2.6.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the services to the Government.

2. The action will not have a severe economic impact on current contractors for the services.

3. The action will result in authorizing small entities to furnish the services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46-48c) in connection with the services proposed for addition to the Procurement List.

Accordingly, the following services are hereby added to the Procurement List:

- Disassembly of Recorders, U.S. Geological Survey, Hydrologic Instrumentation Facility, Stennis Space Center, Mississippi
- Food Service Attendant, Naval Station, Staten Island Galley, New York, New York
- Grounds Maintenance, Building 5513-Dental Clinic, Edwards Air Force Base, California
- Janitorial/Custodial, Federal Building and U.S. Post Office, Fort Collins, Colorado
- Repair and Cleaning of Respirators, Robins Air Force Base, Georgia.

This action does not affect contracts awarded prior to the effective date of this addition or options exercised under those contracts.

Beverly L. Milkman,  
Executive Director.

[FR Doc. 92-4650 Filed 2-27-92; 8:45 am]

BILLING CODE 6820-33-M

#### Procurement List; Proposed Addition

**AGENCY:** Committee for Purchase from the Blind and Other Severely Handicapped.

**ACTION:** Proposed addition to procurement list.

**SUMMARY:** The Committee has received proposals to add to the Procurement List a service to be furnished by nonprofit agencies employing persons with severe disabilities.

**COMMENTS MUST BE RECEIVED ON OR BEFORE:** March 30, 1992.

**ADDRESSES:** Committee for Purchase from the Blind and Other Severely

Handicapped, Crystal Square 5, suite 1107, 1755 Jefferson Davis Highway, Arlington, Virginia 22202-3509.

**FOR FURTHER INFORMATION CONTACT:** Beverly Milkman (703) 557-1145.

**SUPPLEMENTARY INFORMATION:** This notice is published pursuant to 41 U.S.C. 47(a)(2) and 41 CFR 51-2.3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed action.

If the Committee approves the proposed addition, all entities of the Federal Government (except as otherwise indicated) will be required to procure the service listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the service to the Government.

2. The action will result in authorizing small entities to furnish the service to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46-48c) in connection with the service proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

It is proposed to add the following service to the Procurement List: Grounds Maintenance, Naval Station, Treasure Island, and Yerba Buena Island, San Francisco, California.

Beverly L. Milkman,  
Executive Director.

[FR Doc. 92-4651 Filed 2-27-92; 8:45 am]

BILLING CODE 6820-33-M

#### Procurement List; Proposed Additions and Deletions

**AGENCY:** Committee for Purchase from the Blind and Other Severely Handicapped.

**ACTION:** Proposed additions to and deletion from procurement list.

**SUMMARY:** The Committee has received proposals to add to the Procurement List services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities,

and delete commodities and services previously furnished by such agencies.

**COMMENTS MUST BE RECEIVED ON OR BEFORE:** March 30, 1992.

**ADDRESSES:** Committee for Purchase from the Blind and Other Severely Handicapped, Crystal Square 5, suite 1107, 1755 Jefferson Davis Highway, Arlington, Virginia 22202-3509.

**FOR FURTHER INFORMATION CONTACT:** Beverly Milkman (703) 557-1145.

**SUPPLEMENTARY INFORMATION:** This notice is published pursuant to 41 U.S.C. 47(a)(2) and 41 CFR 51-2.3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

#### Additions

If the Committee approves the proposed additions, all entities of the Federal Government (except as otherwise indicated) will be required to procure the services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the services to the Government.

2. The action does not appear to have a severe economic impact on current contractors for the services.

3. The action will result in authorizing small entities to furnish the services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46-48c) in connection with the services proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

It is proposed to add the following services to the Procurement List:

- Commissary Shelf Stocking and Custodial, Brooks Air Force Base, Texas
- Food Service, White Sands Missile Range, Consolidated Dining Facility, White Sands, New Mexico
- Janitorial/Custodial, Federal Complex, 607 Hardesty Street, Kansas City, Missouri

Mailroom Service, General Services  
Administration Regional Office, 1500  
E. Bannister Road, Kansas City,  
Missouri.

#### Deletions

It is proposed to delete the following commodities and services from the Procurement List:

#### Commodities

Gown, Hospital, General Purpose  
6532-01-045-5380  
Pallet Assembly  
8140-01-050-9789

#### Services

Laundry Service, Acoma/Cononcito/  
Laguna PHS Indian Hospital, Acomita,  
New Mexico

Laundry Service, Zuni PHS Indian  
Hospital, Zuni, New Mexico  
Microfilming and Related Services,  
Internal Revenue Service, Western  
Region, Seattle, Washington.

Beverly L. Milkman,  
Executive Director.

[FR Doc. 92-4652 Filed 2-27-92; 8:45 am]

BILLING CODE 6820-33-M

## DEPARTMENT OF DEFENSE

### Office of the Secretary

#### Defense Science Board Task Force on Joint Precision Interdiction (JPI)

**ACTION:** Notice of Advisory Committee Meetings.

**SUMMARY:** The Defense Science Board Task Force on Joint Precision Interdiction (JPI) will meet in closed session on March 19-20, 1992 at the Pentagon, Arlington, Virginia.

The mission of the Defense Science Board is to advise the Secretary of Defense through the Director, Defense Research and Engineering on scientific and technical matters as they affect the perceived needs of the Department of Defense. At this meeting the Task Force will review acquisition strategies needed for an optimum family of surveillance, reconnaissance, and target acquisition systems. C3I systems and weapon systems required to perform the JPI mission.

In accordance with section 10(d) of the Federal Advisory Committee Act, Public Law No. 92-463, as amended (5 U.S.C. App. II, (1988)), it has been determined that this DSB Task Force meeting, concerns matters listed in 5 U.S.C. 552b(c)(1) (1988), and that accordingly this meeting will be closed to the public.

Dated: February 25, 1992.

Linda M. Bynum,  
Alternate OSD Federal Register Liaison  
Officer, Department of Defense.  
[FR Doc. 92-4587 Filed 2-27-92; 8:45 am]  
BILLING CODE 3810-01-M

#### DOD Advisory Panel on Streamlining and Codifying Acquisition Laws

**AGENCY:** Defense Systems Management College, DOD.

**ACTION:** Notice of meeting.

**SUMMARY:** Open to the public on March 12, 1992, starting at 8:30 a.m. in Building 184 of the Defense Systems Management College, Fort Belvoir, Virginia. The panel will hear presentations/recommendations by the task force on its review of the out-of-scope and low-level laws, and by the various panel working groups on the statutes they have reviewed to date.

For further information contact Major Jean Kopala at (703) 355-2665.

Dated: February 25, 1992.

Linda M. Bynum,  
Alternate OSD Federal Register Liaison  
Officer, Department of Defense.  
[FR Doc. 92-4586 Filed 2-27-92; 8:45 am]  
BILLING CODE 3810-01-M

### Department of the Army

#### Army Science Board; Open Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), announcement is made of the following Committee Meeting:

*Name of the Committee:* Army Science Board (ASB).

*Dates of the Meeting:* 25 March 1992.

*Time:* 0800-1630.

*Place:* Aberdeen Proving Ground, MD.

*Agenda:* The Army Science Board's Analysis, Test and Evaluation Issue Group will meet to discuss the technical and educational requirements for the civilian workforce and the utilization of professional development plans. This meeting will be open to the public. Any interested person may attend, appear before, or file statements with the committee at the time and in the manner permitted by the committee. The ASB Administrative Officer, Sally Warner, may be contacted for further information (703) 695-0781.

Sally A. Warner,  
Administrative Officer, Army Science Board.  
[FR Doc. 92-4616 Filed 2-27-92; 8:45 am]

BILLING CODE 3910-01-M

### Corps of Engineers Department of the Army

#### Intent To Prepare a Draft Environmental Impact Statement (DEIS) Proposed Levee Improvement Project; Snake and Gros Ventre Rivers, WY

**AGENCY:** Army Corps of Engineers, DOD.

**ACTION:** Notice of intent to prepare a DEIS.

**SUMMARY:** The Walla Walla District, Corps of Engineers, proposes to extend the left bank Federal levee, above the mouth of the Gros Ventre River, on the Snake River; raise the existing Gros Ventre levees to 100-year protection level; and identify other problem areas through the public scoping process. The project is located in Jackson Hole, Wyoming. This action is necessary to protect cutthroat spawning spring creeks and several homes from damage due to avulsion.

**FOR FURTHER INFORMATION CONTACT:** Comments concerning the project and DEIS should be addressed to Robert D. Volz, LTC, EN, Commanding, Walla Walla District, Corps of Engineers, Walla Walla, Washington 99362-9265, ATTN: Mr. William MacDonald. Mr. MacDonald can be reached at (509) 522-6625.

#### SUPPLEMENTARY INFORMATION:

1. This project is located along the Snake and Gros Ventre Rivers in Jackson Hole, Teton County, Wyoming. Land use in this area has been changing from primarily livestock grazing to recreational and residential development. The rivers in the area are highly braided and tend to spread out during high flows, causing flooding. To prevent flood damage, the Corps of Engineers and State and local entities built a series of levees along the Snake from River Mile 961.5 (on the opposite side of the river from Grand Teton National Park) to River Mile 944, and along the Gros Ventre from the mouth upstream to the Grand Teton National Park boundary. The upstream section of the left bank Federal levee was not completed to the mouth of the Gros Ventre River and leaves an unprotected reach in this area. This area contains Three Channel Spring Creek, an important cutthroat spawning stream, and several homes, which are all subject to avulsion damage from either the Snake River or Gros Ventre River. Levees on the Gros Ventre River have a low level of protection and need to be raised to provide 100-year level of protection. Overtopping of these levees

would damage homes, a golf course, agricultural land, and several spring creeks.

A scoping meeting will be held at Jackson, Wyoming, to determine if other problem areas exist which should be included in the study.

2. Alternatives to be investigated include:

- a. No action.
- b. Extension of left bank Federal levee, approximately 5,500 feet.
- c. Raising Gros Ventre levees to 100-year flood level.
- d. Protection of other areas subject to avulsion (to be identified).

3. Significant issues to be addressed in the DEIS include effects of the alternatives on fisheries, wildlife, endangered species, socioeconomic, and cultural resources. The project will be reviewed under all applicable Federal, State, and local statutes.

4. Affected Federal, State, and local agencies, affected Indian tribes, and other interested organizations and parties are invited to participate in scoping for the DEIS. A formal scoping meeting is planned for March 4, 1992.

5. The DEIS should be available on or about October 30, 1992.

Dated: February 14, 1992.

Donald P. Kurkjian,

Major, EN Deputy Commander.

[FR Doc. 92-4499 Filed 2-27-92; 8:45 am]

BILLING CODE 3710-GC-M

## Defense Logistics Agency

### Privacy Act of 1974; Computer Matching Program Between the Health Resources and Services Administration and the Defense Manpower Data Center of the Department of Defense

**AGENCY:** Defense Manpower Data Center, Defense Logistics Agency, DOD.

**ACTION:** Notice of a computer matching program between the Health Resources and Services Administration (HRSA) and the Defense Manpower Data Center (DMDC) of the Department of Defense (DOD) for public comment.

**SUMMARY:** DMDC, as the matching agency under the Privacy Act of 1974 (5 U.S.C. 552a), as amended, is hereby giving constructive notice in lieu of direct notice to the record subjects of a computer matching program between HRSA and DMDC that their records are being matched by computer. The record subjects are delinquent debtors of the HRSA who are current or former Federal employees receiving Federal salary or benefit payments and indebted and delinquent in their payment of debts

owed to the United States Government under certain programs administered by HRSA (including health professions, student loans, scholarships, traineeships, or grants under Titles III, VII, and VIII of the Public Health Service Act, as amended), so as to permit HRSA to pursue and collect the debt by voluntary repayment or by administrative or salary offset procedures under the provisions of the Debt Collection Act of 1982.

**DATES:** This proposed action will become effective March 30, 1992, and the computer matching will proceed accordingly without further notice, unless comments are received which would result in a contrary determination or if the Office of Management and Budget or Congress objects thereto. Any public comment must be received before the effective date.

**ADDRESSES:** Any interested party may submit written comments to the Director, Defense Privacy Office, 400 Army Navy Drive, Room 205, Arlington, VA 22202-2884.

**FOR FURTHER INFORMATION CONTACT:** Mr. Aurelio Nepa, Jr., at (703) 614-3027.

**SUPPLEMENTARY INFORMATION:** Pursuant to subsection (o) of the Privacy Act of 1974 (5 U.S.C. 552a), as amended, HRSA and DMDC have concluded an agreement to conduct a computer matching program between the agencies. The purpose of the match is to assist HRSA in identifying and locating those delinquent debtors employed in another Federal agency, including retirees receiving a Federal benefit. HRSA will use this information to initiate independent collection of these debts under the Debt Collection Act of 1982 when voluntary payment is not forthcoming or by administrative or salary offset procedures until the obligation is paid in full. These collection efforts will include requests by HRSA of the employing agency to apply administrative and/or salary offset procedures until such time as the obligation is paid in full. The parties to this agreement have determined that a computer matching program is the most efficient, effective and expeditious method for accomplishing this task with the least amount of intrusion of personal privacy of the individuals concerned. It was therefore concluded and agreed upon that computer matching would be the best and least obtrusive manner and choice for accomplishing this requirement.

A copy of the computer matching agreement between HRSA and DMDC is available upon request to the public. Requests should be submitted to the address caption above or to the Health

Resources and Services Administration, Division of Fiscal Services, Debt Management Branch, 5600 Fishers Lane, Rockville, MD 20857.

Set forth below is a notice of the establishment of a computer matching program required by paragraph 6.c. of the Office of Management and Budget Guidelines on Computer Matching published in the *Federal Register* at 54 FR 25818 on June 19, 1989.

The matching agreement as required by 5 U.S.C. 552a(r) and an advance copy of this notice was submitted on February 18, 1992, to the Committee on Government Operations of the House of Representatives, the Committee on Governmental Affairs of the Senate, and the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget pursuant to paragraph 4b of Appendix I to OMB Circular No. A-130, "Federal Agency Responsibilities for Maintaining Records about Individuals," dated December 12, 1985 (50 FR 52738, December 24, 1985). This matching program is subject to review by OMB and Congress and shall not become effective until that review period has elapsed.

Dated: February 24, 1992.

L. M. Bynum,

Alternate OSD Federal Register Liaison Office, Department of Defense.

### Computer Matching Program Between the Health Resources and Services Administration and the Defense Manpower Data Center of the Department of Defense for Debt Collection

**A. Participating agencies:** Participants in this computer matching program are the Health Resources and Services Administration (HRSA) and the Defense Manpower Data Center (DMDC) of the Department of Defense (DOD). HRSA is the source agency, i.e., the agency disclosing the records for the purpose of the match. DMDC is the specific recipient or matching agency, i.e., the agency that actually performs the computer matching.

**B. Purpose of the match:** The purpose of the match is to identify and locate delinquent debtors who are current or former Federal employees receiving any Federal salary or benefit payments and indebted and delinquent in their repayment of debts owed to the United States Government under certain programs administered by HRSA (including health professions, student loans, scholarships, traineeships, or grants under Titles III, VII, and VIII of

the Public Health Services Act, as amended), so as to permit HRSA to pursue and collect the debt by voluntary repayments or by administrative or salary offset procedures under the provisions of the Debt Collection Act of 1982.

*C. Authority for conducting the match:* The legal authority for conducting the matching program is contained in the Debt Collection Act of 1982 (Pub. L. 97-365), 31 U.S.C. chapter 37, subchapter I (General) and subchapter II (Claims of the United States Government), 31 U.S.C. 3711 Collection and Compromise, 31 U.S.C. 3716 - 3718 Administrative Offset, 5 U.S.C. 5514 Installment Deduction for Indebtedness (Salary Offset); 10 U.S.C. 136, Assistant Secretaries of Defense, Appointment Powers and Duties; Section 206 of Executive Order 11222; 4 CFR chapter II, Federal Claims Collection Standards (General Accounting Office - Department of Justice); 5 CFR 550.1101 - 550.1108 Collection by Offset from Indebted Government Employees (OPM); 40 CFR part 30.

*D. Records to be matched:* The systems of records maintained by the respective agencies under the Privacy Act of 1974, as amended, 5 U.S.C. 552a, from which records will be disclosed for the purpose of this computer match are as follows:

1. This match will involve the HRSA record system identified as 09-15-0045, "Health Resources and Services Administration Loan Repayment/Debt Management Records System, HHS/HRSA/OA", last published in the *Federal Register* at 53 FR 41243 on October 20, 1988. The HRSA file contains information on approximately 4000 debtors.

2. The DOD will use the system of records identified as S322.11 DLA-LZ, "Federal Creditor Agency Debt Collection Data Base", last published in the *Federal Register* at 52 FR 37495 on October 7, 1987. The DMDC file contains information on approximately ten million active duty, retired, and Reserve military members, current and former Federal civilian employees.

3. Both record systems contain appropriate routine use disclosure provisions required by the Privacy Act permitting the disclosure of the affected personal information between the HRSA and the DOD. The routine uses are compatible with the purposes for which the information was collected and maintained. Moreover, there will be a disclosure accounting maintained by

DMDC for any disclosures from the S322.11 DLA-LZ record system.

*E. Description of computer matching program:* HRSA, as the source agency, will provide DMDC with a magnetic tape of individuals who are indebted to the HRSA. The tape will contain data elements on individual debtors. DMDC, as the recipient agency, will perform a computer match using all nine digits of the SSN of the HRSA file against a DMDC computer data base. Matching records, "hits" based on the SSN, will produce the member's name, service or agency, and current work or home address. Matching records will be returned to HRSA. HRSA will be responsible for verifying the information and for resolving any discrepancies or inconsistencies on an individual basis. HRSA will be responsible for making the final determinations as to positive identification, amount of indebtedness, and recovery efforts as a result of the match. If the debtor is employed by another Federal agency, a request for salary or administrative offset is issued to the employing agency.

*F. Individual notice and opportunity to contest:* It will be the responsibility of HRSA to verify and determine whether the data from the DMDC match are consistent with the data from the HRSA debtor file, and to resolve any discrepancies or inconsistencies as to positive identification. HRSA will screen the initial data to verify that the matched individual is in fact a delinquent debtor not in a repay status. HRSA will do this by manually comparing the hit file with the HRSA debtor files to verify debtor identity; conducting independent inquiries when necessary to resolve questionable identities; and reviewing records of the suspected debtor's account to confirm that the debt is still in a non-pay status without resolution. Any discrepancies or inconsistencies furnished by DMDC, or developed as the result of the match, such as amount of indebtedness or salaries of hits will be independently investigated and verified by HRSA prior to any final adverse action being taken against the individual by HRSA. There will be no adverse action taken based on raw hits. Raw hit data will be manually reviewed to ensure the individuals identified are eligible for salary offset.

The debtor is given an opportunity to enter into a voluntary agreement to repay the debt under terms agreeable to HRSA. The debtor is given an opportunity to inspect and copy records related to the debt and for review of the

decision related to the debt. Requests for copies of the records relating to the debt shall be made no later than 10 days from the receipt by the debtor of the notice of indebtedness.

The debtor is entitled to a 30 day written notification informing the debtor of the circumstances under which the debt occurred, the amount owed, the intent to collect by deduction from pay if the amount owed is not paid in full, and an explanation of other rights of the debtor under the law.

The debtor is also entitled to an opportunity for a hearing concerning the existence or the amount of the debt, or when a repayment schedule is established other than by written agreement concerning the terms of the repayment schedule. The debtor shall be advised that a challenge to either the existence of the debt, the amount of the debt, or the repayment schedule, must be made within 30 days of receipt by the debtor of the notice of indebtedness or within 30 days after receipt of the records relating to the debt, if such records are requested by the debtor.

*G. Inclusive dates of the matching program:* This computer matching program is subject to review by the Office of Management and Budget and Congress. If no objections are raised by either and the mandatory 30 day public notice period for comment has expired for this *Federal Register* notice with no significant adverse public comments in receipt resulting in a contrary determination, then this computer matching program becomes effective and the respective agencies may begin the exchange of data 30 days after the date of this published notice at a mutually agreeable time and may be repeated no more than once a year. Under no circumstances shall the matching program be implemented before this 30 day public notice period for comment has elapsed as this time period cannot be waived. By agreement between HRSA and DMDC, the matching program will be in effect and continue for 18 months with an option to renew for 12 additional months unless one of the parties to the agreement advises the other by written request to terminate or modify the agreement.

*H. Address for receipt of public comments or inquiries:* Director, Defense Privacy Office, 400 Army Navy Drive, Room 205, Arlington, VA 22202-2884. Telephone (703) 614-3027.

[FR Doc. 92-4589 Filed 2-27-92; 8:45 am]

BILLING CODE 3810-01-F

## DEPARTMENT OF EDUCATION

**Office of Bilingual Education and Minority Languages Affairs; National Research Symposium; Call for Proposals**

**ACTION:** Notice of call for proposals for presentation at National Research Symposium.

**SUMMARY:** The Department of Education's Office of Bilingual Education and Minority Languages Affairs (OBEMLA) invites proposals on selected issues in the education of middle and high school students who are of limited English proficiency (LEP) for its Third National Research Symposium of LEP Student Issues to be held in Washington, DC, August 12-14, 1992.

OBEMLA welcomes proposals that are based on sound research and whose findings have direct application to the teaching and learning processes in classrooms and their surrounding communities. There is a special interest in recent educational approaches and alternative or innovative methods that will assist educators in enabling LEP students to meet the National Education Goals by the year 2000, specifically in:

- Curricular and materials development;
- Classroom strategies;
- Subject matter areas such as mathematics, science, and integrated language arts;
- Teacher education, both preservice and inservice; and
- Family-school collaboration and inter-generational learning.

Maximum proposal length is set at three double-spaced pages. All proposals must include an abstract of not more than 100 words, citations in the text and references. Winning proposal authors will be notified by April 24, 1992. Fifteen to twenty proposals will be selected through peer-review.

The authors of the selected proposals will be commissioned to write papers of up to 40 pages for presentation at the Third National Research Symposium on LEP Student Issues. A \$2,000 honorarium will be paid in addition to round-trip airfare to Washington, DC, and per diem, both at Government rates. The Department expects that an audience of approximately 400 researchers and educators from across the Nation will attend the Symposium. Final versions of the papers must be delivered to OBEMLA by July 1, 1992.

**ADDRESSES:** Proposals should be sent to Dr. Carmen Simich-Dudgeon, Director of Research and Evaluation, U.S. Department of Education, OBEMLA,

5623 Switzer Building, 330 C St. SW., Washington, DC, 20202, by March 20, 1992. Proposals arriving later than this date will not be considered. Proposal writers should include their name, address, telephone and fax numbers

**FOR FURTHER INFORMATION CONTACT:** Dr. Carmen Simich-Dudgeon. Deaf and hearing impaired individuals may call the Federal Dual Party Relay Service at 1-800-877-8339 (in the Washington, DC, 202 area code, telephone 708-9300) between 8 a.m. and 7 p.m., Eastern time.

Dated: February 20, 1992.

Rita Esquivel,

*Director, Office of Bilingual Education and Minority Languages Affairs.*

[FR Doc. 92-4574 Filed 2-27-92; 8:45 am]

BILLING CODE 4000-01-M

**Transitional Bilingual Education Program; Special Alternative Instructional Program; Proposed Priority for Fiscal Year 1992**

**AGENCY:** Department of Education.

**ACTION:** Notice of proposed priority for fiscal year 1992.

**SUMMARY:** The Secretary proposes an absolute priority for a special competition under two programs of the Office of Bilingual Education and Minority Languages Affairs for fiscal year (FY) 1992. The Secretary takes this action to assist local educational agencies (LEAs) that have experienced recent major influxes of limited English proficient (LEP) students. The priority is intended to enable affected LEAs to provide Transitional Bilingual Education (TBE) and Special Alternative Instructional (SAI) programs for these students.

**DATES:** Comments must be received on or before March 30, 1992.

**ADDRESSES:** All comments concerning this proposed priority should be addressed to Harry G. Logel, U.S. Department of Education, 400 Maryland Avenue, SW., room 5086, Switzer Building, Washington, DC 20202-6641.

**FOR FURTHER INFORMATION CONTACT:** Harry G. Logel. Telephone: (202) 732-5715. Deaf and hearing impaired individuals may call the Federal Dual Party Relay Service at 1-800-877-8339 (in the Washington, DC 202 area code, telephone 708-9300) between 8 a.m. and 7 p.m., Eastern time.

**SUPPLEMENTARY INFORMATION:** Awards for TBE and SAI programs are made to LEAs to provide instructional services to LEP children. Authority for these programs is in section 7021 of the Bilingual Education Act (20 U.S.C. 3291).

Bilingual education programs have been funded by the Federal government for over 20 years in an effort to ensure equal educational opportunity for all students. In recent years, some school districts have experienced major influxes of LEP students as a result of immigration and secondary migrations. The Secretary is proposing a special competition to provide these districts with additional assistance. A district qualifying for this competition may apply for funds under either the TBE or the SAI program.

The Secretary will determine eligibility for this competition on the basis of the same criteria used for a competition in FY 1991. An LEA is eligible for this competition if the LEA has had a recent major influx of LEP students. For this purpose, a "recent major influx of LEP students" means—as it did for the FY 1991 competition—the arrival in the LEA, within the last two years, of at least 500 LEP students or of a number of LEP students that equals at least 3 percent of the LEA's total enrollment.

The Secretary has chosen these criteria because they appear to be fair indicators of whether a school district has absorbed a sudden arrival of a substantial number of LEP children and is, therefore, in particular need of additional assistance. These criteria, moreover, are similar to those used in determining eligibility under the Emergency Immigrant Education Program.

The Secretary believes that the proposed priority will contribute significantly to the implementation of AMERICA 2000, the President's strategy for moving the Nation toward the National Education Goals. In particular, the priority will assist affected communities to attain Goal 3 by helping LEP students achieve competence in English while mastering challenging subject matter. The priority will also assist affected communities to attain Goal 5 by helping LEP students develop the skills necessary to compete in a global economy.

The Secretary will announce the final priority in a notice in the Federal Register. The final priority will be determined by responses to this notice, available funds, and other considerations of the Department. Funding of particular projects depends on the availability of funds, the nature of the final priority, and the quality of the applications received. The publication of this proposed priority does not preclude the Secretary from proposing additional priorities, nor does it limit the Secretary to funding only this

priority, subject to meeting applicable rulemaking requirements.

**Note:** This notice of proposed priority does *not* solicit applications. A notice inviting applications under this competition will be published in the *Federal Register* concurrent with or following publication of the notice of final priority. This competition will be in addition to the regular competitions for new TBE and SAI program grants in FY 1992.

#### Priority

Under 34 CFR 75.105(c)(3), the Secretary proposes to give an absolute preference to applications that meet the following priority. The Secretary proposes to fund under this competition only applications that meet this absolute priority:

The local educational agency (LEA) must propose to provide bilingual instructional services to students who are part of both a recent and a major influx of limited English proficient (LEP) children into its district. To be considered part of a recent influx, the LEP children must have arrived in the LEA's district during the two years immediately preceding the LEA's application to the Department for funds under this priority. An LEA will be determined to have received a major influx of LEP children if it can demonstrate that the total number of those recently arrived LEP students is equal to at least either 500 of those students or 3 percent of the LEA's total enrollment.

#### Intergovernmental Review

This program is subject to the requirements of Executive Order 12372 and the regulations in 34 CFR Part 79. The objective of the Executive order is to foster an intergovernmental partnership and a strengthened federalism by relying on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

In accordance with the order, this document is intended to provide early notification of the Department's specific plans and actions for this program.

#### Invitation to Comment

Interested persons are invited to submit comments and recommendations regarding this proposed priority.

All comments submitted in response to this notice will be available for public inspection, during and after the comment period, in room 5611, Switzer Building, 330 "C" Street, SW., Washington, D.C., between the hours of 8:30 a.m. and 4 p.m., Monday through Friday of each week except Federal holidays.

#### Applicable Program Regulations

34 CFR parts 500 and 501.

**Program Authority:** 20 U.S.C. 3291.

(Catalog of Federal Domestic Assistance Numbers: 84.003M Transitional Bilingual Education Program; and 84.003N Special Alternative Instructional Program)

**Dated:** January 28, 1992.

Lamar Alexander,

Secretary of Education.

[FR Doc. 92-4575 Filed 2-27-92; 8:45 am]

BILLING CODE 4000-01-M

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#### DEPARTMENT OF ENERGY

##### **Nuclear Weapons Complex Reconfiguration Programmatic Environmental Impact Statement; Announcement of Reasonable Siting Alternatives, Relocation of Certain Nuclear Facilities**

**AGENCY:** Department of Energy.

**ACTION:** Nuclear Weapons Complex Reconfiguration Programmatic Environmental Impact Statement; announcement of reasonable siting alternatives, relocation of certain nuclear facilities.

**SUMMARY:** The Department of Energy (DOE) has evaluated five candidate sites to determine which should be analyzed in the Nuclear Weapons Complex Reconfiguration Programmatic Environmental Impact Statement (PEIS) as reasonable alternatives to receive certain functions now performed at the Rocky Flats Plant near Denver, Colorado, the Pantex Plant near Amarillo, Texas, and the Y-12 Plant near Oak Ridge, Tennessee. DOE has determined that all five sites are reasonable alternatives for consideration in the PEIS. The five sites are the Hanford Site near Richland, Washington; the Idaho National Engineering Laboratory near Idaho Falls, Idaho; the Oak Ridge Reservation near Oak Ridge, Tennessee; the Pantex Plant near Amarillo, Texas; and the Savannah River Site near Aiken, South Carolina.

**ADDRESSES:** The addresses of the DOE public reading rooms established for this project are provided below.

**FOR FURTHER INFORMATION CONTACT:** Requests for further information on the DOE nuclear weapons complex reconfiguration program should be sent to: Howard R. Canter, Deputy Assistant Secretary, Weapons Complex Reconfiguration Office, DP-40, room 4C-014, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586-2700.

**SUPPLEMENTARY INFORMATION:** On February 11, 1991, DOE published a Notice of Intent (NOI) to prepare a PEIS on reconfiguring the nuclear weapons complex [56 FR 5590]. The PEIS is being prepared pursuant to the National Environmental Policy Act (NEPA), as amended (42 U.S.C. 4321 *et seq.*), the Council on Environmental Quality (CEQ) regulations implementing NEPA (40 CFR parts 1500-1508), and DOE Guidelines for compliance with NEPA (52 FR 47662), as amended (54 FR 12474 and 55 FR 37174).

DOE has identified relocating the plutonium recycling and manufacturing functions now performed at the Rocky Flats Plant as part of its preferred alternative. DOE will also examine the option of collocating either the nuclear materials functions now performed at the Pantex Plant or the uranium processing functions now performed at the Y-12 Plant, or both, with the plutonium functions from Rocky Flats.

Concurrently with the NOI, the DOE published an "Invitation for Site Proposals, Nuclear Weapons Complex Reconfiguration Site" (Invitation) to solicit sites for consideration to receive the relocated functions from the Rocky Flats, Pantex, and Y-12 Plants. Based upon qualifying criteria of size, electrical power and potable water requirements, and mission compatibility, DOE identified the five sites listed above as candidate sites and collected information packages from them. No additional sites were proposed in response to the Invitation.

DOE established a Site Evaluation Panel (SEP) to assist with the development of alternatives to be analyzed in the PEIS. The Panel reviewed the candidate sites and recommended that all five qualified as reasonable siting alternatives. DOE plans to analyze all five in the Reconfiguration PEIS as reasonable siting alternatives, within the meaning of NEPA and the CEQ regulations, to receive the plutonium functions now taking place at Rocky Flats and possibly collocating the nuclear functions now taking place at Pantex and Y-12. The decision whether to relocate any facilities and selection of a relocation site (if any) will be included in a Record of Decision (ROD) to be issued following completion of the PEIS.

This Notice concerns only the sites which will be considered in the PEIS for the potential relocation of the plutonium functions currently conducted at the Rocky Flats Plant and the potential collocation of the nuclear functions currently conducted at the Pantex and Y-12 Plants. However, the PEIS will also

consider siting alternatives for other weapons complex functions. On November 1, 1991, the Secretary of Energy decided to incorporate the environmental impact analysis for the DOE New Production Reactor (NPR) capacity proposal into the Reconfiguration PEIS and include NPR siting and technology decisions in the Reconfiguration ROD. The draft NPR Environmental Impact Statement, issued in April 1991, examined three siting alternatives: the Hanford Site, the Idaho National Engineering Laboratory, and the Savannah River Site; all of these are on the list of sites evaluated by SEP for relocation of the nuclear functions now carried out at the Rocky Flats, Pantex, and Y-12 Plants. Accordingly, for the Hanford, Idaho, and Savannah River sites, the PEIS will assess the effects of collocating tritium production activities with one or more other nuclear functions as well as analyzing locating the tritium activities alone. DOE is currently reevaluating siting options for the NPR to determine if any other sites would be reasonable alternatives for locating tritium supply capacity in light of the Secretary's November 1, 1991, announcement. The possibility of relocating other weapons complex mission elements would also be examined in the PEIS in the interest of further consolidating the weapons complex.

The SEP report that evaluates the suitability of the five sites listed above for the relocation of the nuclear functions currently at the Rocky Flats, Pantex, and Y-12 plants has been placed in the DOE public reading rooms (listed below) established for the Reconfiguration PEIS. The five site information packages that were evaluated in the report are also available for review.

The fourteen public reading rooms established for the Reconfiguration PEIS are as follows:

#### DOE Public Reading Rooms

##### California

U.S. Department of Energy, San Francisco Field Office, 1333 Broadway, Oakland, California 94612, (415) 273-4428.

##### Colorado

U.S. Department of Energy, Rocky Flats Public Reading Room, Front Range Community College Library, 3645 West 112th Avenue, Westminster, Colorado 80030, (303) 469-4435.

##### Florida

U.S. Department of Energy, Public Reading Room, Largo Public Library,

351 East Bay Drive, Largo, Florida 34640, (813) 587-6715.

##### Idaho

U.S. Department of Energy, Idaho Field Office, Public Reading Room, 1776 Science Center Drive, P.O. Box 1625, Idaho Falls, Idaho 83402, (208) 526-1191.

##### Illinois

U.S. Department of Energy, Chicago Field Office, 9800 South Cass Avenue, Argonne, Illinois 60439, (708) 972-2010.

##### Missouri

U.S. Department of Energy, Public Reading Room, Red Bridge Branch, Mid-Continent Public Library, 11140 Locust Street, Kansas City, Missouri 64137, (816) 942-1780.

##### New Mexico

U.S. Department of Energy, Albuquerque Field Office, Pennsylvania and H Streets, P.O. Box 5400, Kirtland Air Force Base, New Mexico 87115, (505) 845-5163.

##### Nevada

U.S. Department of Energy, Nevada Field Office, 2753 South Highland Drive, Las Vegas, Nevada 89193, (702) 295-1274.

##### Ohio

Miamisburg Library, 35 South Fifth Street, Miamisburg, Ohio 45342, Attn: Department of Energy Public Reading Room, (513) 866-1071.

##### South Carolina

U.S. Department of Energy Reading Room, University of South Carolina, Aiken Campus, Writing Center, 171 University Parkway, Aiken, South Carolina 29801, (803) 646-6851, Extension 3262.

##### Tennessee

U.S. Department of Energy, Oak Ridge Field Office, Freedom of Information Officer, 200 Administration Road, Room C-209, P.O. Box 2001, Oak Ridge, Tennessee 37831, (615) 576-9344 or 576-1216.

##### Texas

U.S. Department of Energy Reading Room, Lynn Library—Learning Center, Amarillo College, 2201 South Washington Street, Amarillo, Texas 79109, (806) 371-5400.

##### Washington

U.S. Department of Energy, Richland Field Office, 625 Jadwin Avenue, Room 157, P.O. Box 1970, Mail Stop A1-65, Richland, Washington 99352, (509) 376-6583.

##### Washington, DC

U.S. Department of Energy, Freedom of Information Reading Room, room 1F-190, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586-6020.

For information on the availability of specific documents and hours of operation, please contact the reading rooms at the telephone numbers provided.

Issued in Washington, DC this 24th day of February 1992.

Richard A. Claytor,

Assistant Secretary for Defense Programs.

[FR Doc 92-4655 Filed 2-27-92; 8:45 am]

BILLING CODE 6450-01-M

#### San Francisco Field Office, New Cooperative Agreement; Noncompetitive Award

**AGENCY:** U.S. Department of Energy (DOE).

**ACTION:** Notice of noncompetitive financial assistance award.

**SUMMARY:** The U.S. Department of Energy San Francisco Field Office announces, it is restricting eligibility for award of DE-FG03-92 SF19168 as a Cooperative Agreement to the State of Hawaii for conducting a comprehensive energy study for the state.

**DATES:** The terms of this award will commence on February 28, 1992, and end on February 14, 1993. The total estimated cost of the award is \$685,000.

**ADDRESSES:** Supporting documentation is available for public inspection upon request at the following location: U.S. Department of Energy, San Francisco Field Office, 1333 Broadway, Oakland, CA 94612.

**FOR FURTHER INFORMATION CONTACT:** Maria C. Hernandez of the DOE San Francisco Field Office Contracts Management Division, telephone (510) 273-4133.

**SUPPLEMENTARY INFORMATION:** A comprehensive energy study will be conducted by the State of Hawaii including an assessment of that State's fossil fuel strategic reserve requirements and the most effective and efficient way to meet those needs, the availability and practicality of increasing the use of native energy resources, potential alternative fossil energy technologies such as coal gasification which potentially could enhance the islands' electric and liquid fuel resources, and potential energy efficiency measure which can lead to demand reduction. Within the study, a paramount

consideration shall be accorded to security of supply and energy security by diversity, where appropriate. Environmental concerns, including waste reduction, shall also be given strong consideration in the report.

This announcement is made pursuant to the Financial Assistance Rules, 10 CFR 600.7(b)(2)(i)(C).

Joan Macrusky,

*Acting Director, Contracts Management Division.*

[FR Doc. 92-4656 Filed 2-27-92; 8:45 am]

BILLING CODE 6450-01-M

### Secretary of Energy Advisory Board Task Force on Economic Analysis and Modeling Related to Energy; Open Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770, as amended), notice is hereby given of the following advisory committee task force meeting:

*Name:* Secretary of Energy Advisory Board Task Force on Economic Analysis and Modeling Related to Energy.

*Date and Time:* Tuesday, March 17, 1992, 8:30 a.m.—12:15 p.m.

*Place:* U.S. Department of Energy, Forrestal Building—room 1E-245, 1000 Independence Avenue, SW., Washington, DC 20585.

*Note:* To obtain badge at front desk it will be necessary to have a picture I.D. (For example, Driver's License, Passport or Company I.D.). All visitors will be escorted at all times for security reasons.

*Contact:* Susan D. Heard, Designated Federal Officer, 1000 Independence Avenue, SW., Washington, DC 20585, Telephone: (202) 586-3770.

*Purpose:* The Task Force will advise the Department of Energy on how economic models and tools of analysis can better be used to address issues of energy policy by developing recommendations to clarify analytical needs, facilitate communication between DOE analysts and policy makers, and create institutions within DOE that accumulate knowledge gained through the policy making process.

#### TENTATIVE AGENDA

Tuesday, March 17, 1992

8:30 a.m.—Call to Order—Roger Noll, Kenneth Lay.

8:45-9:15—Progress report by the subgroup on Current and Emerging Issues—Glenn Schleede.

9:15-9:45—Progress Report by the subgroup on Economic Analysis and Modeling Principles—Stephen Peck.

9:45-10—Status of commissioned papers—David Bjornstad.

10-10:20—Break

10:20-11:20—Discussion of the NEMS review—Roger Noll.

11:20-11:45—Discussion of externalities study review—David Bjornstad.

11:45-12—Discussion of preparations for the June workshop—Roger Noll

12 p.m.—Public Comments

12:15—Adjourn

#### Public Participation

The meeting is open to the public. The Chairman of the Task Force is empowered to conduct the meeting in a fashion that will, in the Chairman's judgment, facilitate the orderly conduct of business.

Persons wishing to attend the public meeting should provide their names and social security numbers to (202) 586-7092 by March 13 to arrange for visitor passes to the Forrestal Building.

Any member of the public who wishes to make an oral statement pertaining to agenda items should contact the Designated Federal Officer at the address or telephone number listed above. Requests must be received before 3 pm (E.S.T.) Friday, March 13, 1992, and reasonable provision will be made to include the presentation during the public comment period. It is requested that oral presenters provide 15 copies of their statements at the time of their presentations.

Written testimony pertaining to agenda items may be submitted prior to the meeting. Written testimony must be received by the Designated Federal Officer at the address shown above before 5 pm (E.S.T.) Friday, March 13, 1992, to assure it is considered by Task Force members during the meeting.

#### Minutes

A transcript of the open, public meeting will be available for public review and copying approximately 30 days following the meeting at the Public Reading Room, 1E-190, Forrestal Building, 1000 Independence Avenue SW., Washington, DC, between 9 a.m. and 4 p.m., Monday through Friday except Federal holidays.

Issued: Washington, DC, on February 24, 1992.

Marcia L. Morris,

*Deputy Advisory Committee Management Officer.*

[FR Doc. 92-4657 Filed 2-27-92; 8:45 am]

BILLING CODE 6450-01-M

### Conduct of Employees; Waiver Pursuant to Section 602(c) of the Department of Energy Organization Act (Pub. L. No. 95-91)

Section 602(a) of the Department of Energy ("DOE") Organization Act (Pub. L. No. 95-91, hereinafter referred to as the "Act") prohibits a "supervisory employee" (defined in section 601(a) of the Act) of the Department from knowingly receiving compensation from, holding any official relation with, or

having any pecuniary interest in any "energy concern" (defined in section 601(b) of the Act).

Section 602(c) of the Act authorizes the Secretary of Energy to waive the requirements of section 602(a) where the interest is a pension, insurance, or other similarly vested interest.

Mr. Silas D. Stadler has been appointed to the position of Director of the Performance Assessment Division in the Office of Nuclear Safety. As a result of his past employment with The Detroit Edison Company, Mr. Stadler has a vested pension interest, within the meaning of section 602(c) of the Act, in the company's Employees' Retirement Plan. Accordingly, I have granted Mr. Stadler a waiver of the divestiture requirement of section 602(a) of the Act for the duration of his employment with the Department with respect to this pension interest.

In accordance with section 208, title 18, United States Code, Mr. Stadler has been directed not to participate personally and substantially, as a Government employee, in any particular matter to outcome of which could have a direct and predictable effect upon the The Detroit Edison Company.

Dated: February 13, 1992.

James D. Watkins,

*Admiral, U.S. Navy (Retired), Secretary of Energy.*

[FR Doc. 92-4654 Filed 2-27-92; 8:45 am]

BILLING CODE 6450-01-M

### Office of Fossil Energy

[FE Docket No. 91-97-NG]

### Interenergy Corp.; Order Granting Authorization To Import and Export Natural Gas

**AGENCY:** Office of Fossil Energy, Department of Energy.

**ACTION:** Notice of an order granting blanket authorization to import and export natural gas.

**SUMMARY:** The Office of Fossil Energy of the Department of Energy gives notice that it has issued an order granting Interenergy Corporation blanket authorization to import up to 73 Bcf and export up to 73 Bcf of natural gas from and to Canada, and any other country with which trade in natural gas is not prohibited, over a two-year period commencing with the date of first import or export.

A copy of this order is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F-056, Forrestal Building, 1000 Independence

Avenue SW., Washington, DC 20585, (202) 586-9478. The docket room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, February 24, 1992.

Charles F. Vacek,

Deputy Assistant Secretary for Fuels Programs, Office of Fossil Energy.

[FR Doc. 92-4658 Filed 2-27-92; 8:45 am]

BILLING CODE 6450-01-M

[FE Docket No. 91-90-NG]

### Marathon Oil Company; Order Granting Authorization To Export Natural Gas To Mexico

**AGENCY:** Office of Fossil Energy, Department of Energy.

**ACTION:** Notice of an order granting blanket authorization to export natural gas.

**SUMMARY:** The Office of Fossil Energy of the Department of Energy gives notice that it has issued an order granting Marathon Oil Company blanket authorization to export a total of 73 Bcf of U.S. natural gas to Mexico over a two-year period commencing with the date of first delivery.

A copy of this order is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F-056, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586-9478. The docket room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, February 24, 1992.

Charles F. Vacek,

Deputy Assistant Secretary for Fuels Programs, Office of Fossil Energy.

[FR Doc. 92-4659 Filed 2-27-92; 8:45 am]

BILLING CODE 6450-01-M

[FE Docket No. 91-99-NG]

### Petro Source Corporation; Order Granting Blanket Authorization To Import and Export Natural Gas From and to Canada and Mexico

**AGENCY:** Office of Fossil Energy, Department of Energy.

**ACTION:** Notice of order granting blanket authorization to import and export natural gas from and to Canada and Mexico.

**SUMMARY:** The Office of Fossil Energy of the Department of Energy gives notice that it has issued an order granting Petro Source Corporation authorization to

import from Canada and Mexico up to 100 Bcf of natural gas and export from the United States to Canada and Mexico up to 100 Bcf of natural gas over a two-year period beginning on the date of first delivery.

A copy of this order is available for inspection and copying in the Office of Fuels Programs Docket Room, 3F-056, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586-9478. The docket room is open between the hours of 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, February 24, 1992.

Charles F. Vacek,

Deputy Assistant Secretary for Fuels Programs, Office of Fossil Energy.

[FR Doc. 89-4660 Filed 2-27-89; 8:45 am]

BILLING CODE 6450-01-M

### Economic Regulatory Administration

#### Issuance of Revised Proposed Remedial Order to OXY USA Inc.

**AGENCY:** Economic Regulatory Administration, DOE.

**ACTION:** Notice of issuance of revised proposed remedial order to OXY USA Inc. and notice of opportunity for objection.

**SUMMARY:** Pursuant to 10 CFR 205.192(c), the Economic Regulatory Administration (ERA) of the Department of Energy (DOE) hereby gives notice of a Revised Proposed Remedial Order issued to OXY USA Inc., formerly Cities Service Oil and Gas Corporation, successor in interest to Cities Service Company (collectively Cities). This Revised Proposed Remedial Order charges Cities with filing false monthly entitlements reports, and circumventing the DOE's Entitlements Program, in violation of 10 CFR 211.66(b) and (h), 211.67(j), and 205.202, with respect to 82 reciprocal crude oil "tier trade" transactions which Cities consummated with thirteen crude oil resellers between October 1979 and December 1980. The total violation amount is \$253,766,849.54, plus interest. The impact of Cities' conduct was spread nationwide.

**SUPPLEMENTARY INFORMATION:** The Revised Proposed Remedial Order is issued pursuant to the remand directive in a Remedial Order decision and order issued to Cities by the DOE's Office of Hearings and Appeals (OHA) on September 30, 1988. Cities Service Oil and Gas Corp., 17 DOE ¶ 83,021 (1988). In this Revised Proposed Remedial Order, the ERA seeks restitution of the violation amount noted above, plus

interest, in the alternative to the \$263.9 million, plus interest, in restitution ordered by the OHA in the Remedial Order issued to Cities in 1988.

**ADDRESSES:** A copy of the Revised Proposed Remedial Order may be obtained from the DOE Freedom of Information Reading Room, U.S. Department of Energy, 1000 Independence Avenue SW., room 1E-190, Washington, DC 20585, (202) 586-6020.

**DATES:** Within fifteen (15) days of publication of this notice, any aggrieved person may file a Notice of Objection with the Office of Hearings and Appeals, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585, in accordance with 10 CFR 205.193. If a Notice of Objection is not filed in accordance with § 205.193, the proposed order may be issued as a final Remedial Order by the Office of Hearings and Appeals.

Issued in Washington, DC on the 24th day of February 1992.

Chandler L. van Orman,

Acting Administrator, Economic Regulatory Administration.

[FR Doc. 92-4661 Filed 2-27-92; 8:45 am]

BILLING CODE 6450-01-M

### Office of Energy Research

#### Fusion Energy Advisory Committee; Open Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (Public Law 92-463, 86 Stat. 770), notice is hereby given of the following meeting:

*Name:* Fusion Energy Advisory Committee (FEAC).

*Date and Time:* Wednesday, March 18, 1992-8:30 a.m.-5:30 p.m.; Thursday, March 19, 1992-8:30 a.m.-5 p.m.

*Place:* Melvin B. Gottlieb Auditorium (C-Site), Princeton University, Plasma Physics Laboratory, Forrestal Campus, U.S. Route #1 North, Princeton, New Jersey 08543.

*Contact:* Deborah Lonsdale, U.S. Department of Energy, GTN, Office of Fusion Energy (ER-50), Office of Energy Research, Washington, DC 20585, Telephone: 301-903-4941.

*Purpose of the Committee:* To provide advice on a continuing basis to the Department of Energy on the complex scientific and technical issues that arise in the planning, management, and implementation of its Fusion Energy Program.

*Tentative Agenda:*

Wednesday, March 18, 1992

- Report from Panel #2 on the U.S. Program after the Tokamak Fusion Test Reactor (TFTR).
- Discussion of Panel #2 Report.
- Public Comment (10 Minute Rule).

Thursday, March 19, 1992

- Continued Discussion of Panel #1 Report on the International Thermonuclear Experimental Reactor (ITER).
- Progress Report from Panel #3 on Concept Improvements.
- Tour of Princeton Plasma Physics Laboratory.
- Public Comment (10 Minute Rule).

**Public Participation:** The meeting is open to the public. Written statements may be filed with the Committee either before or after the meeting. Members of the public who wish to make oral statements pertaining to agenda items should contact: Deborah Lonsdale at the address or telephone number listed above. Requests must be received 5 days prior to the meeting and reasonable provision will be made to include the presentation on the agenda. The Chairperson of the Committee is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business.

**Transcripts:** The transcript of the meeting will be available for public review and

copying at the Freedom of Information Reading Room, 1E-190, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

Issued at Washington, DC on February 24, 1992.

Marcia L. Morris,  
Deputy Advisory Committee Management Officer.

[FR Doc. 92-4662 Filed 2-27-92; 8:45 am]

BILLING CODE 6450-01-M

**Office of Hearings and Appeals**

**Cases Filed: Week of January 3 Through January 10, 1992**

During the Week of January 3 through January 10, 1992, the appeals and applications for exception or other relief listed in the Appendix to this Notice

were filed with the Office of Hearings and Appeals of the Department of Energy. Submissions inadvertently omitted from earlier lists have also been included.

Under DOE procedural regulations, 10 CFR part 205, any person who will be aggrieved by the DOE action sought in these cases may file written comments on the application within ten days of service of notice, as prescribed in the procedural regulations. For purposes of the regulations, the date of service of notice is deemed to be the date of publication of this Notice or the date of receipt by an aggrieved person of actual notice, whichever occurs first. All such comments shall be filed with the Office of Hearings and Appeals, Department of Energy, Washington, DC 20585.

Dated: February 24, 1992.

George B. Breznay,  
Director, Office of Hearings and Appeals.

**LIST OF CASES RECEIVED BY THE OFFICE OF HEARINGS AND APPEALS**

[Week of Jan. 3 through Jan. 10, 1992]

Date	Name and location of applicant	Case No.	Type of submission
Jan. 6, 1992	New Dixie Oil Corporation Roanoke Rapids, NC	LEE-0033	Exception to the reporting requirements. If Granted: New Dixie Oil Corporation would not be required to file Form EIA-782B, "Resellers'/Retailers' Monthly Petroleum Product Sales Report."
Jan. 9, 1992	Texaco/City of Elgin, Washington, DC	RR321-103	Request for modification/rescission in the Texaco refund proceeding. If Granted: The September 21, 1990 Decision and Order (Case No. RF321-3475) issued to the City of Elgin would be modified regarding the city's Application for Refund submitted in the Texaco refund proceeding.
Jan. 10, 1992	ARCO/Ahmad's ARCO, Atlantic Beach, FL	RR304-23	Request for modification/rescission in the ARCO refund proceeding. If Granted: The April 24, 1989 Dismissal Letter (Case No. RF304-4130) issued to Ahmad's ARCO would be modified regarding the firm's Application for Refund submitted in the ARCO refund proceeding.
Jan. 10, 1992	Jones, Walker, Waechter, Poitevent, Carrere & Denegre New Orleans, LA.	LFA-0177	Appeal of an information request denial. If Granted: The December 12, 1991 Freedom of Information Request Denial issued by the Strategic Petroleum Reserve Project Management Office (SPRMO) would be rescinded, and Jones, Walker, Waechter, Poitevent, Carrere & Denegre would receive access to all records pertaining to the ADP Disaster Recovery Plan, Master Drawing System Plan, Master Test Plan, Property Control System Document, Radio Communications Operating Procedures, System Safety Program, Plan System Engineering Management Plan, or Technical Data Center Management Plan.
Jan. 10, 1992	Texaco/Transport Service Company, Washington, DC	RR321-104	Request for modification/rescission in the Texaco refund proceeding. If Granted: The December 6, 1990 Decision and Order (Case No. RF321-4085) issued to Transport Service Company regarding the firm's Application for Refund submitted in the Texaco refund proceeding would be modified.
January 10, 1992	Wisconsin Project on Nuclear Arms Control Washington, DC.	LFA-0176	Appeal of an information request denial. If Granted: The Freedom Request Denial issued by the Office of Arms Control and Nonproliferation Technology Support, Defense Programs, Department of Energy would be rescinded, and Wisconsin Project on Nuclear Arms Control would receive access to certain DOE information.

**REFUND APPLICATIONS RECEIVED**

Date Received	Name of refund proceeding/name of refund applicant	Case No.
12/17/91	Burger Bros. Distributing.	RF321-18263.
1/3/92 thru 1/10/92.	Texaco Refund Applications Received.	RF321-18259 thru RF321-18359.

**REFUND APPLICATIONS RECEIVED—Continued**

Date Received	Name of refund proceeding/name of refund applicant	Case No.
1/3/92 thru 1/10/92.	Crude Oil Refund Applications Received.	RF272-91290 thru RF272-91381.

**REFUND APPLICATIONS RECEIVED—Continued**

Date Received	Name of refund proceeding/name of refund applicant	Case No.
1/3/92 thru 1/10/92.	Gulf Oil Refund Applications Received.	RF300-18294 thru RF300-19403.

REFUND APPLICATIONS RECEIVED—  
Continued

Date Received	Name of refund proceeding/name of refund applicant	Case No.
1/3/92 thru 1/10/92.	Atlantic Richfield Applications Received.	RF304-12670 thru RF304-12693.
1/6/92	Warren Exxon Servicenter.	RF307-10210.
1/6/92	David Rupp	RF335-62.
1/6/92	Viola Holmer	RF335-63.
1/6/92	Russ' Super Clark 100 #1797.	RF342-110.
1/6/92	George Cernovich.	RF342-111.
1/7/92	Joe's Clark Super 100.	RF342-112.
1/7/92	Mallory's L.P. Products.	RF340-41.
1/8/92	Castoro GMC Truck Company.	RF307-10211.
1/8/92	Allan's Clark Super 100.	RF342-113.
1/8/92	Reed's Clark Service.	RF342-114.
1/9/92	Barnard Oil Co., Inc.	RF340-42.
1/9/92	Connersville Gasoline.	RF342-115.
1/9/92	Doug's Clark Super 100.	RF342-118.
1/9/92	Sam's Service Station.	RF315-10180.
1/10/92	Raukin Oil Co	RF340-43.
1/10/92	C.W. Heist Bottled Gas Sales.	RF340-44.
1/10/92	La Gloria Oil & Gas Co.	RF340-45.
1/10/92	Cecil's Super 100.	RF342-117.
1/10/92	Cleatus McPhearson.	RF342-118.
1/10/92	Rjo's Clark Super 100.	RF342-119.
1/10/92	Ray Ondreka's Super 100.	RF342-120.
1/13/92	Petroleum Electronics, Inc.	RF333-25.
1/13/92	Jobbers Buying Group.	RF333-26.
1/13/92	Crago & Cook Enterprises, Inc.	RF333-27.
1/13/92	Everdyke Oil Co	RF333-28.

[FR Doc. 92-4663 Filed 2-27-92; 8:45 am]

BILLING CODE 6450-01-M

**Issuance of Decisions and Orders During the Week of January 6 through January 10, 1992**

During the week of January 6 through January 10, 1992, the decisions and orders summarized below were issued with respect to appeals and applications for other relief filed with the Office of Hearings and Appeals of the Department of Energy. The following summary also contains a list of submissions that were dismissed by the Office of Hearings and Appeals.

Copies of the full text of these decisions and orders are available in the Public Reference Room of the Office of Hearings and Appeals, room 1E-234, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585, Monday through Friday, between the hours of 1 p.m. and 5 p.m., except federal holidays. They are also available in Energy Management: Federal Energy Guidelines, a commercially published loose leaf reporter system.

Dated: February 24, 1992.

**George B. Breznay,**  
*Director, Office of Hearings and Appeals.*

**Appeals***Mark S. Boggs, 1/8/92, LFA-0171*

On September 6, 1991, Mark S. Boggs filed an Appeal from a determination issued by the Oak Ridge Operations Office (Oak Ridge) in response to a request from Mr. Boggs submitted under the Freedom of Information Act (FOIA). In that determination, Oak Ridge released documents found to be responsive to Mr. Boggs' request but which contained handwritten corrections. Mr. Boggs appealed, requesting "corrected" copies of the document. The DOE found that Oak Ridge had conducted a search reasonably calculated to uncover the material that Mr. Boggs requested but that no "corrected" copies existed. Therefore, Mr. Boggs' Appeal was denied.

*The Government Accountability Project, 1/8/92, LFA-0169*

The Government Accountability Project (GAP) filed an Appeal from a determination issued by the Richmond Operations Office in response to a request from GAP submitted under the Freedom of Information Act (FOIA). GAP had sought transcripts of four depositions taken in connection with litigation involving alleged illegal retaliation by Westinghouse Hanford Company, the prime contractor at the DOE's Hanford facility, against one of its employees. The transcripts, which were in the possession of Westinghouse, had never come into possession of the DOE. The DOE noted that the transcripts dealt primarily with how Westinghouse managed its internal affairs, not with any governmental function. Under these circumstances, the DOE found that the transcripts did not constitute "agency records" for FOIA purposes. Accordingly, the Appeal was denied.

**Refund Applications**

*Gulf Oil Corp./Aristech Chemical Corp., 1/10/92, RF300-10954*

The DOE issued a Decision and Order denying an Application for Refund filed by Aristech Chemical Corporation (Aristech) in the Gulf Oil Corporation special refund proceeding. Aristech filed its refund based on its purchases of styrene and cumene. But Aristech has not demonstrated that these products for which it requests a refund were covered by any of the relevant regulations. Accordingly, because the evidence before us indicates that these products are ineligible for a refund for the purposes of this proceeding, the Application for Refund was denied.

*Gulf Oil Corp./Union Camp Corp., 1/8/92 RF300-13647*

The DOE issued a Decision and Order concerning an Application for Refund submitted in the Gulf Oil Corporation special refund proceeding by Union Camp Corporation, an end-user who purchased Gulf products both directly from Gulf and indirectly through a distributor, S.W. Rawls. S.W. Rawls has received a refund in the Gulf proceeding under a presumption of injury. Therefore, Union Camp's Application for Refund was analyzed under the same procedures used for a direct purchaser. The Applicant was granted a full volumetric refund for its purchases of 71,079,983 gallons of refined products. The total refund granted in the Decision is \$71,791.

*Murphy Oil Co./Creola Mercantile Co., 1/10/92, RF309-1100*

The DOE issued a Decision and Order concerning the Application for Refund filed in the Murphy Oil Company special refund proceeding by Creola Mercantile Company (Creola). To substantiate its claim, Creola submitted a representative sample of ledger sheets dated from January 1975 to October 1975. Since these ledger sheets indicated the dollar amount paid each month instead of gallons, DOE converted the purchase amounts from dollars to gallons by referring to the State Energy Price and Expenditure Data Systems as compiled by the Energy Information Administration (EIA) of the DOE. DOE found that the computed 1975 gallonage was consistent with Creola's claimed 1975 purchase volume. The OHA concluded that Creola had sufficiently substantiated its total claimed purchase volume. The total refund granted in this Decision was \$198 (comprised of \$139 in principal and \$59 in interest).

*Murphy Oil Co./Crown Oil Co., Inc. American Petroleum Developers, Inc., 1/7/92, RF309-1156, RF309-1157*

The DOE issued a Decision and Order concerning two Applications for Refund filed in the Murphy Oil Company special refund proceeding by two commonly owned firms, Crown Oil Company, Inc. (Crown), and American Petroleum Developers, Inc. (APD). As is customary, the purchase volumes of Crown and APD were combined in order to determine their eligibility for a refund. Crown documented purchases of 15,982,187 gallons of motor gasoline and distillates during the consent order period. APD demonstrated that it purchased 5,637,609 gallons of motor gasoline and distillates during the consent order period. Thus, the maximum basis for a refund was purchases of 21,619,796 gallons of refined products (15,982,187 gallons plus 5,637,609 gallons). Under the procedures in Murphy, the firms could seek a refund under the medium-range presumption of injury. Accordingly, Crown was granted a refund of \$7,405 (\$5,223 principal and \$2,182 interest). APD was granted a refund of \$2,612 (\$1,842 principal and \$770 interest). The total refund granted is \$10,017 (comprised of \$7,065 in principal and \$2,952 in interest).

*Shell Oil Co./Tomco, Inc., 1/8/92, RF315-6513*

The DOE issued a Decision and Order denying an Application for Refund filed in the Shell Oil Company (Shell) special refund proceeding. This Application was filed by Tomco, Inc. (Tomco), a reseller of Shell petroleum products during the consent order period. In 1987, the shareholders of Tomco purchased a 37% interest in Trasher Oil Company (Thrasher), Tomco's exclusive supplier during the consent order period, and purchased a controlling interest in Thrasher subsequent to Tomco's filing in this proceeding in 1989. In light of the current common ownership of the firms, DOE considered the firms to be affiliated. In cases where the product was purchased and subsequently sold to an affiliated firm, DOE has determined that the purchase volumes may only be considered once in calculating the claimant's refund. Because Thrasher has already received a refund in this proceeding under the mid-level presumption of injury, the DOE determined that Tomco's submission be denied.

*Shell Oil Co./Tomco, Inc., 1/8/92, RF315-6513*

The DOE issued a Decision and Order denying an Application for Refund filed in the Shell Oil Company (Shell) special refund proceeding. This Application was filed by Tomco, Inc. (Tomco), a reseller of Shell petroleum products during the

consent order period. In 1987, the shareholders of Tomco purchased a 37% interest in Trasher Oil Company (Thrasher), Tomco's exclusive supplier during the consent order period, and purchased a controlling interest in Thrasher subsequent to Tomco's filing in this proceeding in 1989. In light of the current common ownership of the firms, DOE considered the firms to be affiliated. In cases where the product was purchased and subsequently sold to an affiliated firm, DOE has determined that the purchase volumes may only be considered once in calculating the claimant's refund. Because Thrasher has already received a refund in this proceeding under the mid-level presumption of injury, the DOE determined that Tomco's submission be denied.

**Refund Applications**

The Office of Hearings and Appeals issued the following Decisions and Orders concerning refund applications, which are not summarized. Copies of the full texts of the Decisions and Orders are available in the Public Reference Room of the Office of Hearings and Appeals.

Aminoil U.S.A., Inc.: Poe's Rural & City Gas Co.	RF139-208	01/08/92
Terhune L.P. Gas Co.	RF139-209	
Wildor & Son, Inc.	RF139-210	
Atlantic Richfield Company/ Kavanaugh & Van Fleet, Inc.	RR304-21	01/09/92
Atlantic Richfield Company: Scott's L.P. Gas, Inc.	RF304-5874	01/09/92
Scott's L.P. Gas, Inc.	RF304-5875	
Scott's L.P. Gas, Inc.	RF304-5876	
Scott's L.P. Gas, Inc.	RF304-5877	
Scott's L.P. Gas, Inc.	RF304-5878	
Scott's L.P. Gas, Inc.	RF304-5879	
Atlantic Richfield Company: Tracy E. Gargis Service Stat.	RF304-4504	01/07/92
Pepsi Cola Btlg. Co. of Takima.	RF304-6574	
Noel Canning Corp.	RF304-6575	
Citronelle-Mobile Gathering: Conoco Inc. ....	RF336-35	01/07/92
Mobil Oil Corp. ....	RF336-38	
D.C. Speer Construction Co. <i>et al.</i>	RF272-65181	01/08/92
Allied Corp., Inc. ....	RD272-64433	
Frehner Construction Co.	RD272-66378	

Greer Steel Co. .... Delaware	RD272-69790 RF272-77194	01/09/92
Administration for Regional Transit <i>et al.</i>		
Gulf Oil Corporation/ Beckham Gulf <i>et al.</i>	RF300-14076	01/10/92
Gulf Oil Corporation: C.R. Quesenberry, Inc.	RR300-56	01/07/92
W.E. Jersey & Sons, Inc.	RR300-92	
Gulf Oil Corporation/ET & WNC Transportation Co. <i>et al.</i>	RF300-14001	01/06/92
Gulf Oil Corporation: White & Stewart, Inc.	RF300-13659	01/08/92
Petroleum Products, Inc.	RF300-13663	
F.A. Stein Oil Co... Speedway Petroleum Co., Inc.	RF300-13664 RF300-13668	
Inland Steel Company.	RF272-66565	01/08/92
Inland Steel Mining Company.	RF272-66566	
Inland Steel Company.	RF272-69981	
Lester C. Newton Trucking Co.	RC272-154	01/10/92
Tesoro Petroleum Corp.; Minit Mart #1.	RF326-315	01/09/92
Texaco Inc./Anyzek Fuels <i>et al.</i>	RF321-7039	01/06/92
Texaco Inc./ Automatic Lubrication Service <i>et al.</i>	RF321-2812	01/07/92
Texaco Inc./City of Wauwatosa <i>et al.</i>	RF321-12750	01/06/92
Texaco Inc./ Goodar Oil Company, Inc. <i>et al.</i>	RF321-8259	01/09/92
Texaco Inc./ Medina Texaco <i>et al.</i>	RF321-1415	01/06/92
Texaco Inc./Paul & Frank's Texaco #2.	RF321-13143	01/10/92
Texaco Inc./Smith Texaco.	RF321-18133	01/07/92
United Refining Company: Petroleum Electronics, Inc.	RF333-21	01/09/92
Jobbers Buying Group.	RF333-22	
Crago & Cook Enterprises.	RF333-23	
Everdyke Oil Co. ....	RF333-24	
West Covina Unified School District.	RF272-78771	01/09/92
Rock Falls Elementary School District 13.	RF272-78850	

**Dismissals**

The following submissions were dismissed:

Name	Case No.
ABC Oil Distributor, Inc.	RF304-3775
Aviritt Express	RD272-64979
Bob's Texaco	RF321-4952
Crum's Texaco Station	RF321-5044
Fairfield Texaco	RF321-4959
Haworth Oil Company	RF300-13857
James R. & Linda L. West	RF307-10206
Manning Avenue Texaco	RF321-9614
R & R Texaco	RF321-8533
Stanley Wasserman Real Estate	RF272-63913
Sweeney's Texaco	RF321-18058
T. L. James & Company	RD272-64814
Tascosa Texaco	RF321-1328
Thriftway Company	LEE-0015

[FR Doc. 92-4664 Filed 2-27-92; 8:45 am]

BILLING CODE 6150-01-M

### Federal Energy Regulatory Commission

[Docket No. FA85-71-006]

#### Central Illinois Public Service Co.; Order on Remand Directing Surcharges and Interpretative Rule on Fuel Adjustment Clause Regulation and Accounts 151 and 518

Issued February 20, 1992.

Before Commissioners: Martin L. Allday, Chairman; Charles A. Trabandt, Elizabeth Anne Moler, Jerry J. Langdon and Branko Terzic.

This case is on remand from the United States Court of Appeals for the Seventh Circuit.<sup>1</sup>

#### Background

Before the Commission in this case is the treatment of the proceeds of a settlement between Central Illinois Public Service Company (Central Illinois) and Consolidation Coal Company (Consol). The settlement was the result of a lawsuit filed by Central Illinois against Consol. Central Illinois alleged that Consol failed to deliver the contract-required quantity of coal, failed to deliver coal with the requisite BTU content, and defrauded Central Illinois by tampering with coal samples which were being used to determine the quality of Consol's coal deliveries. Central Illinois sought to recover approximately \$90.4 million in damages from Consol for increased coal costs due to fraud, costs for purchasing settlement coal, increased maintenance costs, lost generation costs, and increased

financing costs. Central Illinois also sought to terminate the coal contract.<sup>2</sup>

After four weeks of trial, Central Illinois and Consol reached a settlement which required Consol to pay Central Illinois \$25 million. Central Illinois apportioned \$7 million of the settlement proceeds and any interest to the shareholders, and \$18 million to the ratepayers through the fuel adjustment clause as a credit to the cost of fuel.

This issue was brought before the Commission following an audit of Central Illinois by the Commission's audit staff. Central Illinois requested that the matter be resolved after evidentiary hearing pursuant to part 41 of the Commission's regulations.<sup>3</sup> Following an evidentiary hearing, the presiding judge found that Central Illinois' disposition of the settlement proceeds was unreasonable. The judge concluded that, in the first instance, all of the settlement proceeds should have been distributed to ratepayers. However, he also concluded that Central Illinois should be permitted to net litigation expenses against the settlement proceeds, and thus refund only the net settlement proceeds.<sup>4</sup>

In Opinion No. 309,<sup>5</sup> the Commission affirmed the presiding judge's ruling that Central Illinois' disposition of the settlement proceeds was unreasonable. The Commission agreed with the judge that the ratepayers should receive all of the settlement proceeds from the fuel supplier as reimbursement for damages the cost of which were flowed through the fuel adjustment clause and borne by the ratepayers.<sup>6</sup> However, the Commission reversed the judge's decision to allow Central Illinois to recover its litigation costs through the fuel adjustment clause absent Commission authorization.<sup>7</sup>

In Opinion No. 309-A,<sup>8</sup> the Commission granted rehearing on the limited issue of the releases executed by the Municipal Intervenor<sup>9</sup> and

<sup>2</sup> Consol counterclaimed against Central Illinois for breach of contract and wrongful cancellation. Consol sought to recover damages totaling approximately \$130 million on its counterclaim and a permanent injunction requiring Central Illinois to continue purchasing coal from Consol for the Central Illinois Coffeen facility.

<sup>3</sup> 18 CFR part 41.

<sup>4</sup> Central Illinois Public Service Company, 40 FERC ¶ 63,018 (1987).

<sup>5</sup> Central Illinois Public Service Company, Opinion No. 309, 44 FERC ¶ 61,191 (1988).

<sup>6</sup> *Id.* at 61,688.

<sup>7</sup> *Id.* at 61,688-89.

<sup>8</sup> Central Illinois Public Service Company, Opinion No. 309-A, 47 FERC ¶ 61,043 (1989).

<sup>9</sup> The following Illinois municipalities comprise the Municipal Intervenor: the Cities of Flora, Bushnell, Cairo, Carmi, Casey, Marshall, Metropolis, Newton, and Roodhouse, and the Villages of Bethany, Greentop, and Rantoul. During the course

determined that the Municipal Intervenor's releases against Central Illinois should be recognized and given effect. As a consequence, the Commission found that the Municipal Intervenor was not entitled to any additional refunds beyond those already voluntarily made by Central Illinois to them.<sup>10</sup> Otherwise, the Commission reaffirmed its earlier findings.<sup>11</sup>

In Opinion No. 309-B,<sup>12</sup> the Commission denied the Municipal Intervenor's request for rehearing, and reaffirmed that the Municipal Intervenor was not entitled to additional refunds.<sup>13</sup>

On appeal, the court considered three issues: (1) Whether the Commission properly found that the plain language of the releases between Central Illinois and the Municipal Intervenor precluded the Municipal Intervenor from sharing in any additional refunds; (2) whether the Commission properly found that Central Illinois' distribution of the settlement proceeds (with approximately \$18 million distributed to ratepayers and approximately \$7 million distributed to shareholders) was unreasonable; and (3) whether Central Illinois was entitled to deduct its litigation expenses from the settlement proceeds refunded.<sup>14</sup>

The court found that the Commission properly determined that the releases, by their very language, cover the monies at issue in this case. The court affirmed the Commission's ruling, stating that the Municipal Intervenor would not be permitted now to deny the plain meaning of the releases they executed and accordingly they were not entitled to any additional refunds.

The court found that there was no record evidence supporting the Commission's disposition of the settlement proceeds, and that the record evidence supported Central Illinois' disposition of the settlement proceeds. Accordingly, the court reversed the Commission on the distribution of the settlement proceeds and concluded that Central Illinois' distribution of the settlement proceeds was fair and reasonable.<sup>15</sup>

of the proceeding, the Cities of Newton and Bushnell withdrew from the proceeding.

<sup>10</sup> 47 FERC at 61,123.

<sup>11</sup> *Id.* at 61,124-25.

<sup>12</sup> Central Illinois Public Service Co., Opinion No. 309-B, 48 FERC ¶ 61,068 (1989).

<sup>13</sup> *Id.* at 61,033-34.

<sup>14</sup> 941 F.2d at 627.

<sup>15</sup> *Id.* at 631.

<sup>16</sup> *Id.* at 627, 301.

<sup>1</sup> Central Illinois Public Service Company v. FERC, 941 F.2d 622 (7th Cir. 1991).

The court determined that on the facts of this case, including that there was no evidence that Central Illinois' failure to seek prior Commission approval was anything more than an inadvertent oversight, the Commission should have allowed Central Illinois to recover its litigation expenses prior to the distribution of the settlement proceeds. Accordingly, the court directed the Commission to permit Central Illinois to recoup its litigation expenses from the settlement proceeds.<sup>17</sup>

#### Discussion

Pursuant to our opinions in this proceeding, Central Illinois has already refunded additional monies to its customers. Accordingly, consistent with the court's findings and directives, we will permit Central Illinois to surcharge the relevant customers for the amounts previously refunded to them pursuant to the Commission's Opinion Nos. 309, 309-A, and 309-B, with interest pursuant to 18 CFR 35.19a (1991) for the period from the date of the refund until the date of payment of the surcharge.<sup>18</sup>

#### Interpretive Rule on Fuel Adjustment Clause Regulation and Accounts 151 and 518

Section 35.14(a)(2)(i) of the Commission's regulations, 18 CFR 35.14(a)(2)(i), provides that what a utility may recover in its fuel adjustment clause is: "(F)ossil and nuclear fuel consumed in the utility's own plants and the utility's share of fossil and nuclear fuel consumed in jointly owned or leased plants."<sup>19</sup>

Section 35.14(a)(6) of the Commission's regulations, 18 CFR 35.14(a)(6), further specifies that the cost of the fossil fuel consumed that may be included in the fuel adjustment clause: "Shall include no items other than those listed in Account 151 of the Uniform System of Accounts for Public Utilities and Licensees." Account 151, in turn, states:

This account shall include the book cost of fuel on hand.

#### Items

1. Invoice price of fuel less any cash or other discounts.
2. Freight, switching, demurrage and other transportation charges, not including, however, any charges for unloading from the shipping medium.

<sup>17</sup> *Id.* at 630.

<sup>18</sup> Central Illinois shall afford the customers the option to pay their surcharge amounts in either a lump sum or in equal installments over 12 months.

<sup>19</sup> The Commission's fuel adjustment clause regulation also permits recovery of "(t)he actual identifiable fossil and nuclear fuel costs" associated with certain energy purchases. 18 CFR 35.14(a)(2)(ii).

3. Excise taxes, purchasing agents' commissions, insurance and other expenses directly assignable to cost of fuel.

4. Operating, maintenance and depreciation expenses and ad valorem taxes on utility-owned transportation equipment used to transport fuel from the point of acquisition to the unloading point.

5. Lease or rental costs of transportation equipment used to transport fuel from the point of acquisition to the unloading point.

18 CFR part 101, Account 151.

Section 35.14(a)(6) of the Commission's regulations, 18 CFR 35.14(a)(6) further specifies that the cost of nuclear fuel that may be included in the fuel adjustment clause: "Shall be that as shown in Account 518 \* \* \*." Account 518, in turn, states:

A. This account shall be debited and account 120.5, Accumulated Provision for Amortization of Nuclear Fuel Assemblies, credited for the amortization of the net cost of nuclear fuel assemblies used in the production of energy. The net cost of nuclear fuel assemblies subject to amortization shall be the cost of nuclear fuel assemblies plus or less the expected net salvage of uranium, plutonium, and other byproducts and unburned fuel. The utility shall adopt the necessary procedures to assure that charges to this account are distributed according to the thermal energy products in such periods.

B. This account shall also include the costs involved when fuel is leased.

C. This account shall also include the cost of other fuels, used for ancillary steam facilities, including superheat.

D. This account shall be debited or credited as appropriate for significant changes in the amounts estimated as the net salvage value of uranium, plutonium, and other byproducts contained in account 157, Nuclear Materials Held for Sale and the amount realized upon the final disposition of the materials. Significant declines in the estimated realizable value of items carried in account 157 may be recognized at the time of market price declines by charging this account and crediting account 157. When the declining change occurs while the fuel is recorded in account 120.3, Nuclear Fuel Assemblies in Reactor, the effect shall be amortized over the remaining life of the fuel.

18 CFR part 101, Account 518.

As the Central Illinois Public Service company proceeding discussed above illustrates, questions have been raised as to whether litigation expenses are properly included in Account 151 (and, by implication, in Account 518) and recovered through the fuel adjustment clause. Likewise, questions have been raised as to whether auditing fees and administrative and general expenses are properly included in Account 151 (and, by implication, in Account 518) and recovered through the fuel adjustment clause.<sup>20</sup>

<sup>20</sup> In addition to the Central Illinois Public Service Company proceeding involving litigation expenses

We note that our fuel adjustment clause regulation, Account 151, and Account 518 are narrowly drawn, and that we have long had a policy—which has been upheld in the courts—of strict construction of the fuel adjustment clause regulation and Account 151 (and, by implication, Account 518).<sup>21</sup> We also note that litigation expenses, auditing fees, and administrative and general expenses, are not listed in the fuel adjustment clause regulation, Account 151, or Account 518.

Accordingly, in order to resolve any ambiguity that may exist as to the future treatment of litigation expenses, auditing fees, and administrative and general expenses, in light of the express language of these various regulations and accounts and in light of our longstanding policy of strict construction, we clarify that, effective upon publication in the *Federal Register*, litigation expenses, auditing fees, and administrative and general expenses are not properly included in Accounts 151 and 518 and also are not, absent prior waiver by the Commission, properly recoverable through a fuel adjustment clause.<sup>22</sup>

discussed above, the inclusion and recovery of litigation expenses, auditing fees, and administrative and general expenses have also been addressed in Indianapolis Power & Light Company, Opinion No. 328, 48 FERC ¶ 61,040 at 61,200-03 (1989) (litigation expenses and auditing fees) and Minnesota Power & Light Company, 39 FERC ¶ 61,192 at 61,707-08, reh'g denied, 40 FERC ¶ 61,042 (1987), aff'd in part and remanded in part, 852 F.2d 1070, 1072-74 (8th Cir. 1988), order on remand, 45 FERC ¶ 61,389 at 62,157-58 (1988) (litigation expenses and administrative and general expenses).

<sup>21</sup> See, e.g., *Cities and Villages of Bangor, et al. v. FERC*, 922 F.2d 861, 862 (D.C. Cir. 1991) (citing *Illinois Power Company, infra*, and Commission's policy of strict construction approvingly); *Minnesota Power & Light Company v. FERC*, 852 F.2d 1070, 1072-73 (8th Cir. 1988); *Illinois Power Company*, 52 FERC ¶ 61,162 at 61,622-23 (1990).

<sup>22</sup> We do not mean to imply by our addressing in this interpretive rule only litigation expenses, auditing fees, and administrative and general expenses that other expenses not properly included in Accounts 151 and 518 or not properly recoverable through the fuel adjustment clause are now includable or recoverable.

In addition, we emphasize again—as we have emphasized repeatedly in the past—that, if questions exist as to whether a cost (or refund amount) is properly includable in Account 151 or 518 or properly included in a fuel adjustment clause, the appropriate course of action is to seek a determination by either the Commission or the Chief Accountant. See 18 CFR 385.207(a)(2) (1991) (requests for declaratory order); 18 CFR part 101, General Instruction 5 (1991) (submission of questions of doubtful interpretation); 18 CFR 375.303(a) (1991) (Chief Accountant authorized to issue interpretation); see also, e.g., *Gulf Power Company*, 55 FERC ¶ 61,352 at 62,043 & n.23 (1991); 52 FERC at 61,623-24 & nn.17-18.

*The Commission Orders:* (A) Within 45 days of the date of this order, Central Illinois may surcharge the customers amounts previously refunded in these proceedings, as discussed in the body of this order.

(B) The Secretary shall promptly publish a copy of this order in the **Federal Register**.

By the Commission.

Lois D. Cashell,  
Secretary.

[FR Doc. 92-4591 Filed 2-27-92; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. GP92-7-000]

**Pike County Citizens for Justice v. Ashland Exploration, Inc., a Subsidiary of Ashland Oil, Inc.; Change in Intervention and Protest Deadline**

February 21, 1992.

Take notice that the deadline for filing motions or notices to intervene or protests in the captioned proceeding has been changed to March 2, 1992. (57 FR 6106, February 20, 1992).

Lois D. Cashell,  
Secretary.

[FR Doc. 92-4592 Filed 2-27-92; 8:45 am]

BILLING CODE 6717-01-M

application for new license and any competing license applications, pursuant to § 16.20 of the regulations, was December 31, 1991, and no other applications for license for this project were filed.

Pursuant to § 16.19 of the Commission's regulations, the licensee is required to make available certain information described in § 16.7 of the regulations. Such information is available from the licensee at Downsville Pike, Hagerstown, Maryland, 21740.

A potential applicant that files a notice of intent within 90 days from the date of issuance of this notice: (1) May apply for a license under part I of the Act and part 4 (except § 4.38) of the Commission's regulations within 18 months of the date on which it files its notice; and (2) must comply with the requirements of § 16.8 of the Commission's regulations.

Lois D. Cashell,  
Secretary.

[FR Doc. 92-4593 Filed 2-27-92; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. QF87-617-001]

**Keystone Energy Service Co., L.P. and Keystone Urban Renewal Limited Partnership; Amendment to Filing**

February 21, 1992.

On February 18, 1992, Keystone Energy Service Company, L.P. and Keystone Urban Renewal Limited Partnership tendered for filing an amendment to its filing in this docket.

The amendment provides additional information pertaining to the ownership structure and clarifies certain technical information. No determination has been made that the submittal constitutes a complete filing.

Any person desiring to be heard or objecting to the granting of qualifying status should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure. All such motions or protests must be filed by March 11, 1992, and must be served on the Applicant. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,  
Secretary.

[FR Doc. 92-4590 Filed 2-27-92; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 2515; West Virginia]

**Potomac Edison Co.; Soliciting Applications**

February 21, 1992.

On December 14, 1988, Potomac Edison Company, the existing licensee for the Harpers Ferry Hydroelectric Project No. 2515, filed a notice of intent to file an application for a new license, pursuant to section 15(b)(1) of the Federal Power Act (Act). The original license for Project No. 2515 was issued effective April 1, 1962, and expires December 31, 1993.

The project is located on the Potomac River in Jefferson County, West Virginia, and Washington County, Maryland. The principal project works consist of: (a) An 18-foot-high, 1,700-foot-long concrete capped log and stone dam; (b) a 4,500-foot-long headrace channel; (c) a powerhouse with an installed capacity of 600 kW; (d) a tailrace; (e) a transmission line; and (f) appurtenant facilities.

The licensee did not file an application for new license because it has reached an agreement in principle with the National Park Service (NPS) wherein the powerhouse, land, and operating rights will be conveyed to the NPS.<sup>1</sup> If and when this conveyance is complete, the NPS will assume responsibility for the project and the project will become nonjurisdictional.

To provide for the possibility that the conveyance to the NPS may not be completed, and pursuant to § 16.25 of the Commission's regulations, the Commission is soliciting applications from potential applicants other than the existing licensee. This is necessary because the deadline for filing an

<sup>1</sup> By order issued May 23, 1985, the Commission approved the licensee's request to sell the project to the NPS, but to retain ownership of the powerhouse, the land it occupies, and the rights necessary to operate the project.

[Project No. 2550—Wisconsin]

**Wisconsin Electric Power Co.; Soliciting Applications**

February 21, 1992.

On December 19, 1988, Wisconsin Electric Power Company, the existing licensee for the Weyauwega Hydroelectric Project No. 2550, filed a notice of intent to file an application for a new license, pursuant to section 15(b)(1) of the Federal Power Act (Act), 16 U.S.C. 808, as amended by section 4 of the Electric Consumers Protection Act of 1986, Public Law 99-495. The original license for Project No. 2550 was issued effective May 1, 1965, and expires December 31, 1993.

The project is located on the Waupaca River in Waupaca County, Wisconsin. The principal project works consist of: (a) A dam which includes a 161-foot-long steel sheet pile faced earth section and a 50-foot-wide spillway; (b) a reservoir of 286 acres; (c) a powerhouse with an installed capacity of 400 kW; (d) a transmission line connection; and (e) appurtenant facilities.

Pursuant to § 16.20 of the Commission's regulations, the deadline for filing an application for new license and any competing license applications was December 31, 1991. No applications for license for this project were filed. Therefore, pursuant to § 16.25 of the Commission's regulations, the

Commission is soliciting applications from potential applicants other than the existing licensee.

Pursuant to § 16.19 of the Commission's regulations, the licensee is required to make available certain information described in § 16.7 of the Commission's regulations. Such information is available from the licensee at Real Estate Department, Public Service Building Room 452, 231 West Michigan Street, Milwaukee, WI 53201.

A potential applicant that files a notice of intent within 90 days from the date of issuance of this notice: (1) May apply for a license under part I of the Act and part 4 (except § 4.38) of the Commission's regulations within 18 months of the date on which it files its notice; and (2) must comply with the requirements of § 16.8 of the Commission's regulations.

*Lois D. Cashell,*

*Secretary.*

[FR Doc. 92-4594 Filed 2-27-92; 8:45 am]

BILLING CODE 6717-01-M

## ENVIRONMENTAL PROTECTION AGENCY

[ER-FRL-4109-9]

### Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared February 10, 1992 Through February 14, 1992 pursuant to the Environmental Review Process (ERP), under section 309 of the Clean Air Act and section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at (202) 260-5076.

An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in the *Federal Register* dated April 05, 1991 (56 FR 14096).

#### Draft EISs

ERP No. D-FHW-K40183-CA Rating E02, Eastern Transportation Corridor (ETC), Construction, CA-231 Between the Riverside (CA-91) and Santa Ana Freeways (I-5), Funding and Section 404 Permit, Orange County, CA.

#### Summary

EPA objects to the contribution to carbon monoxide violations in the project area and to increases in other air pollutants. The placement of fill material into the waters of the US will have significant impacts, and after mitigation,

EPA expects the project to have severe cumulative impacts to water quality, noise levels, wildlife corridors, prime and unique farmlands, and other natural resources.

ERP No. D-FHW-K40184-CA Rating EC2, CA-87/Guadalupe Parkway Upgrading, between Julian Street and US 101 in the City of San Jose, Funding and Section 404 Permit, Santa Clara County, CA.

#### Summary

EPA Expresses environmental concerns for and requests more information in the FEIS to fully assess potential impacts to air quality, the loss of waters of the United States due to the placement of fill material, and potential impacts to water quality and beneficial uses.

ERP No. D-FHW-L40178-WA Rating EC2, First Avenue South Bridge Improvement, from WA-509 at South Cloverdale Street to WA-99/East Marginal Way South crossing the Duwamish River, Funding, Section 10 and 404 Permits, King County, WA.

#### Summary

EPA expresses environmental concerns for the potential adverse effects on water quality this proposed action may cause, and requests more information on monitoring the effectiveness of mitigation measures and the design features for the bridge.

ERP No. D-UAF-K11049-CA Rating E02, Mather Air Force Base Disposal and Reuse, Implementation, Sacramento County, CA.

#### Summary

EPA expressed environmental objections regarding potential wetlands, air quality, ground water, hazardous substance issues associated with base disposal and reuse. Subsequent environmental and decision documents need to further address the above environmental issues.

Dated: February 25, 1992.

*William D. Dickerson,*

*Deputy Director, Office of Federal Activities.*

[FR Doc. 91-4648 Filed 2-27-92; 8:45 am]

BILLING CODE 6560-50-M

[ER-FRL-4109-8]

### Environmental Impact Statements; Availability

#### Responsible Agency

Office of Federal Activities, General Information (202) 260-5075 OR (202) 260-5076.

Availability of Environmental Impact Statements Filed February 17, 1992

Through February 21, 1992, pursuant to 40 CFR 1506.9.

EIS No. 920048, FINAL EIS, AFS, CO, KS, Pike and San Isabel National Forests/Comanche and Cimarron National Grasslands Oil and Gas Exploration and Development, Leasing, Several Counties, CO and KS, Due: April 13, 1992, Contact: Dan Bishop (719) 545-8737.

EIS No. 920049, FINAL EIS, SCS, NY, Beaver Brook Watershed Flood Control Plan, Funding and Implementation, Herkimer County, NY, Due: March 30, 1992, Contact: Paul A. Dodd (315) 423-5521.

EIS No. 920050, FINAL EIS, SCS, KS, Doyle Creek Watershed Protection Plan, Funding and Implementation, Possible 404 Permit, Arkansas-White-Red River Basin, Harvey and Marion Counties, KS, Due: March 30, 1992, Contact: James N. Habiger (913) 823-4565.

EIS No. 920051, FINAL EIS, SFW, AK, Federal Subsistence Management Program for Federal Public Lands in Alaska, Implementation, AK, Due: March 30, 1992, Contact: Richard S. Pospahala (907) 786-3447.

EIS No. 920052, DRAFT SUPPLEMENT, DOE, WA, Washington Water Power and British Columbia Hydro 230kV Transmission Interconnection, Updated Information and Modifications, Construction, Operation and Maintenance, Presidential Permit, Pend Oreille, Spokane, Stevens and Lincoln Counties, WA, Due: April 28, 1992, Contact: Anthony J. Como (202) 586-5935.

EIS No. 920053, DRAFT EIS, USA, HI, Strategic Target System Program, Launching of nonnuclear payloads from the Kauai Test Facility at the Pacific Missile Test Facility, Island of Kauai, HI, Due: April 13, 1992, Contact: D. R. Gallien (205) 955-3058.

EIS No. 920054, FINAL EIS, COE, NC, Las Vegas Wash and Tributaries (Tropicana and Flamingo Washes) Flood Damage Reduction Plan, Implementation and Funding, Las Vegas Valley, Clark County, NV, Due: March 30, 1992, Contact: Ronald MacDonald (213) 894-3661.

EIS No. 920055, FINAL EIS, AFS, AK, Kelp Bay Timber Harvest Project, Availability of Timber to the Alaska Pulp Long-Term Timber Sale Contract, Timber Sale and Road Construction, Implementation, Tongass National Forest, Baran of Islands, AK, Due: March 30, 1992, Contact: Janis S. Burns Buyarski (907) 747-4200.

EIS No. 920056, DRAFT SUPPLEMENT, GSA, VA, U.S. Navy Commands

Consolidation, Office Complex Construction and Rehabilitation, Updated Information and Site Alternative, the City of Alexandria, Arlington County, VA, Due: April 13, 1992, Contact: Linda L. Eastman (202) 708-5334.

#### Amended Notices

EIS No. 910328, DRAFT EIS, FHW, WV, New River Parkway Construction, from Intersection Raleigh Co., 26 and WV 20 near Hinton, north to I-64, Funding Section 404 Permit, and Possible NPDES Permit, Raleigh and Summers Counties, WV, Due: December 02, 1991, Contact: Billy R. Higginbotham (304) 348-3093. Published FR 9-20-91—Officially Withdrawn by Preparing Agency.

EIS No. 910401, DRAFT EIS, FAA, MN, Minneapolis-St. Paul International Airport, Runway 4-22 Extension, Funding, Wold-Chamberlain Field, Hennepin County, MN, Due: April 17, 1992, Contact: Glen Orcutt (612) 725-7221. Published FR-11-15-91—Review period extended.

Dated: February 25, 1992.

William D. Dickerson,  
Deputy Director, Office of Federal Activities.  
[FR Doc. 92-4647 Filed 2-27-92; 8:45 am]  
BILLING CODE 6560-50-M

[FRL-4110-4]

#### Notice of Coke Oven Batteries Advisory Committee Meetings

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of March 16-17 and April 21-22 meetings.

**SUMMARY:** The National Emission Standards for Coke Oven Batteries Advisory Committee will meet again in Washington, DC on March 16-17 and April 21-22. On March 16 and April 21, the meetings will start at 9:30 a.m. and end at 6 p.m. On March 17 and April 22, the meetings will start at 8:30 a.m. and end at 3 p.m. All meetings will be held at the Quality Hotel Capitol Hill, Washington, DC.

**ADDRESSES:** The Committee will meet at the Quality Hotel Capitol Hill, 425 New Jersey Avenue NW., 20001, (202) 636-1616.

**FOR FURTHER INFORMATION CONTACT:** For information on substantive matters, please contact Amanda Agnew, Office of Air Quality Planning and Standards, (919) 541-5268. For information on administrative matters, please contact the Committee's Facilitator, Phil Harter, at (202) 887-1033.

Dated: February 24, 1992.

Chris Kirtz,  
Designated Federal Official, Coke Oven Battery Advisory Committee.  
[FR Doc. 92-4646 Filed 2-27-92; 8:45 am]  
BILLING CODE 6560-50-M

#### FEDERAL RESERVE SYSTEM

##### F & M Bancorporation; Acquisition of Company Engaged in Permissible Nonbanking Activities

The organization listed in this notice has applied under § 225.23(a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23(a)(2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than March 24, 1992.

**A. Federal Reserve Bank of Kansas City** (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *F & M Bancorporation*, Tulsa, Oklahoma; to acquire American Trustcorp, Inc., Tulsa, Oklahoma, and

thereby indirectly acquire Trust Company of Oklahoma of Tulsa, Tulsa, Oklahoma, and thereby engage in trust company activities pursuant to § 225.25(b)(3) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, February 24, 1992.

Jennifer J. Johnson,  
Associate Secretary of the Board.  
[FR Doc. 92-4610 Filed 2-27-92; 8:45 am]  
BILLING CODE 6210-01-F

##### MSB Bancorp, Inc., et al.; Formations of; Acquisitions by; and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than March 24, 1992.

**A. Federal Reserve Bank of New York** (William L. Rutledge, Vice President) 33 Liberty Street, New York, New York 10045:

1. *MSB Bancorp, Inc.*, Middletown, New York; to become a bank holding company by acquiring 100 percent of the voting shares of Middletown Savings Bank, Middletown, New York.

**B. Federal Reserve Bank of Richmond** (Lloyd W. Bostian, Jr., Senior Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. *Peoples Bancorporation, Inc.*, Easley, South Carolina; to become a bank holding company by acquiring 100 percent of the voting shares of The

Peoples National Bank, Easley, South Carolina.

**C. Federal Reserve Bank of Atlanta** (Robert E. Heck, Vice President) 104 Marietta Street, NW., Atlanta, Georgia 30303:

1. *Niota Bancshares, Inc.*, Niota, Tennessee; to become a bank holding company by acquiring 97.95 percent of the voting shares of Bank of Niota, Niota, Tennessee.

**D. Federal Reserve Bank of St. Louis** (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. *Union Planters Corporation*, Memphis, Tennessee, and Union Planters - SBI Acquisition Company, Memphis, Tennessee; to acquire 100 percent of the voting shares of Southeastern Bancshares, Inc., Alexandria, Tennessee, and thereby indirectly acquire DeKalb County Bank & Trust Company, Alexandria, Tennessee. In connection with this application, Union Planters - SBI Acquisition Company has also applied to become a bank holding company.

Board of Governors of the Federal Reserve System, February 24, 1992.

Jennifer J. Johnson,

*Associate Secretary of the Board.*

[FR Doc. 92-4611 Filed 2-27-92; 8:45 am]

BILLING CODE 6210-01-F

**NBD Bancorp, Inc., et al.; Formations of, Acquisitions by, and Mergers of Bank Holding Companies; and Acquisitions of Nonbanking Companies**

The companies listed in this notice have applied under § 225.14 of the Board's Regulation Y (12 CFR 225.14) for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) to become a bank holding company or to acquire voting securities of a bank or bank holding company. The listed companies have also applied under § 225.23(a)(2) of Regulation Y (12 CFR 225.23(a)(2)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies, or to engage in such an activity. Unless otherwise noted, these activities will be conducted throughout the United States.

The applications are available for immediate inspection at the Federal Reserve Bank indicated. Once the

application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than March 24, 1992.

**A. Federal Reserve Bank of Chicago** (David S. Epstein, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *NBD Bancorp, Inc.*, and NBD Indiana, Inc., both of Detroit, Michigan; to acquire 100 percent of the voting shares of Summcorp, Fort Wayne, Indiana, and thereby indirectly acquire Summit Bank, Fort Wayne, Indiana; Summit Bank of Clinton County, Frankfort, Indiana; Summit Bank of Indianapolis, Indianapolis, Indiana; Summit Bank of Marion, Marion, Indiana; and Summit Bank of Muncie, Muncie, Indiana; and 14.84 percent of the voting shares of Decatur Financial Inc., Decatur, Indiana, and thereby indirectly acquire Decatur Bank & Trust Company, Decatur, Indiana.

In connection with this application, Applicants also propose to consolidate Summcorp Financial Services, Inc., Fort Wayne, Indiana, into their subsidiary, NBD Securities, Inc., and thereby engage in discount brokerage services pursuant to § 225.25(b)(15) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, February 24, 1992.

Jennifer J. Johnson,

*Associate Secretary of the Board.*

[FR Doc. 92-4612 Filed 2-27-92; 8:45 am]

BILLING CODE 6210-01-F

**Norman Ashley Bancstock Voting Trust, et al.; Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies**

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than March 20, 1992.

**A. Federal Reserve Bank of St. Louis** (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. *Norman Ashley Bancstock Voting Trust*, Crossett, Arkansas; to acquire 50.66 percent of the voting shares of Ashley Bancstock Company, Crossett, Arkansas, and thereby indirectly acquire First National Bank of Crossett, Crossett, Arkansas.

**B. Federal Reserve Bank of Dallas** (W. Arthur Tribble, Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. *Milford Nelson Bostick*, Waco, Texas; to acquire an additional 22.11 percent of the voting shares of American National Bancshares, Inc., Waco, Texas, for a total of 30.84 percent, and thereby indirectly acquire American Bank, N.A., Waco, Texas.

2. *Elk Trust*, James P. Leake, Dallas, Texas; to acquire 80.74 percent of the voting shares of Bandera Bancshares, Inc., Bandera, Texas, and thereby indirectly acquire Bandera Bank, Bandera, Texas.

Board of Governors of the Federal Reserve System, February 24, 1992.

Jennifer J. Johnson,

*Associate Secretary of the Board.*

[FR Doc. 92-4609 Filed 2-27-92; 8:45 am]

BILLING CODE 6210-01-F

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Centers for Disease Control****Clinical Laboratory Improvement Advisory Committee; Establishment**

**ACTION:** Establishment of Clinical Laboratory Improvement Advisory Committee.

Pursuant to Federal Advisory Committee Act, 5 U.S.C. appendix 2, the Centers for Disease Control announces the establishment by the Secretary of Health and Human Services, on February 19, 1992, of the following Federal advisory committee:

**DESIGNATION:** Clinical Laboratory Improvement Advisory Committee.

**PURPOSE:** This committee will provide scientific and technical advice and guidance to the Secretary and the Assistant Secretary for Health regarding the need for, and the nature of, revisions to the standards under which clinical laboratories are regulated; the impact on medical and laboratory practice of proposed revisions to the standards; and the modification of the standards to accommodate technological advances.

Authority for this committee will expire February 19, 1994, unless the Secretary of Health and Human Services, with the concurrence of the Committee Management Secretariat, General Services Administration, formally determines that continuance is in the public interest.

Dated: February 24, 1992.

Elvin Hilyer,  
*Associate Director for Policy Coordination,  
Centers for Disease Control.*

[FR Doc. 92-4597 Filed 2-27-92; 8:45 am]

**BILLING CODE 4160-18-M**

**Food and Drug Administration****Consumer Participation; Open Meeting**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the following district consumer exchange meeting: Boxton District Office, chaired by Edward McDonnell, District Director. The topic to be discussed is food labeling reform.

**DATES:** Monday, March 16, 1992, 10 a.m. to 11:30 a.m.

**ADDRESSES:** The Chamber of the Assembly of Delegates, First District Courthouse, Barnstable County

Complex, Rte. 6A, Barnstable Village, MA 02630.

**FOR FURTHER INFORMATION CONTACT:** Paula Fairfield, Public Affairs Specialist, Food and Drug Administration, One Montvale Ave., Stoneham, MA 02180, 617-279-1479.

**SUPPLEMENTARY INFORMATION:** The purpose of this meeting is to encourage dialogue between consumers and FDA officials, to identify and set priorities for current and future health concerns, to enhance relationships between local consumers and FDA's district offices, and to contribute to the agency's policymaking decisions on vital issues.

Dated: February 25, 1992.

Michael R. Taylor,  
*Deputy Commissioner for Policy.*  
[FR Doc. 92-4665 Filed 2-27-92; 8:45 am]  
**BILLING CODE 4160-01-M**

**Investigational New Drugs; Procedure To Monitor Clinical Hold Process; Meeting of Review Committee and Request for Submissions**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is asking interested drug companies to submit the name and number of any investigational new drug (IND) trial placed on clinical hold during fiscal years 1991 and 1992 which the drug companies want reviewed by the committee that periodically reviews selected clinical holds of the Center for Drug Evaluation and Research (CDER). FDA imposes clinical holds on drug studies when it believes it necessary to protect the welfare of clinical subjects. Submission should be made to the Chief Mediator and Ombudsman to ensure the confidentiality of the request.

**DATES:** The meeting will be held in March. Drug companies may submit requests for the March meeting before March 16, 1992.

**ADDRESSES:** Submit clinical hold review requests to Amanda B. Pedersen, FDA Chief Mediator and Ombudsman, Office of the Commissioner (HF-7), Food and Drug Administration, rm. 14-84, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1306.

**FOR FURTHER INFORMATION CONTACT:** Center for Drug Evaluation and Research (HFD-362), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-295-8046.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the second in a series of

meetings of the committee that reviews the clinical holds that CDER has placed on certain IND trials. If FDA determines that a proposed or ongoing study may pose significant risks for human subjects, or, for phase 2 or 3 studies, is otherwise seriously deficient, it may impose a clinical hold on a study. FDA is asking interested drug companies to submit to the committee for their review the name and number of any IND placed on clinical hold during fiscal years 1991 and 1992 that the drug companies want the committee to review.

The clinical hold is FDA's primary mechanism for protecting subjects who are involved in IND trials. A clinical hold is an order that FDA issues to a sponsor to delay a proposed investigation or to suspend an ongoing investigation. The clinical hold may be placed on one or more of the investigations covered by an IND. When a proposed study is placed on clinical hold, subjects may not be given the investigational drug as part of that study. When an ongoing study is placed on clinical hold, no new subjects may be recruited to the study and placed on the investigational drug, and patients already in the study should stop receiving therapy involving the investigational drug unless FDA specifically permits it.

In the Federal Register of October 2, 1991 (56 FR 49894), the agency published a notice announcing the establishment of an experimental procedure for reviewing clinical holds. The notice described the IND regulations and the provisions governing clinical holds. The notice also described some concerns which IND sponsors have expressed concerning the reasons for imposition of clinical holds.

The procedure involved the creation of a committee composed of senior agency officials to review the process by which clinical holds are imposed. Under the procedure, the committee reviews a number of clinical holds at each of its regularly scheduled meetings. The Chief Mediator and Ombudsman develops the list of clinical holds to be reviewed. Some are selected randomly from CDER'S management information system, but others are submitted by IND sponsors. The committee process neither replaces, nor prevents firms from using, the dispute resolution procedures described in the IND regulations (see 21 CFR 312.48).

The committee held a pilot meeting in August 1991 and a meeting in November 1991. The March meeting will be the second regular meeting of the committee.

The meetings of the review committee are closed to the public because committee discussions deal with confidential commercial information. Summaries of the committee deliberations, excluding privileged commercial information, are available from the Chief Mediator and Ombudsman. If the status of a clinical hold changes following the committee's review, the appropriate division will notify the sponsor.

FDA invites drug companies to submit to the FDA Chief Mediator and Ombudsman the name and number of any IND that was placed on clinical hold in fiscal year 1991 or 1992 that they want the committee to review at its March meeting. Submissions should be made by March 16, 1992, to Amanda B. Pedersen, FDA Chief mediator and Ombudsman (address above).

Dated: February 24, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 92-4601 Filed 2-27-92; 8:45 am]

BILLING CODE 4160-01-M

## Public Health Service

### Agency Forms Submitted to the Office of Management and Budget for Clearance

Each Friday the Public Health Service (PHS) publishes a list of information collection packages it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). The following requests have been submitted to OMB since the list was last published on Friday, February 7, 1992.

(Call PHS Reports Clearance Officer on 202-245-2100 for copies of package)

1. **Assessment of Seroprevalence and Risk Factors for Hepatitis B Virus Infection Among Public Safety Workers—New—**This request is for a 3-year approval to collect blood specimens and questionnaire responses from public safety workers such as firefighters, police, and prison guards in order to study the occupational risk of hepatitis B virus (HPV) infection. The results of the proposed study will assist in identification of workers who are at occupational risk of HIV infection. Respondents: Individual or households. Number of Respondents: 4,500; Number of Responses per Respondent: 1; Average Burden per Response: .254 hours; Estimated Annual Burden: 1,142.

2. **National AIDS Hotline Survey of Callers—New—**The hotline is intended

to serve populations at increased risk of infection as well as geographical areas in which other sources of information are not readily available, e.g., rural communities. CDC is requesting clearance to gather information in order to manage the hotline more effectively and assess the impact of selected CDC public information programs.

Respondents: Individuals or households; Number of Respondents 19,000; Number of Responses per Respondent: 1; Average Burden per Response: .019 hours; Estimated Annual Burden: 367.

3. **Health Education Assistance Loan (HEAL) Program—Forms—0915-0034—**The forms are needed for lenders to make application to the HEAL insurance program, to report accurately and timely on loan actions, including transfer of loans to a secondary agent, and to establish the repayment status of borrowers. These reports assist DHHS in diligent administration of the HEAL program which protects the Government's financial interest.

Respondents: Individuals or households, Businesses or other for-profit, Non-profit institutions.

Title	Number of respondents	Number of responses per respondent	Average burden per response
Lender Application HRSA Form 504.	66	1	.13 hr.
Lenders Manifest HRSA 505.	31	141	.08 hr.
Loan Transfer Statement HRSA 507.	66	123	.17 hr.
Borrower Status HRSA Form 508 (Borrower).	10,582	1	.17 hr.
Borrower Status HRSA Form 508 (Employer).	6,560	1.6	.08 hr.

Estimated Total Annual Burden—4,368 hours.

4. **National Health Service Corps Loan Repayment Program and the NHSC State Loan Repayment Program (42 CFR Part 62)—0915-0127—**Health professionals applying to the National Health Service Corps (NHSC) Loan Repayment Program (LRP) provide information needed to determine eligibility. NHSC/LRP participants provide information on training status in compliance with program requirements. States applying to the NHSC State LRP provide information needed to determine eligibility. Respondents: Individuals or households, State or local

governments, Businesses or other for-profit.

Title	Number of respondents	Number of responses per respondent	Average burden per response
NHSC/LRP Application.	1000	1	1.5 hrs.
Lender's Confirmation of Loan.	1600	1	.25 hrs.
Training Documentation 62.26(b)(2). State Loan Repayment Program 62.54 Application <sup>1</sup>	1	1	1 hr.

<sup>1</sup> Burden carried with application OMB No. 0937-0189.

Estimated Total Annual Burden—1901.

5. **Hanford Thyroid Disease Study—Pilot Phase—New—**An epidemiologic study will be conducted by the Centers for Disease Control to determine whether thyroid disease is increased among persons exposed as young children to radioactive iodine released from the Hanford Nuclear Site. The current data collection is a feasibility study to test procedures and determine actual levels of exposure. Respondents: Individuals or households; Number of Respondents: 2020; Number of Responses Per Respondent: 2.56; Average Burden Per Response: .557 hours; Estimated Annual Burden: 2887 hours.

6. **A Study of Caregiving and Dementia, Honolulu Heart Program Cohort—New—**The purpose of the project is to describe predictors and outcomes of caregiver burden and quality of life in caregivers and elderly men with dementia. Standard questionnaires will be used in an interview format to obtain information from caregivers and control group. Respondents: Individuals or households; Number of Respondents 400; Number of Responses per Respondent: 1.94; Average Burden per Response: .5 hours; Estimated Annual Burden: 388 hours.

7. **Color Additive Certification (21 CFR part 80, subpart B)—0910-0216—**This information is required by FDA to respond to requests for "Color Certification" of color additives and their lakes as required by Section 706 of the Food, Drug and Cosmetic Act and 21 CFR part 80. The activity includes chemical analysis for batch composition of a representative sample to insure compliance with applicable specifications and issuance of a

certificate with an assigned certification lot number. Respondents are any persons requesting certification of a manufactured batch of color additive. Respondents: Businesses or other for-profit; Small businesses or organizations.

Title	Number of respondents	Number of responses per respondent	Average burden per response
Reporting: Request for Certification (21 CFR 80.21). Samples of Batch Colors (21 CFR 80.22).	28	146	0.217 hrs.
Recordkeeping: Records of Distribution (21 CFR 80.39).	28	146	0.033 hrs.
	28	1	36.5 hrs.

Total Annual Burden—2,044 hours.

**8. Public Health System Impact Statement, Third Party Notification—New—Public Health Service agencies that award financial assistance to community-based, nongovernmental agencies will require applicants to send a portion of their application to affected state and local health agencies. The purpose is to inform state and local agencies about services provided and populations served. Respondents: Non-profit institutions; Number of Respondents: 2,800; Number of Responses Per Respondent: 2.5; Average Burden Per Response: 0.166 hours; Estimated Annual Burden: 1167 hours.**

**Desk Officer:** Shannon Kosa-McCallum.

Written comments and recommendations for the proposed information collections should be sent within 30 days of this notice directly to the OMB Desk Officer designated above at the following address: Human Resources and Housing Branch, New Executive Office Building, room 3002, Washington, DC 20503.

Dated: February 21, 1992.

Sandra K. Mahkorn,

Deputy Assistant Secretary for Public Health Policy.

[FR Doc. 92-4552 Filed 2-27-92; 8:45 am]

BILLING CODE 4160-17-M

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

### Office of the Assistant Secretary for Community Planning and Development

[Docket No. N-92-1917; FR-2934-N-67]

#### Federal Property Suitable as Facilities To Assist the Homeless

**AGENCY:** Office of the Assistant Secretary for Community Planning and Development, HUD.

**ACTION:** Notice.

**SUMMARY:** This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

**ADDRESSES:** For further information, contact James N. Forsberg, room 7262, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410; telephone (202) 708-4300; TDD number for the hearing- and speech-impaired (202) 708-2565 (these telephone numbers are not toll free), or call the toll-free Title V information line at 1-800-927-7588.

**SUPPLEMENTARY INFORMATION:** In accordance with 56 FR 23789 (May 24, 1991) and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless v. Veterans Administration*, No. 88-2503-OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or

made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Judy Breitman, Division of Health Facilities Planning, U.S. Public Health Service, HHS, room 17A-10, 5600 Fishers Lane, Rockville, MD 20857; (301) 443-2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 56 FR 23789 (May 24, 1991).

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1-800-927-7588 for detailed instructions or write a letter to James N. Forsberg at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the *Federal Register*, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (i.e., acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: GSA: Ronald Rice, Federal Property Resources Service, GSA, 18th and F Streets NW., Washington, DC 20405; (202) 501-0067; Dept. of Veterans Affairs: Douglas Shinn,

Management Analyst, Dept. of Veterans Affairs, room 414 Lafayette Bldg., 811 Vermont Ave. NW., Washington, DC 20420; (202) 233-8474; *Dept. of Transportation:* Ronald D. Keefer, Director, Administrative Services & Property Management, DOT, 400 Seventh St. SW., room 10319, Washington, DC 20590; (202) 366-4246; *Dept. of Interior:* Lola D. Knight, Property Specialist, Dept. of Interior, 1849 C St. NW., Mailstop 5512-MIB, Washington, DC 20240; (202) 208-4080; *Dept. of Energy:* Tom Knox, Realty Specialist, AD223.1, 1000 Independence Ave. SW., Washington, DC 20585; (202) 586-1191; (These are not toll-free numbers).

*Correction:* Property numbers 319140005 and 319140004 were inadvertently published as suitable/available in the January 24, 1992 Notice. These properties are not available for homeless assistance use.

Dated: February 21, 1992.

**Paul Roitman Bardack,**  
Deputy Assistant Secretary for Economic Development.

**TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM—FEDERAL REGISTER REPORT FOR 02/28/92**

**Suitable/Available Properties**

**Buildings (by State)**

*California*

Yunker House (07-108)  
Redwood National Park  
Hiouchi Co: Del Norte CA 95531-  
Landholding Agency: Interior  
Property Number: 619140004  
Status: Unutilized  
Comment: 900 sq. ft., 1 story frame residence.  
off-site use only.

Bldg. 116  
VA Medical Center  
Wilshire and Sawtelle Blvds.  
Los Angeles Co: Los Angeles CA 90073-  
Landholding Agency: VA  
Property Number: 979110009  
Status: Underutilized  
Comment: 60309 sq. ft., 3 story brick frame,  
seismic reinforcement defics., underutil.  
port of bldg. used intermitly., needs rehab,  
poss. asbestos in pipes/floor tiles, site  
access lim.

Bldg. 263  
VA Medical Center  
Wilshire and Sawtelle Blvds.  
Los Angeles Co: Los Angeles CA 90073-  
Landholding Agency: VA  
Property Number: 979110010  
Status: Unutilized  
Comment: 1600 sq. ft., 1 story wood frame w/  
stucco exterior, needs rehab, poss.  
asbestos on pipes/floor tiles, site access  
limitations, no operating utilities.

*Colorado*

Otis Repeater Building  
Otis Co: Washington CO 80743-  
Landholding Agency: Energy  
Property Number: 419130001  
Status: Excess  
Comment: 144 sq. ft., one story metal  
structure, most recent use—communication  
equipment storage, off-site use only.  
Limon Repeater Station

Limon Co: Lincoln CO 80828-  
Landholding Agency: Energy  
Property Number: 419130002  
Status: Excess  
Comment: 144 sq. ft., one story metal  
structure, most recent use—communication  
equipment storage, off-site use only.

*Florida*

(P) Jacksonville Job Corps  
236 W. 4th Street  
Jacksonville Co: Duval FL 32206-  
Landholding Agency: GSA  
Property Number: 549140007  
Status: Excess  
Comment: 1250 sq. ft., 2 story residence,  
needs major rehab, subject to compliance  
with federal and local historic preservation  
laws  
GSA Number: 4-L-FL-967

*Idaho*

Storage and Training Facility  
INEL DOE-ID  
Idaho Falls Co: Bonneville ID  
Landholding Agency: Energy  
Property Number: 419040001  
Status: Excess  
Comment: 2072 sq. ft., 1 story wood frame,  
needs major rehab, off-site use only.  
Bldg. 705, Ditchrider House  
Boise Project  
Notus Co: Cayon ID 83656-  
Location: T5N, R3W, Sec 2, SE¼, SW¼,  
SW¼,  
Landholding Agency: Interior  
Property Number: 619120010  
Status: Unutilized  
Comment: 586 sq. ft., 1 story residence, needs  
major rehab, off-site use only.

Bldg. 508—Warehouse  
Black Canyon Dam  
Emmett Co: Gem ID 83611-  
Landholding Agency: Interior  
Property Number: 619120011  
Status: Unutilized  
Comment: 4625 sq. ft., needs major rehab,  
most recent use—storage, off-site use only.

Bldg. 510—Carpenter Shop  
Black Canyon Dam  
Emmett Co: Gem ID 83611-  
Landholding Agency: Interior  
Property Number: 619120012  
Status: Unutilized  
Comment: 4625 sq. ft., needs major rehab,  
most recent use—storage, off-site use only.

*Maryland*

Chesapeake Bay Hydraulic Model  
Matapeake Co: Queen Annes MD 21666-  
Landholding Agency: GSA  
Property Number: 549040007  
Status: Excess  
Comment: 617280 sq. ft., 1 story metal bldg.,  
ceiling height over 40 ft., lease restriction,  
Corps will maintain an antenna on  
property  
GSA Number: 4-D-MD-578

*Michigan*

Bldg. 7348  
Bayshore RBS  
Det 6, 1st Combat Evaluation Group  
Bay Shore Co: Emmet MI 49711-  
Landholding Agency: GSA  
Property Number: 189010044

Status: Excess  
Comment: 225 sq. ft., 1 story wood frame,  
needs rehab, most recent use—storage  
GSA Number: 2-D-MI-751  
Bldg. 7352  
Bayshore RBS  
Det 6, 1st Combat Evaluation Group  
Bay Shore Co: Emmet MI 49711-  
Landholding Agency: GSA  
Property Number: 189010046  
Status: Excess  
Comment: 25 sq. ft., 1 story wood, most recent  
use—storage  
GSA Number: 2-D-MI-751  
Bldg. 7354  
Bayshore RBS  
Det 6, 1st Combat Evaluation Group  
Bay Shore Co: Emmet MI 49711-  
Landholding Agency: GSA  
Property Number: 189010049  
Status: Excess  
Comment: 25 sq. ft., 1 story wood, most recent  
use—storage  
GSA Number: 2-D-MI-751  
Bldg. 7357  
Bayshore RBS  
Det 6, 1st Combat Evaluation Group  
Bay Shore Co: Emmet MI 49711-  
Landholding Agency: GSA  
Property Number: 189010051  
Status: Excess  
Comment: 1080 sq. ft., 1 story wood/frame/  
block, most recent use—hobby shop/  
recreation center  
GSA Number: 2-D-MI-751  
Bldg. 7358  
Bayshore RBS  
Det 6, 1st Combat Evaluation Group  
Bay Shore Co: Emmet MI 49711-  
Landholding Agency: GSA  
Property Number: 189010055  
Status: Excess  
Comment: 96 sq. ft., 1 story wood frame/  
concrete, most recent use—hazard storage  
GSA Number: 2-D-MI-751  
Bldg. 5043  
Bayshore RBS  
Det 6, 1st Combat Evaluation Group  
Bay Shore Co: Emmet MI 49711-  
Landholding Agency: GSA  
Property Number: 189010065  
Status: Excess  
Comment: 694 sq. ft., 1 story concrete/block  
134 sq. ft., latrine with separate entrance  
GSA Number: 2-D-MI-751

*New Mexico*

Old Helium Plant  
Gallup Co: McKinley NM 87301-  
Location: ¼ mile north of Gallup, adjacent to  
Old US Highway 666.  
Landholding Agency: Interior  
Property Number: 619010002  
Status: Excess  
Comment: 7653 sq. ft., 1 story office and  
warehouse space, possible asbestos, on  
4.65 acres, secured area with alternate  
access.

*New York*

Bldg. 1  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-

Landholding Agency: GSA  
Property Number: 549120008  
Status: Excess  
Comment: 31519 sq. ft., 7 story brick frame, presence of asbestos on pipe insulation, scheduled to be vacated Oct. 1992  
GSA Number: 2-N-NY-797  
Bldg. 311  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co. Kings NY 11251-  
Landholding Agency: GSA  
Property Number: 549120017  
Status: Excess  
Comment: 9720 sq. ft., 2 story brick frame, needs heating system repairs, needs rehab, presence of asbestos on pipe insulat., most recent use-cls/storage, sched. to be vacated Oct. 1992  
GSA Number: 2-N-NY-797

*North Carolina*  
Dwellings 1, 2 & 3  
USCG Coinjock Housing  
Coinjock Co: Currituck NC 27923-  
Landholding Agency: DOT  
Property Numbers: 879120083-879120085  
Status: Unutilized  
Comment: One story wood residences, periodic flooding in garage and utility room occurs in heavy rainfall  
USCG Station—Building  
Oregon Inlet Coast Guard Station  
Rodanthe Co: Dare NC 27968-  
Landholding Agency: DOT  
Property Number: 879120089  
Status: Unutilized  
Comment: 1207 sq. ft., two story wood frame, most recent use—office, storage, shops, communications, dining, etc.  
USCG Station—Building  
Oregon Inlet Coast Guard Station  
Rodanthe Co: Dare NC 27968-  
Landholding Agency: DOT  
Property Number: 879120088  
Status: Unutilized  
Comment: 1521 sq. ft., two story lightweight steel frame, most recent use—office, shops, communications, storage, berthing, dining, etc.  
USCG Station—Garage  
Oregon Inlet Coast Guard Station  
Rodanthe Co: Dare NC 27358-  
Landholding Agency: DOT  
Property Number: 879120089  
Status: Unutilized  
Comment: 1920 sq. ft., one story steel frame, most recent use—garage/storage  
USCG Station—Building  
Oregon Inlet Coast Guard Station  
Rodanthe Co: Dare NC 27968-  
Landholding Agency: DOT  
Property Number: 879120090  
Status: Unutilized  
Comment: 320 sq. ft., one story wood frame, most recent use—storage  
USCG Station Oak Island  
300 A Caswell Beach Road  
Caswell Beach Co: Brunswick NC 28461-  
Landholding Agency: DOT  
Property Number 879210001  
Status: Excess  
Comment: 1300 sq. ft., 3 story wood frame, needs rehab, presence of asbestos on pipes,

secured area w/alternate access, off-site removal only.

#### *North Dakota*

Calhoun Radio Relay Tower Site  
5 miles north and 1 mile west of Hannover,  
North Dakota Co: Oliver ND 58563-  
Landholding Agency: GSA  
Property Number: 549130015  
Status: Excess  
Comment: One story 12' x 10'8"  
communication tower on concrete slab w/  
5.74 acres and 0.66 acre easement, potential  
utilities, needs rehab  
GSA Number: 7-B-ND-489

#### *Ohio*

Parcel 2  
Lock and Dam # 16  
Washington Co: Washington OH  
Location: On the Ohio River; 4 miles  
downstream from New Matamoros,  
Grandview Township.  
Landholding Agency: GSA  
Property Number 549110010  
Status: Excess  
Comment: Two story brick frame, subject to  
periodic flooding, possible asbestos on  
pipes, most recent use—office space  
GSA Number: 2-CR(1)-OH-730  
Parcel 1  
Lock and Dam # 16  
Washington Co: Washington OH  
Location: On the Ohio River, 4 miles  
downstream from New Matamoros,  
Grandview Township.  
Landholding Agency: GSA  
Property Number: 549110011  
Status: Excess  
Comment: 2.5 story brick frame, subject to  
periodic flooding, possible asbestos on  
pipes, most recent use—storage  
GSA Number: 2-CR(1)-OH-730  
U.S. Naval Reserve Center  
170 Ashland Road  
Mansfield Co: Richland OH 44902-  
Landholding Agency: GSA  
Property Number: 779010075  
Status: Excess  
Comment: 29000 sq. ft., 1 story quonset hut  
structure, most recent use—office,  
recreation and storage, needs rehab, land  
leased from City through September 1992  
GSA Number: 2-N-OH-783

#### *Oregon*

Bldg. #3 (Ranger Residence)  
1900 Caves Highway  
Cave Junction Co: Josephine OR 97523-  
Landholding Agency: Interior  
Property Number: 619130004  
Status: Excess  
Comment: 732 sq. ft., one story cabin, off-site  
use only.

#### *Tennessee*

Federal Building  
216 North Jackson Street  
Athens Co: McMinn TN 37303-  
Landholding Agency: GSA  
Property Number: 549210003  
Status: Excess  
Comment: 2069 sq. ft., 3 story brick and  
concrete frame, presence of asbestos on  
pipes and air ducts in mechanical areas,  
most recent use—offices.

GSA Number: 4-G-TN-632

#### *Texas*

Administration Bldg.  
Guadalupe Mountains National Park  
Pine Springs Co: Calhoun TX 79647-  
Landholding Agency: Interior  
Property Number: 619130005  
Status: Excess  
Comment: 2016 sq. ft., one story frame  
structure, most recent use—office, off-site  
use only.

#### *Utah*

100 KW Solar Photovoltaic Sys.  
Nat'l. Bridges National Monument  
P.O. Box 1  
Lake Powell Co: San Juan UT 84533-  
Landholding Agency: Energy  
Property Number: 419140001  
Status: Excess  
Comment: Solar panels, off-site use only,  
current use—generate electrical power.

#### *Virginia*

Housing  
Rt. 637—Gwynnville Road  
Gwynn Island Co: Mathews VA 23068-  
Landholding Agency: DOT  
Property Number: 879120082  
Status: Unutilized  
Comment: 929 sq. ft., one story residence

#### *Washington*

Thompson Boathouse  
Lake Crescent Ranger Station  
HC 62, Box 10  
Port Angeles WA 98362-  
Landholding Agency: Interior  
Property Number: 619030011  
Status: Unutilized  
Comment: 693 sq. ft., 1 story boathouse, no  
utilities, needs rehab, off-site use only  
Spracklen Utility Shed  
Quinault Ranger Station  
Route 2, Box 76  
Amanda Park WA 98256-  
Landholding Agency: Interior  
Property Number: 619030012  
Status: Unutilized  
Comment: 150 sq. ft., frame utility shed,  
limited utilities, off-site use only.

#### *Wisconsin*

Bldg. 2  
VA Medical Center  
County Highway E  
Tomah Co: Monroe WI 54660-  
Landholding Agency: VA  
Property Number: 979010055  
Status: Underutilized  
Comment: 18000 sq. ft., 3 story masonry,  
needs rehab, possible asbestos, potential  
utilities.  
Bldg. 8  
VA Medical Center  
County Highway E  
Tomah Co: Monroe WI 54660-  
Landholding Agency: VA  
Property Number: 979010056  
Status: Underutilized  
Comment: 2200 sq. ft., 2 story wood frame,  
possible asbestos, potential utilities,  
structural deficiencies, needs rehab.

**Land (by State)****Alabama**

VA Medical Center  
VAMC  
Tuskegee Co: Macon AL 36083-  
Landholding Agency: VA  
Property Number: 979010053  
Status: Underutilized  
Comment: 40 acres, buffer to VA Medical Center, potential utilities, undeveloped.

**Alaska**

Wrangell Narrows Reservation  
Wrangell Co: Wrangell AK  
Location: Approximately 6 miles south of Petersburg, Alaska along Mitkof highway.  
Landholding Agency: DOT  
Property Number: 879010008  
Status: Excess  
Comment: 42.15 acres

**California**

Receiver Site  
Dixon Relay Station  
7514 Radio Station Road  
Dixon CA 95820-9653  
Location: Approximately 16 miles southeast of Dixon, CA.  
Landholding Agency: GSA  
Property Number: 549010042  
Status: Excess  
Comment: 99 acres, 1560 sq. ft., radio receiver bldg. on site, subject to grazing lease, limited utilities.  
GSA Number: 9-2-CA-1162-A

Receiver Site  
Delano Relay Station  
Route 1, Box 1350  
Delano Co: Tulare CA 93215-  
Location: 5 miles west of Pixley, 27 miles north of Delano.  
Landholding Agency: GSA  
Property Number: 549010044  
Status: Excess  
Comment: 81 acres, 1560 sq. ft., radio receiver bldg. on site, subject to grazing lease, potential utilities  
GSA Number: 9-2-CA-1308

**Colorado**

Portion/Curecanti Substation  
Cimarron Co: Montrose CO 81220-  
Location: 2 miles east of Cimarron on Highway 50  
Landholding Agency: GSA  
Property Number: 419030009  
Status: Excess  
Comment: 36.39 acres, easement restrictions  
GSA Number: 7-B-CO-624  
Railroad Spur and Right-of-Way  
Denver Federal Center  
Lakewood Co: Jefferson CO 80215-  
Landholding Agency: GSA  
Property Number: 549120007  
Status: Excess  
Comment: 1.5 miles long (width varies 35 to 200 ft.), limited access, right-of-way restrictions  
GSA Number: 7-C-CO-441-Q

**Georgia**

Lake Sidney Lanier  
Riverside Dr.  
Gainesville Co: Hall GA  
Landholding Agency: GSA  
Property Number: 549140003

Status: Excess  
Comment: 6.22 acres, leased to City for construction of an alum sludge dewatering and wash water handling facility  
GSA Number: 4-D-GA-731

**Kansas**

Titan II Missile Site 6  
McCConnell AFB  
4.8 miles east of Winfield on State Rd. 15  
Winfield Co: Cowley KS 67156-  
Landholding Agency: GSA  
Property Number: 549130010  
Status: Excess  
Comment: Approx. 25.44 acres, most recent use—missile site complex  
GSA Number: 7-D-KS-477-N  
McCConnell AF Facility S-15  
McCConnell Air Force Base Co: Kingman KS 67201-

Location: Two miles south of Rago on State road 14  
Landholding Agency: GSA  
Property Number: 549130013  
Status: Excess  
Comment: 16.69 fee acres and 2.73 paved easement, potential utilities  
GSA Number: 7-D-KS-477-P

Titan II Missile Site No. 9  
McCConnell Air Force Base Co: Sumner KS 67201-  
Landholding Agency: GSA  
Property Number: 549130014  
Status: Excess  
Comment: 6.43 fee acres and 2.96 acres easement, subject to utility rights by third parties, most recent use—missile site  
GSA Number: 7-D-KS-0477-O

**Louisiana**

Land—8.27 acres  
VA Medical Center  
2501 Shreveport Highway  
Alexandria Co: Rapides LA 71301-  
Landholding Agency: VA  
Property Number: 979010009  
Status: Unutilized  
Comment: 8.27 acres, heavily wooded with natural drainage ravine across property, most recent use—recreation/buffer area.

**Maryland**

VA Medical Center  
9500 North Point Road  
Fort Howard Co: Baltimore MD 21052-  
Landholding Agency: VA  
Property Number: 979010020  
Status: Underutilized  
Comment: Approx. 10 acres, wetland and periodically floods, most recent use—dump site for leaves.

**Michigan**

Facility 93359  
Bayshore RBS  
Det 6, 1st Combat Evaluation Group  
Bay Shore Co: Emmet MI 49711-  
Landholding Agency: GSA  
Property Number: 189010058  
Status: Excess  
Comment: 2.52 acres, utilities and sanitary facilities  
GSA Number: 2-D-MI-751  
Facility 93361  
Bayshore RBS  
Det 6, 1st Combat Evaluation Group

Bay Shore Co: Emmet MI 49711-  
Landholding Agency: GSA  
Property Number: 189010061  
Status: Excess  
Comment: 0.14 acres, access gained through Air Force controlled property  
GSA Number: 2-D-MI-751

**Minnesota**

Land around Bldg. 240-249, 253  
VA Medical Center  
Fort Snelling  
St. Paul Co: Hennepin MN 55111-  
Landholding Agency: VA  
Property Number: 979010007  
Status: Unutilized  
Comment: 3.76 acres, potential utilities.

**North Carolina**

USCG Station—Land  
Oregon Inlet Coast Guard Station  
Rodanthe Co: Dare NC 27968-  
Landholding Agency: DOT  
Property Number: 879120087  
Status: Unutilized  
Comment: 10 acres, potential utilities

**North Dakota**

Valley City Radio Tower Site  
1 mile south and 1 mile east of Valley City, North Dakota  
Valley City Co: Barnes ND 58072-  
Landholding Agency: GSA  
Property Number: 549130016  
Status: Excess  
Comment: 5.74 acres w/one story metal equipment storage bldg. 12' X 10'6", potential utilities  
GSA Number: 7-B-ND-490  
Tappen Radio Relay Tower Site  
2 miles east and 1.5 miles north of Tappen  
Tappen Co: Kidder ND 58487-  
Landholding Agency: GSA  
Property Number: 549130017  
Status: Excess  
Comment: 5.74 fee acres and 0.59 acre easement w/100' guyed communication tower, potential utilities  
GSA Number: 7-B-ND-491

**Oregon**

Tongue Point Job Corps Center (Portion of)  
Astoria Co: Clatsop OR 97103-  
Location: On the east by highway 30; on the west by city of Astoria's sewage treatment plant.  
Landholding Agency: GSA  
Property Number: 549010027  
Status: Excess  
Comment: 22.77 acres, land slopes, some soil erosion, potential utilities  
GSA Number: 9-L-OR-508M  
Sewer and Road Easements  
Camp White  
Medford Co: Jackson OR  
Location: Table Rock Road and Avenue A and Kirtland Road and Newland Road.  
Landholding Agency: GSA  
Property Number: 549110012  
Status: Excess  
Comment: 10 acres, potential utilities, most recent use—road and sewer line easements  
GSA Number: 9-C-OR-38  
Land  
Portland Co: Multnomah OR 97217-

Location: Near SE corner of North Union Ave. and North Marine Dr.  
Landholding Agency: GSA  
Property Number: 549120006  
Status: Excess  
Comment: 83000 sq. ft. (140X450) land, most recent use—part of highway right-of-way, access is restricted.

Port Orford Radio Station  
Port Orford Co: Curry OR 97465—  
Landholding Agency: DOT  
Property Number: 879010007  
Status: Excess  
Comment: 5.17 acres, radio station

#### Texas

Test Tract—Formerly Jet Ind.  
Burlison Road  
Austin Co: Travis TX 78741—  
Location: Approx. 7 mi NW of U.S. Hwy 183 and approx. 3.5 mi SE of Ben White Blvd.  
Landholding Agency: GSA  
Property Number: 549140008  
Status: Excess  
Comment: 75.18 acres, most recent use—one-mile asphalt test track for electric cars, approx. 15 acres in floodplain  
GSA Number: 7-B-TX-970

Land  
Olin E. Teague Veterans Center  
1901 South 1st Street  
Temple Co: Bell TX 76504—  
Landholding Agency: VA  
Property Number: 979010079  
Status: Underutilized  
Comment: 13 acres, portion formerly landfill, portion near flammable materials, railroad crosses property, potential utilities.

VA Medical Center  
4800 Memorial Drive  
Waco Co: McLennan TX 76711—  
Landholding Agency: VA  
Property Number: 979010081  
Status: Underutilized  
Comment: 2.3 acres, leased to Owens-Illinois Glass Plant, expiration date 10/31/91, most recent use—parking lot.

#### Washington

Seaplane Base  
Naval Air Station—Whidbey Island  
Oak Harbor Co: Island WA 98278—  
Landholding Agency: GSA  
Property Number: 549130007  
Status: Excess  
Comment: 5.472 acres, most recent use—roadway and outside boat storage, easement restrictions  
GSA Number: 9-N-WA-585M

#### Wisconsin

VA Medical Center  
County Highway E  
Tomah Co: Monroe WI 54660—  
Landholding Agency: VA  
Property Number: 979010054  
Status: Underutilized  
Comment: 12.4 acres, serves as buffer between center and private property, no utilities.

#### Wyoming

Wind Site A  
Medicine Bow Co: Carbon WY 82329—  
Location: 3 miles south and 2 miles west of Medicine Bow

Landholding Agency: GSA  
Property Number: 419030010  
Status: Excess  
Comment: 46.75 acres, limitation—eastment restrictions

#### Suitable/Unavailable Properties

##### Buildings (by State)

###### California

Bldg. 8, Coast Guard Island  
USCG Support Center, Alameda  
Alameda Co: Alameda, CA 94501—  
Landholding Agency: DOT  
Property Number: 879130005  
Status: Underutilized  
Comment: 16,900 sq. ft., 2 story wood frame, most recent use—barracks, needs major rehab, presence of asbestos, off-site use only

Bldg. 9, Coast Guard Island  
USCG Support Center, Alameda  
Alameda Co: Alameda, CA 94501—  
Landholding Agency: DOT  
Property Number: 879130006  
Status: Unutilized  
Comment: 29,440 sq. ft., 2 story wood frame, most recent use—office, presence of asbestos, needs major rehab, off-site use only

###### Florida

Naval Reserve Center  
2610 Tigertail Avenue  
Miami Co: Dade FL 33133—  
Landholding Agency: CSA  
Property Number: 549120062  
Status: Excess  
Comment: 4,600 sq. ft., 2 story, concrete and wood siding, most recent use—offices/training rooms, vehicle maintenance  
GSA Number: FL-P-192

###### Louisiana

Federal Building  
Mississippi and Vienna Streets  
Ruston Co: Lincoln Parish LA 71273—  
Landholding Agency: GSA  
Property Number: 549040005  
Status: Excess  
Comment: 3,492 sq. ft., 2 story, most recent use—office, listed on National Register of Historic Places  
GSA Number: 7-G-LA-0541

###### Maryland

Bldg. 8A  
DVA Medical Center  
Perry Point  
Perry Point Co: Cecil MD 21902—  
Landholding Agency: VA  
Property Number: 979010047  
Status: Underutilized  
Comment: 17,000 sq. ft., 1 story masonry, needs a roof, no utilities, most recent use—storage.

###### Minnesota

Bldg. 15  
VA Medical Center  
Near 5829 Minnehaha Avenue  
Minneapolis Co: Hennepin MN 55417—  
Landholding Agency: VA  
Property Number: 979010025  
Status: Underutilized

Comment: 15,100 sq. ft., 2 story concrete/brick frame, asbestos present in pipe insulation, most recent use—laundry.

###### Bldg. 16

VA Medical Center  
Near 5629 Minnehaha Avenue  
Minneapolis Co: Hennepin MN 55417—  
Landholding Agency: VA  
Property Number: 979010028  
Status: Underutilized  
Comment: 8,000 sq. ft., 3 story concrete/brick, asbestos present on pipe insulation, most recent use—boiler plant.

###### Bldg. 21

VA Medical Center  
Near 5629 Minnehaha Avenue  
Minneapolis Co: Hennepin MN 55417—  
Landholding Agency: VA  
Property Number: 979010027  
Status: Underutilized  
Comment: 3,200 sq. ft., 1 story prefab/quonset, most recent use—garage for motor vehicles.

###### Bldg. 48

VA Medical Center  
Near 5629 Minnehaha Avenue  
Minneapolis Co: Hennepin MN 55417—  
Landholding Agency: VA  
Property Number: 979010028  
Status: Underutilized  
Comment: 2,000 sq. ft., 1 story concrete/block, most recent use—incinerator/storage.

###### Bldg. 64

VA Medical Center  
Near 5629 Minnehaha Avenue  
Minneapolis Co: Hennepin MN 55417—  
Landholding Agency: VA  
Property Number: 979010029  
Status: Unutilized  
Comment: 380 sq. ft., 1 story prefab, potential utilities.

###### Bldg. T-10

VA Medical Center  
Near 5629 Minnehaha Avenue  
Minneapolis Co: Hennepin MN 55417—  
Landholding Agency: VA  
Property Number: 979010030  
Status: Unutilized  
Comment: 1,800 sq. ft., 1 story prefab/quonset, potential utilities, most recent use—storage.

###### Bldg. 43

VA Medical Center  
Minneapolis Co: Hennepin MN 55441-7  
Location: 54th Street and 48th Avenue S.  
Landholding Agency: VA  
Property Number: 979010032  
Status: Underutilized  
Comment: 26000 sq. ft., 8 story brick/steel frame, asbestos present on pipe insulation, most recent use—office/storage.

###### Bldg. 227

VA Medical Center  
Fort Snelling  
St. Paul Co: Hennepin MN 55111—  
Landholding Agency: VA  
Property Number: 979010033  
Status: Unutilized  
Comment: 850 sq. ft., 2 story wood frame and brick residence, utilities disconnected.

###### Missouri

Bldg. 208-C  
6400 Stratford Avenue

- Portion U.S. Army Reserve Center No. 4  
St. Louis Co: St. Louis MO 63120-  
Landholding Agency: CSA  
Property Number: 549120047  
Status: Excess  
Comment: 2210 sq. ft., most recent use—  
general storage, permitted to Dept. of Labor  
CSA Number: 7-D-MO-460-F  
Bldg. 208-D  
6400 Stratford Avenue  
Portion U.S. Army Reserve Center No. 4  
St. Louis Co: St. Louis MO 63120-  
Landholding Agency: CSA  
Property Number: 549120048  
Status: Excess  
Comment: 750 sq. ft., most recent use—  
general storage, permitted to Dept. of Labor  
CSA Number: 7-D-MO-460-F  
Bldg. 222  
6400 Stratford Avenue  
Portion U.S. Army Reserve Center No. 4  
St. Louis Co: St. Louis MO 63120-  
Landholding Agency: CSA  
Property Number: 549120049  
Status: Excess  
Comment: 16150 sq. ft., most recent use—  
medical/dental, permitted to Dept. of Labor  
CSA Number: 7-D-MO-460-F  
Bldg. 223-A  
6400 Stratford Avenue  
Portion U.S. Army Reserve Center No. 4  
St. Louis Co: St. Louis MO 63120-  
Landholding Agency: CSA  
Property Number: 549120050  
Status: Excess  
Comment: 77340 sq. ft., most recent use—  
dormitory, permitted to Dept. of Labor  
CSA Number: 7-D-MO-460-F  
Bldg. 223-B  
6400 Stratford Avenue  
Portion U.S. Army Reserve Center No. 4  
St. Louis Co: St. Louis MO 63120-  
Landholding Agency: CSA  
Property Number: 549120051  
Status: Excess  
Comment: 21380 sq. ft., most recent use—  
education bldg., permitted to Dept. of Labor  
CSA Number: 7-D-MO-460-F  
Bldg. 230  
6400 Stratford Avenue  
Portion U.S. Army Reserve Center No. 4  
St. Louis Co: St. Louis MO 63120-  
Landholding Agency: CSA  
Property Number: 549120052  
Status: Excess  
Comment: 1640 sq. ft., most recent use—  
facility maintenance, permitted to Dept. of  
Labor  
CSA Number: 7-D-MO-460-F  
Bldg. 230-A  
6400 Stratford Avenue  
Portion U.S. Army Reserve Center No. 4  
St. Louis Co: St. Louis MO 63120-  
Landholding Agency: CSA  
Property Number: 549120053  
Status: Excess  
Comment: 2890 sq. ft., most recent use—  
facility maintenance, permitted to Dept. of  
Labor  
CSA Number: 7-D-MO-460-F  
Bldg. 232-A-H  
6400 Stratford Avenue  
Portion U.S. Army Reserve Center No. 4  
St. Louis Co: St. Louis MO 63120-  
Landholding Agency: CSA  
Property Number: 549120054  
Status: Excess  
Comment: 29280 sq. ft., most recent use—  
vocational training shop, permitted to Dept.  
of Labor  
CSA Number: 7-D-MO-460-F  
Bldg. 234  
6400 Stratford Avenue  
Portion U.S. Army Reserve Center No. 4  
St. Louis Co: St. Louis MO 63120-  
Landholding Agency: CSA  
Property Number: 549120055  
Status: Excess  
Comment: 44620 sq. ft., most recent use—  
admin/food service, permitted to Dept. of  
Labor  
CSA Number: 7-D-MO-460-F  
Bldg. 237  
6400 Stratford Avenue  
Portion U.S. Army Reserve Center No. 4  
St. Louis Co: St. Louis MO 63120-  
Landholding Agency: CSA  
Property Number: 549120056  
Status: Excess  
Comment: 300 sq. ft., most recent use—  
storage, permitted to Dept. of Labor  
CSA Number: 7-D-MO-460-F  
Bldg. 244  
6400 Stratford Avenue  
Portion U.S. Army Reserve Center No. 4  
St. Louis Co: St. Louis, MO 63120-  
Landholding Agency: CSA  
Property Number: 549120057  
Status: Excess  
Comment: 7480 sq. ft., most recent use—  
weld/automotive shop, permitted to Dept.  
of Labor  
CSA Number: 7-D-MO-460-F  
Bldg. 223C  
6400 Stratford Avenue  
Portion U.S. Army Reserve Center No. 4  
St. Louis Co: St. Louis, MO 63120-  
Landholding Agency: CSA  
Property Number: 549120058  
Status: Excess  
Comment: 123 sq. ft., permitted to Dept. of  
Labor  
CSA Number: 7-D-MO-460-F  
Bldg. 224B  
6400 Stratford Avenue  
Portion U.S. Army Reserve Center No. 4  
St. Louis Co: St. Louis, MO 63120-  
Landholding Agency: CSA  
Property Number: 549120059  
Status: Excess  
Comment: 160 sq. ft., permitted to Dept. of  
Labor  
CSA Number: 7-D-MO-460-F  
Bldg. 233A  
6400 Stratford Avenue  
Portion U.S. Army Reserve Center No. 4  
St. Louis Co: St. Louis, MO 63120-  
Landholding Agency: CSA  
Property Number: 549120060  
Status: Excess  
Comment: 837 sq. ft., permitted to Dept. of  
Labor  
CSA Number: 7-D-MO-460-F  
Bldg. 233F  
6400 Stratford Avenue  
Portion U.S. Army Reserve Center No. 4  
St. Louis Co: St. Louis, MO 63120-  
Landholding Agency: CSA  
Property Number: 549120061  
Status: Excess  
Comment: 837 Sq. ft., permitted to Dept. of  
Labor  
CSA Number: 7-D-MO-460-F  
New York  
Bldg. 2  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-  
Landholding Agency: CSA  
Property Number: 549120069  
Status: Excess  
Comment: 35537 sq. ft., 3 story bay brick  
frame, presence of asbestos on pipe  
insulation, most recent use—office, storage,  
auto shop, scheduled to be vacated Oct  
1992  
CSA Number: 2-N-NY-797  
Bldg. 3  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-  
Landholding Agency: CSA  
Property Number: 549120010  
Status: Excess  
Comment: 2700 sq. ft., 2 story brick frame,  
most recent use—office, scheduled to be  
vacated Oct. 1992.  
CSA Number: 2-N-NY-797  
Bldg. 4  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-  
Landholding Agency: CSA  
Property Number: 549120011  
Status: Excess  
Comment: 60400 sq. ft., 1 story bay brick  
frame, most recent use—warehouse and  
rec. center, presence of asbestos on pipe  
insulation, scheduled to be vacated Oct.  
1992  
CSA Number: 2-N-NY-797  
Bldg. 5  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-  
Landholding Agency: CSA  
Property Number: 549120012  
Status: Excess  
Comment: 3330 sq. ft., 2 story brick frame,  
most recent use—office, scheduled to be  
vacated Oct. 1992  
CSA Number: 2-N-NY-797  
Bldg. 10  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-  
Landholding Agency: CSA  
Property Number: 549120015  
Status: Excess  
Comment: 3100 sq. ft., 1 story, concrete and  
fiberglass frame, no utilities, most recent  
use—storage, scheduled to be vacated Oct.  
1992  
CSA Number: 2-N-NY-797  
Bldg. 306  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-  
Landholding Agency: CSA  
Property Number: 549120016  
Status: Excess  
Comment: 8364 sq. ft., 1 story brick frame,  
presence of asbestos on pipe insulation,

- most recent use—storage, scheduled to be vacated Oct. 1992  
GSA Number: 2-N-NY-797
- Bldg. 316**  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-  
Landholding Agency: GSA  
Property Number: 549120019  
Status: Excess  
Comment: 3952 sq. ft., 1 story brick frame, needs heating system repairs, potential utils., pres. of asbestos on pipe insula, most recent use—storage, sched. to be vacated Oct. 1992  
GSA Number: 2-N-NY-797
- Bldg. 353**  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-  
Landholding Agency: GSA  
Property Number: 549120020  
Status: Excess  
Comment: 670 sq. ft., 1 story brick frame, limited utilities, needs rehab, most recent use—storage, needs heating system repairs, scheduled to be vacated Oct. 1992  
GSA Number: 2-N-NY-797
- Bldg. 670**  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-  
Landholding Agency: GSA  
Property Number: 549120021  
Status: Excess  
Comment: Concrete block gasoline station, no sanitary or heating facilities, scheduled to be vacated Oct. 1992  
GSA Number: 2-N-NY-797
- Bldg. 672**  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-  
Landholding Agency: GSA  
Property Number: 549120023  
Status: Excess  
Comment: 400 sq. ft., 1 story wood frame, most recent use—pool house, scheduled to be vacated Oct. 1992  
GSA Number: 2-N-NY-797
- Bldg. R1**  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-  
Landholding Agency: GSA  
Property Number: 549120025  
Status: Excess  
Comment: 5274 sq. ft., 2 story single family housing, brick veneer/wood frame, presence of asbestos on pipe insulation, scheduled to be vacated Oct. 1992  
GSA Number: 2-N-NY-797
- Bldg. R2**  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-  
Landholding Agency: GSA  
Property Number: 549120026  
Status: Excess  
Comment: 2400 sq. ft., 2 story single family hsg., cement asbestos/wood frame, needs heating system repairs, presence of asbestos on pipe insulation, sched. to be vacated Oct. 1992  
GSA Number: 2-N-NY-797
- Bldg. R3**  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-  
Landholding Agency: GSA  
Property Number: 549120027  
Status: Excess  
Comment: 2400 sq. ft., 2 story single family housing, cement asbestos/wood frame, scheduled to be vacated Oct. 1992  
GSA Number: 2-N-NY-797
- Bldg. R4**  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-  
Landholding Agency: GSA  
Property Number: 549120028  
Status: Excess  
Comment: 2517 sq. ft., 3 story four-family housing, brick asbestos/tile frame, scheduled to be vacated Oct. 1992  
GSA Number: 2-N-NY-797
- Bldgs. R5, R6, R7**  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-  
Landholding Agency: GSA  
Property Number: 549120029-549120031  
Status: Excess  
Comment: 2140 sq. ft. each, 1-story single family residences, brick frame, scheduled to be vacated Oct. 1992  
GSA Number: 2-N-NY-797
- Bldg. R103**  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-  
Landholding Agency: GSA  
Property Number: 549120032  
Status: Excess  
Comment: 1650 sq. ft., 2 story brick frame, needs heating system repairs, limited utils., most recent use—storage, presence of asbestos on pipe ins., scheduled to be vacated Oct. 1992  
GSA Number: 2-N-NY-797
- Bldg. R103A**  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-  
Landholding Agency: GSA  
Property Number: 549120033  
Status: Excess  
Comment: 2620 sq. ft., 1 story concrete block frame, limited utils., most recent use—garage, presence of asbestos on pipe insulation, scheduled to be vacated Oct. 1992  
GSA Number: 2-N-NY-797
- Bldg. R104**  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-  
Landholding Agency: GSA  
Property Number: 549120034  
Status: Excess  
Comment: 712 sq. ft., 2 story brick frame, most recent use—bachelor officers quarters, scheduled to be vacated Oct. 1992  
GSA Number: 2-N-NY-797
- Bldg. R109**  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-  
Landholding Agency: GSA
- Property Number: 549120035  
Status: Excess  
Comment: 2 story brick frame, limited utilities, needs heating syst. repairs, most recent use—storage & garage, presence of asbestos on pipe insul., scheduled to be vacated Oct. 1992  
GSA Number: 2-N-NY-797
- Bldg. R426**  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-  
Landholding Agency: GSA  
Property Number: 549120036  
Status: Excess  
Comment: 2409 sq. ft., 1 story brick frame, needs heating system repairs, most recent use—storage, presence of asbestos on pipe ins., limited utils., scheduled to be vacated Oct. 1992  
GSA Number: 2-N-NY-797
- Bldg. R446**  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-  
Landholding Agency: GSA  
Property Number: 549120037  
Status: Excess  
Comment: 969 sq. ft., 1 story concrete & glass frame, limited utilities, needs major rehab, most recent use—greenhouse, scheduled to be vacated Oct. 1992  
GSA Number: 2-N-NY-797
- Bldg. R475**  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-  
Landholding Agency: GSA  
Property Number: 549120039  
Status: Excess  
Comment: 1789 sq. ft., 1 story concrete block frame, most recent use—auto hobby shop, presence of asbestos on pipe insulation, scheduled to be vacated Oct. 1992  
GSA Number: 2-N-NY-797
- Bldg. R476**  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-  
Landholding Agency: GSA  
Property Number: 549120040  
Status: Excess  
Comment: 36 sq. ft., 1 story metal frame, most recent use—security gate house, needs heating system repairs, scheduled to be vacated Oct. 1992  
GSA Number: 2-N-NY-797
- Bldg. RG**  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-  
Landholding Agency: GSA  
Property Number: 549120041  
Status: Excess  
Comment: 15490 sq. ft., 3 story brick & stucco frame, needs heating system repairs, needs major rehab, presence of asbestos on pipe ins., scheduled to be vacated Oct. 1992  
GSA Number: 2-N-NY-797
- Bldg. R8R9**  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-  
Landholding Agency: GSA

Property Number: 549120042  
 Status: Excess  
 Comment: 2800 sq. ft., 2 story brick frame, most recent use—residential duplex, scheduled to be vacated Oct. 1992  
 GSA Number: 2-N-NY-797  
 Bldg. R95  
 Naval Station  
 207 Flushing Avenue  
 Brooklyn Co: Kings NY 11251-  
 Landholding Agency: GSA  
 Property Number: 779010258  
 Status: Excess  
 Comment: 41800 sq. ft., 2 story stone frame, needs heating system repairs, pres. of asbestos on pipe ins., needs major rehab, NYS Historical Landmark, sched. to be vacated Oct. 1992  
 GSA Number: 2-N-NY-797  
 Bldg. RD  
 Naval Station  
 207 Flushing Avenue  
 Brooklyn Co: Kings NY 11251-  
 Landholding Agency: GSA  
 Property Number: 779010257  
 Status: Excess  
 Comment: 14120 sq. ft., 2 story brick and stone frame, needs heating system repairs, pres. of asbestos on pipe ins., needs major rehab, sched. to be vacated Oct. 1992  
 GSA Number: 2-N-NY-797  
 Bldg. 305  
 Naval Station  
 207 Flushing Avenue  
 Brooklyn Co: Kings NY 11251-  
 Landholding Agency: GSA  
 Property Number: 779010258  
 Status: Excess  
 Comment: 18920 sq. ft., 2 story brick frame, limited util., needs major rehab, presence of asbestos on pipe insulation, needs heating system repairs, scheduled to be vacated Oct. 1992  
 GSA Number: 2-N-NY-797  
 Bldg. 5  
 V.A. Medical Center  
 Redfield Parkway  
 Batavia Co: Genesee NY 14020-  
 Landholding Agency: VA  
 Property Number: 979030001  
 Status: Underutilized  
 Comment: Portion of 16800 sq. ft., 3 story, brick and masonry bldgs., needs minor repairs.

*Texas*  
 Peary Place #1  
 Naval Air Station  
 Corpus Christi Co: Nueces TX 78419-5000  
 Landholding Agency: GSA  
 Property Number: 779030002  
 Status: Excess  
 Comment: 9160 sq. ft., 1 story, possible asbestos, most recent use—remote transmitter site.  
 GSA Number: 7-N-PX-402-V  
 Brownsville Urban System  
 (Grantee)  
 700 South Iowa Avenue  
 Brownsville Co: Cameron TX 78520-  
 Landholding Agency: DOT  
 Property Number: 879010003  
 Status: Underutilized  
 Comment: 3500 sq. ft., 1 story concrete block, (2nd floor of Admin. Bldg.) on 10750 sq. ft.

land, contains underground diesel fuel tanks.

*Utah*

Bryce Canyon Admin. Site  
 Near Bryce Canyon National Park  
 Bryce Canyon Co: Garfield UT 84717-  
 Landholding Agency: Interior  
 Property Number: 619140005  
 Status: Underutilized  
 Comment: 7 houses and other bldgs. on 66 acre site, seasonal use, one story wood frame structures, 48 thru 1400 sq. ft., environmentally protected.

*Washington*

Mica Peak Radio Station  
 Approx. 15 miles SE of Spokane  
 Spokane Co: Spokane WA 99210-  
 Landholding Agency: GSA  
 Property Number: 549120065  
 Status: Excess  
 Comment: 25X48 ft. on 0.4 acres 1 story concrete block, most recent use—radio communications, only accessible from late June to October.  
 GSA Number: 9-B-WA-895  
 Thompson Main Residence  
 Lake Crescent Ranger Station  
 HC 62, Box 10  
 Port Angeles WA 98362-  
 Landholding Agency: Interior  
 Property Number: 619030001  
 Status: Unutilized  
 Comment: 2 story residence, no utilities, needs rehab, off-site use only.

Thompson Older Residence  
 Lake Crescent Ranger Station  
 HC 62, Box 10  
 Port Angeles WA 98362-  
 Landholding Agency: Interior  
 Property Number: 619030002  
 Status: Unutilized  
 Comment: 888 sq. ft., 1 story residence, no utilities, needs rehab, off-site use only.

Thompson Garage  
 Lake Crescent Ranger Station  
 HC 62, Box 10  
 Port Angeles WA 98362-  
 Landholding Agency: Interior  
 Property Number: 619030003  
 Status: Unutilized  
 Comment: 240 sq. ft., 1 story garage, no utilities, needs rehab, off-site use only.

Thompson Shop  
 Lake Crescent Ranger Station  
 HC 62, Box 10  
 Port Angeles WA 98362-  
 Landholding Agency: Interior  
 Property Number: 619030009  
 Status: Unutilized  
 Comment: 300 sq. ft., 1 story shop, no utilities, needs rehab, off-site use only.

Thompson Powerhouse  
 Lake Crescent Ranger Station  
 HC 62, Box 10  
 Port Angeles WA 98362-  
 Landholding Agency: Interior  
 Property Number: 619030010  
 Status: Unutilized  
 Comment: 160 sq. ft., 1 story powerhouse, no utilities, needs rehab, off-site use only.

Dahinden Storage Building  
 Quinalt Ranger Station  
 Route 2, Box 76

Amanda Park WA 98526-  
 Landholding Agency: Interior  
 Property Number: 619030013  
 Status: Unutilized  
 Comment: 240 sq. ft., frame storage building, no utilities, needs rehab, off-site use only.

Bldg. 1185  
 Lake Crescent Ranger Station  
 HC 62, Box 10  
 Carter Storage Building  
 Port Angeles WA 98362-  
 Landholding Agency: Interior  
 Property Number: 619030016  
 Status: Unutilized  
 Comment: 92 sq. ft., 1 story storage building, no utilities, off-site use only.

Haas Barn  
 % Quinalt Ranger Station  
 Route 2, Box 76  
 Amanda Park Co: Grays Harbor WA 98526-  
 Landholding Agency: Interior  
 Property Number: 619040001  
 Status: Excess  
 Comment: 1408 sq. ft., 1 story wood frame barn, potential utilities, poor condition, off-site use only.

Haas Shed  
 % Quinalt Ranger Station  
 Route 2, Box 76  
 Amanda Park Co: Grays Harbor WA 98526-  
 Landholding Agency: Interior  
 Property Number: 619040002  
 Status: Excess  
 Comment: 480 sq. ft., wood frame shed, poor condition, off-site use only.

Haas Shed  
 % Quinalt Ranger Station  
 Route 2, Box 76  
 Amanda Park Co: Grays Harbor WA 98526-  
 Landholding Agency: Interior  
 Property Number: 619040003  
 Status: Excess  
 Comment: sq. ft., wood frame shed, poor condition, off-site use only.

Haas Residence  
 % Quinalt Ranger Station  
 Route 2, Box 76  
 Amanda Park Co: Grays Harbor WA 98526-  
 Landholding Agency: Interior  
 Property Number: 619040006  
 Status: Excess  
 Comment: 624 sq. ft., 1 story wood frame residence, potential utilities, poor condition, off-site use only.

Bldg. 1323  
 Jensen Barn  
 % Quinalt Ranger Station  
 Route 2, Box 76  
 Amanda Park Co: Grays Harbor WA 98526-  
 Landholding Agency: Interior  
 Property Number: 619040007  
 Status: Excess  
 Comment: 4200 sq. ft., wood frame barn, most recent use—storage, no utilities, off-site use only.

*Wyoming*

Administration Bldg.  
 Fontenelle Camp  
 Fontenelle Co: Lincoln WY  
 Location: Approximately 24 miles southeast of Labarge, off State Road 372 and on County Road 316.  
 Landholding Agency: Interior

Property Number: 619030017

Status: Excess

Comment: 4464 sq. ft., 2 story brick structure with a 2880 sq. ft. wood frame addition, needs rehab, possible asbestos, off-site use only.

Bldg 13

Medical Center

N.W. of town at the end of Fort Road

Sheridan Co: Sheridan WY 82801-

Landholding Agency: VA

Property Number: 979110001

Status: Unutilized

Comment: 3613 sq. ft., 3 story wood frame masonry veneered, potential utilities, possible asbestos, needs rehab.

Bldg 79

Medical Center

N.W. of town at the end of Fort Road

Sheridan Co: Sheridan WY 82801-

Landholding Agency: VA

Property Number: 979110003

Status: Unutilized

Comment: 45 sq. ft., 1 story brick and tile frame, limited utilities, most recent use—reservoir house, use for storage purposes.

Land (by State)

*Alaska*

Portion, Dyke Range

Old Richardson Hwy.

North Pole Co: Fairbanks AK 00005-

Landholding Agency: GSA

Property Number: 549130018

Status: Excess

Comment: 0.73 acre—75% of land encroached upon by private residence

GSA Number: 9-D-AK-727

*Arizona*

Liberty Substation

Buckeye Co: Maricopa AZ 85326-

Location: 3 miles south of Interstate 10 on Tuthill Road

Landholding Agency: Energy

Property Number: 419030001

Status: Underutilized

Comment: 15 acres, buffer area for substation.

*California*

Remote Transmitter

Section 35

Red Bluff Co: Tehama CA 96030-

Landholding Agency: DOT

Property Number: 879010010

Status: Unutilized

Comment: 4 acres, paved road, current use—storage.

Land

VA Medical Center

Wilshire and Sawtelle Boulevards

Los Angeles Co: Los Angeles CA 90073-

Landholding Agency: VA

Property Number: 979010077

Status: Underutilized

Comment: Approx. 30 acres of 80 acre tract, 7 acre portion contaminated, portions may be environmentally protected.

*Florida*

Parcel A & B

U.S. Coast Guard Light Station

Lots 1, 8 & 11, Section 31

Jupiter Inlet Co: Palm Beach FL 33420-

Location: Township 40 south, range 43 east

Landholding Agency: DOT

Property Number: 879010009

Status: Unutilized

Comment: 56.61 acres, area is uncleared, vegetation growth is heavy, no utilities

*Illinois*

Portion, JAAP

Joliet Army Ammunition Plant

Co: Will IL 60436-

Location: Approx. 15 miles south of Joliet on the east side of Interstate 55

Landholding Agency: GSA

Property Number: 549130019

Status: Excess

Comment: 1.25 acres, most recent use—aquatic sampling station, subject to occasional flooding

DSA Number: 2-GR(1)-IL-450-FF

VA Medical Center

3001 Green Bay Road

North Chicago Co: Lake IL 60054-

Landholding Agency: VA

Property Number: 979010082

Status: Underutilized

Comment: 2.5 acres, currently being used as a construction staging area for the next 6-8 years, potential utilities.

*Iowa*

Sioux City Substation

Hinton Co: Plymouth IA 51024-

Location: 1 mile south of Hinton Iowa on Highway 75.

Landholding Agency: Energy

Property Number: 419030003

Status: Underutilized

Comment: 34 acres, limitation—easement restrictions, most recent use—transmission line corridor and buffer area.

*Kansas*

Titan II Missile S-17

McConnell Air Force Base Co: Kingman, KS 67068-

Location: 4 miles east of US Hwy 54 and 3 miles north on FAS 361

Landholding Agency: GSA

Property Number: 549210001

Status: Excess

Comment: 10.26 acres fee and  $\frac{3}{4}$  acres easement (paved), potential utilities, PCB's underground on 1 acre, most recent use—missile site.

GSA Number: 7-D-KS-477-Q

Titan II Missile S-12

McConnell Air Force Base Co: Sumner KS 67221-

Location: 1.5 miles south of Conway Springs, KS on State Hwy 49

Landholding Agency: GSA

Property Number: 549210002

Status: Excess

Comment: 16.75 acres fee and 3.79 acres easement (paved), potential utilities, PCB's underground on 1 acre, most recent use—missile site.

GSA Number: 7-D-KS-477-R

*Kentucky*

Portion of Tract 409-2

Upper Cumberland River Basin

Pineville Co: Bell KY 40977-

Location: Portions of Lots 1 & 2 in Blk 9 of Hull and Barclay Addition at the intersection of Mtn. View and Tenn. Ave.

Landholding Agency: GSA

Property Number: 549130008

Status: Excess

Comment: 0.01 acres/640 sq. ft., most recent use—flood control project

GSA Number: 4-D-KY-0588

*Massachusetts*

Por. of Former Navy Ammo. Plt.

Fort Hill Street

Hingham Co: Plymouth MA 02043-

Location: Across from Bus Company Parking Garage.

Landholding Agency: GSA

Property Number: 549030017

Status: Excess

Comment: 1.129 acres, gravel pavement, most recent use—parking lot

GSA Number 2-GR-MA-581B

*Michigan*

VA Medical Center

5500 Armstrong Road

Battle Creek Co: Calhoun MI 49018-

Landholding Agency: VA

Property Number: 979010015

Status: Underutilized

Comment: 20 acres, used as exercise trails and storage areas, potential utilities.

*Minnesota*

Bldg. 43 Land Site

VA Medical Center

54th Street & 48th Avenue South

Minneapolis Co: Hennepin MN 55417-

Landholding Agency: VA

Property Number: 979010005

Status: Underutilized

Comment: 8.9 acres, most recent use—parking, potential utilities.

Bldg. 227-229 Land

VA Medical Center

Fort Snelling

St. Paul Co: Hennepin MN 55111-

Landholding Agency: VA

Property Number: 979010006

Status: Underutilized

Comment: 2.0 acres, potential utilities, buildings occupied, residence/garage.

VA Medical Center

Near 5629 Minnehaha Avenue

Minneapolis Co: Hennepin MN 55417-

Location: Land (Site of Building 15, 16, 21, 48, 64, T10)

Landholding Agency: VA

Property Number: 979010024

Status: Underutilized

Comment: 12.1 acres, most recent use—parking, potential utilities.

Land—12 acres

VAMC

Near 5629 Minnehaha Avenue

Minneapolis Co: Hennepin MN 55417-

Landholding Agency: VA

Property Number: 979010031

Status: Unutilized

Comment: 12 acres, possible asbestos, leased to Department of Natural Resources as a park walking trail.

*Montana*

Miles City Substation

Miles City Co: Custer MT 59301-

Location: 1 mile east of Miles City

Landholding Agency: Energy

Property Number: 419030004  
 Status: Underutilized  
 Comment: 59 acres, limitation—easement restrictions subject to grazing lease, most recent use—buffer area for substation.  
 Custer Substation  
 Custer Co: Yellowstone MT 59024—  
 Location: 2 miles east of the town of Custer—east of Highway 47  
 Landholding Agency: Energy  
 Property Number: 419030006  
 Status: Underutilized  
 Comment: 18 acres, buffer area for substation.

#### Nebraska

Grand Island Substation  
 Phillips Co: Merrick NE 68865—  
 Location: 5 miles east of Grand Island and 4 miles west of Phillips.  
 Landholding Agency: Energy  
 Property Number: 419030002  
 Status: Underutilized  
 Comment: 11 acres, buffer area for substation, right-of-way for transmission lines for Nebraska Public Power District.

#### New York

Land 671  
 Naval Station New York  
 Brooklyn Co: Kings NY 11251—  
 Landholding Agency: GSA  
 Property Number: 549120022  
 Status: Excess  
 Comment: 50 ft. by 25 ft., most recent use—swimming pool concrete frame, scheduled to be vacated Oct. 1992.  
 GSA Number: 2-N-NY-797  
 Playing Field—675  
 Naval Station New York  
 207 Flushing Avenue  
 Brooklyn Co: Kings NY 11251—  
 Landholding Agency: GSA  
 Property Number: 549120024  
 Status: Excess  
 Comment: 67974 sq. ft., limited utilities, most recent use—baseball field, scheduled to be vacated Oct. 1992  
 GSA Number: 2-N-NY-797  
 Land R464/R474  
 Naval Station New York  
 Brooklyn Co: Kings NY 11251—  
 Landholding Agency: GSA  
 Property Number: 549120043  
 Status: Excess  
 Comment: 90' x 45' each, concrete over gravel, most recent use—tennis courts, scheduled to be vacated Oct. 1992  
 GSA Number: 2-N-NY-797  
 VA Medical Center  
 Fort Hill Avenue  
 Canandaigua Co: Ontario NY 14424—  
 Landholding Agency: VA  
 Property Number: 979010017  
 Status: Underutilized  
 Comment: 27.5 acres, used for school ballfield and parking, existing utilities easements, portion leased.

#### North Dakota

Fargo Substation  
 Fargo Co: Cass ND 58102—  
 Landholding Agency: Energy  
 Property Number: 419030005  
 Status: Underutilized

Comment: 25 acres, most recent use—transmission line corridor and buffer.

#### Pennsylvania

VA Medical Center  
 New Castle Road  
 Butler Co: Butler PA 16001—  
 Landholding Agency: VA  
 Property Number: 979010016  
 Status: Underutilized  
 Comment: Approx. 9.29 acres, used for patient recreation, potential utilities.  
 Land No. 645  
 VA Medical Center  
 Highland Drive  
 Pittsburgh Co: Allegheny PA 15206—  
 Location: Between Campania and Wiltsie Streets.  
 Landholding Agency: VA  
 Property Number: 979010080  
 Status: Unutilized  
 Comment: 52.42 acres, heavily wooded, property includes dump area and numerous site storm drain outfalls.

#### South Carolina

Georgetown Wayside Park  
 U.S. 701  
 Approx. 9-10 mi north of Georgetown  
 Georgetown Co: Georgetown SC 29440—  
 Landholding Agency: GSA  
 Property Number: 549130011  
 Status: Excess  
 Comment: 31.74 acres, approx. 1150 ft. of highway frontage through the property  
 GSA Number: 4-CR-SC-521

#### South Dakota

Por. of Pactola Dist. Ad. Site  
 803 Soo San Drive  
 Rapid City Co: Pennington SD 57702—  
 Landholding Agency: GSA  
 Property Number: 159130003  
 Status: Excess  
 Comment: 5.58 acres, potential utilities  
 GSA Number: 7-A-SD-511

#### Virginia

St. Helena Annex (former portion)  
 Treadwell and South Main Streets  
 Norfolk Co: Norfolk VA 23523—  
 Landholding Agency: GSA  
 Property Number: 549120005  
 Status: Excess  
 Comment: 7.89 acres, most recent use—paved parking lot  
 GSA Number: 4-CR(2)-VA525AA

#### Washington

Raver Substation Co: King WA  
 Location: Approximately 16 miles east of Kent.  
 Landholding Agency: Energy  
 Property Number: 419030012  
 Status: Unutilized  
 Comment: 10+ acres, potential utilities, heavily treed.

#### West Virginia

VA Medical Center  
 1540 Spring Valley Drive  
 Huntington Co: Wayne WV 25704—  
 Landholding Agency: VA  
 Property Number: 979010022  
 Status: Unutilized  
 Comment: 72 acres, very rough terrain and wooded, potential utilities

#### Suitable/To Be Excessed

##### Buildings (by State)

###### South Carolina

Bldg. #1 J.S. Coast Guard  
 Folly Island Loran Station  
 Folly Island Co: Charleston SC 29401—  
 Landholding Agency: DOT  
 Property Number: 879120096  
 Status: Unutilized  
 Comment: 2340 sq. ft., 1 story concrete block, most recent use—communications station  
 Bldg. #2 U.S. Coast Guard  
 Folly Island Loran Station  
 Folly Island Co: Charleston SC 29401—  
 Landholding Agency: DOT  
 Property Number: 879120097  
 Status: Unutilized  
 Comment: 2050 sq. ft., 1 story concrete block, most recent use—communications station

##### Land (by State)

###### Michigan

U.S. Coast Guard—Air Station  
 Traverse City Co: Grand Traverse MI 49684—  
 Landholding Agency: DOT  
 Property Number: 879120099  
 Status: Underutilized  
 Comment: 21.7 acres, most recent use—helo landings

###### South Carolina

Land—U.S. Coast Guard  
 Folly Island Loran Station  
 Folly Island Co: Charleston SC 29401—  
 Landholding Agency: DOT  
 Property Number: 879120098  
 Status: Unutilized  
 Comment: 55 acres (88 acres submerged) tidal marshland, potential utilities

##### Unsuitable Properties

##### Buildings (by State)

###### Alabama

5 Buildings  
 USCG Mobile Pt. Station  
 Ft. Morgan  
 Gulfshores Co: Baldwin AL 36542—  
 Landholding Agency: DOT  
 Property Numbers: 879120001-879120005  
 Status: Excess  
 Reason: Floodway

###### Alaska

Bldg. No. 10, Firehouse  
 Jct. of 5th St. & Ave. B  
 Kodiak Co: Kodiak Island AK 99619—  
 Landholding Agency: DOT  
 Property Number: 879120100  
 Status: Unutilized  
 Reason: Other  
 Comment: Extensive deterioration  
 Bldg. 22  
 USCG Support Center, Kodiak  
 Jct. of 5th Street and C Avenue  
 Kodiak Co: Kodiak Island AK 99619—  
 Landholding Agency: DOT  
 Property Number: 879130003  
 Status: Unutilized  
 Reason: Other  
 Comment: Extensive deterioration  
 USCG MSD Office (2 buildings)  
 2958 Tongass Avenue

Ketchikan Co: Ketchikan AK 99901-  
Landholding Agency: DOT  
Property Number: 879130004  
Status: Unutilized  
Reason: Other  
Comment: Extensive deterioration  
Galley/Rec. Bldg.  
USCG Base Ketchikan  
1300 Stedman Street  
Ketchikan Co: Ketchikan AK 99901-  
Landholding Agency: DOT  
Property Number: 879140002  
Status: Excess  
Reason: Secured Area  
Supply Warehouse  
USCG Base Ketchikan  
1300 Stedman Street  
Ketchikan Co: Ketchikan AK 99901-  
Landholding Agency: DOT  
Property Number: 879140003  
Status: Excess  
Reason: Secured Area  
Old Barracks  
USCG Base Ketchikan  
1300 Stedman Street  
Ketchikan Co: Ketchikan AK 99901-  
Landholding Agency: DOT  
Property Number: 879140004  
Status: Excess  
Reason: Secured Area  
Bldg. 517  
USCG Support Center Kodiak  
Kodiak Island  
Kodiak Co: Kodiak Island AK 99918-5000  
Landholding Agency: DOT  
Property Number: 879140007  
Status: Excess  
Reason: Secured Area; Within airport runway  
clear zone

#### California

Bldg. 17  
Coast Guard Island  
USCG Support Center, Alameda  
Alameda Co: Alameda CA 94501-  
Landholding Agency: DOT  
Property Number: 879130002  
Status: Unutilized  
Reason: Other  
Comment: Structural deficiencies  
3 Buildings  
Former Long Beach Radio Station  
Palos Verde Drive  
Palos Verde Co: Los Angeles CA 90274-  
Landholding Agency: DOT  
Property Numbers: 879140008-879140010  
Status: Excess  
Reason: Secured Area  
4 Bldgs., Loran Station  
Johnston Island  
APO San Francisco, CA (Sand Island)  
Johnston ATOLL CA 96305-5000  
Landholding Agency: DOT  
Property Number: 879210004  
Status: Excess  
Reason: Secured Area

#### Colorado

Alameda Facility  
350 S. Santa Fe Drive  
Denver Co: Denver CO 80223-  
Landholding Agency: DOT  
Property Number: 879010014  
Status: Unutilized  
Reason: Other environmental

Comment: contamination

#### Florida

Bldg. #3, Recreation Cottage  
USCG Station  
Marathon Co: Monroe FL 33050-  
Landholding Agency: DOT  
Property Numbers: 879210008  
Status: Unutilized  
Reason: Secured Area; Floodway

#### Hawaii

14 Buildings  
USCG Base Honolulu  
Sand Island  
Honolulu Co: Honolulu HI 96819-4398  
Landholding Agency: DOT  
Property Number: 879140011-879140024  
Status: Excess  
Reason: Secured Area; Within 2000 ft. of  
flammable or explosive material.  
9 Bldgs., Loran Station  
Kure Island  
FPO San Francisco, CA Co: Honolulu HI  
96819-0006  
Landholding Agency: DOT  
Property Number: 879210005  
Status: Excess  
Reason: Secured Area  
Barracks/Recreation Bldg.  
Loran Station Upolu Point  
Box 2  
Hawi Co: Hawaii HI 96719-0002  
Landholding Agency: DOT  
Property Number: 879210006  
Status: Excess  
Reason: Secured Area  
Transmitter Bldg.  
Loran Station Upolu Point  
Hawi Co: Hawaii HI 96719-0002  
Landholding Agency: DOT  
Property Number: 879210007  
Status: Excess  
Reason: Secured Area

#### Illinois

Former Martin L. King Center  
3312 West Crenshaw Avenue  
Chicago Co: Cook IL 60624-  
Landholding Agency: GSA  
Property Number: 549130005  
Status: Excess  
Reason: Other  
Comment: Extensive deterioration  
GSA Number: 2(R)-F-IL-691

#### Massachusetts

115 Buildings  
Massachusetts Military Reservation  
Bourne Co: Barnstable MA 02542-  
Landholding Agency: DOT  
Property Numbers: 879210009-879210123  
Status: Excess  
Reason: Other  
Comment: Extensive deterioration

#### New Jersey

Bldg. 120  
USCG Training Center Cape May  
North side of Munro Ave.  
Cape May Co: Cape May NJ 08204-  
Location: Opposite GSK Bldg. 204  
Landholding Agency: DOT  
Property Number: 879210007  
Status: Unutilized  
Reason: Secured Area

#### New Mexico

Farmington Office and Yard  
900 La Plata Highway  
Farmington Co: San Juan NM 87499-  
Landholding Agency: Interior  
Property Number: 619010001  
Status: Unutilized  
Reason: Within airport runway clear zone

#### New York

Plum Island Light Station  
Plum Island  
Southfield Township Co: Suffolk NY  
Landholding Agency: GSA  
Property Number: 549030004  
Status: Excess  
Reason: Secured Area  
CSA Number: 2-A-NY-798  
3 Buildings  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-  
Landholding Agency: GSA  
Property Numbers: 549120013-549120014,  
549120038  
Status: Excess  
Reason: Other  
Comment: Electrical substation  
GSA Number: 2-N-NY-797  
Hospital Area Steam Tunnel  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-  
Landholding Agency: GSA  
Property Number: 549120045  
Status: Excess  
Reason: Other  
Comment: Structurally unsound  
GSA Number: 2-N-NY-797  
North Street Steam Tunnel  
Naval Station New York  
207 Flushing Avenue  
Brooklyn Co: Kings NY 11251-  
Landholding Agency: GSA  
Property Number: 549120046  
Status: Excess  
Reason: Other  
Comment: Structurally unsound  
GSA Number: 2-N-NY-797

#### North Carolina

Bldg. 9  
VA Medical Center  
1100 Tunnel Road  
Asheville Co: Buncombe NC 28905-  
Landholding Agency: VA  
Property Number: 979010008  
Status: Underutilized  
Reason: Other  
Comment: Friable asbestos.

#### Oregon

Eugene District Office Site  
751 South Danebo  
Eugene Co: Lane OR 97402-  
Landholding Agency: Interior  
Property Number: 619010003  
Status: Underutilized  
Reason: Within 2000 ft. of flammable or  
explosive material  
USCG Air Station North Bend  
2000 Connecticut Avenue  
North Bend Co: Coos OR 97549-2399  
Landholding Agency: DOT

Property Number: 879140001  
 Status: Excess  
 Reason: Secured Area  
 Storage Building  
 USCG Marine Safety Office  
 6767 North Basin Avenue  
 Portland Co: Multnomah OR 97217-3992  
 Landholding Agency: DOT  
 Property Number: 879210002  
 Status: Excess  
 Reason: Other  
 Comment: Extensive deterioration

#### *Puerto Rico*

Mona Island  
 Punta Este Co: Mona Island PR  
 Landholding Agency: DOT  
 Property Number: 879010004  
 Status: Excess  
 Reason: Other  
 Comment: Inaccessible

#### *Texas*

3 Buildings  
 Olin E. Teague Veterans Center  
 1901 South 1st Street  
 Temple Co: Bell TX 76504-  
 Landholding Agency: VA  
 Property Numbers: 979010050-979010052  
 Status: Unutilized  
 Reason: Other  
 Comment: Friable asbestos.

#### *Washington*

Dahinden Chicken Coop  
 Quinault Ranger Station  
 Route 2, Box 76  
 Amanda Park WA 98526-  
 Landholding Agency: Interior  
 Property Number: 619030014  
 Status: Unutilized  
 Reason: Other  
 Comment: Chicken coop  
 Dahinden Outhouse  
 Quinault Ranger Station  
 Route 2, Box 76  
 Amanda Park WA 98526-  
 Landholding Agency: Interior  
 Property Number: 619040004  
 Status: Excess  
 Reason: Other  
 Comment: Detached latrine  
 Haas Chicken Coop  
 % Quinault Ranger Station  
 Route 2, Box 76  
 Amanda Park Co: Grays Harbor WA 98526-  
 Landholding Agency: Interior  
 Property Number: 619040004  
 Status: Excess  
 Reason: Other  
 Comment: Chicken coop  
 Haas Lean-to  
 Quinault Ranger Station  
 Route 2, Box 76  
 Amanda Park Co: Grays Harbor WA 98526-  
 Landholding Agency: Interior  
 Property Number: 619040005  
 Status: Excess  
 Reason: Other  
 Comment: Lean-to  
 Bldg. #36—Stehekin District  
 Company Creek Road  
 Stehekin Co: Chelan WA 98853-  
 Landholding Agency: Interior  
 Property Number: 619130001

Status: Unutilized  
 Reason: Other  
 Comment: Extensive deterioration  
 Bldg. 889—Comfort Station  
 Olympic Hot Springs Wilderness  
 Backcountry  
 Port Angeles Co: Clallam WA 98362-8798  
 Landholding Agency: Interior  
 Property Number: 619130002  
 Status: Excess  
 Reason: Other  
 Comment: Extensive deterioration  
 Bldg. 252—Storage Shed  
 Olympic Hot Springs Wilderness  
 Backcountry  
 Port Angeles Co: Clallam WA 98362-8798  
 Landholding Agency: Interior  
 Property Number: 619130003  
 Status: Excess  
 Reason: Other  
 Comment: Extensive deterioration  
 Bldgs. L-103, L-234  
 Mount Rainier National Park  
 Longmire Maintenance Complex  
 Longmire Co: Pierce WA 98397-  
 Landholding Agency: Interior  
 Property Number: 619130007-619130008  
 Status: Excess  
 Reason: Other  
 Comment: Extensive deterioration  
 2 Buildings  
 USCG Station Cape Disappointment  
 Foot of Canby Road  
 Ilwaco Co: Pacific WA 98624-0460  
 Landholding Agency: DOT  
 Property Numbers: 879140005-879140008  
 Status: Excess  
 Reason: Secured Area  
 Bldg. #1, USCG Support Center  
 1519 Alaskan Way South  
 Seattle Co: King WA 98134-  
 Landholding Agency: DOT  
 Property Number: 879210003  
 Status: Excess  
 Reason: Within 2000 ft. of flammable or  
 explosive material; Secured Area

#### *Wyoming*

Bldg. 95  
 Medical Center  
 N.W. of town at the end of Fort Road  
 Sheridan Co: Sheridan WY 82801-  
 Landholding Agency: VA  
 Property Number: 979110004  
 Status: Unutilized  
 Reason: Other  
 Comment: Sewage digester for disposal plant.  
 Bldg. 96  
 Medical Center  
 N.W. of town at end of Fort Road  
 Sheridan Co: Sheridan WY 82801-  
 Landholding Agency: VA  
 Property Number: 979110005  
 Status: Unutilized  
 Reason: Other  
 Comment: Pump house for sewage disposal  
 plant.  
 Structure 99  
 Medical Center  
 N.W. of town at the end of Fort Road  
 Sheridan Co: Sheridan WY 82801-  
 Landholding Agency: VA  
 Property Number: 979110006  
 Status: Unutilized  
 Reason: Other

Comment: Mechanical screen for sewage  
 disposal plant.  
 Structure 100  
 Medical Center  
 N.W. of town at the end of Fort Road  
 Sheridan Co: Sheridan WY 82801-  
 Landholding Agency: VA  
 Property Number: 979110007  
 Status: Unutilized  
 Reason: Other  
 Comment: Dosing tank for sewage disposal  
 plant.  
 Structure 101  
 Medical Center  
 N.W. of town at the end of Fort Road  
 Sheridan Co: Sheridan WY 82801-  
 Landholding Agency: VA  
 Property Number: 879110008  
 Status: Unutilized  
 Reason: Other  
 Comment: Chlorination chamber for sewage  
 disposal plant.

#### **Land (by State)**

##### *Alaska*

Nike Site, Tract 104  
 Jig Battery "D"  
 Eielson Defense Area  
 Fairbanks Co: Fairbanks AK 99701-  
 Landholding Agency: GSA  
 Property Number: 549120001  
 Status: Excess  
 Reason: Other  
 Comment: Property is landlocked  
 GSA Number: 9-D-AK-056-AD  
 Sanak Harbor Daybeacon  
 Sanak Island  
 Sanak Co: Aleutian AK  
 Landholding Agency: DOT  
 Property Number: 879010012  
 Status: Unutilized  
 Reason: Other  
 Comment: Isolated area on Arctic Coast

##### *Arizona*

Elliott Homes—Canal  
 West of 77th Ave. and South of Cholla Street  
 Peoria Co: Maricopa AZ 85345-  
 Landholding Agency: Interior  
 Property Number: 619130006  
 Status: Surplus  
 Reason: Other  
 Comment: Lateral canal

##### *California*

Elverta Substation  
 736 W. Elverta Road  
 Elverta Co: Sacramento CA 95626-  
 Landholding Agency: Energy  
 Property Number: 419030006  
 Status: Underutilized  
 Reason: Secured Area  
 DVA Medical Center  
 4951 Arroyo Road  
 Livermore Co: Alameda CA 94550-  
 Landholding Agency: VA  
 Property Number: 979010023  
 Status: Unutilized  
 Reason: Other  
 Comment: 750,000 gal water reservoir.

##### *Colorado*

Sunset Canyon Field Station  
 Boulder Co: Boulder CO 80502-

Location: 5 miles west of Wall Street on  
County Road 118  
Landholding Agency: GSA  
Property Number: 549030019  
Status: Excess  
Reason: Floodway  
GSA Number: 7-C-CO-602  
Beaver Creek Well Site  
Approx. 1 1/2 miles east of Brush  
Brush Co: Morgan CO 80723-  
Landholding Agency: GSA  
Property Number: 549120064  
Status: Excess  
Reason: Floodway  
GSA Number: 7-B-CO-604

#### Georgia

(P) Dobbins AFB/(P) NAS Atlanta  
N.E. Quadrant of Intersection between  
Fairground & South Cobb Drive  
Marietta Co: Cobb GA 30060-  
Landholding Agency: GSA  
Property Number: 549140001  
Status: Surplus  
Reason: Within 2000 ft. of flammable or  
explosive material  
GSA Number: 4-GR-GA-557 & 4-GR-GA-  
587A

#### Kentucky

E.C. Clements Job Corps Cntr.  
1 Mile East of Morganfield, Ky.  
Morganfield Co: Union KY 42437-  
Landholding Agency: GSA  
Property Number: 549120002  
Status: Excess  
Reason: Within 2000 ft. of flammable or  
explosive material; Within airport runway  
clear zone  
GSA Number: 4-L-KY-432-E

#### Louisiana

Land—3.4 acres  
VA Medical Center  
2501 Shreveport Highway  
Alexandria Co: Rapides LA 71301-  
Landholding Agency: VA  
Property Number: 979010010  
Status: Unutilized  
Reason: Within 2000 ft. of flammable or  
explosive material

#### Michigan

Middle Marker Facility  
Ypsilanti Co: Washtenaw MI 48198-  
Location: 549 ft. north of intersection of  
Coolidge and Bradley Ave. on East side of  
street  
Landholding Agency: DOT  
Property Number: 879120006  
Status: Unutilized  
Reason: Within airport runway clear zone

#### Minnesota

VAMC  
VA Medical Center  
4801 8th Street No.  
St. Cloud Co: St. Cloud MN 56303-  
Landholding Agency: VA  
Property Number: 979010049  
Status: Underutilized  
Reason: Within 2000 ft. of flammable or  
explosive material

#### Missouri

Portion (120.60 acres)  
Harry S. Truman Dam & Reservoir

County Road BB Co: St. Clair MO 63077-  
Landholding Agency: GSA  
Property Number: 549140005  
Status: Excess  
Reason: Floodway  
GSA Number: 7-D-MO-607E

#### Montana

Dawson County Substation  
Glendive Co: Dawson, MT 59330-  
Location: 3 miles east of Glendive, MT on  
highway 20  
Landholding Agency: Energy  
Property Number: 419030011  
Status: Underutilized  
Reason: Secured Area  
Anaconda Substation Co: Deer Lodge, MT  
Location: 4 miles southeast of Anaconda  
Landholding Agency: Energy  
Property Number: 419030013  
Status: Unutilized  
Reason: Other environmental  
Comment: contamination

#### New York

Tracts 1, 2, 3, & 4,  
VA Medical Center  
Bath Co: Steuben NY 14810-  
Location: Exit 38 off New York State Route  
17.  
Landholding Agency: VA  
Property Numbers: 979010011-979010014  
Status: Unutilized  
Reason: Secured Area

#### North Dakota

VAM & ROC—Land—6.1 acres  
2101 Elm Street, N.  
Fargo Co: Cass ND 58102-  
Landholding Agency: VA  
Property Number: 979010018  
Status: Underutilized  
Reason: Floodway  
VAM & ROC—Land—8.9 acres  
2101 Elm Street, N.  
Fargo Co: Cass ND 58102-  
Landholding Agency: VA  
Property Number: 979010019  
Status: Underutilized  
Reason: Floodway

#### Washington

Snoqualmie Substation  
King County, WA  
Location: 12 miles southwest of North Bend.  
Landholding Agency: Energy  
Property Number: 419030007  
Status: Unutilized  
Reason: Secured Area  
Portion  
Chehalis-Mayfield access road right-of-way  
Approx. 2 mi. east of Onalaska Co: Lewis  
WA 98570-  
Landholding Agency: GSA  
Property Number: 549140006  
Status: Excess  
Reason: Other  
Comment: Inaccessible  
GSA Number: 9-B-WA-1014  
Land  
Puffin Island Light House Res.  
San Juan Co: San Juan WA  
Landholding Agency: DOT  
Property Number: 879010013  
Status: Excess  
Reason: Other

Comment: Island

[FR Doc. 92-4341 Filed 2-27-92; 8:45 am]

BILLING CODE 4210-29-M

## DEPARTMENT OF THE INTERIOR

### Joint Tribal/BIA/DOI Advisory Task Force on Bureau of Indian Affairs Reorganization, Public Meeting

**AGENCY:** Department of the Interior.

**ACTION:** Notice of meeting.

**SUMMARY:** Pursuant to Public Law 101-512, the Office of the Assistant Secretary—Indian Affairs is announcing the forthcoming meeting of the Joint Tribal/BIA/DOI Advisory Task Force on Bureau of Indian Affairs Reorganization (Task Force).

**DATES:** March 17, 18, and 19, 1992; 8 a.m. to 5:30 p.m. on March 17 and 9 a.m. to 5:30 p.m. on March 18 and 19; Bally's Casino Resort, 3645 Las Vegas Boulevard South, Las Vegas, Nevada. Adjournment time on March 17, 1992, may be later than the 5:30 p.m. time set above in order to accommodate all those persons signing up to present comments to the Task Force. The meeting of the Task Force is open to the public.

**FOR FURTHER INFORMATION CONTACT:** Veronica L. Murdock, Designated Federal Officer, Office of the Assistant Secretary—Indian Affairs; MS 4140 MIB; 1849 C Street NW.; Washington, DC 20240; Telephone number (202) 208-4173.

**SUPPLEMENTARY INFORMATION:** The Task Force welcomes public oral and written comments, and it regularly schedules public comment time during each meeting. In order to broaden Tribal Government participation, however, the first day of this meeting of the Task Force has been designated as a "Public Hearing" to obtain Tribal Government, Indian and Tribal Organization, and individual comments on the "1991 Cumulative Report of the Joint Tribal/BIA/DOI Advisory Task Force on Bureau of Indian Affairs Reorganization" and on other Task Force activities. The order for speaking at this Public Hearing will be determined by the order in which persons sign up to speak and in the following categorical order: (1) Tribal Council Chairpersons and persons designated in writing to speak on behalf of Tribal Governing Bodies, (2) Representatives of National, Regional, Inter-Tribal, and Tribal organizations, and (3) individuals speaking on their own behalf. Persons wishing to present testimony or speak to the Task Force may sign up in advance by calling

Veronica L. Murdock at (202) 208-4173 until 4 p.m. on March 12, 1992. Sign up sheets will also be available at the meeting site on March 16, 1992, from 2 p.m. until 10 p.m. in the Task Force work room and on March 17, 1992, from 7:30 a.m. to 10:15 a.m. at the Task Force registration table at the meeting room. Speakers are encouraged to prepare written testimony, background material, comments, and other documents for presentation to the Task Force because time for oral presentations will be limited. All written documentation should be submitted with an original and 50 copies to ensure distribution to all Task Force members during this meeting. Also written comments may be submitted by individuals unable to attend the meetings. The Task Force appreciates written comments at any time, but comments mailed to the Task Force for this meeting should be received prior to March 12, 1992, to ensure their consideration at this meeting. Written comments received too late for consideration at this meeting will be made a part of the official record and used for discussion at future meetings of the Task Force. Written comments for this meeting are to be addressed to Veronica L. Murdock, Office of the Assistant Secretary—Indian Affairs, Mail Stop 4140 MIB, Department of the Interior, 1849 C Street NW., Washington, DC 20240. The Task Force will discuss the comments obtained from the public, identify goals and objectives and the means for achieving these during the remainder of the Task Force's activities, and discuss the means by which public comments will be incorporated into future activities. The Task Force will also continue old business with concentration on Area/Agency structures, the Bureau's budget process, and the directives systems under which the Bureau operates.

Dated: February 25, 1992.

Eddie F. Brown,

Assistant Secretary—Indian Affairs.

[FR Doc. 92-4617 Filed 2-27-92; 8:45 am]

BILLING CODE 4310-02-M

#### Fish and Wildlife Service

##### Grizzly Discovery Center, West Yellowstone, Montana

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Receipt of Application for a Permit.

**SUMMARY:** The following applicant applied for a subpermit under the Fish and Wildlife Permit number PRT 704930

for the purposes of holding a threatened species for zoological exhibition and educational purposes. This is consistent with the purposes of section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended.

**ADDRESSES:** Applicant: Lewis S. Robinson, III, President, Firehole Land Corporation, P.O. Box 1020, West Yellowstone, Montana 59758.

#### SUPPLEMENTARY INFORMATION:

##### Background

The applicant proposes to develop an 87-acre parcel of land in West Yellowstone, Montana, adjacent to the west entrance of Yellowstone National Park. This proposed development is now known as "Grizzly Park" and would feature as its main attraction the "Grizzly Discovery Center." The proposed Grizzly Discovery Center would be a grizzly bear (*Ursus arctos horribilis*) exhibition facility for which the applicant is seeking an Endangered Species Permit to hold and display up to 28 grizzly bears. The purpose of this zoological exhibit will be to house grizzly bears in "natural exhibit areas" for the education and entertainment of paying visitors. The Grizzly Discovery Center will provide information on grizzly bears and their habitat in the Yellowstone Ecosystem and will include an "Imax" theater for this purpose. The applicant requests that grizzly bears for this facility be obtained from a variety of sources including zoos, research centers, and wild "orphan," or "problem" bears in the possession of State wildlife agencies, pending the agencies' determination to remove them from the wild under provisions of the Interagency Grizzly Bear Guidelines.

**FOR FURTHER INFORMATION CONTACT:** Written comments should be submitted to the Field Supervisor, Fish and Wildlife Enhancement, P.O. Box 10023, Federal Building and U.S. Courthouse, 301 South Park, room 464, Helena, Montana 59626, telephone (406) 449-5322 or FTS 585-5322. Comments must be received within 60 days of the date of this publication.

Documents and other information submitted with this application are available to the public by appointment during normal business hours at the above Fish and Wildlife Enhancement Office. For further information, interested persons should contact the Field Supervisor at the above address.

##### Author

Dale Harms, State Supervisor, Fish and Wildlife Enhancement, P.O. Box 10023, Federal Building and U.S. Courthouse, 301 South Park, room 464,

Helena, Montana 59626, telephone (406) 449-5225 or FTS 585-5225.

**Authority:** Endangered Species Act of 1973, as amended.

Dated: February 21, 1992.

Robert D. Jacobsen,

Acting Regional Director.

[FR Doc. 92-4599 Filed 2-27-92; 8:45 am]

BILLING CODE 4310-55-M

#### Availability of the Draft Environmental Assessment and Land Protection Plan; Proposed Establishment of Mandalay National Wildlife Refuge Terrebonne Parish, LA

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of availability of the draft environmental assessment and land protection plan for the proposed establishment of Mandalay National Wildlife Refuge.

**SUMMARY:** This notice advises the public that the U.S. Fish and Wildlife Service, Southeast Region, proposes to establish a national wildlife refuge in the vicinity of Terrebonne Parish, Louisiana. The purpose of the proposed refuge is to protect and manage approximately 15,000 acres of nationally significant freshwater marshes and wetlands in the Bayou Penchant Basin of southcentral Louisiana for the benefit of migratory waterfowl and other wildlife. A Draft Environmental Assessment and Land Protection Plan for the proposed refuge has been developed by Service biologists in coordination with the Louisiana Department of Wildlife and Fisheries, the U.S. Army Corps of Engineers, The Nature Conservancy, and other federal and state agencies and private conservation organizations. The assessment considers the biological, environmental, and socioeconomic effects of establishing the refuge. The assessment also evaluates five alternative actions and their potential impacts on the environment. Written comments or recommendations concerning the proposal are welcomed, and should be sent to the address below.

**DATES:** Land acquisition planning for the project is currently underway. The draft assessment will be available to the public for review and comment on March 16, 1992. Written comments must be received no later than April 30, 1992 to be considered.

**ADDRESSES:** Comments and requests for copies of the assessment and further information should be addressed to Mr. Charles R. Danner, Chief, Branch of

Project Development, Office of Refuges and Wildlife, U.S. Fish and Wildlife Service, 75 Spring Street SW., room 1240, Atlanta, Georgia 30303.

**SUPPLEMENTARY INFORMATION:** The primary objectives of the proposed refuge are to provide (1) wintering habitat for migratory waterfowl, (2) production habitat for wood ducks and mottled ducks, (3) habitat for a natural diversity of wildlife, (4) habitat for nongame migratory birds, (5) habitat for threatened and endangered species, and (6) opportunities for environmental education, interpretation, and wildlife-oriented recreation. The proposed refuge would also serve as a focal point for the overall protection and management of the Bayou Penchant Basin in cooperation with other federal and state agencies, conservation organizations, and the private sector.

The proposed refuge area is located in Terrebonne Parish, Louisiana, about 5 miles west of Houma and 20 miles east of Morgan City. The proposed area is bisected by the Gulf Intracoastal Waterway and lies south of the Bayou Black Ridge between Houma and Morgan City near U.S. Highway 90. Three major oil and gas fields are located within the boundary of the proposed refuge.

The area's biological diversity is high. Thousands of migratory waterfowl are attracted to the area's freshwater marshes, including mallards, blue- and green-winged teal, gadwalls, wigeons, and mottled ducks. Wood ducks are common, both as migrants and breeders, and mottled ducks commonly nest throughout the area. American coots heavily use this part of coastal Louisiana, as do several other species of rails and gallinules. Pintails, lesser scaups, geese, and shovelers also winter in the area. It is not uncommon for this area to reach peaks of 75,000 or more ducks.

In addition, the proposed refuge area provides critical spring and fall habitat for neotropical migratory birds. Wading birds also use the area in significant numbers and several rookeries are present. One major rookery consists of several thousand pairs of white ibis, great egrets, little blue herons, snowy egrets, and tricolored herons. A few roseate spoonbills also nest in the area.

Bald eagles use the proposed refuge heavily and at least four active nests have been documented. One nest near Hansons Canal in the proposed refuge area fledged two young in 1989. The proposed refuge area represents the primary core nesting area for bald eagles west of Florida. The area's marshes also support high populations

of other wildlife, including nutria, alligators, and white-tailed deer. Freshwater fishing for largemouth bass, crappie, and catfish is popular in the canals and open water areas.

The draft environmental assessment was developed by the Service in consultation with representatives from the Louisiana Department of Wildlife and Fisheries, The Nature Conservancy, the U.S. Army Corps of Engineers, Ducks Unlimited, the USDA Soil Conservation Service, the Environmental Protection Agency, and the National Marine Fisheries Service. The biological, environmental, and socioeconomic effects of acquiring approximately 15,000 acres of freshwater marshes and wetlands for the establishment of the refuge have been considered. Five alternatives and their potential impacts on the environment are presented and evaluated. The Service believes the preferred alternative, Protection and Management of Approximately 15,000 Acres by the U.S. Fish and Wildlife Service, is a positive step in preserving a nationally significant wetland ecosystem for the benefit of migratory waterfowl, neotropical migrant birds, endangered species, and other native wildlife.

Dated: February 20, 1992.

James W. Pulliam, Jr.,  
Regional Director.

[FR Doc. 92-4547 Filed 2-27-92; 8:45 am]  
BILLING CODE 4310-55-M

#### Issuance of Permit for Marine Mammals

On November 21, 1991, a notice was published in the *Federal Register*, Vol. 56, No. 225, Page(s) 58705, that an application had been filed with the Fish and Wildlife Service by The Seattle Aquarium (PRT-763288) for a permit to import 1 male Alaskan Sea otter (*Enhydra lutris lutris*) for public display. Notice is hereby given that on 02/10/92, as authorized by the provisions of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*) and the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, *et seq.*), the Fish and Wildlife Service issued the requested permit subject to certain conditions set forth therein.

The permit documents themselves are available for public inspection by appointment during normal business hours (7:45-4:15) at the Fish and Wildlife Service's Office of Management Authority, 4401 North Fairfax Drive, room 432, Arlington, Virginia 22203 (703/358-2104).

Other information in permit file is available under the Freedom of Information Act to any person who submits a written request to the Service's Office of Management Authority at the above address, in accordance with procedures set forth in Department of the Interior regulations, 43 CFR 2.

Dated: February 25, 1992.

Maggie Tieger,  
Acting Chief, Branch of Permits, Office of Management Authority.  
[FR Doc. 92-4624 Filed 2-27-92; 8:45 am]  
BILLING CODE 4310-55-M

#### Intent To Prepare an Environmental Impact Statement (EIS) for the Proposed Patoka River Wetlands Project in Pike and Gibson Counties, IN

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice.

**SUMMARY:** This Notice advises the public that the U.S. Fish and Wildlife Service (Service) intends to prepare an EIS for the proposed Patoka River Wetlands Project (Project) located in southwestern Indiana along the Patoka River near the communities of Oakland City and Winslow in Pike and Gibson Counties. The Project is proposed to protect and manage wetlands in a significant bottomland hardwood forest ecosystem.

The EIS will evaluate eight preliminary alternatives on the basis of their biological and socioeconomic impacts. Preparation of the EIS is in response to new resource and socioeconomic impacts uncovered during the preparation of an Environmental Assessment for the proposed establishment of a national wildlife refuge in the same area.

This Notice is being furnished as required by the National Environmental Policy Act (NEPA) Regulations (40 CFR 1501.7) to obtain suggestions and information from other agencies and the public on the scope of issues to be addressed in the EIS. Comments and participation in this scoping process are solicited.

**DATES:** Written comments should be received by March 30, 1992. A Service office located adjacent to the proposed project in Winslow, Indiana, is currently open from 8 a.m. to 4:30 p.m., Monday through Friday, for personal comments and input, phone (812) 789-2102.

**ADDRESSES:** Comments should be addressed to: Regional Director, U.S.

Fish and Wildlife Service, Bishop Henry Whipple Federal Building, 1 Federal Drive, Fort Snelling, Minnesota 55111-4056; Attention Jeanne Holler, RE-AP.

**FOR FURTHER INFORMATION CONTACT:** William McCoy, Project Leader, U.S. Fish and Wildlife Service, P.O. Box 510, Winslow, Indiana 47598-0510, (812) 789-2102.

Copies of a map of the proposed Wetlands Project are available from the Project Leader.

**SUPPLEMENTARY INFORMATION:** The Service proposes to restore, protect and manage a significant bottomland hardwood forest wetland complex within an area totalling approximately 21,000 acres along the Patoka River in southwestern Indiana.

The purposes of the Patoka River Wetlands Project are to:

1. Restore, protect, and manage a bottomland hardwood forest ecosystem for the many values associated with these wetlands.
2. Restore, protect, and manage uplands that complement and/or protect wetlands.
3. Restore, protect, and manage migratory bird habitat with special emphasis on habitat for wood ducks.
4. Restore, protect, and manage habitat for endangered and threatened species of plants and animals.
5. Increase public opportunities for outdoor recreation and environmental education that are compatible with the primary resource objectives of the Project area.
6. Provide more responsive wildlife extension services and restore wetland habitat in southwestern Indiana per landowner requests according to guidelines of the Service's Partners for Wildlife Program.
7. Improve water quality in the Patoka River watershed to reduce adverse impacts on human health and wildlife productivity, enhance the fishery resource, and increase the attractiveness of the water resources for wildlife-oriented public recreation.

Primary alternatives to be considered in preparation of the EIS are:

1. *No Action*—Rely on existing Federal, State, and local government laws, regulations, and ordinances to protect resources.
2. *Waterbank/Wetland Reserve*—Rely on Department of Agriculture wetland protection or set-aside programs to provide protection of existing or restored wetlands along the Patoka River.
3. *Expansion of Land Use and Zoning Regulations*—Encourage Federal, State, and local governments to enact new

laws and regulations to protect the Patoka River's resources.

4. *Acquisition/Management by Others*—This alternative would involve other Federal, State, non-profit, and citizen's groups in the protection of the area's resources through fee title, easement, and lease acquisition.

5. *Private Lands Agreements*—Rely on a program of technical outreach sponsored by the Service and Indiana Department of Natural Resources to assist landowners in the restoration and enhancement of wildlife and fish habitats in the area.

6. *Acquisition of 20,774 acres by the Service for the Patoka River National Wildlife Refuge as Previously Defined in the Environmental Assessment*—Under this alternative, the Service would establish a national wildlife refuge and acquire fee title, easements, and leases from willing sellers, subject to appropriated funds.

7. *Acquisition of Interests in Lands by the Service as Wildlife Management Areas from within a 20,774-acre Selection Area*—Under this alternative, the Service would acquire fee title, easements, and leases to habitats within a selection area based upon availability of funds and willing sellers. These areas would be known as wildlife management areas and would be actively managed by the Service.

8. *Acquisition of Interests in 7,505 acres by the Service for the Patoka River National Wildlife Refuge, and Acquisition of Interests in Other Lands within a 13,269-acre Selection Area to be Managed as Wildlife Management Areas*—This alternative combines features of alternatives 7 and 8. The Service would acquire fee title, easements, and leases from willing sellers to establish a national wildlife refuge from within a 7,505-acre national wildlife refuge acquisition boundary. The Service would also acquire fee title, easements, and lease interests from willing sellers within a 13,269-acre selection area to be managed as wildlife management areas. All acquisition would be subject to appropriation of funds.

The purpose for considering the acquisition alternatives is to provide long term assurance that critical wetland habitat would be preserved while promoting conservation of our Nation's wetlands in accordance with national plans.

The Department of the Interior developed a National Wetlands Priority Conservation Plan as directed by section 301 of the Emergency Wetlands Resources Act of 1986. The North Central Region of the Service developed a Regional Wetlands Concept Plan that

identified priority wetland habitat for preservation based on areas where wetland losses are highest and where the threat of additional loss is greatest. Since forested, bottomland wetlands have experienced a high rate of loss, the Patoka River was identified as a high priority area for preservation.

Additional focus has been placed on the Patoka River area as a result of the North American Waterfowl Management Plan signed by the U.S. and Canada in 1986. The plan calls for restoration of continental waterfowl populations by the year 2000 through partnerships of Federal, State, and provincial agencies as well as private conservation organizations and individuals.

One of the partnerships formed is the Lower Mississippi Valley Joint Venture to emphasize the protection and restoration of bottomland hardwood wetlands. The New Madrid Wetlands Project Initiative was developed as one of several thrusts by this multi-agency group. The goal of this initiative is to acquire, develop, and manage important waterfowl habitat in the four cooperating States of Indiana, Illinois, Kentucky, and Missouri.

Sites identified for protection represent the most important habitat still in existence. A total of 30,000 acres have been identified for acquisition by different agencies in Indiana. Of this total, approximately 21,000 acres along the Patoka River have been identified in the New Madrid initiative for acquisition by the Service.

At this time the Service does not have a preferred alternative. The major impacts expected, should the proposed action be carried out, are the conversion of cropland to wildlife habitat use, curtailment of timber harvest, improved economic conditions due to tourism, and change in land ownership from private to Federal. The possible impacts on the surface mining of coal have yet to be quantified. These anticipated impacts will be highly variable between alternatives.

The major issues expected include Service acquisition policy, avian diseases related to the poultry industry, wetland and water level management, effects on the tax base, local employment, effects on adjacent cropland, effects on rights to surface mine coal resources, loss of cropland, and effects on existing and proposed public roads.

Additional studies and report completed since release of the original Environmental Assessment in May 1989, include:

Coal Reserve Evaluation of the Proposed Patoka River National Wildlife Refuge. October 1991. Office of Surface Mining.

Plants and Plant Community Survey. 1991. Indiana Department of Natural Resources, Division of Nature Preserves.

Fish Survey of the Patoka River. July 1991. Indiana Department of Natural Resources, Division of Fisheries.

Wetland Development and Management Alternative Concept Management Plan. April 1991. U.S. Fish and Wildlife Service.

Hydrographics of Daily Water Elevations at Four Selected Points on the Patoka River, 1974 through 1989. January 1991. U.S. Army Corps of Engineers, Louisville, Kentucky.

The environmental review of this project will be conducted in accordance with the requirements of the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4371 *et seq.*), NEPA Regulations (40 CFR part 1500-1508), other appropriate Federal regulations, and Service procedures for compliance with those regulations.

The Draft EIS will be made available to the public on or before July 1, 1992. Public meetings will then be announced and held to solicit additional comment for preparing the Final EIS.

Dated: February 21, 1992.

Marvin E. Moriarity,  
Acting Regional Director.

[FR Doc. 92-4465 Filed 2-27-92; 8:45 am]

BILLING CODE 4310-55-M

## Bureau of Land Management

[G010-4351-10/G2-0104]

### Albuquerque District, New Mexico; Emergency Closure of Public Lands, New Mexico

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice.

**SUMMARY:** Notice is hereby given that all public lands in sections 11, 12, 13, 14, 24, 25, T. 29 N., R. 9 E., NMPM, and sections 17, 18, 19, 20, 28, 29, 31, T. 29 N., R. 10 E., NMPM located in the vicinity of the No Agua Peaks, New Mexico, also known as the Buffalo Piñon Ranch, are closed to unauthorized vehicles.

The purposes of this closure is to protect resident and migratory herds of wild ungulates from the displacement caused by motorized vehicles and to protect forest resources. The area will be closed to all vehicles, except authorized vehicles.

The authority for this closure is found in 43 CFR 8341.2. Any person who

violates the closure is subject to fines of not more than \$1,000 or imprisonment for not longer than 12 months or both.

**EFFECTIVE DATE:** February 28, 1992. The closure will remain in effect until rescinded or modified by the authorized officer upon completion of the transportation planning for the North Unit Transportation Access Area.

**FOR FURTHER INFORMATION CONTACT:** Chuck Schultz, Supervisory Multi-Resource Specialist, Taos Resource Area, 224 Cruz Alta Road, Taos, New Mexico 87571. Phone (505) 758-8851; FTS 479-8801.

Dated: February 20, 1992.

Robert T. Dale,  
District Manager.

[FR Doc. 92-4555 Filed 2-27-92; 8:45 am]

BILLING CODE 4310-FB-M

[ID-010-02-4350-08]

### Management Framework Plan Amendment Draft and Environmental Assessment Availability; Cascade Resource Area; ID

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of availability of draft Management Framework Plan Amendment; and draft Area of Critical Environmental Concern Designations.

**SUMMARY:** Pursuant to the BLM Planning Regulations (43 CFR part 1600) and the National Environmental Policy Act (NEPA, section 102(2)(C)) the Boise District, BLM has prepared a draft amendment to the Cascade Resource Management Plan on a proposal to designate six sites as areas of critical environmental concern (ACECs) and to consider transfer of four parcels of land from Federal ownership. This notice is also issued pursuant to § 1610.7-2(b) of the BLM Planning Regulation. The draft plan amendment and an environmental assessment (EA) prepared on the amendment are now available for public review and comment.

**DATES:** The 90-day public comment period for the draft plan amendment will close on May 29, 1992. Written comments should be mailed to the address listed below. Public meetings have not been scheduled.

**ADDRESSES:** Written Comments should be mailed to: Cascade Area Manager, Bureau of Land Management, 3948 Development Avenue, Boise, ID 83705.

**FOR FURTHER INFORMATION CONTACT:** John Fend, Cascade Area Manager or Fred Minckler, Team Leader at the Bureau of Land Management, 3984

Development Avenue, Boise, ID 83705, telephone (208) 384-3300.

**SUPPLEMENTARY INFORMATION:** The Cascade Resource Management Plan (RMP) is a land use plan for public lands within the Cascade Resource Area administered by BLM in southwest Idaho. The Boise District has prepared an amendment which addresses special management actions and designation of six sites ranging in size from 40 acres to 1,250 acres as ACECs to protect *Allium aseae* (Aase'e onion), an onion species being considered by the U.S. Fish and Wildlife Service for listing as threatened or endangered. The six sites are: Cartwright Canyon, 400 acres; Hulls Gulch, 120 acres; Sand-capped Knob, 40 acres; Sand Hollow, 1,250 acres; Willow Creek, 1,060 acres and Woods Gulch, 40 acres. Resource use limitations proposed for these areas address: Livestock grazing; motorized vehicle use; rights-of-way; mineral leasing, location and disposal; water developments and fire suppression and rehabilitation. The draft amendment also considers possible transfer of four parcels of public land from Federal ownership. An environmental assessment (EA) has been prepared on the amendment. The draft amendment and the EA have been distributed for public review and comment. Additional copies are available at the Boise District Office at the address listed above.

Dated: February 21, 1992.

Rodger E. Schmitt,

Associate District Manager.

[FR Doc. 92-4576 Filed 2-27-92; 8:45 am]

BILLING CODE 4310-GG-M

[AZ-050-4410-02]

### Arizona: Availability of the Final Yuman District Resource Management Plan Amendment and Environmental Assessment, Yuma District

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of Availability of the Yuman District Resource Management Plan Amendment and Environmental Assessment, Yuma District.

**SUMMARY:** In compliance with the Federal Land Policy and Management Act of 1976 and section 102(2)(c) of the National Environmental Policy Act of 1969, the Bureau of Land Management has prepared an amendment and environmental assessment to its Yuma District Resource Management Plan.

The management actions prescribed in the Final Amendment include: (1) No surface occupancy on oil and gas leases in riparian areas; (2) categorization of desert tortoise habitat; (3) designation of the Bill Williams Riparian Management Area; (4) adjustments in lands available for disposal; (5) additions to lands identified for acquisition; (6) withdrawal of the La Posa Long-Term Visitor Area; (7) adjustments to District off-highway vehicle designations; and (8) adjustments in competitive-use, off-highway vehicle area designations.

The protest period will begin upon publication of this notice in the *Federal Register* and will run for 30 days, after which the decision will become final.

The document contains procedures for protesting the plan or any part of it. These procedures can also be found in the Code of Federal Regulations (43 CFR 1610.5-2).

Except for any portions under protest, the Bureau of Land Management's Arizona State Directory may approve the plan after 30 days from the date of this notice.

**SUPPLEMENTARY INFORMATION:** A limited number of copies of the Amendment and Environmental Assessment are available upon request to the Yuman District Manager, Bureau of Land Management, 3150 Winsor Avenue, Yuma, Arizona 85365. There are also copies available for review at the above location.

**FOR FURTHER INFORMATION CONTACT:** Environmental Protection Specialist Dave Curtis, Bureau of Land Management, 3150 Winsor Avenue, Yuma, Arizona 85365, telephone (602) 726-6300.

Dated: February 19, 1992.  
Mervin Boyd,  
*Acting District Manager.*  
[FR Doc. 92-4490 Filed 2-27-92; 8:45 am]  
BILLING CODE 4310-32-M

[AZ-020-00-4320-12]

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Correction of *Federal Register* publication.

On February 3, 1992, the location for the Kingman Resource Area Grazing Advisory Board meeting was incorrectly published in the *Federal Register* Volume 57, No. 22., Page 4052. The correct location for the meeting will be the Kingman Resource Area Conference Room, 2475 Beverly Avenue, Kingman, Arizona 86401.

Dated: February 20, 1992.

Henri R. Bisson,  
*District Manager.*  
[FR Doc. 92-4579 Filed 2-27-92; 8:45 am]  
BILLING CODE 4310-32-M

[ID-050-4212-13; I-26689]

**Realty Action: Private Exchange Involving Public Land in Blaine County, ID; Amendment**

**AGENCY:** Bureau of Land Management; Interior.

**ACTION:** Amendment to Notice of Realty Action, I-26689; exchange of public and private land in Blaine County, Idaho. Original Notice of Realty Action was published in the *Federal Register* on March 9, 1989 (Vol. 54, No. 45, page 10054).

**SUMMARY:** Publication of this amendment reinstates the segregation of the public land and closes them to the operation of the public land laws, including the mineral laws, for a period of two years from date of publication of this amendment in the *Federal Register*.

**SUPPLEMENTARY INFORMATION:** Detailed information concerning this action is available from the Shoshone District office of the Bureau of Land Management, 400 West F Street, Shoshone, Idaho 83352 or telephone (208) 886-2206.

Dated: February 19, 1992.  
Mary C. Gaylord,  
*District Manager.*  
[FR Doc. 92-4580 Filed 2-27-92; 8:45 am]  
BILLING CODE 4310-32-M

[ID-030-02-4212-11]

**Realty Action; ID**

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Amendment of Pocatello Resource Management Plan (RMP), notice of Realty Action (NORA), Recreation and Public Purposes (R&PP) Act Classification (IDI-27984) in Bannock County, ID.

**NOTICE:** Notice is hereby given that the Bureau of Land Management (BLM) has amended the Pocatello RMP to provide for the management of certain lands acquired by Quit Claim Deed and lease relinquishment in Bannock County, Idaho. Notice is further given that portions of these lands have been examined and found suitable for lease under the R&PP Act, as amended (43 U.S.C. 869 et seq.) to the Boy Scouts of America for a scout camp.

The effective date of this R&PP classification will be 60 days from the date of *Federal Register* publication. The lease will be subject to the following terms and conditions:

1. Development in accordance with the approved plan of development.
2. Civil Rights requirements.
3. Nine (9) specific environmental protection stipulations will be made a part of the lease.
4. All conditions contained in Sections 1-8 of Lease Form 2912-1.

**SUMMARY:** The following described acquired lands have been examined and through the public supported land use planning process have been identified to be managed through multiple use management pursuant to the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1716).

**Boise Meridian, Idaho**

T. 7 S., R. 36 E.,  
Sec. 34, E $\frac{1}{2}$ SE $\frac{1}{4}$ .  
T. 8 S., R. 36 E.,  
Sec. 2, Lot 4, SW $\frac{1}{4}$ NW $\frac{1}{4}$ , W $\frac{1}{2}$ SW $\frac{1}{4}$ ;  
Sec. 3, Lot 1, S $\frac{1}{2}$ NE $\frac{1}{4}$ , E $\frac{1}{2}$ SE $\frac{1}{4}$ SW $\frac{1}{4}$ , SE $\frac{1}{4}$ ;  
Sec. 10, NE $\frac{1}{4}$ , E $\frac{1}{2}$ E $\frac{1}{2}$ NW $\frac{1}{4}$ , N $\frac{1}{2}$ SE $\frac{1}{4}$ ,  
E $\frac{1}{2}$ SW $\frac{1}{4}$ SE $\frac{1}{4}$ , SE $\frac{1}{4}$ SE $\frac{1}{4}$ ;  
Sec. 11, W $\frac{1}{2}$ W $\frac{1}{2}$ ;  
Sec. 14, W $\frac{1}{2}$ ;  
Sec. 15, NE $\frac{1}{4}$ NE $\frac{1}{4}$ , E $\frac{1}{2}$ SE $\frac{1}{4}$ NE $\frac{1}{4}$ ,  
E $\frac{1}{2}$ E $\frac{1}{2}$ SE $\frac{1}{4}$ ;  
Sec. 22, E $\frac{1}{2}$ NE $\frac{1}{4}$ NE $\frac{1}{4}$ , SE $\frac{1}{4}$ NE $\frac{1}{4}$ , E $\frac{1}{2}$ SE $\frac{1}{4}$ ,  
E $\frac{1}{2}$ NW $\frac{1}{4}$ SW $\frac{1}{4}$ ;  
Sec. 23, NW $\frac{1}{4}$ , W $\frac{1}{2}$ SW $\frac{1}{4}$ ;  
Sec. 26, NW $\frac{1}{4}$ NW $\frac{1}{4}$ , S $\frac{1}{2}$ NW $\frac{1}{4}$ , SW $\frac{1}{4}$ ;  
Sec. 27, E $\frac{1}{2}$ NE $\frac{1}{4}$ ;  
Sec. 34, SE $\frac{1}{4}$ NE $\frac{1}{4}$ , NE $\frac{1}{4}$ SE $\frac{1}{4}$ ,  
N $\frac{1}{2}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$ , SE $\frac{1}{4}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$ ;  
Sec. 35, W $\frac{1}{2}$ , SW $\frac{1}{4}$ NE $\frac{1}{4}$ , W $\frac{1}{2}$ SE $\frac{1}{4}$ .  
T. 9 S., R. 36 E.,  
Sec. 2, Lots 3-5, S $\frac{1}{2}$ N $\frac{1}{2}$ , SE $\frac{1}{4}$ SW $\frac{1}{4}$ ,  
N $\frac{1}{2}$ SW $\frac{1}{4}$ .

Comprising 3,137.54 acres.

The public lands obtained by lease relinquishment are described as:

**Boise Meridian, Idaho**

T. 8 S., R. 36 E.,  
Sec. 3, W $\frac{1}{2}$ SE $\frac{1}{4}$ SW $\frac{1}{4}$ ;  
Sec. 10, W $\frac{1}{2}$ E $\frac{1}{2}$ NW $\frac{1}{4}$ , W $\frac{1}{2}$ SW $\frac{1}{4}$ SE $\frac{1}{4}$ ;  
Sec. 15, W $\frac{1}{2}$ SE $\frac{1}{4}$ NE $\frac{1}{4}$ , W $\frac{1}{2}$ E $\frac{1}{2}$ SE $\frac{1}{4}$ ;  
Sec. 22, W $\frac{1}{2}$ NE $\frac{1}{4}$ NE $\frac{1}{4}$ , SW $\frac{1}{4}$ NE $\frac{1}{4}$ , W $\frac{1}{2}$   
NW $\frac{1}{4}$ SE $\frac{1}{4}$ ; SW $\frac{1}{4}$ SE $\frac{1}{4}$ ;  
Sec. 27, E $\frac{1}{2}$ SE $\frac{1}{4}$ ;  
Sec. 34, SW $\frac{1}{4}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$ , NE $\frac{1}{4}$ NE $\frac{1}{4}$ ;  
T. 9 S., R. 36 E.,  
Sec. 3, Lot 1.  
Comprising 422.50 acres.

The following public lands have been examined and found suitable for R&PP Act lease. These lands are hereby classified as suitable for lease under the provisions of the R&PP Act (Act of June 14, 1928 as amended).

**Boise Meridian, Idaho**

T. 8 S., R. 36 E.,  
Sec. 36, W $\frac{1}{2}$ W $\frac{1}{2}$ SW $\frac{1}{4}$ ;

Sec. 27, E½SE¼;  
 Sec. 34, E½E½;  
 Sec. 35, W½W½, SE¼SW¼.  
 T. 9 S., R. 36 E.,  
 Sec. 2, Lot 5, SW¼NW¼, NW¼SW¼,  
 E½W½;  
 Sec. 3, Lot 1.  
 Comprising 668 acres.

The classification is based on the following reasons:

1. The lands are physically suitable to Boy Scout camp site development.
2. The lands meet the guidelines for lease as contained in 43 CFR 2741.5.
3. These lands are valuable for public purposes as stated in 43 CFR 2430.4(a) and may properly be classified for lease under the R&PP Act as stated in 43 CFR 2430.4(c).

The previously described 668 acres of land are hereby segregated from appropriation under the public land laws, except the R&PP Act, including the mining laws for a period of 18 months.

**SUPPLEMENTARY INFORMATION:** Detailed information concerning the conditions of the lease can be obtained by contacting Debbie Kovar, Realty Specialist, at (208) 236-6860.

#### Planning Protest

Any party that participated in the plan amendment and is adversely affected by the amendment may protest this action as it affects issues submitted for the record during the planning process. The protest shall be in writing and filed with the Director (760), Bureau of Land Management, 1800 "C" Street NW., Washington, DC 20240, within 30 days of this notice.

#### R&PP Act Lease Comments

For a period of 45 days from the date of publication of this notice in the **Federal Register**, interested parties may submit comments to the District Manager, Bureau of Land Management, 940 Lincoln Road, Idaho Falls, Idaho 83401. Objections will be reviewed by the State Director who may sustain, vacate, or modify this realty action. In the absence of any planning protests or objections regarding the R&PP Act lease, this realty action will become the final determination of the Department of the Interior.

Dated: February 21, 1992.

Lloyd H. Ferguson,  
 District Manager.

[FR Doc. 92-4554 Filed 2-27-92; 8:45 am]

BILLING CODE 4310-66-M

[MT-020-02-4333-08]

#### Montana, South Dakota Resource Management Plan Amendment—Fort Meade Recreation Area

**AGENCY:** Bureau of Land Management, Miles City District Office, Interior.

**ACTION:** Notice of intent to prepare an amendment to the South Dakota Resource Management Plan for the Fort Meade Recreation Area in Meade County, South Dakota.

**SUMMARY:** The South Dakota Resource Area is initiating a revision of the Recreation Management Plan for the Fort Meade Recreation Area near Sturgis, South Dakota. The revision will update the present plan, which was approved in 1981 and incorporated into the South Dakota Resource Management Plan (RMP) in 1985. The revision will therefore constitute an amendment to the RMP.

The revised plan will prescribe long-term management objectives, allocations and actions for all affected resources in the recreation area. No major issues have been identified to date. The plan amendment will consolidate past planning efforts and provide more detailed management guidance for some resources. Potential issues include the balancing of public demands for increased development and dispersed recreational activities and management actions necessary to ensure human health and safety. Disciplines represented in the preparation of the plan amendment will include forestry, archeology, fisheries, wildlife, recreation, range, watershed, realty, geology and law enforcement. Opportunities for public involvement will include scoping of issues and concerns, periodic updates on progress and review of the final plan amendment. Various state and federal agencies, including the South Dakota Game, Fish and Parks Department, the Department of Veterans Affairs and the public will be involved. Contact with agencies and the public will be made through meetings, update letters and written comments.

**DATES:** Comments and recommendations of issues and concerns to be considered will be received until at least 30 days after February 28, 1992.

**FOR FURTHER INFORMATION CONTACT:** Mark W. Stiles, Area Manager, South Dakota Resource Area, 310 Roundup

Street, Belle Fourche, South Dakota 57717, phone (605) 892-2526.

Sandra E. Sacher,  
 Acting District Manager.

[FR Doc. 92-4578 Filed 2-27-92; 8:45 am]

BILLING CODE 4310-DN-M

#### INSTITUTE OF AMERICAN INDIAN AND ALASKA NATIVE CULTURE AND ARTS DEVELOPMENT

#### Request for Nominations to the Board of Trustees

**AGENCY:** Institute of American Indian and Alaska Native Culture and Arts Development (aka Institute of American Indian Arts).

**ACTION:** Request for nominations.

**SUMMARY:** The Board directs the administration of the Institute of American Indian and Alaska Native Culture and Arts Development, including soliciting, accepting, and disposing of gifts, bequests, and other properties for the benefit of the Institute. The Institute, established under Public Law 99-498 (20 U.S.C. 4411 et seq.), provides scholarly study of and instruction in Indian art and culture, and establishes program which culminate in the awarding of degrees in the various fields of Indian arts and culture.

The Board consists of thirteen members appointed by the President of the United States, by and with the consent of the U.S. Senate, who are American Indians or persons knowledgeable in the field of Indian art and culture. This notice requests nominations to fill five appointments on the Board of Trustees.

**DATES:** Nominations will be accepted until March 30, 1992.

**ADDRESSES:** Nominations may be sent to the Chairman, Board of Trustees, Institute of American Indian Arts, Post Office Box 1836, Santa Fe, New Mexico 87504.

**FOR FURTHER INFORMATION CONTACT:** William Stewart Johnson, Chairman of the Board of Trustees, Institute of American Indian Arts, Post Office Box 1836, Santa Fe, New Mexico 87504, 505-988-6288.

**SUPPLEMENTARY INFORMATION:** Public Law 99-498 (20 U.S.C. 4412(a)(2)(B)), requires the President to publish in the **Federal Register** an announcement regarding nominations of the Presidentially appointed members of the Board of Trustees of the Institute. On February 22, 1991 (56 FR 8099, February 26, 1991), the President delegated to the Chairman of the Board of Trustees the

responsibility to publish an announcement regarding these nominations in the *Federal Register*. All nominations submitted will be forwarded to the President for consideration.

Dated: February 21, 1992, Santa Fe, New Mexico.

William Stewart Johnson,  
Chairman, Board of Trustees, Institute of  
American Indian Arts.

[FR Doc. 92-4553 Filed 2-27-92; 8:45 am]

BILLING CODE 0000-00-M

## INTERNATIONAL TRADE COMMISSION

[Investigation No. 731-TA-518 (Final)]

### Aspherical Ophthalmology Lenses From Japan; Commission Determination To Conduct a Portion of the Hearing In Camera

**AGENCY:** U.S. International Trade  
Commission.

**ACTION:** Closure of a portion of a  
commission hearing to the public.

**SUMMARY:** Upon request of respondent, and subsequent request of petitioner, in the above-captioned final investigation, the Commission has unanimously determined to conduct a portion of its hearing scheduled for February 26, 1992, *in camera*. See Commission rules 207.23(a), 201.13 and 201.35(b)(3) (19 CFR 207.23(a), 201.13 and 201.35(b)(3)). The remainder of the hearing will be open to the public. The Commission unanimously has determined that the 10-day advance notice of the change to a meeting was not possible. See Commission rule 201.35(a), (c)(1) (19 CFR 201.35(a), (c)(1)).

**FOR FURTHER INFORMATION CONTACT:**  
Robin L. Turner, Esq., Office of the  
General Counsel, U.S. International  
Trade Commission, 500 E Street SW.,  
Washington, DC 20436, telephone 202-  
205-3103. Hearing impaired individuals  
are advised that information on this  
matter may be obtained by contacting  
the Commission's TDD terminal on 202-  
205-1810.

**SUPPLEMENTARY INFORMATION:** The  
Commission believes that good cause  
exists in this investigation so as to make  
it appropriate to hold a portion of the  
hearing *in camera*. The majority of the  
information collected by the  
Commission is business proprietary  
information (BPI) because there is one  
domestic producer. In light of these  
facts, the Commission has determined  
that a full discussion of petitioner's  
financial condition and of many of the  
indicators that the Commission

examines in assessing material injury by  
reason of subject imports could only  
take place if at least part of the hearing  
was held *in camera*. In making this  
decision, the Commission nevertheless  
reaffirms its belief that wherever  
possible its business should be  
conducted in public.

The hearing will include the usual  
public presentations by petitioner and  
by respondent, with questions from the  
Commission. In addition the hearing will  
include *in camera* sessions for  
discussion of petitioner's BPI, for  
discussion of respondent's BPI, and for  
comparative discussion of BPI submitted  
by respondent and BPI of petitioner, as  
necessary. For any *in camera* session,  
the room will be cleared of all persons  
except: Those who have been granted  
access to business proprietary  
information under a Commission  
administrative protective order (APO)  
and are included on the Commission's  
APO service list in this investigation.  
See 19 CFR 201.35(b) (1), (2). In addition,  
if petitioner's BPI will be discussed in  
the *in camera* session, personnel of  
petitioner also will be granted access to  
the closed session. See 19 CFR 201.35(b)  
(1), (2). In the alternative, if respondent's  
BPI will be discussed in the *in camera*  
session, personnel of respondent also  
will be granted access to the closed  
session. See 19 CFR 201.35(b) (1), (2).  
The time for the parties' presentations  
and rebuttals in the *in camera* session  
will be taken from their respective  
overall allotments for the hearing. All  
those planning to attend the *in camera*  
portions of the hearing should be  
prepared to present proper  
identification.

**Authority:** The General Counsel has  
certified, pursuant to Commission Rule 201.39  
(19 CFR 201.39) that, in her opinion, a portion  
of the Commission's hearing in Aspherical  
Ophthalmology Lenses from Japan, Inv. No.  
731-TA-518 (Final) may be closed to the  
public to prevent the disclosure of business  
proprietary information.

Issued: February 25, 1992.

By order of the Commission.

Kenneth R. Mason,

Secretary.

[FR Doc. 92-4628 Filed 2-25-92; 8:45 am]

BILLING CODE 7020-02-M

## INTERSTATE COMMERCE COMMISSION

### Intent To Engage in Compensated Intercorporate Hauling Operations

This is to provide notice as required  
by 49 U.S.C. 10524(b)(1) that the named  
corporations intend to provide or use  
compensated intercorporate hauling

operations as authorized in 49 U.S.C.  
10524(b).

1. Parent corporation—American  
Telephone & Telegraph Company, 32  
Avenue of the Americas, New York,  
New York 10013.

2. Subsidiaries—AT&T Paradyne  
Corporation (Delaware), AT&T  
Universal Card Service Corp.  
(Delaware), NCR Corporation  
(Maryland).

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 92-4604 Filed 2-27-92; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-3 (Sub-No. 98X)]

### Missouri Pacific Railroad Co. Abandonment Exemption—in St. Louis County, MO

Applicant has filed a notice of  
exemption under 39 CFR 1152 subpart  
F—Exempt Abandonments, to abandon  
its 6.2-mile line of railroad between  
milepost 15.8, near Billman Spur, and  
milepost 22.0, near Broadway Junction,  
in St. Louis County, MO.

Applicant has certified that: (1) No  
local traffic has moved over the line for  
at least 2 years; (2) any overhead traffic  
on the line can be rerouted over other  
lines; and (3) no formal complaint filed  
by a user of rail service on the line (or a  
State or local government entity acting  
on behalf of such user) regarding  
cessation of service over the line either  
is pending with the Commission or with  
any U.S. District Court or has been  
decided in favor of the complainant  
within the 2-year period. The  
appropriate State agency has been  
notified in writing at least 10 days prior  
to the filing of this notice.

As a condition to use of this  
exemption, any employee affected by  
the abandonment shall be protected  
under Oregon Short Line R. Co.—  
Abandonment—Goshen, 360 I.C.C. 91  
(1979), to address whether this condition  
adequately protects affected employees,  
a petition for partial revocation under 49  
U.S.C. 10505(d) must be filed.

Provided no formal expression of  
intent to file an offer of financial  
assistance has been received, this  
exemption will be effective on March 29,  
1992 (unless stayed). Petitions to stay  
that do not involve environmental  
issues,<sup>1</sup> formal expressions of intent to

<sup>1</sup> A stay will be routinely issued by the  
Commission in those proceedings where an  
informed decision on environmental issues (whether  
raised by a party or by the Section of Energy and  
Environment in its independent investigation)

Continued

file an offer of financial assistance under 49 CFR 1152.27(c)(2),<sup>2</sup> and trail use/rail banking statements under 49 CFR 1152.29 must be filed by March 9, 1992.<sup>3</sup> Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by March 19, 1992, with: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

A copy of any petition filed with the Commission should be sent to applicant's representative: Joseph D. Anthofer, 1416 Dodge Street, room 830, Omaha, NE 68179.

If the notice of exemption contains false or misleading information, use of the exemption is void *ab initio*.

Applicant has filed an environmental report which addresses environmental or energy impacts, if any, from this abandonment.

The Section of Energy and Environment (SEE) will prepare an environmental assessment (EA). SEE will issue the EA by March 4, 1992. Interested persons may obtain a copy of the EA from SEE by writing to it (room 3219, Interstate Commerce Commission, Washington, DC 20423) or by calling Elaine Kaiser, Chief, SEE at (202) 927-6248. Comments on environmental and energy concerns must be filed within 15 days after the EA becomes available to the public.

Environmental, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

*Decided:* February 24, 1992.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Sidney L. Strickland, Jr.

Secretary.

[FR Doc. 92-4605 Filed 2-27-92; 8:45 am]

BILLING CODE 7035-01-M

## JUDICIAL CONFERENCE OF THE UNITED STATES

### Meeting of the Judicial Conference Advisory Committee on Appellate Rules

**AGENCY:** Judicial Conference of the United States.

**SUBAGENCY:** Advisory Committee on Rules of Appellate Procedure.

**ACTION:** Notice of open meeting.

**SUMMARY:** There will be a one-day meeting of the Advisory Committee on Appellate Rules. The meeting will be open to public observation but not participation. The meeting will commence at 9 a.m.

**DATES:** April 30, 1992.

**ADDRESSES:** Administrative Office of the United States Courts, 811 Vermont Avenue, N.W., room 638, Washington, DC 20544.

**FOR FURTHER INFORMATION CONTACT:** Joseph F. Spaniol, Jr., Secretary, Committee on Rules of Practice and Procedure, Washington, DC 20544, telephone (202) 633-6021.

Dated: February 21, 1992.

Joseph F. Spaniol, Jr.,  
Secretary, Committee on Rules of Practice and Procedure.

[FR Doc. 92-4588 Filed 2-27-92; 8:45 am]

BILLING CODE 2210-01-M

## DEPARTMENT OF LABOR

### Employment and Training Administration

#### Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the appendix to this

notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under title II, chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than March 9, 1992.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than March 9, 1992.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue N.W., Washington, DC 20210.

Signed at Washington, DC this 18th day of February 1992.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

## APPENDIX

Petitioner: Union/workers/firm—	Location	Date received	Date of petition	Petition No.	Articles produced
Allied Signal, Inc. (workers).....	Eatontown, NJ.....	02/18/92	02/10/92	26,849	Tank generators.
Baxter Healthcare, Corp (workers).....	Savage, MD.....	02/18/92	11/17/91	26,850	Intravenous infusion pumps.
Classic Leather Corp (company).....	Johnstown, NY.....	02/18/92	01/24/92	26,851	Sheepskin leather.
Concurrent Computer Corp. (workers).....	Oceanport, NJ.....	02/18/92	02/07/92	26,852	Computers.

cannot be made prior to the effective date of the notice of exemption. See Exemption of Out-of-Service Rail Lines, 5 I.C.C.2d 377 (1989). Any entity seeking a stay involving environmental concerns is encouraged to file its request as soon as possible in order to permit this Commission to review and act on the request before the effective date of this exemption.

<sup>2</sup> See Exempt. of Rail Abandonment—Offers of Finan. Assist., 4 I.C.C.2d 164 (1987).

<sup>3</sup> By letter filed February 8 (confirmed by letter filed February 19), 1992, Gateway Trailnet, Inc. (Gateway), requested that a notice of interim trail use/rail banking (NITU) be issued. Gateway indicates that a copy of each letter was served on applicant. Under 49 CFR 1152.29(b)(5), the railroad must reply to a request for interim trail use within 10 days after the request is filed in an exemption proceeding. Computed under 49 CFR 1152.25(d)(3), the actual due date for applicant's reply to

Gateway's request was February 18, 1992. No reply had been filed with the Commission as of February 24, 1992. Accordingly, in order to meet the target publication date, the Commission is constrained to defer action on the trail use request pending a reply. Applicant is admonished to comply with the Commission's rules, including prompt replies to any additional trail use requests filed in this proceeding. The Commission will accept a late-filed trail use request as long as it retains jurisdiction to do so.

APPENDIX—Continued

Petitioner: Union/workers/firm—	Location	Date received	Date of petition	Petition No.	Articles produced
D & R Cedar (company).....	Fork, WA.....	02/18/92	01/23/92	26,853	Red cedar shakes and shingle.
DeKalb Energy Co (company).....	Bakersfield, CA.....	02/18/92	02/07/92	26,854	Oil, gas exploration, production.
DeKalb Energy Co (company).....	Artesia, NM.....	02/18/92	02/07/92	26,855	Oil, gas exploration, production.
DeKalb Energy Co (company).....	Williston, ND.....	02/18/92	02/03/92	26,856	Oil, gas exploration, production.
Electronic Measurements, Inc (workers).....	Neptune, NJ.....	02/18/92	02/07/92	26,857	Power supplies.
ENSCO Drilling Co (company).....	Broussard, LA.....	02/18/92	02/03/92	26,858	Drilling contractor.
Gerber Childrenswear, Inc. (company).....	Ephrata, PA.....	02/18/92	02/07/92	26,859	Cloth diapers.
Gerber Childrenswear, Inc. (company).....	Tempe, AZ.....	02/18/92	02/07/92	26,860	Cloth diapers.
Gerber Childrenswear, Inc. (company).....	Peizer, SC.....	02/18/92	02/07/92	26,861	Cloth diapers.
Golden Ribbon Corp (company).....	Boulder, CO.....	02/18/92	02/07/92	26,862	Computer printer ribbons.
Grimes Aerospace Corp (IAM).....	Columbus, OH.....	02/18/92	02/03/92	26,863	Fuel control valves.
Halliburton Services (workers).....	Lafayette, LA 70502.....	02/18/92	01/22/92	26,864	Oilfield services.
ISC-Bunker Ramo (company).....	Fostonia, OH.....	02/18/92	02/03/92	26,865	Provide computer systems.
ISC-Bunker Ramo (company).....	Sharonville, OH.....	02/18/92	02/03/92	26,866	Provides computer systems.
ISC-Bunker Ramo (company).....	Dayton, OH.....	02/18/92	02/03/92	26,867	Provide computer systems.
ISC-Bunker Ramo (company).....	Broadview Hgts, OH.....	02/18/92	02/03/92	26,868	Provide computer systems.
ISC-Bunker Ramo (company).....	Columbus, OH.....	02/18/92	02/03/92	26,869	Provides computer systems.
K W Well Service, Inc (company).....	Abilene, TX.....	02/18/92	02/07/92	26,870	Oil, gas well servicing.
Mid-West Waltham Abrasives Co (workers).....	New Castle, IN.....	02/18/92	02/07/92	26,871	Bonded and coated abrasives.
National-Oilwell (company).....	Garland, TX.....	02/18/92	01/27/92	26,872	Oil drilling.
NCR Corp NCRIU.....	Middletown, OH.....	02/18/92	02/03/92	26,873	Computer equipment.
Stevenson Co-Ply, Inc (company).....	Stevenson, WA.....	02/18/92	01/31/92	26,874	Softwood plywood.
TMBR/Sharp Drilling, Inc. (company).....	Midland, TX.....	02/18/92	01/31/92	26,875	Oil, gas well drilling.
Trainer Surveys, Inc. (company).....	Shreveport, LA.....	02/18/92	02/03/92	26,876	Logging and perforating services.
Trico Products Corp (UAW).....	Buffalo, NY.....	02/18/92	01/27/92	26,877	Windshield wiper systems.

[FR Doc. 92-4630 Filed 2-27-92; 8:45 am]  
BILLING CODE 4510-30-M

[TA-W-26,713]

**Atlas Wireline Services, Abilene, TX; Notice of Termination of Investigation**

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on January 6, 1992 in response to a worker petition which was filed on January 6, 1992 on behalf of workers at Atlas Wireline Services, A Division of Western Atlas International, Incorporated, Abilene, Texas. The workers are engaged in activities related to exploration and drilling for unaffiliated firms in the oil and gas industry.

The petitioning group of workers is subject to an ongoing investigation for which a determination has not yet been issued (TA-W-26,588). Consequently, further investigation in this case would serve no purpose, and investigation has been terminated.

Signed at Washington, DC this 21st day of February 1992.

Marvin M. Fooks,  
Director, Office of Trade Adjustment Assistance.

[FR Doc. 92-4631 Filed 2-27-92; 8:45 am]  
BILLING CODE 4510-30-M

[TA-W-26,765]

**Atlas Wireline Services, Midland, TX; Termination of Investigation**

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on January 27, 1992 in response to a worker petition which was filed on January 27, 1992 on behalf of workers at Atlas Wireline Services, a Division of Western Atlas International, Incorporated, Midland, Texas. The workers are engaged in activities related to exploration and drilling for unaffiliated firms in the oil and gas industry.

The petitioning group of workers is subject to an ongoing investigation for which a determination has not yet been issued (TA-W-26,588). Consequently, further investigation in this case would serve no purpose, and the investigation has been terminated.

Signed at Washington, DC this 21st day of February 1992.

Marvin M. Fooks,  
Director, Office of Trade Adjustment Assistance.

[FR Doc. 92-4632 Filed 2-27-92; 8:45 am]  
BILLING CODE 4510-30-M

[TA-W-26,523]

**North American Refractories Co., Womelsdorf, PA; Negative Determination Regarding Application for Reconsideration**

By an application dated February 12, 1992, Local #3269 of the United Steelworkers of America (USW)

requested administrative reconsideration of the subject petition for trade adjustment assistance. The denial notice was signed on January 23, 1992 and will soon be published in the Federal Register.

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) If in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

The workers produce refractory products for U.S. steelmaking firms.

In order for a worker group to be certified eligible to apply for adjustment assistance benefits, it must meet all three of the Group Eligibility Requirements—(1), a significant decrease in employment; (2), an absolute decrease in sales or production and (3), an increase of imports which contributed importantly to worker separations and declines in sales or production. The "contributed importantly" test is generally demonstrated through a survey of the workers' firm's customers.

Investigation findings show that the workers' petition did not meet the

"contribution importantly" test of the Group Eligibility Requirements of the Trade Act. The Department's survey of North American's major declining customers indicated that none of the respondents purchased imported refractory products during the period under investigation.

The investigation findings show that although some special types of refractory products are imported from a company in Scotland, Womelsdorf never produced the imported products. With respect to the Japanese refractory products, North American purchased Japanese technology in 1983 and imported products in the mid-1980s for reshipment; however, North American never produced these products. North American still imports a small quantity of Japanese refractory products but the types and quantities needed do not lend themselves for production at Womelsdorf.

Company officials indicated that worker separations occurred at Womelsdorf mainly because of the slow business conditions in U.S. steelmaking and a corporate restructuring.

#### Conclusion

After review of the application and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's prior decision. Accordingly, the application is denied.

Signed at Washington, DC, this 20th day of February 1992.

Stephen A. Wandner,

Deputy Director, Office of Legislation & Actuarial Services, Unemployment Insurance Service.

[FR Doc. 92-4633 Filed 2-27-92; 8:45 am]

BILLING CODE 4510-30-M

### Employment Standards Administration

#### Wage and Hour Division

#### Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on

construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (48 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR part 1, appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribe in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedeas decisions thereto, contain no expiration dates and are effective from their date of notice in the *Federal Register*, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under The Davis-Bacon Related Acts," shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest

in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department. Further information and self-explanatory forms for the purposes of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, NW., room S-3014, Washington, DC 20210.

#### New General Wage Determination Decisions

The numbers of the decisions added to the Government Printing Office document entitled "General Wage Determinations Issued Under the Davis-Bacon and Related Acts" are listed by Volume, State, and page number(s).

##### Volume I:

Virginia:

VA91-64 (FEB. 28, 1992) ..... p. All.

VA91-73 (FEB. 28, 1992) ..... p. All.

VA91-77 (FEB. 28, 1992) ..... p. All.

##### Volume II:

Missouri MO91-13 (FEB. 28, 1992) ..... p. All.

#### Modification to General Wage Determination Decisions

The numbers of the decisions listed in the Government Printing Office document entitled "General Wage Determinations Issued Under the Davis-Bacon and Related Acts" being modified are listed by Volume, State, and page number(s). Dates of publication in the *Federal Register* are in parentheses following the decisions being modified.

##### Volume I:

Pennsylvania:

PA91-1 (FEB. 22, 1991) ..... p. 943.

p. 954.

PA91-2 (FEB. 22, 1991) ..... p. 965  
pp. 966, 970.

PA91-18 (FEB. 22, 1991) ..... p. 1085.  
p. 1086.

Virginia:

VA91-10 (FEB. 22, 1991) ..... p. All.

VA91-33 (FEB. 22, 1991) ..... p. All.

##### Volume II:

Illinois IL91-1 (FEB. 22, 1991) .. p. 69.

p. 70.

Wisconsin WI91-10 (FEB. 22, 1991) ..... p. 1247.  
p. 1253.

##### Volume III:

California

CA91-1 (FEB. 22, 1991) ..... p. All.

CA91-2 (FEB. 22, 1991) ..... p. All.

### General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under The Davis-Bacon And Related Acts". This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country. Subscriptions may be purchased from: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (202) 783-3238.

When ordering subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the three separate volumes, arranged by State. Subscriptions include an annual edition (issued on or about January 1) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates will be distributed to subscribers.

Signed at Washington, DC, this 21st day of February 1992.

Alan L. Moss,

Director, Division of Wage Determinations.

[FR Doc. 92-4405 Filed 2-27-92; 8:45 am]

BILLING CODE 4510-27-M

### NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

#### National Endowment for the Humanities

#### Agency Information Collection Under OMB Review

**AGENCY:** National Endowment for the Humanities, National Foundation on the Arts and the Humanities.

**ACTION:** Notice.

**SUMMARY:** The National Endowment for the Humanities (NEH) has sent to the Office of Management and Budget (OMB) the following proposals for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

**DATES:** Comments on this information collection must be submitted on or before March 30, 1992.

**ADDRESSES:** Send comments to Ms. Susan Daisey, Assistant Director, Grants Office, National Endowment for the Humanities, 1100 Pennsylvania Avenue, NW., room 310, Washington, DC 20506 (202-786-0494) and Mr. Daniel

Chenok, Office of Management and Budget, New Executive Office Building, 726 Jackson Place, NW., room 3002, Washington, DC 20503 (202-395-7316).

**FOR FURTHER INFORMATION CONTACT:** Ms. Susan Daisey, Assistant Director, Grants Office, National Endowment for the Humanities, 1100 Pennsylvania Avenue, NW., room 310, Washington, DC 20506, (202) 786-0494 from whom copies of forms and supporting documents are available.

**SUPPLEMENTARY INFORMATION:** All of the entries are grouped into new forms, revisions, extensions, or reinstatements. Each entry is issued by NEH and contains the following information: (1) The title of the form; (2) the agency form number, if applicable; (3) how often the form must be filled out; (4) who will be required or asked to report; (5) what the form will be used for; (6) an estimate of the number of responses; (7) the frequency of response; (8) an estimate of the total number of hours needed to fill out the form; (9) an estimate of the total annual reporting and recordkeeping burden. None of these entries are subject to 44 U.S.C. 3504(h).

#### Category: Extension

**Title:** Summary Report for Institute Participants (ES).

**Form Number:** OMB #3136-0057.

**Frequency of Collection:** Annual.

**Respondents:** Individuals; academic scholars—teachers, administrators.

**Use:** Used by staff and reviewers to evaluate projects funded by the Endowment.

**Estimated Number of Respondents:** 43.

**Frequency of Response:** Annually.

**Estimated Hours for Respondents to Provide Information:** 3 per Respondent.

**Estimated Total Annual Reporting and Recordkeeping Burden:** 129 hours.

**Title:** Summary Report for Institute Participants (EH).

**Form Number:** OMB #3136-0058.

**Frequency of Collection:** Annual.

**Respondents:** Individuals; academic scholars—teachers, administrators.

**Use:** Used by staff and reviewers to evaluate projects funded by the Endowment.

**Estimated Number of Respondents:** 19.

**Frequency of Response:** Annually.

**Estimated Hours for Respondents to Provide Information:** 3 per respondent.

**Estimated Total Annual Reporting and Recordkeeping Burden:** 57 hours.

**Title:** Forms for Reporting Project Activities.

**Form Number:** 3136-0126.

**Frequency of Collection:** Annual.

**Respondents:** Individuals; academic scholars—teachers, administrators.

**Use:** Used by staff and reviewers to evaluate projects funded by the Endowment.

**Estimated Number of Respondents:** 2,144.

**Frequency of Response:** Once.

**Estimated Hours for Respondents to Provide Information:** 1 per respondent.

**Estimated Total Annual Reporting and Recordkeeping Burden:** 4,288 hours.

Thomas S. Kingston,

Assistant Chairman for Operations.

[FR Doc. 92-4582 Filed 2-27-92; 8:45 am]

BILLING CODE 7530-01-M

### Humanities Panel; Meeting

**AGENCY:** National Endowment for the Humanities, NFAH

**ACTION:** Notice of meetings.

**SUMMARY:** Pursuant to the provisions of the Federal Advisory Committee Act (Public Law 92-463, as amended), notice is hereby given that the following meetings of the Humanities Panel will be held at the Old Post Office, 1100 Pennsylvania Avenue, NW., Washington, DC 20506:

**FOR FURTHER INFORMATION CONTACT:** David C. Fisher, Advisory Committee Management Officer, National Endowment for the Humanities, Washington, DC 20506; telephone 202/786-0322. Hearing-impaired individuals are advised that information on this matter may be obtained by contacting the Endowment's TDD terminal on 202/786-0282.

**SUPPLEMENTARY INFORMATION:** The proposed meetings are for the purpose of panel review, discussion, evaluation and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by grant applicants. Because the proposed meetings will consider information that is likely to disclose: (1) Trade secrets and commercial or financial information obtained from a person and privileged or confidential; or (2) information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, pursuant to authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee meetings, dated September 9, 1991, I have determined that these meeting will be closed to the public pursuant to subsections (c)(4), and (e) of section 552b of title 5, United States Code.

1. *Date:* March 12-13, 1992.

*Time:* 8:30 a.m. to 5 p.m.

*Room:* 415.

*Program:* This meeting will review applications to the Preservation Program for projects submitted to the Division of Preservation and Access Programs, for projects beginning after July 1, 1992.

2. *Date:* March 13, 1992.

*Time:* 8:30 a.m. to 5 p.m.

*Room:* 315.

*Program:* This meeting will review applications for Centers for Advanced Study submitted to the Division of Research Programs, for projects beginning after July 1, 1992.

3. *Date:* March 25, 1992.

*Time:* 9 a.m. to 5:30 p.m.

*Room:* 315.

*Program:* This meeting will review applications for Distinguished Teaching Professorships, submitted to the February 15, 1992 deadline in the Challenge Grant Program and reviewed in the Division of Education Programs, for projects beginning after September 1992.

4. *Date:* March 27, 1992.

*Time:* 9 a.m. to 5:30 p.m.

*Room:* 315.

*Program:* This meeting will review applications for Distinguished Teaching Professorships, submitted to the February 15, 1992 deadline in the Challenge Grant Program and reviewed in the Division of Education Programs, for projects beginning after September 1992.

David C. Fisher,

*Advisory Committee, Management Officer.*

[FR Doc. 92-4581 Filed 2-27-92; 8:45 am]

BILLING CODE 7536-01-M

## NATIONAL SCIENCE FOUNDATION

**Directorate for Education and Human Resources; Division of Research Career Development; Graduate Research Traineeship Program; Program Announcement and Guidelines; Closing Date: May 15, 1992**

This Printed Information Contains the Essence of the Announcement for This Program, and is not a Full Copy of the Actual Brochure Containing the Guidelines for Submission. Before Submitting a Proposal, Obtain a Printed Copy of the Guidelines by Writing or Calling the Publications Office of NSF.

The national Science Foundation (NSF) supports graduate students through a variety of mechanisms. Graduate fellowships provide portable support to enable individual students the widest latitude in planning their graduate study. Research assistantships permit graduate students to participate

with senior investigators in research projects at the forefront of science and engineering.

With this document, the National Science Foundation announces a new program of Graduate Research Traineeships (GRT) beginning in 1992. The principal objective of this program is to increase the numbers of talented American undergraduates enrolling in doctoral programs in critical and emerging areas of science and engineering. Proposals are solicited from institutions whose existing facilities and staff can accommodate additional graduate students in Ph.D. programs of high quality.

This program is also intended to contribute to strengthening the Nation's human resource base in all geographical sectors and among all underrepresented groups. NSF has made a commitment to human resource development within the scientific and technological community, and the GRT Program will promote diversity with respect to both student and institutional participation. As an integral part of this strategy, proposals are encouraged from departments of comprehensive university systems in which one or more institutional components enroll significant numbers of women and/or minorities underrepresented in graduate science or engineering programs. Such proposals should include explicit plans for recruitment of minority students from the system feeder institutions to graduate programs of departments in science or engineering in the research-intensive graduate institutions of such systems.

Graduate Research Traineeship awards are packages of student support. The colleges and universities that receive the awards are responsible for the selection of trainees, retention of trainees, and administration of traineeships.

Approximately 180 traineeship positions will be made in this competition on a fully-funded basis (i.e., up to a maximum of 5 years support per traineeship). Within each award, traineeships will provide initially a \$14,000/year stipend and a \$7,500/year cost-of-education allowance in lieu of tuition and fees normally charged to students of similar academic standing (unless such charges are optional or refundable). A one-time \$3,500 per trainee project enhancement allowance to be directly matched by the institution as stated under conditions of Awards below will be provided in the initial year of an award. Successful proposers are encouraged to design flexible periods of support for their trainees, thereby enhancing the impact of the

program on Science and Engineering graduate education.

### Eligibility Information

#### *Eligible Institutions*

Any university or other academic institution in the United States and its territories that awards a Ph.D. in a field of science or engineering normally supported by the NSF is eligible to submit proposals.

#### *Focus on Proposed Critical Area*

Each proposal must be developed around a selected, and fully justified, critical area of anticipated national human resource priorities.

#### *Eligible Disciplinary (Focus) Area*

The disciplinary area of the proposal must lead to the Ph.D. in the proposed area or in a related area. Interdisciplinary or multidisciplinary proposals must include only combinations of fields of science and engineering that are normally supported by the Foundation, including research in engineering education or science education.

The Foundation normally will not support biomedical research with disease-related goals, including work on the etiology, diagnosis, abnormality, or malfunction in human beings or animals. Animal models of such conditions or development or testing of drugs or other procedures for their treatment also are not generally eligible for support.

#### *Eligible Students*

Only U.S. citizens or permanent residents are eligible for appointment to a GRT. Verification of citizenship status of trainees will be required.

#### *Numbers of Submissions*

Only one proposal may be submitted by a department or comparable organizational unit within the institution. There is no limit, however, on the number of departmental units within an eligible institution submitting GRT proposals.

Proposals must request a minimum of five traineeships. There is no limit on the maximum number of traineeships that may be requested in an individual proposal or by all proposals submitted by an institution.

#### *Principal Investigator*

The principal investigator designated in a GRT proposal will have overall responsibility for the administration of the awards and for discussions with NSF. This individual should be the department head, other senior officer, or faculty member who can represent the

focus area and lead the effort toward achievement of the goals and objectives stated in the proposal.

#### Proposal Preparation

Proposals submitted in response to this program announcement should be prepared and submitted in accordance with the guidelines provided in the NSF brochure, Grants for Research and Education in Science and Engineering (GRESE), NSF90-77(8/90). Single copies of this brochure are available at no cost from the Forms and Publications Unit, phone (202) 357-7881, or via e-mail (Bitnet:pubs@nsf or Internet:pubs@nsf.gov).

#### Proposal Format

A GRT submission consists of the following:

(1) One copy of NSF Form 1225 (attached to the original signed copy of the proposal).

(2) Five complete sets of basic proposal documents (one original signed proposal) as specified and assembled in the order given below (page limits must be strictly observed):

- Completed Cover Page (NSF Form 1207), including one copy of the "Certification Regarding Lobbying," if applicable.

- Table of Contents.
- Summary (200 words maximum).
- Narrative—The Proposal Content topics (maximum ten single-spaced pages) are described in the following section and should be treated in the order indicated.

- Basic data regarding degree productivity. In tabular form provide statistics by participating departments indicating ethnic and gender distribution of the following: (1) Ph.D. degrees awarded in each of the past three years; (2) number of graduate students currently enrolled in Ph.D. programs; and (3) average number of years to complete Ph.D. degree.

- Basic data regarding other sources of graduate support. In tabular form provide statistics by participating departments indicating the following: (1) Source of funding; (2) number of students receiving indicated funding; (3) level of funding (amount per student); and (4) duration of funding.

- A list of principal faculty participants, followed by a brief biographical sketch or curriculum vitae for each individual, including a brief list of major publications, descriptions of their research and teaching programs (maximum two pages per individual). The number of graduate students currently being trained by each faculty participant should also be indicated.

- Appendices, if any. The use of appendices is strongly discouraged, and should be included only in exceptional circumstances. The Foundation will accept them as part of the proposal if submitted, but will not require evaluating panelists to review them.

#### Proposal Content

The proposal narrative must contain (in the order given) in sufficient detail for review by evaluating panelists the following:

(1) A strong case for the national need for additional doctoral professionals in the critical disciplinary area;

(2) An explanation of how the relevant aspects of the component disciplines of multidisciplinary proposals are integrated into the chosen focus area;

(3) Evidence of research and teaching excellence in the fields covered by the proposal;

(4) A justification of the proposed number of graduate research traineeships requested by the institution relative to its ability to accommodate additional graduate students in the proposed focus area, including evidence that the requested student support represents a truly new effort, and does not represent simply a replacement of other support by NSF funds;

(5) A description of the training to be provided, including any new enhanced activities that are planned and a plan for retention of students to completion of the Ph.D.;

(6) A plan for student recruitment for traineeships. For relatively new fields of national importance there may be a need for extensive recruitment efforts. In these cases, a delay of up to two years may be requested with respect to participant support costs to allow time for recruitment of undergraduates. Proposers would be expected, in such cases, to present a complete strategy for stimulating student interest;

(7) A description of the institution's commitment to and plans for recruiting minorities underrepresented in science and engineering, women, and students with disabilities for the traineeships requested;

(8) The institution's commitment for matching the departmental project enhancement allowance and a plan for its use. Examples of possible use include: Supplementing the stipend and/or the cost-of-education allowance, purchasing research equipment, strengthening human resource development programs, or recruiting students. Institutions may supplement project enhancement allowances to a greater extent than the amount matched

by NSF. Creative use of these funds for program development is encouraged.

#### Proposal Submission

Copies of all forms to be used may be found in the NSF GRESE publication further described below. All proposal copies, including one copy bearing original signatures, should be mailed to: Proposal Processing Unit—room 223, Attention: Graduate Research Traineeship Program, National Science Foundation, 1800 G Street, NW., Washington, DC 20550.

Proposals may also be submitted electronically. For information, contact the Electronic Proposal Submission Program Director, Office of Information Systems (OIS), phone (202) 357-9767, or via e-mail, nsfprops@nsf (Bitnet) or nsfprops@nsf.gov (Internet). Proposals submitted electronically will be dated when they enter the NSF system.

#### Proposal Deadline

Proposal must be postmarked not later than May 15, 1992.

#### Proposal Review

Proposals will be reviewed in accordance with the general criteria described in GRESE. In addition, each proposal will be evaluated on the following criteria:

- The quality of the ongoing research and teaching effort in the proposed critical area, including cited indicators of quality;

- The need for additional Ph.D.'s in the proposed program, including citations of demands in, and national importance of, the chosen focus area;

- The institution's existing capacity to utilize the requested number of traineeships for additional graduate students (including cited current and projected numbers of graduate students in the selected area, and the institution's plans for handling more students);

- The institution's record for producing Ph.D.'s in the selected area (if it is an established area), and the projected Ph.D. productivity resulting from the proposed activity;

- The recruiting plan for appointing trainees, including the institution's plans to interest and appoint eligible minorities, women, and students with disabilities;

- The appropriateness of the proposed training and retention programs, including the integration of activities associated with multidisciplinary programs;

- The proposed use of the project enhancement allowance, including the matching institutional funds.

## Award Information

### Announcement of Awards

The foundation expects to announce Graduate Traineeship Awards in Fall, 1992. Traineeship positions may be filled at any time after awards are made.

### Conditions of Awards

Each new traineeship will be funded by the Foundation for up to \$25,000 for the first year. Of this \$25,000, a minimum of \$14,000 is designated for stipend support of the trainee, and \$7,500 is provided for a cost-of-education allowance to the institution. The balance of \$3,500 will be available, on a one-time basis, subject to a 100% match from the institution, to assist the institution with the costs of strengthening its capabilities in the proposed focus area.

The Foundation expects to provide fully funded support for up to a maximum of five years.

The Foundation may elect to adjust the terms of grants to keep the stipends and the cost-of-education allowances of GRT's approximately equal to those for NSF Graduate Research Fellowships.

All traineeship appointments by a grantee institution must be made in the area specified in the successful proposal. Since traineeships are designed to support truly new efforts on the part of the institution, it is expected that newly recruited graduate students will be the principal recipients of traineeships. Any plan that anticipates appointment of current graduate students to traineeships should be described and justified in the proposal. No student may be appointed to a graduate research traineeship for a period of more than five years.

NSF will permit institutions to require appropriate service of trainees by appointment to positions that can generate additional income to cover any difference between the cost-of-education allowance and tuition. Any such required service must be contributory to the progress of the trainee toward a Ph.D. and must not be expected to delay that progress. Except as provided above in the various allowances, no other indirect costs will be included in GRT awards.

### Grant Administration

Except as modified by this program announcement, standard NSF guidelines on proposal submission and general information on awards, declination, and withdrawals are as stated in the NSF booklet Grants for Research and Education in Science and Engineering (GRESE) (NSF 90-77). Grants awarded as a result of this announcement are

administered in accordance with the terms and conditions of NSF GC-1, "Grant General Conditions. Copies of these documents are available at no cost from the NSF Forms and Publications Unit, phone (202) 357-7861, or via e-mail (Bitnet:pubs@nsf or Internet:pubs@nsf.gov). More comprehensive information is contained in the NSF Grant Policy Manual (NSF 88-47, July 1989), for sale through the Superintendent of Documents, Government Printing Office, Washington, DC 20402. The telephone number at GPO is (202) 783-3286 for subscription information.

If the submitting institution has never received an NSF award, it is recommended that appropriate administrative officials become familiar with the policies and procedures in the NSF Grant Policy Manual which are applicable to most NSF awards. If a proposal is recommended for an award, the NSF Division of Grants and Contracts will request certain organizational, management, and financial information. These requirements are described in Chapter III of the NSF Grant Policy Manual.

### Contact Person

Roosevelt Johnson (202) 357-9453,  
Program Director.

Dated: February 24, 1992.

Roosevelt Johnson,  
Program Director.

[FR Doc. 92-4618 Filed 2-27-92; 8:45 am]

BILLING CODE 7555-01-M

## NUCLEAR REGULATORY COMMISSION

[Docket No. 50-320]

### GPU Nuclear Corporation; Availability of Safety Evaluation for Post-Defueling Monitored Storage of Three Mile Island Nuclear Station, Unit 2

The U.S. Nuclear Regulatory Commission has published its Safety Evaluation Report associated with GPU Nuclear Corporation's (the licensee) proposal for long term storage of Three Mile Island Nuclear Station, Unit 2, termed Post-Defueling Monitored Storage, or PDMS, by the licensee.

Copies of the Safety Evaluation Report have been placed in the NRC's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, and in the Local Public Document Room, Government Publications Section, State Library of Pennsylvania, Walnut Street and Commonwealth Avenue, Harrisburg, Pennsylvania 17105, for review by

interested persons. Single copies of the Safety Evaluation may be requested in writing from Michael Masnik, Senior Project Manager, OWFN MS: 11-B-20, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

Dated at Rockville, Maryland this 21st day of February 1992.

For the Nuclear Regulatory Commission.

Richard F. Dudley, Jr.,

Acting Director, Non-Power Reactors,  
Decommissioning and Environmental Project  
Directorate, Division of Advanced Reactors,  
Office of Nuclear Reactor Regulation.

[FR Doc. 92-4622 Filed 2-27-92; 8:45 am]

BILLING CODE 7593-01-M

[Docket No. 50-322]

### Long Island Lighting Co.; Shoreham Nuclear Power Station; Environmental Assessment and Finding of no Significant Impact

The U.S. Nuclear Regulatory Commission (the NRC or Commission) is considering issuance of an amendment to Facility License No. NPF-82 issued to Long Island Lighting Company (LILCO or the licensee) for the possession of the Shoreham Nuclear Power Station, Unit 1 (SNPS or the facility), located in Suffolk County, New York.

### Environmental Assessment

#### Identification of Proposed Action

The proposed amendment would change license conditions and Technical Specifications (TS) to allow the possession and management of Shoreham by the Long Island Power Authority (LIPA).

The proposed action is in accordance with the licensee's and LIPA's joint application dated June 28, 1990, and as supplemented June 13, June 27, October 31, and December 5, 1991.

#### The Need for the Proposed Action

Under the 1989 Settlement Agreement between New York State and LILCO, LILCO is contractually committed never to operate Shoreham as a nuclear facility and to transfer the Shoreham facility to LIPA for decommissioning. The proposed amendment would transfer the SNPS Facility Operating License (Possession Only License or POL) to LIPA. There will be no physical changes to the Shoreham facility associated with this amendment other than the change in owner to Long Island Power Authority.

**Environmental Impacts of the Proposed Action**

The Commission has completed its evaluation of the proposed changes to the license conditions and TS. The proposed changes involve transferring the Possession Only License from LILCO to LIPA. Under the proposed amendment, all responsibilities and obligations associated with the Possession Only License, Technical Specifications, as well as applicable plans, procedures, and programs referenced therein will be transferred to LIPA. Accordingly, LIPA's activities after license transfer will be consistent with the Defueled Safety Analysis Report (DSAR) and the established safety margins. The direct environmental impacts of LIPA's activities under the license transfer are within those previously evaluated by LILCO in their DSAR and the Commission's approval of the POL on June 14, 1991. There will be no changes to the facility or the environment as a result of the license amendment and the corresponding administrative and managerial changes to the TS reflecting the change in ownership and the permanently defueled condition of the plant. Accordingly, the Commission concludes that this action would result in no radiological or non-radiological environmental impact.

**Alternative to the Proposed Action**

It has been determined that there is no impact associated with the proposed amendment; any alternatives to the amendment will have either no environmental impact or greater environmental impact. The principal alternative would be to deny the proposed transfer. This would not reduce the environmental impacts associated with the facility as currently licensed.

**Alternative Use of Resources**

This action does not involve the use of resources not considered in the Final Environmental Statement for the Shoreham Nuclear Power Station.

**Agencies and Persons Consulted**

The NRC staff reviewed the licensee's request and did not consult other agencies or persons.

**Finding of no Significant Impact**

Based on the foregoing environmental assessment, the Commission concludes that the proposed action will not have a significant affect on the quality of the human environment. Accordingly, the Commission has determined not to prepare an environmental impact statement for the proposed amendment.

A Notice of Consideration of Issuance of Amendment to Facility Operating License and Proposed No Significant Hazards Consideration Determination and Opportunity for Hearing in connection with this action was published in the **Federal Register** on March 20, 1991, (56 FR 11781). On April 19, 1991, the Scientists and Engineers for Secure Energy and the Shoreham Wading River Central School District (the petitioners) filed petitions and comments to intervene and request for hearing concerning the license transfer application. The NRC staff (staff) addressed the petitioner's comments in their Safety Evaluation concerning this amendment and concluded that nothing in the petitioner's comments affects the staff's proposed no significant hazards consideration.

For further details with respect to this action, see the request for amendment dated June 28, 1990, and supplements of June 13, June 27, October 31, and December 5, 1992, which are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC 20555, and at the Shoreham-Wading River Public Library, Route 25A, Shoreham, New York 11786-9697.

Dated at Rockville, Maryland this 24th day of February 1992.

For the Nuclear Regulatory Commission,  
Seymour H. Weiss,  
*Director, Non-Power Reactors,  
Decommissioning and Environmental Project  
Directorate, Division of Advanced Reactors  
and Special Projects, Office of Nuclear  
Reactor Regulation.*

[FR Doc. 92-4620 Filed 2-27-92; 8:45 am]

BILLING CODE 7590-01-M

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**PRESIDENT'S COMMISSION ON  
MANAGEMENT OF THE AGENCY FOR  
INTERNATIONAL DEVELOPMENT  
PROGRAMS**
**Meetings**

The President's Commission on the Management of the Agency for International Development Programs will hold a public meeting on Wednesday, March 18, 1992.

The subject of discussion will be the Commission's Draft Action Plan findings and recommendations on management of A.I.D. programs.

**DATE:** Wednesday, March 18, 1992.

**TIME:** 2 to 6 p.m.

**PLACE:** 1333 H Street, NW., Third Floor, Washington, DC, Postal Rate Commission Hearing Room.

Persons or organizations wishing to be heard by the Commission or to receive copies of the draft should call Ms. Brenda Jones at (202) 647-4399 or write to The President's Commission on the Management of A.I.D. Programs, 320 Twenty-First Street, NW., room 5665 NS, Washington, DC, 20523-0062.

Dated: February 25, 1992.

Frank B. Kimball,  
*Executive Director, Presidential Commission  
on the Management of A.I.D. Programs.*  
[FR Doc. 92-4623 Filed 2-27-92; 8:45 am]  
BILLING CODE 6116-01-M

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**SECURITIES AND EXCHANGE  
COMMISSION**

[Release No. 34-30381; File No. SR-DTC-92-05]

**Self-Regulatory Organizations; The  
Depository Trust Co.; Notice of Filing  
and Immediate Effectiveness of a  
Proposed Rule Change Concerning  
Revised Service Fees**

February 18, 1992.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),<sup>1</sup> notice is hereby given that on February 10, 1992, The Depository Trust Company ("DTC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

**I. Self-Regulatory Organization's  
Statement of the Terms of Substance of  
the Proposed Rule Change**

DTC is filing the proposed rule change to revise its fee schedule in accord with its estimated 1992 service costs (see *Exhibit A*), including an additional fee of \$0.65 to the deliverer per pending delivery order cancellation for the new PEND service.

**II. Self-Regulatory Organization's  
Statement of the Purpose of, and  
Statutory Basis for, the Proposed Rule  
Change**

In its filing with the Commission, DTC included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. DTC

<sup>1</sup> 15 U.S.C. 78s(b)(1).

has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

**(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change**

The purpose of the proposed rule change, which will be effective for services provided after February 29, 1992, is to adjust the fees charged for various services to bring them closer to, or to, their respective estimated service costs for 1992.

Prior to 1985, DTC attempted to relate service fees to their respective service costs at intervals of several years. During these intervals, unit service costs could diverge substantially from current fees, necessitating large changes when service fees were realigned with their costs. To prevent such divergence after adopting major fee changes at its December 1985 meeting which moved toward cost-based fees, the DTC Board then adopted and announced a new procedure, as follows:

In adopting new fees, the Board also declared its belief and intention that DTC should revise its basic fee schedule each year so that, through modest changes gradually over approximately five years, DTC service fees will be based on service cost in the absence of policy considerations which would justify limited exceptions. Large changes in service fees after intervals of several years would thereby be avoided.

The present fee schedule for DTC services, marked the completion of that 5-year effort to bring DTC service fees and costs into alignment. To ensure that this alignment continues, the depository's Board recently completed a review of DTC's estimated service costs for 1992 and has adopted changes in a

number of service fees designed to move those fees closer to estimated 1992 service costs.

DTC believes that the proposed rule change is consistent with the requirements of section 17A of the Act and the rules and regulations thereunder applicable to DTC because the fees will more equitably be allocated amount DTC participants.

**(B) Self-Regulatory Organization's Statement on Burden on Competition**

DTC does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

**(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others**

DTC informed participants and other users of its services of the proposed fee revisions (other than the fee for deliver order cancellations in the new PEND service) by a memorandum dated January 13, 1992, entitled "1992 Revisions of DTC Service Fees." Because participants have supported gradual moves toward cost-based fees in the past and because, overall, the subject fee changes are modest, a formal period for participant comment was not considered necessary this year.

**III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

The foregoing rule change has become effective pursuant to section 19(b)(3)(A) of the Act and subparagraph (e) of the rule 19b-4 thereunder, because the proposed rule change establishes or changes a due, fee, or other charge imposed by the self-regulatory

organization. At any time within 60 days of the filing of such rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

**IV. Solicitation of Comments**

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. section 552, will be available for inspection and copying in the Commission's Public Reference Room at the address above. Copies of such filing will also be available for inspection and copying at the principal office of DTC. All submissions should refer to the file Number SR-DTC-92-05 and should be submitted by March 19, 1992.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.<sup>2</sup>

**Margaret H. McFarland,**  
*Deputy Secretary.*

**BILLING CODE 8010-01-M**

<sup>2</sup> 17 C.F.R. 200.30-3(a)(12).

1992 REVISED DTG SERVICE FEES

Revised Fee

Present Fee

Service

A. Registered Securities

I. Deposits

The fee for deposits of certificates in active issues is determined by the time of receipt by DTG: (1)

- Zone A - 4:00 PM to 8:00 PM (Prior PM)
- Zone B - 7:30 AM to 10:00 AM
- Zone C - 10:00 AM to 11:00 AM
- Zone D - 11:00 AM to 12:00 Noon

\$1.70	} includes certificate charge*	\$2.24*
\$2.35		
\$4.05		
\$7.75		

\$ 2.20	} includes certificate charge*	\$2.76*
\$ 3.00		
\$ 5.20		
\$10.00		

The fee for deposits of certificates in less-active issues is determined by the time of receipt by DTG: (1)

- Zone A - 4:00 PM to 8:00 PM (Prior PM)
- Zone B - 7:30 AM to 10:00 AM
- Zone C - 10:00 AM to 11:00 AM
- Zone D - 11:00 AM to 12:00 Noon

\$2.65	} includes certificate charge*	\$2.76
\$3.30		
\$5.00		
\$8.70		

\$ 3.15	} includes certificate charge*	\$3.28
\$ 3.95		
\$ 6.15		
\$10.60		

No Change

A certificate charge per deposit per group of 10 certificates beyond the first 10 certificates in addition to the Zone fee

All footnotes in this Annex are found on the last page.

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## 1992 REVISED DTC SERVICE FEES

Service	Present Fee	Revised Fee
Legal Deposits		
Full-Service Deposit Fee (includes examination by DTC)	\$4.40 per deposit	\$4.07 per deposit
Telephone Notification Fee (optional addition available for Full-Service only)	\$4.20 per deposit	No Change
Basic Deposit Fee (no examination by DTC)	\$3.05 per deposit	\$2.72 per deposit
Tracking Service (available for both Full and Basic Service)	\$ .20 per deposit	No Change
A record date deposit surcharge for bond interest, cash and stock dividends and proxy	\$3.15 per record date deposit	\$2.94 per record date deposit
11. Withdrawals-by-Transfer (WTS)		
• For each assignment in an active issue submitted on PTS, MDR or GCF	\$2.30 per assignment	\$2.18 per assignment
• For each assignment in an active issue concluding in direct mail	\$1.50 per assignment(2)	\$1.38 per assignment(2)
• For each paper assignment in an active issue	\$3.60 per assignment	\$3.48 per assignment
• For each assignment in a less-active issue** submitted on PTS, MDR or GCF	\$3.95 per assignment	\$3.83 per assignment
• For each assignment in a less-active issue** concluding in direct mail	\$3.15 per assignment(2)	\$3.03 per assignment(2)
• For each paper assignment in a less-active issue**	\$5.25 per assignment	\$5.13 per assignment

All footnotes in this Annex are found on the last page.

1992 REVISED DTC SERVICE FEES

Service	Present Fee	Revised Fee
III. Urgent Withdrawals . For each Certificate-on-Demand (COD) withdrawal requested: Submitted by FTS Submitted by paper . For each Rush Transfer requested	\$ 16.45 per withdrawal \$ 17.95 per withdrawal \$ 29.50 per assignment plus a pass-through of any rush transfer fees charged by the agent	\$22.10 per withdrawal \$23.60 per withdrawal \$31.95 per assignment plus a pass-through of any rush transfer fees charged by the agent
IV. Collateral Loans (Pledges/Releases) . For each security (line item) pledged, released or substituted via FTS . Collateral Loan Report A detailed daily report of a bank or broker Participant's DTC collateral loans valued to the "Market" . Individual daily copies of this report, available upon request	\$ .09 per line item payable by both the pledgee and pledgor in each transaction \$ .02 per line item with a minimum charge of \$250.00 monthly for each subscribing Participant \$ 25.00 per copy	\$ .12 per line item payable by both the pledgee and pledgor in each transaction \$ .03 per line item with no minimum charge No Change
V. Error Charge . For each deposit, WT, COD and Collateral Loan pledge/release corrected or returned to a Participant because of error: From 0 to 5% Over 5% . A surcharge for each deposit of called bearer securities	\$ 27.00 per reject \$ 37.00 per reject \$ 35.00 plus a deposit reject fee	\$23.50 per reject \$33.50 per reject No Change

All footnotes in this Annex are found on the last page.

Service	Present Fee	Revised Fee
VI. Deliveries		
• Deliver orders via CMS	\$ .08 for each item delivered or received	\$ .085 for each item delivered or received
• Deliver orders via ID System	\$ .18 for each item delivered or received	\$ .17 for each item delivered or received
• Deliver orders via PTS, MDH or CCF For each deliver item presented Prior PM AM opening to 1:15 PM	\$ .19 to the deliverer \$ .44 to the deliverer \$ .29 for each item received (regardless of time)	\$ .18 to the deliverer \$ .43 to the deliverer \$ .28 for each item received (regardless of time)
VII. SDFS Deliveries		
• Deliver orders via PTS, MDR or CCF For each deliver item presented Prior PM AM opening to 2:30 PM	\$1.86 to the deliverer \$2.11 to the deliverer \$1.96 for each item received	\$1.26 to the deliverer \$1.51 to the deliverer \$1.36 for each item received
• Deliver orders via ID System	\$1.86 for each item delivered or received	\$1.26 for each item delivered or received
• Receiver Authorized Delivery (RAD) Receiver Cancellation	\$4.00 to the deliverer	\$ .65 to the deliverer
VIII. Commercial Paper Activity		
• Deliver orders	\$1.96 for each item delivered or received	\$1.30 to the deliverer \$1.15 to the receiver
• Maturity presentations	\$1.81 for each item delivered or received	\$1.10 for each item delivered or received
• Issuance instruction (both dealer-placed and directly-placed)	\$3.00 to the issuer	\$1.85 to the issuer
IX. Dropped Deliveries		
• For each Deliver Order (DO) not completed due to insufficient position in a Participant's account, unless DTC's system shows the submitting Participant's drop was caused by notice of potential receive of a delivery from another Participant which subsequently dropped	\$4.00 for each item dropped	\$2.00 for each item dropped

All footnotes in this Annex are found on the last page.

1992 REVISED DTC SERVICE FEES

Service	Present Fee	Revised Fee	
X. ID Service <ul style="list-style-type: none"> <li>For each confirm distributed by paper, tape, PIS, CCF or dial-in terminal</li> <li>For each confirm transmitted in magnetic tape form</li> <li>For each Pre-Authorized Delivery Quantity (PDQ) Delivered/Not Delivered and Received/Not Received Report line item</li> <li>For each Unaffirmed Report line item</li> <li>For each Cumulative and Daily Eligible Trade Report line item</li> <li>For each Daily Eligible Trade Report line item</li> <li>For each Ineligible Trade Report line item</li> <li>Ability to dial-in to DTC's ID system via personal computer to transmit instructions and receive reports</li> </ul>	<p>\$ .17 to broker (and interested party), if agent requests confirm; \$ .17 to investment manager for each confirm received, whether or not affirmed</p> <p>\$ .31 per confirm, plus telephone line costs</p> <p>\$ .06 to the deliverer and \$ .06 to the receiver</p> <p>\$ .06 to the broker</p> <p>\$ .06 to broker and clearing agent</p> <p>\$ .06 to broker and for reports received by any interested party</p> <p>\$ .06 to broker and clearing agent and \$ .06 to broker for reports received by any interested party</p> <p>\$400.00 per year access fee</p>	<p>\$ .16 to broker (and interested party), if agent requests confirm; \$ .16 to investment manager for each confirm received, whether or not affirmed</p> <p>\$ .30 per confirm, plus telephone line costs</p> <p>No Change</p> <p>No Change</p> <p>No Change</p> <p>No Change</p> <p>No Change</p> <p>\$500.00 per year access fee</p>	
		\$ .27 includes reports*	\$ .26 includes reports*

All footnotes in this Annex are found on the last page.

1992 REVISED DTG SERVICE FEES

Service	Present Fee	Revised Fee
<p><b>XI. Long Position</b></p> <ul style="list-style-type: none"> <li>For each active issue monthly (for registered corporate issues when a daily average of more than 15 Participants have position; and for registered municipal issues when a daily average of more than 2 Participants have position)</li> </ul>	\$ .51 per issue	No Change
<ul style="list-style-type: none"> <li>For each less-active registered corporate issue monthly (when a daily average of 15 or fewer Participants have position)</li> </ul>	\$ .76 per issue	No Change
<ul style="list-style-type: none"> <li>For each less-active registered municipal issue monthly (when a daily average of 1 or 2 Participants have position)</li> </ul>	\$1.26 per issue	No Change
<ul style="list-style-type: none"> <li>For each 100 shares or \$4,000 bonds (monthly) based on the average daily number of shares or bonds:                             <ul style="list-style-type: none"> <li>- 0-25 million shares</li> <li>- Excess over 25 million up to 200 million shares</li> <li>- Excess over 200 million up to 300 million shares</li> <li>- Excess over 300 million shares</li> </ul> </li> </ul>	\$ .0052 \$ .0013 \$ .000652 \$ .00005	No Change No Change No Change No Change
<ul style="list-style-type: none"> <li>For each book-entry-only issue (monthly)</li> </ul>	\$ .35 per issue; no per bond/per share charge	No Change
<ul style="list-style-type: none"> <li>For each Medium-Term Note (MTN) and Commercial Paper (CP) issue (monthly)</li> </ul>	\$ .60 per issue; no per bond/per share charge	No Change

\$ .83\*

All footnotes in this Annex are found on the last page.

1992 REVISED DTG SERVICE FEES

Services	Present Fee	Revised Fee
XII. Reorganization and Warrant Subscriptions For each common stock resulting from the conversion of bonds or preferred stocks/for each instruction submitted	- From 1 to 400 common shares	No Change
	- 401 to 2,000 common shares	\$96.00*
	- 2,001 and over common shares	
• Unit Swingovers	\$ 8.80 per swingover instruction plus 3 DO fees	\$ 7.75 per swingover instruction plus 3 DO fees
• Mandatory Exchanges/Redemptions Corporate issues		\$27.95 per Participant position
	Registered municipal issues	\$29.05 per Participant position plus \$ .25 per \$1,000 with a \$70.00 maximum transaction fee (3)
• Voluntary Exchanges/Tender Offers		\$43.42*
		\$38.85 per letter of transmittal

All footnotes in this Annex are found on the last page.

Service	Present Fee	Revised Fee
XIII. Underwritings		
. Issues Having 1 (one) CUSIP Number	\$198.50 plus \$ 3.00 per million with a total maximum fee of \$2,000 (4) and any unusual expenses	No Change
Book-Entry-Only Issues	\$198.50 (4) and any unusual expenses	No Change
Full FAST Issues	\$198.50 plus \$ 3.00 per million with a total maximum fee of \$2,000 (4) and any unusual expenses	\$198.50 (4) and any unusual expenses
. Issues Having More Than 1 (one) CUSIP Number	\$438.50 plus \$ 3.00 per million with a maximum of \$2,000 (4) and any unusual expenses	\$403.50 plus \$ 3.00 per million with a maximum of \$2,000 (4) and any unusual expenses
Book-Entry-Only Issues	\$438.50 (4) and any unusual expenses	\$403.50 (4) and any unusual expenses
Full FAST Issues	\$438.50 plus \$ 3.00 per million with a total maximum fee of \$2,000 (4) and any unusual expenses	\$403.50 (4) and any unusual expenses
. Certificates of Deposit	\$ 90.00 (4) and any unusual expenses	No Change
. Medium-Term Notes (MTNs)	\$ 20.00 (4) and any unusual expenses per tranche	\$ 4.00 (4) and any unusual expenses per tranche

All footnotes in this Annex are found on the last page.

1992 REVISED DTC SERVICE FEES

<u>Services</u>	<u>Present Fee</u>	<u>Revised Fee</u>
XIV. Dividends		
. For each cash dividend or interest payment: Corporate Issues	\$ 1.30 per credit (\$)	\$ 1.30 per credit (\$)
Registered municipal issues	\$ 1.88 per credit	\$ 1.91 per credit
. For each stock dividend payment	\$16.90 per credit	\$12.90 per credit
. For each Dividend Reinvestment Service instruction to receive stock in lieu of a cash dividend	\$23.90 per instruction	\$12.65 per instruction
. For each Change Mode of Payment (CMOP)	\$ 8.80 per CMOP plus 2 DO fees	\$ 7.75 per CMOP plus 2 DO fees

All footnotes in this Annex are found on the last page.

1992 REVISED DTC SERVICE FEES

Service	Present Fee	Revised Fee
XV. <b>PTS Reports</b>		
• Inquiries, Unsolicited Messages and Messages	\$ .075 per inquiry or message	\$ .085 per inquiry or message
• Participant inquiries about security positions, security eligibility, aged W instructions, and money settlement figures; messages about activities affecting a Participant's securities, etc.	\$ 30.00 per month per report series plus \$ .075 per line	\$ 30.00 per month per report series plus \$ .085 per line
• Reports		
• Dropped Deliveries Report	\$ .075 per edit	\$ .085 per edit
• Dropped COB's Report		
• Cash Dividend Report		
• Pre-Update Edits		
• Allows a Participant to edit a DO or withdrawal instruction prior to update by DTC's system	\$ .165 per 300 character message per addressee	\$ .175 per 300 character message per addressee
• Broadcast		
• To send messages to other Participants in the DTC terminal network	\$ .33 per form	\$ .34 per form
• Participant Exchange Service (PEX)		
• To transmit forms for buy-in notices	\$552.50 per month each account up to 5	\$576.50 per month each account up to 5
	\$232.50 per month each account over 5	\$256.50 per month each account over 5
	\$412.50 per month	\$436.50 per month
	\$232.50 per month	\$256.50 per month
XVI. <b>Usage Charge</b>		
• For each Participant account	\$461.09*	\$485.09*
• For each non-Participant Pledgee account		
• For each Pledgee that is also a Participant		

All footnotes in this Annex are found on the last page.

1992 REVISED DTC SERVICE FEES

<u>Service</u>	<u>Present Fee</u>	<u>Revised Fee</u>
<b>XVII. Inter-Depository Interface Fees to Participants</b>		
• RIO delivery	\$ .45 to MSCC	\$ .40 to MSCC
• Third-party delivery	\$ .53 surcharge for each item delivered, received or reclaimed on the regular DO fee	\$ .47 surcharge for each item delivered, received or reclaimed on the regular DO fee
<b>XVIII. Use of DTC Interface Department</b>		
• Participant usage		
Basic services:		
Settlement	\$44.30 per month	\$45.50 per month
Sorting	\$65.70 per month	\$69.20 per month
Shipping	\$78.75 per month	\$87.75 per month
Physical certificate forwarding fees:		
Deposit	\$ .39	\$ .38
Withdrawal-by-Transfer	\$ .49	No Change
Urgent Withdrawal	\$ 3.07	\$ 3.08
For preparation or correction of a Shipping Manifest:		
Preparation due to Participant omission	\$40.00 per occurrence	No Change
Correction because of error	\$20.00 per occurrence	No Change

## 1992 REVISED DTG SERVICE FEES

Service	Present Fee	Revised Fee
• Depository Facility usage Facility usage	To the Facility, \$ .92 per deposit with a \$100.00 minimum per month plus telephone costs	No Change
Facility deposit	\$ .60 per deposit chargeable to the Participant, plus the regular Deposit fee (Zone A) and certificate charge	No Change
XIX. Participant Output Services		
• Legal Notices via the LEMP function on FIS	\$ .25 per page	\$ .12 per page
• Computer-to-Computer Facility (CCF) Output Transmissions: Eligible Securities list with security descriptions	\$115.00 per request	\$89.00 per request
Eligible Securities list (CUSIPs only)	\$ 40.00 per request	\$31.00 per request
Daily changes in Eligible Securities list	\$ 25.00 per month	\$20.00 per month
Eligible Participants list	\$ 10.00 per request	No Change
Daily Participant Account Activity	\$100.00 per month	\$75.00 per month
Daily Participant Closing Balances	\$ 75.00 per month	\$58.00 per month
Daily Cash Settlement	\$ 50.00 per month	\$38.50 per month
Reorganization, Dividend and Proxy Record Date position information	\$ 50.00 per month	\$38.50 per month

## 1992 REVISED DTG SERVICE FEES

<u>Service</u>	<u>Present Fee</u>	<u>Revised Fee</u>
Withdrawal-by-Transfer Detail Balances	\$50.00 per month	\$38.50 per month
Completed WT Items	\$75.00 per month	\$38.00 per month
Participant Account Return Payment Order Transactions	\$50.00 per month	\$38.50 per month
Municipal Bond System Announcements	\$50.00 per month	\$38.50 per month
Dividend and Proxy Announcements	\$50.00 per month	\$38.50 per month
Reorganization Data	\$50.00 per month	\$38.50 per month
Collateral Loan Report for Pledgee Banks	None	\$38.50 per month
Call Letter Results	None	\$38.50 per month
ID Master File	None	\$20.00 per request
Legal Deposit Tracking Data	None	\$38.50 per month

Service	Present Fee	Revised Fee
<b>XX. Charges to DTC Passed Through to Users</b> Participant Terminal System (PTS) PTS Terminal: A basic configuration comprised of 1 CRT and 1 printer at a Participant's site	\$500.00 per month, plus line charge and applicable sales tax	\$400.00 per month, plus line charge and applicable sales tax
Dial Back-Up: Equipment and associated telephone lines for use when a Participant's dedicated line is inoperable	\$165.00 per month	\$125.00 per month
Contingency Site: For CCF, PTS and Mainframe Dual Host installations connections to the DTC contingency site in Philadelphia	\$ 85.00 per month	No Change
PTS Jr. Terminal (To be secured by the Participant)	\$100.00 per month access fee, plus line charge and applicable sales tax	\$ 55.00 per month access fee, plus line charge and applicable sales tax
Additional CRT: Each additional CRT added to the basic configuration of 1 CRT and 1 printer (maximum of 5)	\$100.00 per month, plus applicable sales tax	\$ 75.00 per month, plus applicable sales tax
Additional Printer: Each additional printer added to the basic configuration of 1 CRT and 1 printer	\$175.00 per month, plus applicable sales tax	\$150.00 per month, plus applicable sales tax
Installation Charges: One-time vendor charges to install telephone lines, ship equipment and provide DTC training: - Dedicated and dial back-up lines - Basic PTS configuration - Additional CRT - Additional Printer - Modem - Shipping of equipment - Training by DTC on site	Out-of-pocket expenses Out-of-pocket expenses Out-of-pocket expenses Out-of-pocket expenses Out-of-pocket expenses Out-of-pocket travel expenses	No Change No Change No Change No Change No Change No Change
Mainframe Dual Host and CCF Dedicated Line	Monthly charge of \$725.00 for modem and related equipment plus applicable line charges	No Change

1992 REVISED DTG SERVICE FEES

Service

B. Bearer Bond Securities

I. Deposits (by issue)

**Present Fee**  
 \$ 2.95 plus a charge after the first 10 certificates of \$ 2.00 per group of 10 certificates with a maximum total deposit charge of \$10.95.<sup>\*\*\*</sup> Deposits between 12:00 noon and 1 P.M. for same day credit \$40.00. A bulk deposit discount is available under certain conditions.

\$ 3.77\*

**Revised Fee**  
 \$ 3.55 plus a charge after the first 10 certificates of \$ 2.00 per group of 10 certificates with a maximum total deposit charge of \$11.55.<sup>\*\*\*</sup> Deposits between 12:00 noon and 1 P.M. for same day credit \$40.00. A bulk deposit discount is available under certain conditions.

\$ 4.37\*

. A surcharge per deposit of certificates without CUSIP numbers

No Change

II. Withdrawals (CODEs)  
 . Overmight CODEs Submitted by FTS

**Present Fee**  
 \$10.55 plus a charge after the first 10 certificates of \$ 4.00 per group of 10 certificates with a maximum total withdrawal charge of \$26.55<sup>\*\*\*</sup>

\$11.10\*

**Revised Fee**  
 \$11.90 plus a charge after the first 10 certificates of \$ 4.00 per group of 10 certificates with a maximum total withdrawal charge of \$27.90<sup>\*\*\*</sup>

\$12.45\*

Submitted by paper

**Present Fee**  
 \$11.35 plus a charge after the first 10 certificates of \$ 4.00 per group of 10 certificates with a maximum total withdrawal charge of \$27.35<sup>\*\*\*</sup>

\$11.90\*

**Revised Fee**  
 \$12.70 plus a charge after the first 10 certificates of \$ 4.00 per group of 10 certificates with a maximum total withdrawal charge of \$28.70<sup>\*\*\*</sup>

\$13.25\*

All footnotes in this Annex are found on the last page.

1992 REVISED DTG SERVICE FEES

Service	Present Fee	Revised Fee
iii. Long Position . For each active issue per month (held by more than 2 Participants) . For each less-active issue per month (held by 1 or 2 Participants) . Monthly charge on face value \$0 - \$.5 billion Excess over \$.5 billion up to \$1 billion Excess over \$1 billion up to \$8 billion Excess over \$8 billion	\$ .52 per issue  \$1.27 per issue  \$ .00000825 \$ .0000020625 \$ .00000103125 \$ .000000515625	No Change  No Change  \$ .0000075 \$ .0000018765 \$ .00000092813 \$ .000000464063
. A monthly surcharge on all positions in Book Bond issues . A monthly surcharge on all positions requiring coupon collection from paying agents located outside Metropolitan New York area . A monthly surcharge on all positions in multiple purpose issues . A monthly surcharge on all positions in issues denominated in units of \$1,000	\$1.05 per issue  \$ .25 per issue  \$ .50 per issue  \$ .50 per issue	No Change  No Change  No Change  No Change
	\$1.62*	\$1.57*

All footnotes in this Annex are found on the last page.

1992 REVISED DTC SERVICE FEES

Service	Present Fee	Revised Fee
IV. Interest Payments	\$ 4.42 per credit plus \$ .05 per \$1,000	\$ 5.77* \$ 4.75 per credit plus \$ .07 per \$1,000
V. Maturities/Redemptions (Full or Partial)	\$33.10 per Participant position plus \$ .20 per \$1,000 with a \$70.00 maximum transaction fee	\$43.42* \$29.85 per Participant position plus \$ .20 per \$1,000 with a \$70.00 maximum transaction fee
VI. Deliver Orders (Bearer Issues) . ID	\$ .18 for each item delivered or received	\$ .17 for each item delivered or received
. PTS, MDW or CCF	\$ .37 for each item delivered, \$ .29 for each item received	No Change

Notes:

- \* Weighted rate based on current mix of transactions in this service.
- \*\* A less-active issue fee applies to certain issues each calendar quarter based on prior period of activity averaging 2 or fewer transactions on days when activity occurred.
- \*\*\* In a deposit or withdrawal of more than 150 certificates, each group of 150 certificates is charged as a separate deposit or withdrawal.
- (1) All deposits shipped to DTC from outside the NYC area are regarded as Zone A deposits.
- (2) Presently, an additional \$1.95 charge is added to this fee for each assignment resulting in direct mail by DTC. This charge will now be reduced to \$1.79.
- (3) The portion of the fee associated with face value will not be applied to Registered Municipal book-entry-only issues.
- (4) A surcharge of \$350.00 applies to issues with a put option feature to cover the costs associated with reviewing the official statement and establishing a data base through which put periods are monitored. Issues requiring consultation and special development efforts will be charged an additional surcharge to cover DTC's additional costs. The impact of these surcharges is not included in the weighted rates.
- (5) Monthly refunds of dividends investment income are reduced \$650,000 annually for unrecovered costs associated with efforts to collect cash dividends and interest payments in same-day funds on payable date. The reduction of such monthly refunds will now be eliminated, as these costs are recovered in the service fee.

[FR Doc. 92-4451 Filed 2-27-92; 8:45 am]  
BILLING CODE 8010-01-C

[Release No. 34-30392; File No. SR-NASD-91-50]

**Self-Regulatory Organizations; Notice of Proposed Rule Change and Amendment by National Association of Securities Dealers, Inc.; Relating to Transaction Reporting for Nasdaq Securities**

February 21, 1992.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on September 25, 1991, and January 31, 1992, the National Association of Securities Dealers, Inc. ("NASD" or "Association") filed with the Securities and Exchange Commission ("Commission" or "SEC") the proposed rule change and amendment as described in Items I, II, and III below, which items have been prepared by the NASD. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

**I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change**

The NASD is proposing to amend Schedule D to the NASD By-Laws to add requirements for trade reporting for Nasdaq securities that are similar to the trade reporting requirements currently in place for Nasdaq National Market System securities.

**II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change**

In its filing with the Commission, the NASD included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The NASD has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

**A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change**

The Association is proposing transaction reporting requirements for all Nasdaq securities, similar to the requirements currently in place for Nasdaq National Market System securities ("Nasdaq/NMS"). Transaction reporting is a fundamental component of a national marketplace that facilitates several important functions: Reporting enhances transparency of information

for investors and issuers, permits immediate collection and scrutiny of trading information for regulatory purposes, and permits the compilation of historical price and volume data for analysis and research. The NASD has had over nine years of experience with real-time reporting Nasdaq/NMS securities and believes that capturing trade-by-trade data for dissemination to the public through the Nasdaq and vendor networks is beneficial to investors and issuers, as capturing transactional information as it occurs is fundamental to ensure regulatory and self-regulatory oversight of the markets. Moreover, transaction reporting allows investors to monitor effectively the quality of executions they receive. Therefore the NASD is proposing to expand transaction reporting to include all Nasdaq securities.<sup>1</sup>

Proposed amendments to Schedule D contain trade reporting requirements similar to those currently in place for Nasdaq/NMS securities. The rules will require transactions in Nasdaq securities to be reported to the NASD within 90 seconds after execution. Members are currently reporting broker-to-broker transactions into the Automated Confirmation Transaction service ("ACT") for comparison processing, and ACT will also be the vehicle for transaction reporting. Current ACT requirements call for firms to report transactions in regular Nasdaq securities within 15 minutes after execution—these time frames will be condensed to 90 seconds to comply with the new trade reporting requirements. The proposed rules also specify which party to a transaction is required to report (in most transactions, the market maker registered in the security in the Nasdaq system is the reporting party) and provide reporting policies, such as reporting transactions at the selling or purchasing price, irrespective of mark-ups and mark-downs, or commissions. These requirements parallel those currently in place for Nasdaq National Market System securities. Finally, the trade reporting state that aggregating trade reports is allowable under certain circumstances, and sets forth permissible aggregation practices.

Last sale information for Nasdaq/NMS securities contains the execution price of each trade reported and the number of shares executed. This information is required to be reported to the NASD within 90 seconds after execution and is validated, processed, and disseminated to information

vendors for publication to subscribers. Information vendors also provide in their own format, on a real-time basis, the daily high, low and last sale prices as well as aggregate volume throughout the trading day to the investment community and the investing public. Currently members and others are able to monitor trade reports of Nasdaq/NMS securities through the last sale reports disseminated via the vendor networks and also through the Nasdaq Workstation service that permits subscribers to customize their own information displays to monitor trade reports in specific Nasdaq securities real-time. The NASD's digital interface service also supplies last sale information to subscribers.

When trade reporting of regular Nasdaq securities is implemented, the trade reports will be collected and disseminated in a similar manner, real-time, as they are submitted to the NASD. Vendor networks will be supplied the data over high speed lines, as they are currently receiving Nasdaq/NMS last sale information, and trade reports from regular Nasdaq transactions will be disseminated to subscribers through the Workstation and digital interface services as well.

The NASD is also proposing real-time transaction reporting for Nasdaq securities because of the impact of the SEC's proposed "Penny Stock Disclosure Rules"<sup>2</sup> on regular Nasdaq securities. As proposed, the rules define any stock selling for less than \$5.00 per share as a penny stock unless it meets one of the itemized exemptions from the definition. Approximately 1,600 Nasdaq issues would fall into this category.

One of the exemptions to the "less than \$5.00" classification is for a "reported security," subject to a transaction reporting plan approved by the SEC pursuant to section 11A rules. Therefore, all Nasdaq/NMS, New York and American Stock Exchange issues are exempt from the penny stock definition because they are trade reported, notwithstanding the fact that some of those issues may trade at prices under \$5.00.

Although the proposed rule change to Schedule D of the NASD By-Laws is not a national market system plan pursuant to section 11A of the Act, the NASD believes that real-time reporting and dissemination of transaction reports is the objective of the exemption set out in the SEC's penny stock rules and this objective is equally served by the proposed rule changes. Trade reporting

<sup>1</sup> An appropriate service charge for last sale data for Nasdaq securities is being developed and will be the subject of a separate rule proposal.

<sup>2</sup> See Securities Exchange Act Release No. 29093 (April 17, 1991).

of all Nasdaq issues will enhance the information available to the public and provide investors with instant, up-to-the-minute information on the securities traded throughout the Nasdaq market. Trade reporting will also greatly enhance the NASD's ability to detect or deter manipulative or abusive trading practices.

In proposing real-time reporting for Nasdaq securities, the NASD evaluated the ramifications of such a requirement on the membership. Members are currently reporting only inter-dealer transactions into ACT for comparison purposes and are reporting total volume of purchases and sales in Nasdaq securities at the end of the day. The proposed rule changes would, therefore, reduce the time-frames for reporting transactions into ACT from 15 minutes to 90 seconds, and increase the transactions eligible for reporting to include internalized transactions. These changes will be an added burden on members, but elimination of end-of-day volume reporting, which the NASD anticipates eliminating shortly after real-time trade reporting has been implemented, will be a beneficial offset.<sup>3</sup>

The NASD also does not believe that the extension of trade reporting to regular Nasdaq securities will adversely impact the liquidity of those securities. Experience with NMS securities demonstrates that the increased visibility associated with trade reporting expands the universe of institutional and public investors willing to purchase the security and therefore generally provides a net increase in liquidity.

Also, for members that trade infrequently, the NASD will make the ACT service desk available for trade reporting purposes. The NASD operates the ACT service desk to facilitate members that account for fewer than five trades a day on average and that do not have Nasdaq Workstation equipment. Therefore, the ACT service desk will also be made available to members for trade reporting that qualify under the same criteria of five or fewer trades a day on average. The NASD believes that the benefits to be gained by the Nasdaq market as a whole outweigh any burdens experienced by members in complying with the new reporting requirements.

From a regulatory perspective, real-time reporting requirements will

enhance market surveillance oversight and will provide more immediate and useful information for investigating questionable conduct, such as insider trading and manipulative activity. Up until now, the NASD had to rely on end-of-day volume statistics as the primary source of surveillance information for trades in regular Nasdaq securities, but real-time transaction reporting will increase the NASD's ability to conduct surveillance of trading as it occurs. For example, as real-time trade reporting is fully implemented, the trading data will be available on the NASD's equity audit trail, which integrates last sale, clearing, and inside quotation data for reported securities. In addition, transaction data will be added to daily quote and trade comparison reports and to exception-based systems that monitor for marking-the-close violations, trading during trading halts, volume concentrations, late trade reporting, and other activity monitored by Market Surveillance. The trade reports will also be added to weekly and monthly trade summary and volume concentration reports for purposes of surveillance and analysis of historical data.

The NASD believes the proposed rule change is consistent with section 15A(b)(6) of the Act. Section 15A(b)(6) requires that the rules of a national securities association be designed to "foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market." Trade reporting of all Nasdaq securities facilities transparency of information for investors and issuers and permits immediate collection and scrutiny of transactional data for regulatory purposes.

#### *B. Self-Regulatory Organization's Statement on Burden on Competition*

The NASD believes that the proposed rule change will not result in any burden on competition that is not necessary or appropriate in furtherance of purposes of the Act.

#### *C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others*

Comments were neither solicited nor received.

#### **III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

Within 35 days of the date of publication of this notice in the Federal

Register or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the NASD consents, the Commission will:

A. By order approve such proposed rule change, or

B. Institute proceedings to determine whether the proposed rule change should be disapproved.

#### **IV. Solicitation of Comments**

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to the file number in the caption above and should be submitted March 20, 1992.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority, 17 CFR 200.30-3(a)(12)

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 92-4583 Filed 2-27-92; 8:45 am]

BILLING CODE 8010-01-M

#### **DEPARTMENT OF TRANSPORTATION**

**Office of the Secretary**

[Docket No. 48001]

#### **New Air Transportation Opportunities (U.S.-China)**

Through an exchange of notes concluded February 11, 1992, the Governments of the United States and the People's Republic of China finalized amendments to the 1980 U.S.-China Air Transport Services Agreement, as amended. As described more fully below, the new agreement provides for, among other things, a new all-cargo route, and an initial increase in total U.S. carrier frequencies to eighteen

<sup>3</sup> The NASD proposes to eliminate end-of-day volume reporting shortly after the commencement of real-time transaction reporting to ensure that there will be no gaps in regulatory information collected, and will make the appropriate rule filing at this time.

weekly roundtrip flights, four of which are available immediately for operations on the new all-cargo route.

By this notice, we are inviting applications from U.S. carriers interested in providing U.S.-China all-cargo services.

#### All-Cargo Services

Under the amended agreement, a third route has been established available for all-cargo services only. The United States may designate one U.S. carrier to operate all-cargo services over the following route:

#### Route 3

From any point or points in the United States, via any intermediate points to any point or points in the People's Republic of China open to scheduled international operations, and beyond to any points outside the People's Republic of China.

In operating such services, the designated U.S. airline may, at its option, omit any point or points on the route on any or all flights in either or both directions, provided that the service begins or terminates at a point on the specified route in the United States.<sup>1</sup> Under the terms of the amended agreement, on the all-cargo route, U.S. carriers may operate up to four weekly all-cargo frequencies through 1992. These frequencies increase to six weekly all-cargo flights for both 1993 and 1994. For 1995 and 1996, there is no specific limitation on all-cargo frequencies on the all-cargo route. However, during the 1995-1996 period U.S. carrier combination and all-cargo frequencies collectively may not exceed a total of 27 weekly flights.

In view of the new route opportunity, we invite all U.S. carriers interested in providing all-cargo service in the U.S.-China market to file exemption and/or certificate applications to serve the market. Except for the filing dates, certificate applications should be filed pursuant to subpart Q of part 302 of the Department's regulations, and exemption applications should conform to subpart D of part 302 of the Department's regulations. Applications should be filed no later than 15 calendar days from the date of service of this

<sup>1</sup> Prior to the amendment, the United States could designate two airlines, one on each of two routes, to provide scheduled services between the U.S. and China. The designated airlines for these routes could operate combination or all-cargo services or both. United Air Lines and Northwest Airlines are designated on Routes 1 and 2, respectively, to provide U.S.-China services. Under the 1992 amendment, the operation of all-cargo flights by carriers designated under Routes 1 and 2 does not reduce the frequencies available for all-cargo services on the new Route 3.

notice. Competing applications and answers shall be due no later than 7 calendar days thereafter, and responsive pleadings to the above, 5 calendar days thereafter.

Applications should be filed with the Department's Docket Section (Docket 48001), room 4107, 400 Seventh Street, SW., Washington, DC 20590. Further procedures for acting on the applications filed, if necessary, shall be established by future Department order.

Dated: February 24, 1992.

Paul L. Gretch,

Director, Office of International Aviation.

[FR Doc. 92-4614 Filed 2-27-92; 8:45 am]

BILLING CODE 4910-62-M

#### Coast Guard

[CGD 92-010]

#### Central Pacific Loran-C Closure

**AGENCY:** Coast Guard, DOT.

**ACTION:** Notice; request for comments.

**SUMMARY:** On November 5, 1991, the Coast Guard published a notice of intent (56 FR 56539) for early closure of the Central Pacific Loran-C chain, Rate 4990 on 31 December 1992. The Coast Guard is considering terminating the Loran-C service provided by the Central Pacific Loran-C chain, in the Hawaiian Islands, on 30 June 1992, in lieu of continuing operations until 31 December 1992. Continued operation of the Central Pacific Loran-C chain is not economically justified. Earlier closure of this Loran-C chain on 30 June 1992 will allow the Coast Guard to dismantle and clean up Loran-C station Kure and Johnston Island with minimal impact on the wildlife.

**DATES:** Comments must be received on or before March 30, 1992.

**ADDRESSES:** Comments should be mailed to the Executive Secretary (G-LRA/3406) (CGD 92-010), U.S. Coast Guard, Washington, DC, 20593-0001. Comments will be available for public inspection and copying between 8 a.m. and 3:30 p.m., Monday through Friday, except holidays, at the Marine Safety Council (G-LRA), room 3406, U.S. Coast Guard Headquarters, 2100 Second Street, SW., Washington, DC 20593-0001. Comments may also be hand delivered to this address.

#### FOR FURTHER INFORMATION CONTACT:

Commander Richard J. Armstrong, Chief, Radio Aids Management Branch (G-RRN-1), room 1413, U.S. Coast Guard Headquarters, 2100 2nd St., SW., Washington, DC 20593-0001, phone (202) 267-0990.

**SUPPLEMENTARY INFORMATION:** The Central Pacific Loran-C Chain, in the Hawaiian area, was installed in the mid-60's in response to a Department of Defense requirement. The coverage provided by the satellite-based Global Positioning System (GPS) is increasing while the cost of GPS receivers is decreasing. GPS presently provides coverage where Loran-C cannot and this coverage includes the Hawaiian Islands. The 1990 edition of the Federal Radionavigation Plan, provides for termination of overseas and Hawaiian Loran-C stations when the Department of Defense requirement for Loran-C ends on December 31, 1994. The new satellite based Global Positioning System may allow the Department of Defense to end its requirement for Loran-C in the Hawaiian area as early as the end of June 1992. Because of the poor coverage area and limited number of users, the continued operation of the Central Pacific Loran-C chain past June 1992 is not economically justified. The Loran-C system serving the continental U.S., its coastal areas, and Alaska with the exception of Hawaii, will remain part of the radionavigation mix and would not be terminated with the Central Pacific system.

Kure Atoll is a designated Hawaiian monk seal critical habitat, a State Seabird Sanctuary, and is part of the State Wildlife Refuge System. Johnston Island is located in a wildlife refuge which provides protection to seabirds. Earlier closure of this Loran-C chain on 30 June 1992 will allow the Coast Guard to dismantle and clean up these stations without interfering with seal pupping or bird nesting and breeding.

Comments are requested concerning possible termination of Loran-C service provided by the Central Pacific Loran-C Chain, Rate 4990, in the Hawaiian area, by 30 June 1992, in lieu of the end of calendar year 1992 as is currently planned.

The Coast Guard encourages interested persons to participate by submitting written data, views, or arguments. Persons submitting comments should include their name and address, identify this Notice (CGD 92-010) and how each comment relates to the proposed action. Persons wanting acknowledgment of receipt of comments should enclose a stamped, self-addressed postcard or envelope.

Dated: February 25, 1992.

W.J. Ecker,

Rear Admiral, Coast Guard, Chief, Office of Navigation Safety and Waterway Services.

[FR Doc. 92-4645 Filed 2-27-92; 8:45 am]

BILLING CODE 4910-14-M

[CGD 91-15]

**Coast Guard Academy Advisory Committee; Meetings****ACTION:** Open meeting.

**SUMMARY:** Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463; 5 U.S.C. App I) notice is hereby given of a meeting of the Coast Guard Academy Advisory Committee to be held in Hamilton Hall at the U.S. Coast Guard Academy, New London, CT, on Monday and Tuesday, March 23 and 24, 1992. The open sessions on Monday will be held from 9:30 a.m. to 10:30 a.m. and 1:15 p.m. to 2:15 p.m. Open sessions on Tuesday will be held from 2:30 p.m. to 3:15 p.m. The agenda for the meeting consists of the following items:

1. Recruiting and Admissions
2. Athletics
3. Faculty and Curricula
4. Library

The Coast Guard Academy Advisory Committee was established in 1937 by Public Law 75-38 to advise on the course of instruction at the Academy and to make recommendations as necessary. Attendance is open to the public. With advance notice, members of the public may present oral statements at the meeting. Persons wishing to attend or present oral statements at the meeting should notify the U.S. Coast Guard Academy not later than March 8, 1992.

Any member of the public may present a written statement to the Committee at any time.

**FOR FURTHER INFORMATION CONTACT:** Dr. William A. Sanders, Dean of Academics, U.S. Coast Guard Academy, New London, CT 06320, ph (203) 444-8275.

Issued in Washington, DC, on February 21, 1992.

**G. D. Passmore,**  
Rear Admiral, U.S. Coast Guard Chief, Office of Personnel and Training.

[FR Doc. 92-4644 Filed 2-27-92, 8:45 am]

BILLING CODE 4910-14-M

**Federal Aviation Administration****Advisory Circular 21-31, Quality Control for the Manufacture of Non-metallic Compartment Interior Components**

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Notice of availability.

**SUMMARY:** This notice announces the availability of Advisory Circular 21-31,

Quality Control for the Manufacture of Non-metallic Compartment Interior Components. Advisory Circular 21-31, provides information and guidance to the general public and the aviation industry concerning compliance with Federal Aviation Regulation (FAR) part 21, Certification Procedures for Products and Parts.

**ADDRESSES:** Copies of AC 21-31 can be obtained from the following: Federal Aviation Administration, Department of Transportation, Utilization and Storage Section, M443.2, 400 Seventh Street SW., Washington, DC 20591.

Issued in Washington, DC, on November 15, 1991.

**Ronald T. Wojnar,**

Manager, Aircraft Manufacturing Division.

[FR Doc. 92-4607 Filed 2-27-92; 8:45 am]

BILLING CODE 4910-13-M

**Receipt of Noise Compatibility Program and Request for Review; Tucson International Airport, Tucson, AZ**

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Notice.

**SUMMARY:** The Federal Aviation Administration (FAA) announces that it is reviewing a proposed noise compatibility program that was submitted for Tucson International Airport under the provisions of title I of the Aviation Safety and Noise Abatement Act of 1979 (Pub. L. 96-193) (hereinafter referred to as "the Act") and 14 CFR part 150 by the Tucson Airport Authority. This program was submitted subsequent to a determination by FAA that associated noise exposure maps submitted under 14 CFR part 150 for Tucson International Airport were in compliance with applicable requirements effective May 11, 1990. The proposed noise compatibility program will be approved or disapproved on or before August 9, 1992.

**EFFECTIVE DATE:** The effective date of the start of FAA's review of the noise compatibility program is February 11, 1992. The public comment period ends April 11, 1992.

**FOR FURTHER INFORMATION CONTACT:** David B. Kessler, Airport Planner, Airports Division, AWP-611.2, Mailing Address: P.O. Box 92007, Worldway Postal Center, Los Angeles, California 90009-2007, telephone: 310/297-1534. Comments on the proposed noise compatibility program should also be submitted to the above office.

**SUPPLEMENTARY INFORMATION:** This notice announces that the FAA is reviewing a proposed noise compatibility program for Tucson International Airport which will be approved or disapproved on or before August 9, 1992. This notice also announces the availability of this program for public review and comment.

An airport operator who has submitted noise exposure maps that are found by FAA to be in compliance with the requirements of Federal Aviation Regulations (FAR) part 150, promulgated pursuant to title I of the Act, may submit a noise compatibility program for FAA approval which sets forth the measures the operator has taken or proposes for the reduction of existing noncompatible uses and for the prevention of the introduction of additional noncompatible uses.

The FAA has formally received the noise compatibility program for Tucson International Airport, effective on February 11, 1992. It was requested that the FAA review this material and that the noise mitigation measures, to be implemented jointly by the airport and surrounding communities, be approved as a noise compatibility program under section 104(b) of the Act. Preliminary review of the submitted material indicates that it conforms to the requirements for the submittal of noise compatibility programs, but that further review will be necessary prior to approval or disapproval of the program. The formal review period, limited by law to a maximum of 180 days, will be completed on or before August 9, 1992.

The FAA's detailed evaluation will be conducted under the provisions of 14 CFR part 150, § 150.33. The primary consideration in the evaluation process are whether the proposed measures may reduce the level of aviation safety, create an undue burden on interstate or foreign commerce, or be reasonably consistent with obtaining the goal of reducing existing noncompatible land uses and preventing the introduction of additional noncompatible land uses.

Interested persons are invited to comment on the proposed program with specific reference to those factors. All comments, other than those properly addressed to local land use authorities, will be considered by the FAA to the extent practicable. Copies of the noise exposure maps, the FAA's evaluation of the maps, and the proposed noise compatibility program are available for examination at the following locations:

Federal Aviation Administration, 800 Independence Avenue, SW., room 617, Washington, DC 20591.

Federal Aviation Administration, Western-Pacific Region, Airports Division, room 3E24, 15000 Aviation Boulevard, Hawthorne, California 90281.  
Tucson Airport Authority, 7005 South Plumer Avenue, Tucson, Arizona 85706.

Questions may be directed to the individual named above under the heading, **FOR FURTHER INFORMATION CONTACT:**

Issued in Hawthorne, California on February 11, 1992.

**Herman C. Bliss,**  
*Manager, Airports Division, AWP-600,  
Western-Pacific Region.*

[FR Doc. 92-4608 Filed 2-27-92; 8:45 am]

**BILLING CODE 4910-13-M**

### **Research and Special Programs Administration**

#### **Meeting of Technical Pipeline Safety Standards Committee**

This notice amends the notice appearing in the February 21, 1992 **Federal Register** (57 FR 6275) of the meeting of the Technical Pipeline Safety Standards Committee, pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463, 5 U.S.C. app. 1).

The Technical Pipeline Safety Standards Committee meeting scheduled for 1:30 p.m., on March 11, 1992, in room 2201 of the Department of Transportation Building, 400 Seventh Street, SW., Washington, DC, will also include a short discussion on excess flow valves (Docket No. PS-118), in addition to the agenda items appearing in the February 21, 1992 **Federal Register** notice.

Dated: February 24, 1992.

**Cesar De Leon,**  
*Executive Director, TPSSC.*

[FR Doc. 92-4543 Filed 2-27-92; 8:45 am]

**BILLING CODE 4910-60-M**

#### **[Docket No. P-91-4W; Notice 1]**

#### **Transportation of Natural and Other Gas by Pipeline, Petition for Waiver; Northwest Pipeline Corp.**

Northwest Pipeline Corporation (Northwest) has petitioned the Research and Special Programs Administration (RSPA) for a waiver from compliance with 49 CFR 192.611(c), which requires confirmation or revision of the maximum allowable operating pressure (MAOP) within 18 months of a change in class location. Northwest determined that, effective October 4, 1990, the class location for the 26-inch main line and 30-inch loop line between mileposts 1393.79

and 1394.57 (0.78 miles) and mileposts 1395.99 and 1396.52 (0.53 miles), Snohomish County, Washington, changed from Class Location 2 to Class Location 3. Such class location change determination was made pursuant to a study required by § 192.609 due to an increase in population density. Absent a waiver, Northwest would be required, on April 4, 1992, to either (1) reduce MAOP on the 26-inch main line from 674 psig to 562 psig, or (2) retest the lines for operation at 674 psig (60 percent of the specified minimum yield of the pipe) pursuant to § 192.611(a)(1). Northwest seeks a waiver of the requirements of § 192.611(c) for a 6 month period ending September 30, 1992. No action is required for the 30-inch loop line because it meets Class 3 standards.

The waiver would allow Northwest to maintain throughput pending replacement of the sections of the 26-inch main line requiring waiver from § 192.611(c) and testing of a 46.25 mile portion of the system. Northwest filed a certificate application with the Federal Energy Regulatory Commission (FERC) on December 31, 1990, seeking approval to expand and upgrade certain existing facilities (Docket No. CP91-780-000, 002). Northwest estimates construction and requalification of the pipelines should be complete by September 30, 1992, assuming timely receipt of FERC approval. Further, Northwest states that, without the waiver, they must retest the lines for operation at 674 psig prior to April 4, 1992, to avoid disruption of service to customers.

A close interval potential survey was performed between mileposts 1392 and 1397 on the 26-main line in May 1990. Readings of pipe to soil potential at 3 foot intervals indicated the segments meet or exceed the minimum corrosion control requirements. Northwest's corrosion consultant concluded that it is unlikely that the segments of pipeline are suffering from any form of corrosion. Northwest states that both lines are in good operating condition, have not had any leaks or failures, and have been cathodically protected to required levels. The pipelines are patrolled every week.

Northwest estimates an additional cost of \$162,000 for duplicate hydrostatic testing, gas loss and excavation under wet winter conditions when compared to concurrent construction. They also state that simultaneous construction of pipelines will minimize the extent and duration of disturbance to the environment and ecology of the area. The two sections requiring replacement are near major rivers which have wintering populations of bald eagles. By deferring construction activities until

late spring, Northwest would reduce the potential for displacing the bald eagles. Northwest's statements seem reasonable.

Because of the previous safe and reliable history of the pipeline, and the additional cost and disruption that an additional construction period would cause, it seems reasonable to waive the requirements of § 192.611(c) for a 6 month period, and allow the operator sufficient time to install and qualify pipelines in a single construction period. There is no reason to anticipate a lesser level of safe performance for the existing lines than the previous record shows, or any additional risks to the population in proximity to the line. In view of these reasons and those stated in the foregoing discussion, it appears that a waiver of compliance with § 192.611(c) is not inconsistent with gas pipeline safety, and as a consequence, RSPA proposes to grant the waiver.

Interested parties are invited to comment on the proposed waiver by submitting in duplicate such data, views, or arguments as they may desire. Comments should identify the Docket and Notice numbers, and be submitted to the Dockets Unit, room 8417, Research and Special Programs Administration, 400 Seventh Street, SW., Washington, DC 20590.

All comments received before March 30, 1992 will be considered before final action is taken. Late filed comments will be considered so far as practicable. All comments and other docketed material will be available for inspection and copying in room 8419 between the hours of 8:30 a.m. and 5 p.m. before and after the closing date. No public hearing is contemplated, but one may be held at a time and place set in a Notice in the **Federal Register** if requested by an interested person desiring to comment at a public hearing and raising a genuine issue.

Issued in Washington, DC on February 25, 1992.

George W. Tenley, Jr.,  
Associate Administrator for Pipeline Safety.  
[FR Doc. 92-4625 Filed 2-27-92; 8:45 am]

BILLING CODE 4910-60-M

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## DEPARTMENT OF THE TREASURY

### Public Information Collection Requirements Submitted to OMB for Review

February 24, 1992.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under

the Paperwork Reduction Act of 1980, Public Law 96-511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

#### Internal Revenue Service

*OMB Number:* 1545-0757.

*Regulation ID Number:* LR-209-76 Final Regulations.

*Type of Review:* Extension.

*Title:* Special Lien for Estate Taxes Deferred Under section 6166 or 6166A Procedure and Administration.

*Description:* Section 6324A permits the executor of a decedent's estate to elect a lien on section 6166 property in favor of the United States in lieu of a bond or personal liability if an election under section 6166A was made.

*Respondents:* Individuals or households, Businesses or other for-profit.

*Estimated Number of Respondents:* 34,600.

*Estimated Burden Hours Per Respondent:* 15 minutes.

*Frequency of Response:* Other (Nonrecurring).

*Estimated Total Reporting Burden:* 8,650 hours.

*OMB Number:* 1545-0889.

*Form Number:* IRS Forms 8275 and 8275-R.

*Type of Review:* Revision.

*Title:* Disclosure Statement and Regulation Disclosure Statement.

*Description:* Internal Revenue Code (IRC) section 6662 imposes accuracy related penalties for substantial understatement of tax liability or negligence or disregard of rules and regulations. Section 6694 imposes similar penalties on return preparers. Regulations section 1.6662-4(e)&(f) provide for reduction of these penalties if adequately disclosure of the tax treatment is made on Form 8275 or, if the position is contrary to a regulation, new Form 8275-R.

*Respondents:* Individuals or households, Farms, Businesses or other for-profit, Non-profit institutions, Small businesses or organizations.

*Estimated Number of Respondents/Recordkeepers:* 595,000.

*Estimated Burden Hours Per Respondent/Recordkeeper:*

Recordkeeping..... 3 hours, 7 minutes

Learning about the law or the form..... 48 minutes

Preparing and sending the forms to the

IRS..... 58 minutes

*Frequency of Response:* Annually.  
*Estimated Total Reporting/Recordkeeping Burden:* 3,975,000 hours.

*OMB Number:* 1545-1102.

*Regulation ID Number:* Notice 89-1.

*Type of Review:* Revision.

*Title:* Low-Income Housing Tax Credit—Election of Appropriate Percentage Month; Carryover of Post 1987 Low-Income Housing Credit Dollar Amounts.

*Description:* The Technical and Miscellaneous Revenue Act of 1988 allows a taxpayer to use the appropriate percentage for a month other than the month a building is placed in service and (2) to obtain an allocation of credits prior to the building's placed in service date.

*Respondents:* Individuals or households, State or local governments, Businesses or other for-profit, Non-profit institutions, Small businesses or organizations.

*Estimated Number of Respondents/Recordkeepers:* 2,000.

*Estimated Burden Hours Per*

*Respondent/Recordkeeper:* 5 hours, 5 minutes.

*Frequency of Response:* Other (One-time election and/or allocation).

*Estimated Total Reporting/Recordkeeping Burden:* 10,150 hours.

*Clearance Officer:* Garrick Shear (202) 535-4297, Internal Revenue Service, room 5571, 1111 Constitution Avenue, NW., Washington, DC 20224.

*OMB Reviewer:* Milo Sunderhauf (202) 395-6880, Office of Management and Budget, room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 92-4613 Filed 2-27-92; 8:45 am]

BILLING CODE 4830-01-M

#### Public Information Collection Requirements Submitted to OMB for Review

Dated: February 20, 1992.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96-511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the

Treasury, room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

Special Request: The Department of the Treasury's Office of the Assistance for International Affairs is requesting approval from the Office of Management and Budget of this information collection by February 21, 1992 in a timely manner.

#### Departmental Offices

OMB Number: New.

Form Number: None.

Type of Review: New collection.

Title: *Questionnaire on State Rules, Laws, and Measures That May Conflict with Proposal in North Atlantic Free Trade Agreement (NAFTA).*

Description: We need to know state laws, rules, and other measures that may conflict with nondiscrimination obligations of the investment chapter of the draft NAFTA agreement. Knowing such measures in advance, and recording them in an annex to the agreement will enable the U.S. to exempt such measures from NAFTA obligations.

Respondents: State of local governments.

Estimated Number of Respondents: 50.

Estimated Burden Hours Per Response: 4 hours.

Frequency of Response: Other (one time).

Estimated Total Reporting Burden: 200 hours.

Clearance Officer: Lois K. Holland, (202) 566-6579, Departmental Offices, room 3171, Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

OMB Reviewer: Milo Sunderhauf, (202) 395-6880, Office of Management and Budget, room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports, Management Officer.

Dear \_\_\_\_\_:

I am writing to ask your help in identifying the laws, regulations or practices ("measures") in your state which treat investment fully or partially owned by foreign investors differently than investments owned by either residents of your state or U.S. citizens.

The U.S. Government is in the process of negotiating a free trade agreement with Mexico and Canada known as the North American Free Trade Agreement ("NAFTA"). The NAFTA will include rules to liberalize investment among parties. The rules will provide rights for U.S. investors and their investments in Mexico and Canada. Just as we are seeking that the rules apply to treatment by all levels of government in Canada and Mexico, Mexico and Canada are

seeking that the rules apply to the treatment of their investors and investments by the U.S. federal, state and local governments.

One basic rule in the NAFTA investment chapter will be that the governments of the NAFTA parties treat investors of other parties, and their investments, no less favorably than they treat domestic investors. In addition, NAFTA parties will also assure that investors from other NAFTA parties will be treated no less favorably than investors from outside the NAFTA territory.

Under our proposal investors of the parties will have the right to take a dispute over a measure inconsistent with these nondiscrimination principles to international arbitration. Consequently, the U.S. must also seek to except any current federal, state or local measures which conflict with the rules and which we intend to maintain.

Your state may have laws which conflict with the proposed rules. We have the opportunity to maintain any or all of such conflicting measures if and only if the measures are correctly identified as exceptions in an annex to the agreement. If such measures are not listed, they could be determined to be violations of the agreement.

In order to provide a complete list of such U.S. exceptions, we need your assistance in identifying your state's measures which do not conform to the proposed rules. The attached questionnaire is designed to verify and solicit information on such measures. Since President Bush has stated that he may present the NAFTA to the Congress this year for approval, we need your assistance now.

We have coordinated our questionnaire with another request for information to an official of your state from the Office of the United States Trade Representative to avoid your having to respond to duplicate questions. The latter questionnaire relates to the services negotiation of the Uruguay Round. Accordingly, for certain of the attached questions, we only ask for information in sectors other than financial services and other service sectors.

Please return completed questionnaires to: Fran Huegel, Department of Treasury, Room 5100, 1500 Pennsylvania Ave., NW., Washington, D.C. 20220.

Ms. Huegel may be reached by phone at (202) 535-6211 and by fax at (202) 786-8453 regarding any questions on the NAFTA or on the questionnaire.

Thank you very much for your prompt assistance.

Sincerely,

Olin Wethington,

Assistant Secretary (International Affairs).

#### NAFTA Investment Questionnaire

*Paperwork Reduction Act Notice:* This is in accordance with the Paperwork Reduction Act of 1980, P.L. 96-511. The information collection is voluntary pursuant to 19 U.S.C. 1101 and is necessary to seek the help of the attorney generals in each of the 50 states to identify laws, regulations or practices which treat investments fully or partially owned foreign investors differently than investments owned by either residents of the state or U.S. citizens.

*Burden Estimate Statement:* The estimated average burden associated with this

collection of information is 4 hours per individual respondent. Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be addressed to the Office of International Investment, Room 5100 Main Treasury Building, 15th & Pennsylvania Avenue, NW., Washington, DC 20220 and the Office of Management and Budget, Paperwork Reduction Project (1505-XXXX), Washington, DC 20503.

**Note:** For the purposes of this questionnaire, "foreign investor" means a national other than a U.S. national or a company fully or partially owned by a national other than a U.S. national, whether the investment is made directly from abroad or through a company incorporated in the United States.

1. Last year, in connection with ongoing negotiations in the Organization for Economic Cooperation and Development, the State Department sought a description of the laws of your state which limit ownership by foreign investors, by residents or companies of another state, or otherwise accord foreign investors, or residents or companies of other states, differential treatment. Examples of such differential treatment are:

- Restrictions on land ownership by foreign investors or non-residents;
- Reporting requirements for foreign investors or non-residents;
- Foreign investors or non-residents do not qualify for government small business loans or access to public lands; or
- Foreign investors are not eligible for agricultural loans.

A summary of your response to last year's questionnaire is attached. We would appreciate your confirming whether the attached information on laws in your state remains accurate.

If it is not accurate, please correct the information and provide a reference to the statutory or other authority on which the measure is based.

2. Other than the measures listed for your state in the attachment, do you maintain any measure, in any sector other than a services sector, which upon making an investment or after the establishment of an investment:

- (1) Treats foreign investors differently than U.S. nationals or companies wholly-owned by U.S. nationals; or
- (2) Treats residents or companies of another state differently than residents or companies of your state?

If so, please describe the measure and provide a reference to the statutory or other authority on which the measure is based.

3. For any of the measures listed above, could foreign investors, or residents or companies of another state, receive the same treatment accorded to U.S. nationals or residents of your state by incorporating in your state?

If so, please provide a reference to the statutory or other authority on which the treatment is based.

4. Other than the measures listed on the attachment, does your state maintain any measure, in any sector other than a services sector, which treats one foreign investor differently than another foreign investor

based on the nationality of the investor? A difference in treatment among foreign investors might arise, for instance, if treatment of foreign investors is based on the treatment accorded U.S. investors by that foreign investor's home government ("reciprocity"), or if the treatment accorded the foreign investor is based on a treaty.

If so, please describe the measure and provide a reference for the statutory or other authority on which the measure is based.

5. Do you maintain any measures restricting acquisitions by foreign investors?

If so, please describe the measure and provide a reference to the statutory or other authority on which the measure is based.

6. In your incorporation laws, are there any requirements that any directors or managers be U.S. citizens or residents of your state?

If so, please describe the measure and provide a reference to the statutory or other authority on which the measure is based.

7. If they do not appear in the attachment, please list any subsidies that are not available to foreign investors or non-residents, or are only available to businesses located/incorporated/headquartered/regulated in your state. Examples of possible subsidies include low interest/interest free loans, direct payments, loan guarantees, government financed research and development, and government financed utilities/support services.

8. For any of the measures listed in answers to previous questions, please provide definitions and relevant criteria (e.g., percentage ownership, control, location, etc.) under your state's law of the following terms if they are relevant to your state's measures:

- Resident
- Non-resident
- Foreign
- Domestic
- Alien
- Domestication

9. Please provide the name, address and phone number of an official of your state government that we may contact for clarifications and future updates.

[FR Doc. 92-4627 Filed 2-27-92; 8:45 am]

BILLING CODE 4810-25-M

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## UNITED STATES INFORMATION AGENCY

### Culturally Significant Objects Imported for Exhibition

#### Determination

Notice is hereby given of the following determination: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985, 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978 (43 FR 13359, March 29, 1978), and Delegation Order No. 85-5 of June 27, 1985 (50 FR 27393, July 2, 1985), I hereby determine that the objects to be included in the exhibit, "Picasso and Things: The Still Lifes of Picasso" (see

list<sup>1</sup>) imported from abroad for the temporary exhibition without profit within the United States are of cultural significance. The objects are imported pursuant to a loan agreement with the foreign lender. I also determine that the temporary exhibition or display of the listed exhibit objects at the Cleveland Museum of Art, Cleveland, Ohio, beginning on or about February 26, 1992, to on or about May 3, 1992; at the Philadelphia Museum of Art, Philadelphia, Pennsylvania, on or about June 7, 1992, to on or about August 23, 1992, is in the national interest.

Public notice of this determination is ordered to be published in the Federal Register.

Dated: February 24, 1992.

Alberto J. Mora,  
General Counsel.

[FR Doc. 92-4626 Filed 2-27-92; 8:45 am]

BILLING CODE 5320-01-M

<sup>1</sup> A copy of this list may be obtained by contacting Mr. R. Wallace Stuart of the Office of the General Counsel of USIA. The telephone number is 202/619-5078, and the address is room 700, U.S. Information Agency, 301 Fourth Street, SW., Washington, DC 20547.

## DEPARTMENT OF VETERANS AFFAIRS

### Special Medical Advisory Group, Meeting

The Department of Veterans Affairs gives notice under Public Law 92-463 that a meeting of the Special Medical Advisory Group will be held on March 26-27, 1992, at the Ramada Renaissance Hotel, 999 9th Street, NW., and Department of Veterans Affairs, 801 I Street, NW., Washington, DC. The purpose of the Special Medical Advisory Group is to advise the Secretary and Chief Medical Director relative to the care and treatment of disabled veterans, and other matters pertinent to the Department's Veterans Health Administration. The session on March 26 will convene at 6 p.m. and the session on March 27 will convene at 8 a.m. All sessions will be open to the public up to the seating capacity of the rooms. Because this capacity is limited, it will be necessary for those wishing to attend to contact Ginny Rassman, Office of the Chief Medical Director, Department of Veterans Affairs (phone 202/535-7605) prior to March 24, 1992.

Dated: February 14, 1992.

By Direction of the Secretary.

Diane H. Landis,  
Committee Management Officer.

[FR Doc. 92-4602 Filed 2-27-92; 8:45 am]

BILLING CODE 5320-01-M

# Sunshine Act Meetings

Federal Register

Vol. 57, No. 40

Friday, February 28, 1992

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

## AFRICAN DEVELOPMENT FOUNDATION

Board of Directors Meeting

TIME: 2:30-4:30 p.m.

PLACE: African Development Foundation.

DATE: Monday, 09 March 1992.

STATUS: Open.

### Agenda

1. Chairman's Report.
2. President's Report.
3. Other.

If you have any questions or comments, please direct them to Ms. Janis McCollim, Executive Assistant to the President, who can be reached at (202) 673-3916.

Gregory Robeson Smith,  
President.

[FR Doc. 92-4702 Filed 2-26-92; 9:02 am]  
BILLING CODE 6116-01-M

## FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Changes in Subject Matter of Agency Meeting

Pursuant to the provisions of subsection (e)(2) of the "Government in the Sunshine Act" (5 U.S.C. 552b(e)(2)), notice is hereby given that at its open meeting held at 2:03 p.m. on Tuesday, February 25, 1992, the Corporation's Board of Directors determined, on motion of Director C.C. Hope, Jr. (Appointive), seconded by Director Robert L. Clarke (Comptroller of the Currency), concurred in by Director T. Timothy Ryan, Jr. (Office of Thrift Supervision), Vice Chairman Andrew C. Hove, Jr., and Chairman William Taylor, that Corporation business required the withdrawal from the agenda for consideration at the meeting, on less than seven days' notice to the public, of the following matter:

Memorandum and resolution re: Delegations of Authority to the Resolution Trust Corporation's Division of FSLIC Operations.

The Board further determined, by the same majority vote, that Corporation business required the addition to the agenda for consideration at the meeting on less than seven days' notice to the public, of the following matter:

Resolution re: Expression of Appreciation to Director Robert L. Clarke (Comptroller of the Currency) for His Years of Service on the Corporation's Board of Directors.

By the same majority vote, the Board further determined that no earlier notice of the changes in the subject matter of the meeting was practicable.

Dated: February 26, 1992.  
Federal Deposit Insurance Corporation.  
Robert E. Feldman,  
Deputy Executive Secretary.  
[FR Doc. 92-4768 Filed 2-26-92; 2:15 pm]  
BILLING CODE 6714-0-M

## LEGAL SERVICES CORPORATION BOARD OF DIRECTORS

Operations and Regulations Committee Meeting

TIME AND DATE: A meeting of the Board of Directors Operations and Regulations Committee will be held on March 8, 1992. The meeting will commence at 4 p.m.

PLACE: The Washington Marriott Hotel, 1221 22nd Street, NW., The Dupont Ballroom, Washington, D.C. 20037, (202) 872-1500.

STATUS OF MEETING: Open.

MATTERS TO BE CONSIDERED:

### OPEN SESSION:

1. Approval of Agenda.
2. Approval of Minutes of February 16-17, 1992 Meetings.
3. Consideration of Draft Request for Proposals for Demonstration Project Funding.
4. Consideration of Staff Proposal on Timekeeping.
5. Consideration of Report by Staff Competition Committee.

CONTACT PERSON FOR INFORMATION:  
Patricia Batie, Executive Office, (202) 863-1839.

Date Issued: February 26, 1992.  
Patricia D. Batie,  
Corporate Secretary.  
[FR Doc. 92-4764 Filed 2-26-92; 2:14 pm]  
BILLING CODE 7050-01-M

## LEGAL SERVICES CORPORATION BOARD OF DIRECTORS

Audit and Appropriations Committee Meeting

TIME AND DATE: A meeting of the Board of Directors Audit and Appropriations Committee will be held on March 8, 1992. The meeting will commence at 2:00 p.m.

PLACE: The Washington Marriott Hotel, 1221 22nd Street, NW., The Dupont Ballroom, Washington, DC 20037. (202) 872-1500.

STATUS OF MEETING: Open.

MATTERS TO BE CONSIDERED:

1. Approval of Agenda.
2. Approval of Minutes of February 16, 1992 Meeting.
3. Consideration of Budget and Expenses Through January 1992.
4. Consideration of Report by Grant/Thornton On Corporation's 1991 Financial Audit and Management Report.
5. Consideration of the Inspector General's Comments On the Auditing and Appropriations Committee's Operating Guidelines.
6. Consideration of Public and Staff Comments On the Audit and Appropriations Committee's Operating Guidelines.
7. Consideration of the Audit and Appropriations Committee's Operating Guidelines.
8. Consideration of Management Request to Modify Management and Administration Fiscal Year 1992 Budget Within and Between Line Items.
9. Consideration of Written Rationale Supporting Fiscal Year 1993 Appropriations Request.
10. Consideration of Options to Ensure Adequate Funding for the Micronesian Legal Services Corporation.

### CONTACT PERSON FOR INFORMATION:

Members of the public wishing to comment on the above-referenced matter are requested to contact Patricia Batie at (202) 863-1839 by March 5, 1992.

Date Issued: February 26, 1992.  
Patricia D. Batie,  
Corporate Secretary.  
[FR Doc. 92-4765 Filed 2-26-92; 2:14 pm]  
BILLING CODE 7050-01-M

## LEGAL SERVICES CORPORATION BOARD OF DIRECTORS

Provision for the Delivery of Legal Services Committee Meeting

TIME AND DATE: A meeting of the Board of Directors Provision for the Delivery of Legal Services Committee will be held on March 8, 1992. The meeting will commence at 12:00 p.m.

PLACE: The Washington Marriott Hotel, 1221 22nd Street, N.W., The Dupont Ballroom, Washington, D.C. 20037, (202) 872-1500.

STATUS OF MEETING: Open.

MATTERS TO BE CONSIDERED:

1. Approval of Agenda.

2. Approval of January 12, 1992 Meeting Minutes.

3. Consideration of Procedures for Proposals for Corporation Grants.

4. Consideration of the Corporation Policy Governing Interstate Subgrants.

5. Consideration of Vehicles Through Which the Corporation Could Assist LSC-Funded Grantees To Recruit and Retain Staff Attorneys.

**CONTACT PERSON FOR INFORMATION:**  
Patricia Batie, Executive Office, (202) 863-1839.

Date Issued: February 26, 1992.

Patricia D. Batie,

*Corporate Secretary.*

[FR Doc. 92-4766 Filed 2-26-92; 2:14 pm]

**BILLING CODE 7050-01-M**

# Corrections

Federal Register

Vol. 57, No. 40

Friday, February 28, 1992

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

## FEDERAL MARITIME COMMISSION

### Ocean Freight Fowarder License Revocations

#### Correction

In notice document 92-3758 appearing on page 6026 in the issue of Wednesday, February 19, 1992, make the following correction:

In the third column, "*License Number: 2990*" should read "*License Number: 2900*".

BILLING CODE 1505-01-D

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 88N-0003]

RIN 0905-AA06

### Antacid and Acetaminophen Combination Drug Products in a Solid Dosage Form; Marketing Status for Over-the-Counter Human Use; Notice of Enforcement Policy

#### Correction

In the correction to notice document 92-2727 appearing on page 6165 in the issue of Thursday, February 20, 1992, make the following correction:

In the second column, in the second paragraph, in the second line, "second" should read "third".

BILLING CODE 1505-01-D

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Consumer Participation; Open Meeting

##### Correction

In notice document 92-3867 appearing on page 6122 in the issue of Thursday, February 20, 1992, in the second column, under **SUPPLEMENTARY INFORMATION**, in the last line, "decision" should read "decisions".

BILLING CODE 1505-01-D

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 558

### New Animal Drugs for Use in Animal Feeds; Butynorate, Phenothiazine, Piperazine in Combination

#### Correction

In rule document 92-3865 appearing on page 6072 in the issue of Thursday, February 20, 1992, make the following corrections:

1. In the first column, in the **SUMMARY**, in the fourth line from the bottom, "chicks" should read "chickens".

2. In the second column, under **SUPPLEMENTARY INFORMATION**, in the first paragraph, in the third line from the bottom, "piperazine," should be removed.

#### §558.4 [Corrected]

3. In the third column, in the amendatory instruction to § 558.4, in the first paragraph, in the third line, "table for" should read "table by".

BILLING CODE 1505-01-D

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 558

### New Animal Drugs for Use in Animal Feeds; Certain Drug Combinations Involving Melengestrol Acetate, Monensin, Lasalocid and Tylosin

#### Correction

In rule document 92-3301 beginning on page 5052 in the issue of Wednesday, February 12, 1992, make the following correction:

On page 5053, in the first column, under **SUPPLEMENTARY INFORMATION**, in the second paragraph, in the fourth line from the bottom, "(C)(4)(ii)" should read "(c)(4)(ii)".

BILLING CODE 1505-01-D

**Final Rule**

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**Friday  
February 28, 1992**

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**Part II**

**Department of  
Health and Human  
Services**

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**Health Care Financing Administration  
Public Health Service**

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**42 CFR Part 405, et al.  
Clinical Laboratory Improvement  
Amendments of 1988; Final Rule**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Care Financing Administration**

**Public Health Service**

**42 CFR Parts 405, 410, 416, 417, 418, 440, 482, 483, 484, 485, 488, 491, 493, and 494**

[HSQ-176-FC]

RIN 0938-AE47

**Medicare, Medicaid and CLIA Programs; Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA)**

**AGENCY:** Health Care Financing Administration (HCFA), and Public Health Service (PHS), HHS.

**ACTION:** Final rule with comment period.

**SUMMARY:** This final rule revises regulations applicable to laboratories and implements provisions of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578. The regulation applies to laboratories that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. They specify the performance requirements, based on 19 test complexity and risk factors related to erroneous test results, that apply to laboratories that are subject to CLIA. They also list requirements for laboratories performing certain limited testing to be eligible for a certificate of waiver. These laboratories will not be inspected routinely, nor will they be required to meet certain other CLIA requirements.

**DATES:** *Effective date:* These rules are effective on September 1, 1992 except as follows: § 493.3 is effective March 30, 1992. For laboratories not subject to 42 CFR part 493 published in the *Federal Register* on March 14, 1990 at 55 FR 9538, prior to September 1, 1992, Subpart H applies January 1, 1994. In addition, § 493.1203 is effective September 1, 1994.

*Comment date:* Written comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on April 28, 1992.

**ADDRESSES:** Mail written comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HSQ-176-FC, P.O. Box 26676, Baltimore, Maryland 21207.

If you prefer, you may deliver your written comments to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland 21207.

Due to staffing and resource limitations, we cannot accept audio, video, or facsimile (FAX) copies of documents. In commenting, please refer to file code HSQ-176-FC. Written comments received timely will be available for public inspection as they are received, beginning approximately three weeks after publication of this document, in room 309-G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: 202-245-7890).

Organizations and individuals desiring to submit comments on the reporting requirements discussed under the section on "Collection of Information Requirements" of this preamble should direct them to the Health Care Financing Administration at one of the addresses cited above, and to the Office of Information and Regulatory Affairs, Attention: Allison Herron Eydt, Office of Management and Budget, New Executive Office Building (room 3002), Washington, DC 20503.

**Copies:** To order copies of the *Federal Register* containing this document, send your request to: Government Printing Office, Attn: New Order, P.O. Box 371954, Pittsburgh, PA 15250-7954.

Specify the date of the issue requested and stock number (069-001-00042-4). Enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or MasterCard number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 783-3238 or by faxing to (202) 512-2250. The cost for each copy is \$3.50. In addition, you may view and photocopy the *Federal Register* document at most libraries designated as U.S. Government Depository Libraries and at many other public and academic libraries throughout the country that receive the *Federal Register*. The order desk operator will be able to tell you the location of the U.S. Government Depository Library nearest to you.

**FOR FURTHER INFORMATION CONTACT:** Wayne Smith, Ph.D., (410) 966-6801.

**SUPPLEMENTARY INFORMATION:**

**Background**

*Historical Review*

On August 5, 1988 (53 FR 29590), HHS published a proposed rule on requirements for clinical laboratories.

The proposal was the result of a Departmental effort to update, consolidate, and recodify into 42 CFR part 493 all requirements applicable to clinical laboratories engaged in testing in interstate commerce, some of which were licensed under the Clinical Laboratories Improvement Act of 1967 (CLIA '67), and laboratories participating in the Medicare and Medicaid programs. The rule was intended to update laboratory requirements, delete obsolete regulations, impose new quality assurance standards applicable to all such laboratories, and make numerous other technical revisions.

Shortly after our publication on August 5, 1988, of the proposed rule, the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, was enacted on October 31, 1988. CLIA greatly revised portions of the Public Health Service Act, the underlying statute for a portion of the August 5, 1988 proposed regulation. Attendant publicity from the public, laboratories, and their personnel generated numerous timely comments that provided an impetus and basis for many changes that we were able to incorporate in a final rule published March 14, 1990 (55 FR 9536). Additionally, the March 14, 1990, rule included several self-implementing provisions of CLIA (for example, proficiency testing and cytology). On the other hand, we chose not to make proposed personnel requirements final so that we could propose and establish personnel standards that are in accordance with testing performed, as mandated by CLIA. The March 14, 1990 final rule, then, has been the basis for regulating the quality of laboratory services while we are going through the rulemaking procedure to implement fully the provisions of CLIA.

On May 21, 1990 (55 FR 20896), we published as a proposed rule an expanded 42 CFR part 493 which would incorporate many CLIA requirements. For sake of completeness and due to some reorganization of text, we repeated in our proposal virtually the entire part, which had the consequence of allowing public comment on many of the CLIA changes that had been incorporated in the March 14, 1990 final rule by reason of either their self-executing nature or public comment suggesting they be added to the rule as proposed on August 5, 1988. This final rule addresses issues raised in connection with our proposed rule of May 21, 1990 (55 FR 20896). Readers interested in additional background may wish to review the preamble to that rule

as well as the preamble to the other cited proposals or rules.

#### *Regulation Requirements to Implement CLIA*

CLIA established a new section 353 of the Public Health Service (PHS) Act to replace the existing section 353. New section 353 requires the Department of HHS to establish certification requirements for any laboratory that performs tests on human specimens, and certify through issuance of a certificate that those laboratories meet the certificate requirements established by HHS. Also, the legislation contains certificate requirements and specifies circumstances that permit waiver of the certificate. The law also includes requirements for approval of accreditation bodies and State licensure bodies, inspections, sanctions, judicial review, fees, and disclosure of information to the public.

Section 6141 of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89), Public Law 101-239, requires that laboratories participating in the Medicare program comply with CLIA requirements. Subject to specified exceptions, laboratories must have a current unrevoked and unsuspended certificate to be eligible for reimbursement in the Medicare or Medicaid programs or both.

This rule implements the following sections of CLIA:

- Section 353(a) Definitions.
  - Section 353(b) Certificate Requirements.
  - Section 353(d) Requirements for Certificates.
  - Section 353(c) Issuance and Renewal of Certificates.
  - Section 353(f) Standards.
  - Section 353(g) Inspections.
- We are implementing the following sections through separate rulemakings which we may refer to in subsequent discussion in this preamble.
- Section 353(e) Accreditation.
  - Section 353(h) Intermediate sanctions.
  - Section 353(i) Suspension, Revocation and Limitation.
  - Section 353(j) Injunctions.
  - Section 353(k) Judicial Review.
  - Section 353(l) Sanctions.
  - Section 353(m) Fees.
  - Section 353(p) State laws.

#### *Related Rulemaking Activities*

On August 3, 1990 (55 FR 31758), we published a proposed rule that set forth the requirements that all laboratories must meet to apply for and be issued a registration certificate, certificate of waiver, certificate, certificate of accreditation, or be licensed by an

approved State licensure program as being exempt from CLIA requirements. It also set forth the methodology for determining the amount of fees for the certificates and the fee schedules for determining a laboratory's compliance with CLIA standards. The final rule is published elsewhere in this issue of the Federal Register.

On August 20, 1990 (55 FR 33936), we published a proposed rule that set forth the criteria we would use to approve and withdraw approval of State or private accreditation programs. The final rule is under development. Upon the effective date of this rule, accreditation programs and State licensing organizations can apply for recognition of their programs under CLIA.

On April 2, 1991 (56 FR 13430), we published a proposed rule that set forth the rules and sanctions that we would consider imposing on laboratories that do not meet Federal requirements instead of, or before suspending, limiting, or revoking the laboratory's certificate and canceling the laboratory's approval to receive Medicare payment for its services. The final rule concerning sanctions appears elsewhere in this issue of the Federal Register.

#### **Actions Taken to Develop Final Rules**

##### *Analysis of Comments*

The May 21, 1990 proposed rule generated a response from approximately 60,000 public commenters. Each commenter's letter was screened and comments were associated with like or related comments. Many comments were identical, indicating that form letters had been developed. After association of like comments, they were placed in categories based on subject matter or portion of the regulation affected, and reviewed. All general comments similarly were reviewed and considered. This process led to development of possible changes which needed to be reviewed in terms of their effect on policy, consistency, or clarity of the rules.

##### *Use of Consultants from Outside HHS*

The Public Health Service (PHS) held several work sessions in Atlanta with technical experts. These individual consultants were not part of any advisory committee, and no group consensus was sought at any of the sessions. The PHS obtained the technical expertise of each consultant in order to assist in its internal deliberations to develop a practical and effective regulation. This process of

using consultants after the close of a comment period to assist the agency in assessing an NPRM is within the agency's authority and discretion and has been upheld in *United Steelworkers v. Marshall*, 647 F.2d 1189 (D.C. Cir. 1980). Copies of the summaries of the work sessions held in June, July and September, 1991 have been associated with the rulemaking record and are available for review by the public. Copies may be reviewed on Monday through Friday of each week from 8:30 a.m. to 5 p.m. at the Health Care Financing Administration, Regulations Staff, room 132 East High Rise Building, 6325 Security Boulevard, Baltimore, MD 21207 (phone: (410) 966-4659). They also may be reviewed during the same times in room 309-G of our Department's offices at 200 Independence Ave., SW., Washington, DC (phone: 202-245-7890).

##### *Principles for Developing Final Rules*

The huge outpouring of public interest with thousands of technical comments required that we approach them with clear goals. The principles evolved as we analyzed the many comments and found that there were several major concerns, summarized below.

- Most commenters, in summarizing their views, predicted that, if the NPRM were made final, access to convenient, low cost, accurate laboratory testing would be severely curtailed, especially in rural areas, and costs throughout the system would increase dramatically.

- The complexity model (which CLIA requires be used in regulating laboratories by test, as opposed to our regulating laboratories by location under current rules) in the proposed rule, based almost entirely on a system of classifying analytes, did not adequately represent "real world" testing patterns and did not adequately account for the multitude of methodologies and instruments in current use, thereby rendering, in the opinion of the commenters, the classification scheme in the proposed rule essentially unworkable as a regulatory model.

- The use of personnel qualifications as the sole differentiating characteristic between Level I and Level II testing resulted in a far greater number of laboratories (for example, physician's offices, rural health clinics) being required to meet the more stringent Level II requirements, since far more laboratories would have become Level II laboratories under the analyte classification system than we anticipated in the NPRM.

- Most commenters, while strongly supportive of proficiency testing (PT) as

a valuable educational tool in the overall laboratory quality assurance scheme, felt strongly that the use of PT in a punitive way defeats the value of PT and encourages cheating.

Consequently, numerous changes have been incorporated in these final rules based on the following principles:

- The final rules should not unduly impede current laboratory practice in *all* testing that is subject to the requirements of CLIA.

- The complexity model should include analytes, methodologies and current and emerging technologies, including a recognition that never before regulated laboratories will require some length of time to achieve compliance with these requirements.

- The final rules should provide greater flexibility to accommodate testing environments, such as physician office laboratories, nursing homes, health fairs, etc.

- The final rules should maintain at their core a reliance on strong patient test management, quality control, quality assurance and proficiency testing (PT) requirements as the basis of good laboratory practice, all under the responsibility of a director and trained, qualified staff.

#### Highlights of Major Revisions

We earlier noted the principles used in developing the final rules and the major areas of concern that prompted their development. In view of the large number of commenters and their interest in several specific areas of regulation, the following is a description of major changes made from the proposed rule in response to comments. Elsewhere in this preamble we discuss the rationale and considerations leading to the adoption of a particular change.

- We have modified the criteria for the categorization of analytes and have included test systems/assays/examinations in the categorization scheme.

There are still 3 categories of test systems/assays/examinations:

—*Certificate of Waiver*—The criteria for the revised list of waived tests include (1) simple and accurate methodologies, as to render the likelihood of erroneous results negligible, (2) pose no reasonable risk of harm if performed incorrectly, or (3) are cleared by FDA for home use.

Only 8 tests have been determined to meet these criteria. They are:

- dipstick/tablet urinalysis (includes 10 analytes)
- ovulation test kits
- urine pregnancy test
- erythrocyte sedimentation rate (non-automated)

- hemoglobin (copper sulfate)

- fecal occult blood

- blood glucose by glucose monitoring devices cleared by FDA specifically for home use.

- spun microhematocrit

Laboratories which conduct only tests on the waived list are eligible for a certificate of waiver and will not be inspected routinely, nor will they be required to meet certain other CLIA requirements. They are expected, however, to adhere to good laboratory practices.

—*Tests of Moderate Complexity and Tests of High Complexity*—Test systems, assays, and examinations have been classified as moderate or high complexity using the following differentiating criteria: (1) Knowledge needed to perform the test, (2) training and experience required, (3) complexity of reagent and materials preparation, (4) characteristics of operational steps, (5) availability of calibration, quality control and PT materials, (6) troubleshooting and maintenance required, and (7) degree of interpretation and judgement. Using these criteria, virtually hundreds of test systems, assays, and examinations have been classified as moderately complex, while fewer, highly specialized tests (for example, cytogenetics, histopathology, histocompatibility, cytology, and some highly specialized tests in other specialties) have been classified as high complexity.

The expansion of tests in the moderate category coupled with a categorization of test systems, assays, and examinations, enables each laboratory to determine easily what level of regulation it must follow. The intent in this final rule is that testing environments not eligible for a certificate of waiver, and which do not conduct highly specialized testing, will be certified to perform moderate complexity testing.

- We continue to view personnel standards as a significant differentiating element in the regulation of moderate and high complexity testing. However, in response to the major concerns raised about personnel requirements, we have significantly revised the personnel requirements. For moderate complexity testing, the director remains responsible and accountable for the safety and accuracy of the testing conducted. We have ensured that most directors currently conducting laboratory testing (including physicians) will either qualify under the final rule immediately or will be able to qualify within a year. If the director does not have a needed skill, he

or she must use the services of a technical and/or clinical consultant. In addition, individuals who, as of September 1, 1992, are serving as laboratory directors and must have qualified or could have qualified under 42 CFR part 493, published March 14, 1990, would remain qualified under this rule. Individuals with a high school degree and training and experience can serve as testing personnel. These changes should not cause current laboratory personnel to lose their jobs. The director's responsibilities are numerous and specific since the director is ultimately responsible for the laboratory operation. We have emphasized personnel performance as well as credentials of personnel employed in laboratories performing moderate complexity testing. Since we placed only the most difficult test systems, assays, and examinations in the high complexity category, we strengthened somewhat the high complexity testing personnel requirements by requiring individuals conducting such testing to have, at a minimum, an associate degree in science. Until September 1, 1997, we will allow a high school graduate to perform high complexity testing under the on-site supervision of a general supervisor. The director requirements remain at the M.D., D.O. or doctoral levels, or previously qualified under the March 14, 1990 regulation. For certain qualifications where employees have to upgrade their education in order to meet the regulatory requirements, we have provided a phase-in period to allow time for completion of the necessary coursework. Most importantly, we stress that the personnel requirements refer to roles rather than to individuals, so that a qualified person can assume more than one role. For example, a director can serve as a technical supervisor as well, if he or she is qualified to do so.

- Generally, we have retained the 5 challenges per testing event in the PT requirements, but we have reduced the number of events from 4 to 3 per year. We estimate that this change will still result in identifying poorly performing laboratories, and will be more workable for PT programs and laboratories alike. We have provided laboratories that will be subject to Federal rules for the first time sufficient time to adjust and comply with these regulations by permitting laboratories until January 1, 1994 to enroll in an approved PT program. However, laboratories currently subject to March 1990 rules must continue to participate in PT. Likewise, we would not impose sanctions for failure to participate

successfully in PT in the first year, though laboratories would be required to correct whatever problems lead to failure. (Of course, immediate action would be taken if the failure suggests that patient health and safety is jeopardized.)

- We have attempted to make the sections dealing with patient test management, quality control, and quality assurance as flexible and adaptable to a wide variety of testing environments as possible while ensuring the quality of preanalytical, analytical, and postanalytical phases of testing. If the physician conducts the test for his or her own patient, the patient record will suffice as the "requisition," as well as the "report."

- We have included a new quality control provision that, when fully implemented September 1, 1994, will enable a laboratory to meet quality control requirements by following manufacturer's instructions, if the manufacturer's instructions are determined by the FDA under its medical devices approval process to be in compliance with the CLIA requirements. This provision also involves a phase-in of the full range of ways a laboratory can meet the quality control requirements and not only provides greater flexibility to laboratories in how they meet quality control requirements, but it provides manufacturers with an incentive to ensure that their instructions provide for strong quality control measures.

- We have retained the role of the Technical Advisory Committee, now identified as the Clinical Laboratory Improvement Advisory Committee (CLLAC) in the final rule. This committee will assist HHS in resolving technical and scientific issues as well as reevaluating criteria used for categorizing test systems, assays, and examinations.

- We have made significant changes to the cytology requirements as well. Requirements are now technically and scientifically feasible, while retaining the essential elements to assure quality. In cytology PT, we have reduced the number of testing events from two to one per year, altered the grading system, and eliminated the 500 slide rescreening requirement. We have changed the workload limit to 100 slides per 24 hours and deleted the separate limit for unevaluated slides. We have allowed flexibility in the reporting nomenclature and have altered the slide retention rules. We also have clarified the personnel requirements to ensure that individuals currently screening slides will be able to demonstrate that they meet the qualification requirements.

- In subpart K, Quality Control, reference is made to appendix C of the State Operations Manual (HCFA Publication 7). Appendix C offers guidance to State agency inspectors and occasionally describes protocols which achieve equivalent outcomes to those stated in the regulations. These equivalent protocols are designed to serve as substitutes or alternatives in situations where the quality control (QC) procedures used fall outside of the routine testing methodologies to which the regulation is directed. These protocols are not only less burdensome and in many instances, less costly to the laboratory, but they also accommodate new advances in technology that may not require the time and manual interaction of the procedures still in use by many laboratories for the same testing. These equivalent QC protocols provide the same outcome as the requirements in the regulations; that is, minimum requirements for laboratories that are intended to assure accurate and reliable test results.

Numerous other changes have been made throughout the final rule to articulate the principles we used in the development of the final rule. The net effect of these changes is to ensure that safe and accurate testing occurs throughout the laboratory testing systems while still enabling health care providers to offer convenient, low cost laboratory services in an ever broader range of environments.

#### Organization of Final Rule

This regulation contains revisions to several parts of title 42 of the Code of Federal Regulations (CFR). Because part 493 contains all the rules applicable to laboratories, and in consolidating laboratory provisions in part 493, we make numerous technical and conforming changes to parts 405, 410, 416, 417, 418, 440, 482, 483, 484, 485, 488, 491, and 494, we discuss in this preamble changes to part 493 first, and then discuss in numerical order the other parts of the CFR affected. For the convenience of the reader, we are repeating in this preamble the listing of subparts and sections included in part 493 of these final rules. This portion of the preamble is organized to parallel the construction of the regulation. Following this listing, each subpart's discussion begins with a summary of the provisions of the proposed rule, has a summary of comments and our responses to those comments, and a summary of changes to the regulations. In some instances, changes to one subpart require corresponding changes to another subpart discussed earlier. Readers are cautioned not to rely on any one

summary as exhaustively identifying all changes made to that subpart.

**Note:** The subpart and section headings in this discussion portion may reflect headings that vary from the headings actually shown in the final rule.

The final rule for part 493 consists of the following:

#### Subpart A—General Provisions

##### Sec.

- 493.1 Basis and scope.
- 493.2 Definitions.
- 493.3 Applicability.
- 493.10 Categories of tests by complexity.
- 493.15 Laboratories performing waived tests.
- 493.17 Test categorization.
- 493.20 Laboratories performing tests of moderate complexity.
- 493.25 Laboratories performing tests of high complexity.

#### Subpart B—Certificate of Waiver

- 493.35 Application for a certificate of waiver.
- 493.37 Requirements for a certificate of waiver.
- 493.39 Notification requirements for laboratories issued a certificate of waiver.

#### Subpart C—Registration Certificate and Certificate

- 493.43 Application for registration certificate and certificate.
- 493.45 Requirements for a registration certificate.
- 493.49 Requirements for a certificate.
- 493.51 Notification requirements for laboratories issued a certificate.

#### Subpart D—Certificate of Accreditation

- 493.55 Application for registration certificate and certificate of accreditation.
- 493.57 Requirements for a registration certificate.
- 493.61 Requirements for a certificate of accreditation.
- 493.63 Notification requirements for laboratories issued a certificate of accreditation.

#### Subpart E—[Reserved]

#### Subpart F—General Administration

- 493.638 Registration certificate and certificate fees.
- 493.639 Fee for revised certificate.
- 493.643 Fee for determination of program compliance.
- 493.645 Fee(s) applicable to accredited laboratories/State licensure programs.
- 493.646 Payment of fees.
- 493.649. Methodology for determining fee amount.

#### Subpart G—[Reserved]

#### Subpart H—Participation in Proficiency Testing for Laboratories Performing Tests of Moderate or High Complexity, or Both

- 493.801 Condition: Enrollment and testing of samples.

493.803 Condition: Successful participation.  
 493.807 Condition: Reinstatement of laboratories performing tests of moderate or high complexity, or both, after failure to participate successfully.

**Proficiency Testing by Specialty and Subspecialty for Laboratories Performing Tests of Moderate or High Complexity, or Both**

493.821 Condition: Microbiology.  
 493.823 Standard; Bacteriology.  
 493.825 Standard; Mycobacteriology.  
 493.827 Standard; Mycology.  
 493.829 Standard; Parasitology.  
 493.831 Standard; Virology.  
 493.833 Condition: Diagnostic immunology.  
 493.835 Standard; Syphilis serology.  
 493.837 Standard; General immunology.  
 493.839 Condition: Chemistry.  
 493.841 Standard; Routine chemistry.  
 493.843 Standard; Endocrinology.  
 493.845 Standard; Toxicology.  
 493.849 Condition: Hematology.  
 493.851 Standard; Hematology.  
 493.853 Condition: Pathology.  
 493.855 Standard; Cytology; gynecologic examinations.  
 493.857 Condition: Immunohematology.  
 493.859 Standard; ABO group and D (Rho) typing.  
 493.861 Standard; Unexpected antibody detection.  
 493.863 Standard; Compatibility testing.  
 493.865 Standard; Antibody identification.

**Subpart I—Proficiency Testing Programs for Tests of Moderate or High Complexity, or Both**

493.901 Approval of proficiency testing programs.  
 493.903 Administrative responsibilities.  
 493.905 Nonapproved proficiency testing programs.

**Proficiency Testing Programs by Specialty and Subspecialty**

493.909 Microbiology.  
 493.911 Bacteriology.  
 493.913 Mycobacteriology.  
 493.915 Mycology.  
 493.917 Parasitology.  
 493.919 Virology.  
 493.921 Diagnostic immunology.  
 493.923 Syphilis serology.  
 493.927 General immunology.  
 493.929 Chemistry.  
 493.931 Routine chemistry.  
 493.933 Endocrinology.  
 493.937 Toxicology.  
 493.941 Hematology (including routine hematology and coagulation).  
 493.945 Cytology; gynecologic examinations.  
 493.959 Immunohematology.

**Subpart J—Patient Test Management for Moderate or High Complexity Testing, or Both**

493.1101 Condition: Patient test management; moderate or high complexity testing, or both.  
 493.1103 Standard; Procedures for specimen submission and handling.  
 493.1105 Standard; Test requisition.  
 493.1107 Standard; Test records.  
 493.1109 Standard; Test report.  
 493.1111 Standard; Referral of specimens.

**Subpart K—Quality Control for Tests of Moderate or High Complexity, or Both**

493.1201 Condition: General quality control for tests of moderate or high complexity, or both.  
 493.1202 Standard; Moderate or high complexity testing, or both: Effective from September 1, 1992 to September 1, 1994.  
 493.1203 Standard; Moderate or high complexity testing, or both: Effective beginning September 1, 1994.  
 493.1204 Standard; Facilities.  
 493.1205 Standard; Test methods, equipment, instrumentation, reagents, materials, and supplies.  
 493.1211 Standard; Procedure manual.  
 493.1213 Standard; Establishment and verification of method performance specifications.  
 493.1215 Standard; Equipment maintenance and function checks.  
 493.1217 Standard; Calibration and calibration verification procedures.  
 493.1218 Standard; Control procedures.  
 493.1219 Standard; Remedial actions.  
 493.1221 Standard; Quality control records.  
 493.1223 Condition: Quality control—specialties and subspecialties for tests of moderate or high complexity, or both.  
 493.1225 Condition: Microbiology.  
 493.1227 Condition: Bacteriology.  
 493.1229 Condition: Mycobacteriology.  
 493.1231 Condition: Mycology.  
 493.1233 Condition: Parasitology.  
 493.1235 Condition: Virology.  
 493.1237 Condition: Diagnostic immunology.  
 493.1239 Condition: Syphilis serology.  
 493.1241 Condition: General immunology.  
 493.1243 Condition: Chemistry.  
 493.1245 Condition: Routine chemistry.  
 493.1247 Condition: Endocrinology.  
 493.1249 Condition: Toxicology.  
 493.1253 Condition: Hematology.  
 493.1255 Condition: Pathology.  
 493.1257 Condition: Cytology.  
 493.1259 Condition: Histopathology.  
 493.1261 Condition: Oral pathology.  
 493.1263 Condition: Radioassay.  
 493.1265 Condition: Histocompatibility.  
 493.1267 Condition: Clinical cytogenetics.  
 493.1269 Condition: Immunohematology.  
 493.1271 Condition: Transfusion services and bloodbanking.  
 493.1273 Standard; Immunohematological collection, processing, dating periods, labeling, and distribution of blood and blood products.  
 493.1275 Standard; Blood and blood products storage facilities.  
 493.1277 Standard; Arrangement for services.  
 493.1279 Standard; Provision of testing.  
 493.1283 Standard; Retention of samples of transfused blood.  
 493.1285 Standard; Investigation of transfusion reactions.

**Subpart L—[Reserved]**

**Subpart M—Personnel for Moderate and High Complexity Testing**

493.1401 General.

**Laboratories Performing Moderate Complexity Testing**

493.1403 Condition: Laboratories performing moderate complexity testing; Laboratory director.  
 493.1405 Standard; Laboratory director qualifications.  
 493.1407 Standard; Laboratory director responsibilities.  
 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant.  
 493.1411 Standard; Technical consultant qualifications.  
 493.1413 Standard; Technical consultant responsibilities.  
 493.1415 Condition: Laboratories performing moderate complexity testing; clinical consultant.  
 493.1417 Standard; Clinical consultant qualifications.  
 493.1419 Standard; Clinical consultant responsibilities.  
 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel.  
 493.1423 Standard; Testing personnel qualifications.  
 493.1425 Standard; Testing personnel responsibilities.

**Laboratories Performing High Complexity Testing**

493.1441 Condition: Laboratories performing high complexity testing; laboratory director.  
 493.1443 Standard; Laboratory director qualifications.  
 493.1445 Standard; Laboratory director responsibilities.  
 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor.  
 493.1449 Standard; Technical supervisor qualifications.  
 493.1451 Standard; Technical supervisor responsibilities.  
 493.1453 Condition: Laboratories performing high complexity testing; clinical consultant.  
 493.1455 Standard; Clinical consultant qualifications.  
 493.1457 Standard; Clinical consultant responsibilities.  
 493.1459 Condition: Laboratories performing high complexity testing; general supervisor.  
 493.1461 Standard; General supervisor qualifications.  
 493.1463 Standard; General supervisor responsibilities.  
 493.1467 Condition: Laboratories performing high complexity testing; Cytology general supervisor.  
 493.1469 Standard; Cytology general supervisor.  
 493.1471 Standard; Cytology general supervisor responsibilities.  
 493.1481 Condition: Laboratories performing high complexity testing; cytotechnologist.  
 493.1483 Standard; Cytotechnologist qualifications.  
 493.1485 Standard; Cytotechnologist responsibilities.

- 493.1487 Condition: Laboratories performing High Complexity testing; testing personnel.
- 493.1489 Standard; Testing personnel qualifications.
- 493.1495 Standard; Testing personnel responsibilities.

*Subparts N and O—[Reserved]*

*Subpart P—Quality Assurance for Moderate or High Complexity Testing, or Both*

- 493.1701 Condition: Quality assurance for moderate or high complexity testing, or both.
- 493.1703 Standard; Patient test management assessment.
- 493.1705 Standard; Quality control assessment.
- 493.1707 Standard; Proficiency testing assessment.
- 493.1709 Standard; Comparison of test results.
- 493.1711 Standard; Relationship of patient information to patient test results.
- 493.1713 Standard; Personnel assessment.
- 493.1715 Standard; Communications.
- 493.1717 Standard; Complaint investigations.
- 493.1719 Standard; Quality assurance review with staff.
- 493.1721 Standard; Quality assurance records.

*Subpart Q—Inspection*

- 493.1775 Condition: Inspection of laboratories issued a certificate of waiver.
- 493.1777 Condition: Inspection of all laboratories not issued a certificate of waiver or a certificate of accreditation.
- 493.1780 Condition: Inspection of accredited and State-exempt laboratories.

*Subpart R—[Reserved]*

*Subpart S—[Reserved]*

*Subpart T—Consultations*

- 493.2001 Establishment and function of the Clinical Laboratory Improvement Advisory Committee.

**Response to Public Comments**

Because of the large volume of public comments that we usually receive on rules, we cannot acknowledge or respond to them individually. However, we will address all public comments that we receive by the date specified in the "DATES" section of this preamble and respond to them in the preamble to any subsequent final rule issued.

**Collection of Information Requirements**

The following sections of this rule contain information collection requirements that are subject to the Office of Management and Budget (OMB) review under the Paperwork Reduction Act of 1980:

Sections 493.35, 493.37, 493.39, 493.43, 493.45, 493.49, 493.51, 493.55, 493.57, 493.61, 493.63, 493.801, 493.823, 493.825, 493.827, 493.829, 493.831, 493.833, 493.835, 493.837, 493.841, 493.842, 493.845, 493.851, 493.855,

493.859, 493.861, 493.863, 493.865, 493.901, 493.903, 493.911, 493.913, 493.915, 493.917, 493.919, 493.923, 493.927, 493.931, 493.933, 493.937, 493.941, 493.945, 493.959, 493.1101, 493.1103, 493.1105, 493.1107, 493.1109, 493.1111, 493.1201, 493.1205, 493.1211, 493.1213, 493.1215, 493.1217, 493.1218, 493.1219, 493.1221, 493.1223, 493.1227, 493.1229, 493.1231, 493.1233, 493.1235, 493.1239, 493.1241, 493.1245, 493.1247, 493.1249, 493.1253, 493.1255, 493.1257, 493.1259, 493.1261, 493.1263, 493.1265, 493.1267, 493.1269, 493.1271, 493.1273, 493.1275, 493.1283, 493.1425, 493.1701, 493.1703, 493.1705, 493.1707, 493.1715, 493.1717, 493.1719, 493.1721, 493.1775, 493.1777, 493.1780, and 493.2001.

Public reporting burden for this collection of information is estimated to average 134 hours per response including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. This estimate may vary significantly in each laboratory, depending upon: (1) The variety of tests and test systems used in the laboratory; (2) the volume of tests conducted; (3) the number and variety of proficiency testing programs in which the laboratory enrolls; and (4) how extensively the laboratory used manual vs. computerized management systems. This estimate is targeted to a "typical" comprehensive reference laboratory. The estimate could be much less for a very small laboratory, such as a physician office laboratory, and higher for a huge interstate laboratory that conducts millions of tests per year. These reporting and recordkeeping requirements are not effective until cleared by the Office of Management and Budget. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Office of Financial Management, HCFA, P.O. Box 26684, Baltimore, Maryland 21207, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503. A notice will be published in the Federal Register when approval is obtained.

*Subpart A—General Provisions*

Summary of the Proposed Rule

*Section 493.1 Basis and Scope*

In § 493.1, Basis and scope, we proposed that all laboratories as defined under "laboratory" in § 493.2, Definitions, would be subject to the requirements specified in part 493. However, this rule would not apply to any laboratory or component or function of a laboratory that maintains a valid certification by the National Institute on

Drug Abuse for the performance of forensic urine drug testing. The laboratories subject to CLIA certification provisions on January 1, 1990, include, but are not limited to the following entities that perform test procedures or examinations:

- Accredited hospital-based facilities;
- Nonaccredited hospital-based facilities;
- Federal hospitals, such as military, and Public Health Service hospitals;
- Independent laboratories;
- Critical care units;
- Physician office laboratories;
- Skilled nursing facilities;
- End stage renal disease facilities;
- Intermediate care facilities, including intermediate care facilities for the mentally retarded;
- Laboratories associated with tissue banks and tissue repositories;
- Ambulatory surgical centers;
- Rural health clinics;
- Laboratory Accreditation Program of the College of American Pathologists (CAP) Accredited, New York State Approved, and low volume exempt laboratories;
- Industrial laboratories that monitor employee health and test for drugs of abuse;
- Insurance company laboratories;
- City, State and county laboratories;
- Federal clinics; and
- All other facilities that perform laboratory tests such as: Planned Parenthood clinics, mobile laboratories, drug screening laboratories, and health maintenance organizations and any other facility including pharmacies and health fairs that perform quantitative, qualitative or screening test procedures or examinations.

Laboratories that perform research testing on human specimens, but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patient would be exempt from the CLIA regulations.

*Section 493.3 Applicability*

In proposed § 493.3, Applicability, we restated the CLIA requirement that any laboratory, as defined in § 493.2, may not perform tests on materials derived from the human body unless the laboratory has a certificate issued by the Department of Health and Human Services (HHS) applicable to the category of procedures performed by the laboratory. This is specified in the law under certificate requirements. Section 6141 of OBRA '89 amended the Social Security Act to require that Medicare

laboratories meet the CLIA certification requirements.

Several commenters inquired as to whether *in vivo* and externally attached patient dedicated monitoring devices (for example, pulse oximetry, SvO<sub>2</sub> pulmonary artery catheters, extra corporeal blood gas testing and capnographs) are subject to the provisions of CLIA. While it is possible that eventually this testing will be determined to be subject to CLIA by definition, the issue of whether this testing involves "materials derived from the human body," as CLIA uses the term, has not been resolved. Therefore, until the definitional and technical issues have been resolved, *in vivo* and externally attached patient dedicated monitoring is not subject to CLIA. Should it be determined at a later date that it is subject to CLIA, proper notice and opportunity for public comment will be provided before this testing is subject to CLIA.

While we have always required laboratories to identify and perform only tests for which the laboratory is approved and propose to continue to do so in this regulation, we were interested in receiving comments on whether we should consider some mechanism to permit physicians to conduct testing not included on the laboratory's certificate when the test is essential to emergency patient care or emergency treatment.

Since the tests would not be included on the laboratory's certificate, the laboratory would not be evaluated for compliance with the CLIA requirements for these tests. We asked commenters to respond to the following questions:

What criteria should be developed to allow emergency testing, when appropriate, while providing assurance that these emergency tests are conducted in a manner to ensure quality results?

Should we require prior notification for approval of those laboratories that may need to perform emergency tests not included on their certificates? Should we specify the tests that could be performed in emergency situations although not included on the laboratory's certificate? How would we prevent physicians from using the emergency test authorization to bypass the regulatory requirements? What are the circumstances that would require a physician to perform an emergency test for which the laboratory is not certified or for which access to a certified laboratory is not possible or feasible?

#### *Section 493.10 Categories of Tests by Complexity*

We proposed to establish three levels of tests by complexity: Certificate of

waiver tests as defined in § 493.15; level I tests as defined in § 493.20; and level II tests as defined in § 493.25. We proposed that only one certificate would be issued to a laboratory. Laboratories performing only certificate of waiver tests would be issued a certificate of waiver; laboratories performing one or more tests not on the list of waived tests, would be issued a certificate. The certificate would reflect the complexity of tests the laboratory performed—waiver, level I or level II or any combination of complexity of testing. For example, if a laboratory performed certificate of waiver, and level I and level II tests, the certificate would specify certificate of waiver, level I, including appropriate specialties/subspecialties, and level II, including appropriate specialties/subspecialties. Regardless of the combination of tests performed by a laboratory, level II standards would be applied only to level II testing, level I standards would be applied only to level I testing and no standards, as specified under section 353(f) of the PHS Act, would be applied to certificate of waiver testing.

HHS designated the PHS, specifically the Centers for Disease Control (CDC) and the Food and Drug Administration (FDA) as the components within PHS responsible for providing scientific expertise in the evaluation of tests and methodologies as they relate to the provisions of certificate of waiver and testing complexity. Beyond certificate of waiver tests, which were not subject to regulation, we proposed two levels of test complexity (level I and level II) that would be subject to a standards enforcement program. The tests proposed for the certificate of waiver and level I lists were selected after an extensive review of existing State licensure requirements and comments from voluntary professional organizations. Test categorization was based upon specific criteria outlined in our discussion of proposed §§ 493.15 and 493.20, respectively. Twenty-eight tests were proposed as tests qualifying for certificate of waiver. These were simple tests which we proposed as procedures that pose no reasonable risk of harm to the patient even if the test were performed incorrectly. Eleven tests were proposed for level I testing complexity. We proposed that these tests were relatively simple to perform but that there may be a reasonable risk of harm to the patient if they were performed incorrectly.

We recognized that a number of tests which can be performed using diagnostic medical devices deemed Class I or Class II under the Food and Drug Administration's (FDA) regulatory

process would not be classed as waived or Level I tests under the proposed rules. This could be the case even for some relatively simple and reliable Class I *in vitro* diagnostic medical devices. (Class I is the FDA category for devices which, because they present little or no hazard to the patient, are subject to only general regulatory controls such as labelling requirements, reporting of adverse experience, and good manufacturing practices.)

We believed it appropriate that many devices regulated under Class I or II standards be subject to the proposed level I or II laboratory requirements. The FDA mandate and regulatory efforts have a different and narrower focus than does the legislation underlying these proposed rules. The FDA process is intended to assess a device when used according to the manufacturer's instructions, that is, the assessment is based on information provided by the manufacturer. And, as the criteria reflected, we felt that the technology was only one important factor in the overall quality of the testing process. Many contextual factors, such as the adequacy of the sample size, whether the device has been misused or maintained correctly, the skills of the person operating the machine or using the device, and the clinical context, would also affect the accuracy and reliability of tests. Thus, we did not feel a one-on-one comparison between the FDA Class I category and the waiver category of the rule could be made.

In order to accommodate emerging technology, advances in instrumentation, new test methodologies, and changing clinical needs, we proposed the creation of a technical advisory committee. This group would be comprised of individuals representing the providers and users of laboratory services and would have the responsibility for making recommendations to HHS. We proposed that this committee have the following functions:

- An ongoing review of test complexity criteria;
- The periodic review of requests for test classification or reclassification; and
- The periodic review of quality control/quality assurance standards for level I and level II test performance.

Tests that involved a new methodology or new instrumentation would be considered level II tests until the Technical Advisory Committee had evaluated the new tests and HHS had made a decision on the appropriate level of test complexity for publication in the **Federal Register**.

In the proposed rule, we asked commenters to provide their recommendations on this review process.

#### *Section 493.15 Laboratories Performing Waived Tests*

We proposed to establish the requirements that a laboratory must meet to qualify for a certificate of waiver. We also included in this section a list of proposed tests that could be performed by these laboratories.

As specified in section 353(d)(3) of CLIA, we considered the following criteria in the selection of tests qualifying for certificate of waiver:

- No reasonable risk of harm to the patient if the test is performed incorrectly, such as tests which are used to detect non-pathologic conditions, tests which are not used as the only indication of underlying disease, or tests used in situations which do not usually require immediate clinical intervention and are generally followed-up with more specific testing or medical evaluation;

- The likelihood of erroneous results is negligible;

- Simplicity of testing method. Tests do not usually involve complicated instrumentation, calibration, extensive quality control, reagent preparation, multiple steps, or environmental control. In addition, they are characterized by stable test systems which have minimal or no calculations, require a minimal degree of independent judgment, a minimal degree of interpretation, minimal or no patient preparation, minimal or no sample preparation, and minimal training and experience; and
- Availability of home use methodology.

We proposed that laboratories performing certificate of waiver tests would not be subject to the requirements in the regulations for proficiency testing (PT), patient test management, quality control, personnel, quality assurance, routine inspections or computer systems. Thus a laboratory issued a certificate of waiver would not need to meet requirements of the subparts dealing with Participation in Proficiency Testing, Patient Test Management, Quality Control, Laboratory Information Systems, Personnel, and Quality Assurance. However, we proposed that these laboratories would be subject to random inspections to verify that only certificate of waiver tests were performed, to investigate complaints, and to collect information for the addition, deletion, or continued inclusion of tests on the waiver list.

We proposed that the concept of waiving certain tests from regulations

should not be misconstrued to mean that these tests were "foolproof," or that the person performing the test need not adhere to the basic tenets of quality control and quality assurance. It would only mean that these tests, because they had met the criteria outlined above, would be exempt from Federal regulation.

In the proposed rule, we specifically asked commenters to make suggestions as to which test should be added to or deleted from the proposed certificate of waiver tests and the reasons for the recommendation.

We proposed that the laboratory would only perform and report tests or examinations that were specified as a waived test in proposed § 493.15.

We proposed that laboratories issued a certificate of waiver would be required to report to HHS within six months any deletions and/or changes in the test methodologies for which a certificate of waiver was issued. Prior to performing a non-waived test or examination, we proposed that the laboratory would be required to notify HHS to upgrade its certificate of waiver to a certificate for the performance of level I or level II tests.

#### *Section 493.20 Laboratories Performing Level I Tests (Now Laboratories Performing Tests of Moderate Complexity)*

We are renaming this section as Laboratories performing tests of moderate complexity because this terminology better describes the tests that meet the criteria specified in § 493.17(a) of the regulations.

We proposed that, to be certified for performance of level I tests, laboratories must limit test performance to those tests listed under certificate of waiver in § 493.15 and one or more of the eleven tests proposed as tests to be categorized as level I tests. The following criteria, listed in priority order, were used to categorize these tests:

- There may be a reasonable risk of harm to the patient if the test is performed incorrectly;

- The risk of erroneous results is present, but is minimized because testing methodologies are not complex and are characterized by: few steps, previously prepared or minimal reagent preparation, equipment which requires few operational steps (minimal interaction between operator and equipment) and is easy to maintain and troubleshoot, minimal calibration requirements—testing systems are often self-calibrated, quality control materials which are readily available, and limited analyst interpretation;

- Test performance involves the exercise of some independent judgment and a basic knowledge of the method, instrumentation, and interpretation of data, but decision-making is less complex because options for action steps are few and are well characterized; and

- Interpretation of test results requires knowledge of a limited number of factors which can influence test results.

In the proposed rule, we specifically asked commenters to make suggestions as to which tests should be added or deleted to the proposed list of level I tests and the reasons for the recommendations.

We proposed to require that laboratories performing level I tests, regardless of their setting, meet the applicable requirements of the following subparts of the proposed regulations: Administration, Participation in Proficiency Testing, Patient Test Management, Quality Control, Laboratory Information Systems, Personnel (for level I tests), Quality Assurance, and Inspection.

We proposed personnel standards for laboratories performing level I tests which would permit the director (who would be qualified under current requirements as an M.D., D.O., or Ph.D. or qualified under State law or "grandfather" provision) to select and train his or her analysts. Analysts would not be required to have baccalaureate degrees, but rather could be high school graduates or the equivalent. We understood that these proposed requirements might exceed those in existing physician office laboratories and hospital-based settings. In the proposed rule, we requested that commenters provide data describing additional benefits and costs that might result from the proposed personnel standards and asked for alternative suggestions.

#### *Section 493.25 Laboratories Performing Level II Tests (Now Laboratories Performing Tests of High Complexity)*

We are renaming this section Laboratories performing tests of high complexity because this terminology better describes the tests that meet the criteria specified in § 493.17(a) of the regulations.

We proposed to define laboratories performing level II tests as those facilities performing one or more tests not included on the certificate of waiver or level I test list. The following criteria were used to categorize level II tests:

- There is a reasonable risk of harm to the patient if the test is performed incorrectly, and for some tests this risk is substantial;

- The risk of erroneous results is substantial because testing methodologies are often complex, usually involving multiple steps and are characterized by: complicated reagent preparation or the requirement for special reagents; equipment which requires multiple operational steps (maximum operator-equipment interaction), complicated/extensive maintenance, and troubleshooting; calibration requirements which may be extensive and require operator intervention; quality control which may require special materials and analyst interpretation;

- Test performance involves the exercise of independent judgment and decisions may require a comprehensive understanding of the method, instrumentation, physiology, interpretation of data and clinical significance of the result;

- Interpretation of test results requires knowledge of the myriad factors which can influence test results, including: preanalytic, analytic, and post-analytic variables; and

- Training is required prior to performing level II testing. In addition to more extensive procedure specific training (reflecting the greater complexity of level II testing), training is included in all aspects of the total testing process.

Regardless of their setting, we proposed to require that laboratories performing level II tests comply with the applicable requirements of Federal, State and local laws, proficiency testing, patient test management, quality control, personnel, quality assurance, inspections and computer systems. However, we solicited public comments on whether there are specific additional *in vitro* diagnostic medical devices which should be subject to the lesser requirements of the certificate of waiver or level I category, rather than level II.

#### *Section 493.30 Categorization of Certificate of Waiver, Level I and Level II Tests (now Subpart T—Consultations)*

We proposed to establish a Technical Advisory Committee (TAC). In this final rule, we are removing § 493.30 and replacing it with a new Subpart T, Consultation, which contains the provisions concerning the TAC, renamed Clinical Laboratory Improvement Advisory Committee (CLIAC).

We proposed to establish a TAC that would assist HHS to revise test complexity criteria and the periodic

review of requests for test classification or reclassification as a waived or level I test. Also, we proposed to use the TAC to evaluate the appropriateness of applicable requirements for proficiency testing, patient test management, quality control, personnel, quality assurance, and computer services for level I and level II tests. This committee was to be comprised of technical professionals representing both the providers and users of laboratory services and would meet on at least an annual basis. We proposed that, following the publication of a final rule, individuals or organizations could submit to HHS in writing, requests for test classification or reclassification. We proposed that these requests must include the following information:

- Name of analyte or test;
- Precise methodology to be employed;
- Degree of independent judgement involved by the individual performing the test;
- Amount of interpretation involved by the individual performing the test;
- Difficulty of the calculations involved;
- Calibration and quality control requirements of test methodology, including instrumentation or equipment used;
- Availability of quality control material;
- Number of reagents and difficulty of preparation of reagents;
- Stability of test systems;
- Patient preparation involved;
- Sample preparation involved;
- Amount of interaction between operator and instrumentation or equipment is operator dependent;
- Factors that can influence test results;
- Specific training required to perform the test or examination, including the operation of the instrumentation or equipment used in the test methodology;
- The specificity, sensitivity, accuracy and precision of the test or the examination and/or methodology;
- Risks to the patient if clinical intervention is initiated based on the results of an incorrectly performed or interpreted test;
- Data to support the validity, accuracy, and reliability of the test when used as intended;
- Intended use of the results; and
- Other factors that HHS may define.

We proposed to develop more complete protocols when the regulations were implemented.

We solicited comments on whether additional information would be needed for review by the committee.

## Comments and Responses

### *Section 493.1 Basis and Scope*

Approximately 4000 comments were received on this section of the proposed rule, over 50 percent were opposed to the requirements. The majority of the commenters represented physicians, particularly those in family practice, and approximately 25 percent of the comments were from the general public.

*Comment:* Over 400 commenters offered recommendations or alternative suggestions to the scope of the proposed rule and its application. Included in these alternatives were suggestions that we—

- Rely on proficiency testing (PT) results to identify problems.
- Permit physician supervision or performance of laboratory tests.
- Permit a physician to serve as the director/technical supervisor of his/her laboratory that performs level II testing.
- Apply regulations only to those laboratories that do not provide accurate testing.
- Allow for technological advances in categorization of tests so that when "state of the art computerized systems" are developed for level II tests, the tests will be recategorized as level I procedures.
- Rely on existing quality control mechanisms employed by facilities in lieu of regulating laboratories under CLIA.
- Regulate manufacturers of laboratory systems rather than the providers of laboratory services.
- Permit "affiliated certification" in which a medical center could assume responsibility for testing performed by affiliated physician office laboratories (POLs).
- Test the regulations in a cross-section of laboratories on a trial basis prior to implementation.
- Delay enforcement of these rules until data supporting the need for such regulation is obtained.

*Response:* Some of these suggestions have been incorporated into the regulations and are addressed in the applicable sections. Regulation of products by the Food and Drug Administration (FDA) does not eliminate the need for Federal oversight of the provision of laboratory services. CLIA specifically requires the regulation of the provision of laboratory services. On the other hand, CLIA and those implementing regulations are not intended to affect FDA's existing jurisdiction under the Federal Food, Drug and Cosmetic act to regulate as devices, products used by providers of laboratory services. With respect to

permitting "affiliated certification", we have modified the regulation to permit multiple sites within a hospital to receive one certificate if they are located at the same street address and under common direction. In addition, not for profit or Federal, State or local government laboratories that engage in limited public health testing may operate under one certificate. In response to the last two suggestions, we are unable to delay enforcement of the regulation or test the regulations on a trial basis since CLIA stipulates specific time frames and effective dates for implementation.

*Comment:* We received many comments suggesting that the following types of facilities be exempt or subject to less stringent regulation:

- Operating room "stat" laboratories;
- Health screening facilities;
- Women, Infant and Children (WIC) clinics and Planned Parenthood facilities;
- Colleges;
- Private practices where physicians perform all tests, POLs with low volumes (less than 500 tests per year);
- Public schools;
- Armed Forces facilities and ships at sea;
- Indian Health Service facilities and Alaska Community Health Aides/Practitioners
- Law enforcement agencies/breathalyzer test;
- Tests performed in the home by home health agencies and hospices;
- Nursing facilities utilizing blood glucose monitors for testing glucose levels in diabetic residents;
- Blood centers and hospital blood banks that are regulated by FDA;
- End-stage renal disease (ESRD) facilities that perform simple laboratory tests necessary for safe dialysis treatment;
- Rural areas; and
- Research laboratories (Commenters suggested that if research laboratories are not exempt, a category should be identified that includes "orphan" laboratory tests. This category should contain tests deemed appropriate by the Clinical Laboratory Improvement Advisory Committee for performance only by research laboratories. They recommended that special regulations developed to apply to these laboratories).

Other commenters believed that the proposed regulations should apply to the following entities:

- Home health agencies; and
- Satellite locations within an institution, such as a hospital or other health care facility that operate independently of the centralized

laboratory, (for example, emergency and operating rooms, nursing stations).

*Response:* Many of the entities asking for exemptions from the law have been previously unregulated. CLIA clearly defines the type of facility subject to regulation and is specific with respect to its applicability to facilities that conduct testing for the medical diagnosis, prevention, or treatment of individuals. Law enforcement agencies that are not determining a health status but rather a legal status are exempt by definition, and § 493.3 has been revised to reflect this exemption.

We are covering Federal laboratories not exempt by definition as a matter of public policy that is consistent with the scope of the public law. We have included a provision which allows us to work with the Department of Defense and other Federal agencies regarding oversight of their laboratories due to the special problems and requirements that these laboratories have. We believe that recipients of laboratory services in the Federal sector deserve the same reliable and accurate testing that other members of the public would receive by virtue of these regulations. We recognize, however, that laboratory operations in the Federal government are not always completely analogous to testing elsewhere and that some accommodations may need to be made to acknowledge these differences. For example, the kind of training given to military personnel to be laboratory technicians may not coincide perfectly with what is required in these regulations. Yet comparable training and qualifications offered by the military may very well result in equivalent testing accuracy and reliability. Accordingly, we have included in the regulations a provision that would enable the Secretary to make accommodations for Federal laboratories when he considers it appropriate to do so. Note that on October 28, 1991, Public Law 102-139 (the Department of Veterans Affairs Appropriation Act of 1991) was signed into law. Therefore, laboratories under the jurisdiction of the Department of Veterans Affairs (VA) will be subject only to regulations the VA publishes and the enforcement authority of the VA. The VA regulations are to be comparable to those issued by HHS.

As we indicated in the preamble of the proposed rule, the list of entities performing laboratory services which would be subject to CLIA was not intended to be inclusive. While we have modified the regulations to respond to concerns raised about access of care if an entity is performing laboratory testing for diagnosis and treatment of

patients, they must meet CLIA requirements. We have made modifications to the application sections to allow certain entities doing limited public health testing to apply for one certificate for all testing sites. See §§ 493.35(b), 493.43(b) and 493.55(b). The facility is responsible for determining whether to apply for one or more certificates to cover multiple testing sites as required in §§ 493.35(a), 493.43(a), and 493.55(a).

*Comment:* A few commenters indicated that standards for decentralized testing, that is, satellite locations, should be as rigorous as those applied to hospital or independent laboratories although they may not be as comprehensive as required in a full service laboratory.

*Response:* The requirements are based on test complexity rather than the location of the laboratory. Thus entities performing tests of certain complexity levels, regardless of location, will be subject to the same requirements that hospital or independent laboratories performing the same tests must meet.

*Comment:* We received a few comments supporting regulation of laboratories testing human specimens but suggested the use of one set of standards for ease of inspection.

*Response:* In establishing the standards, we have attempted to implement the statute which requires the regulation of laboratories based on the complexity of testing. If a laboratory performs a variety of tests in different categories, the laboratory will be subject to varying regulations based on the testing performed. Laboratories performing only waived tests will not be subject to CLIA standards and routine inspections. However, these laboratories have a general responsibility to follow manufacturers' instructions for performing tests.

*Comment:* Several commenters believed that facilities currently in compliance with the Medicare/Medicaid requirements (that is, nursing homes) should be deemed to meet the CLIA rules.

*Response:* If laboratory services are provided by a nursing home that participates in Medicare/Medicaid, the existing requirements for long term care facilities at § 483.75 state that the facility must meet the applicable requirements of part 493. These regulations revise part 493, and any nursing home testing human specimens for health purposes is subject to CLIA. Also, if a facility does not provide laboratory services directly it must have an agreement to obtain laboratory

services from a laboratory which meets the CLIA requirements.

*Comment:* Many commenters recommended that State licensure programs and private accreditation organizations, already operating quality assurance or quality control programs, should be recognized to meet CLIA rules.

*Response:* CLIA authorizes the recognition of accreditation and State programs that have standards equal to or more stringent than the CLIA requirements. Once we publish in the Federal Register the final rule outlining the criteria for recognition of accreditation and State programs, accreditation programs and State programs will be able to apply for recognition under CLIA. Those programs determined to have standards equal to or more stringent than CLIA will be recognized, and a laboratory accredited by an approved accreditation program will be deemed to meet the CLIA requirements provided the laboratory submits an application, meets the application requirements, and pays the appropriate fee for a certificate of accreditation. In addition, laboratories that are licensed by an approved State licensure program would be exempt from CLIA requirements (i.e., State-exempt), as indicated by section 353(p) of the PHS Act.

*Comment:* Many commenters supported laboratory certification requirements and particularly the need for oversight of laboratory testing in all environments. Commenters believed that the regulations would protect public health and ensure that individuals receive services worthy of payment. An overwhelming number of commenters agreed with the need to improve the quality of testing but expressed concern that rural areas of the country would not be able to meet the proposed regulations, particularly the personnel requirements. Commenters noted that economic constraints facing rural areas should be considered and believed that the proposed rule would ultimately result in reducing the quality of health care in rural areas by forcing entities to close, leaving the rural population without ready access to basic health care services.

*Response:* We appreciate the concerns the commenters expressed about the regulations forcing entities to close or no longer offer testing. We have attempted to respond to these concerns, as will be discussed more fully later, by appropriately categorizing tests to reflect the level of regulation needed to ensure accurate testing for patient health and safety, and through more flexible personnel requirements than

those that appeared in the proposed rule.

*Comment:* Several commenters supported the regulation of physician office laboratories (POLs). Many other commenters, representing physicians, military service laboratories, Indian Health clinics, home health agencies, and public health departments, indicated that the overall impact of CLIA would interfere with the provision of services and increase costs to patients who can least afford it. Commenters believed that the proposed regulations were too stringent, would limit access to laboratory services and go beyond the basic requirements necessary to ensure quality and maintain broad access to accurate test services.

*Response:* HHS has specifically reviewed the commenters' concerns and used the suggestions proposed by the commenters to revise the proposed rule, as will be more fully discussed below. In accordance with CLIA, we have made every effort to establish regulations that are commensurate with the simplicity and accuracy of testing as well as the risk of harm to patients due to an incorrect result.

*Comment:* In response to the March 14, 1990 final rule with comment period, one commenter indicated that several provisions of the March 14, 1990 (55 FR 9538) final rule were less restrictive than those enforced by the Medicaid program. The commenter wanted confirmation that a State Medicaid program may continue to impose more restrictive requirements than those implemented under part 493.

*Response:* A State may impose requirements for its Medicaid program that are more restrictive than those contained in part 493.

*Comment:* Several other commenters on the March 14, 1990 final regulations indicated that they should apply to all laboratories, including Federal and State government laboratories and POLs.

*Response:* The prior (March 14, 1990) rule completed the rulemaking initiated to revise Federal requirements for laboratories participating in Medicare, Medicaid and testing specimens in interstate commerce. Although certain provisions of CLIA were implemented as part of the March 14, 1990 rule, the CLIA applicability section was not part of that rulemaking. This final rule for the first time establishes regulation of all entities performing laboratory testing on human specimens for health purposes.

*Comment:* We received a few comments suggesting that the definition of a "challenge" include the amount of substance or analyte measured in a sample because not all substances can

be measured directly. One commenter requested clarification of the difference between challenge and sample.

*Response:* The definition of "challenge" has been changed to incorporate this suggestion. The terms "challenge" and "sample" have been distinctly defined.

*Comment:* A few commenters suggested that referee laboratories not be used to establish target values for proficiency testing since they might use sophisticated methods that could bias the target value. However, they felt that the use of referee laboratories would be valid if PT samples consistently mimicked patient specimens. One commenter suggested that the definition for "reference" be changed to include a laboratory that has a record of satisfactory performance for "a specific analyte" for the purpose of establishing the target value for the analyte.

*Response:* The expanded definition of target value, which specifically permits the use of "by method" target values to assess performance if such "by method" groupings are deemed necessary by the proficiency testing program provider, should correct problems in target value bias due to use of referee laboratories. The suggested rewording for the definition of referee laboratory has been incorporated.

*Comment:* One commenter proposed defining the word sample for ABO and compatibility testing.

*Response:* The definition for sample has been modified to reflect the fact that tests involving a donor and a recipient, such as ABO and compatibility testing, require two separate vials or materials.

*Comment:* One commenter suggested clarifying a screening test as it relates to the proposed Level I test, because it appeared that all Level I tests were screening tests. One commenter recommended a set of specific criteria that a test must meet before it would be categorized as a screening test.

*Response:* Since Level I tests are no longer designated as a "screening test" the term does not need to be defined, and is being deleted.

*Comment:* Many commenters wanted the definition of a "target value" changed to permit a target value based on a "by method" or "peer group" mean as well as the "all result" mean, whichever is determined to be more scientifically valid and appropriate by the proficiency testing service. Commenters were concerned that a single target value could not be used for many analytes due to matrix effects, physical parameters of a measurement or different methodologies used in measuring various properties of an

analyte. A few commenters suggested that the comparative method group be changed from 20 to 10 participants since the use of 20 laboratories could limit the introduction of new technology.

*Response:* The definition of "target value" has been changed to explicitly permit the use of a "by method" or "peer group" mean in assessment of laboratory performance and the number of participants in such groups has been reduced to 10.

*Comment:* A few commenters suggested the following terms be added in the definitions category or more clearly defined so that those affected will understand the requirements: Discharge, exudate, terminated, revoked, suspended, limited, pertinent clinical information, definitive value, investigational status, and standard deviation.

*Response:* The terms discharge and exudate are no longer included in this regulation. The terms terminated, revoked, suspended, and limited are defined in the regulation pertaining to sanctions, which is also published in this issue of the *Federal Register*. The terms pertinent clinical information and investigational status are defined by context. Standard deviation is a mathematically defined term. A definitive value refers to a target value which has been determined using a definitive method. Definitions have been added for the terms accredited institution, performance characteristic, performance specification, reference range, reportable range, unsatisfactory PT performance, and unsuccessful PT performance.

*Comment:* A few commenters noted that under Medicare, payment may be made for laboratory tests ordered by physician assistants. Commenters were concerned that the proposed definition of "authorized person" was not consistent with Medicare coverage policy.

*Response:* We agree with the commenters and have modified the definition of "authorized person" to state that "tests may be ordered by individuals authorized under State law to order tests or receive test results."

*Comment:* Many commenters requested that the definition of "authorized person" be expanded to include individuals authorized under State law to order tests and receive test results, such as nurse practitioners, State, county and municipal health directors, Federal courts, police officers, etc.

*Response:* We agree with the commenters. While we have modified the regulation by deleting specific reference to Medicare concerning the

definition of "authorized person," we have retained that part of the regulation which currently states that an "authorized person" means "individuals authorized under State law to order tests or receive test results." This allows deference to State law in any situation involving the ordering of laboratory tests or examinations.

*Comment:* We received a few comments requesting that the last sentence of the definition of "authorized person" be changed to read, "authorized under State law to order tests and receive test results." Commenters believed that changing the "or" to "and" would be more restrictive and would preclude individuals authorized under State law to receive test results unless such individuals also were authorized to order tests.

*Response:* The intent of the current regulation is to reduce the conflict between Federal and State laws concerning who can order tests and/or receive results. Some States may preclude individuals from ordering tests while allowing them to receive test results. Others may not. We are retaining the existing regulation to allow States to determine who is authorized to order tests and who is authorized to receive results.

*Comment:* Several commenters expressed concern that under the proposed definition of "authorized person," home health care personnel would not be permitted to receive test results and would be restricted from making emergency medical interventions and necessary changes in the patient's plan of care.

*Response:* The regulations have been modified to allow the ordering of laboratory tests or examinations by an authorized person as defined by State law. It would be up to the State to determine who would have this authority, and this determination may vary from State to State. Emergency situations have been addressed at § 493.1109(f) of this regulation in which the laboratory is required to report imminent life-threatening results to the individual or entity requesting the test or the individual responsible for utilizing test results.

*Comment:* One commenter believed that the proposed definition of "authorized person" was more restrictive than existing regulations. The commenter noted that the proposed definition may not be in conformity with CLIA and that such a requirement would force health fairs to stop testing.

*Response:* The regulation, as revised, permits authorized individuals, as defined by State law, to request tests or receive test results. While we have

deleted the part of the proposed definition referencing title XVIII of the Social Security Act, we have retained that portion that defers to State law to define who is authorized to order tests or receive test results, which is in conformance with the section 353(p) of the PHS Act.

*Comment:* A few commenters recommended that the definition of "laboratory" be expanded to require facilities only collecting specimens to be owned and operated by certified laboratories. Commenters believed that the omission of collecting facilities from regulatory oversight provided a loophole that would create unregulated laboratory referral services.

*Response:* Section 353(b) of the PHS Act requires that "no person may solicit or accept materials derived from the human body for laboratory examinations or other procedures unless there is in effect for the laboratory a certificate \* \* \*." If a facility only collects specimens and does not perform testing, the facility would not be subject to CLIA certification requirements because it does not meet the definition of "laboratory" as defined by the statute.

*Comment:* One commenter noted that the definition of a laboratory had been successfully challenged in a related context in the case of *Association of American Physicians and Surgeons, et al. v. Bowen*. The appellate court in this case found that individual physicians offices were not considered to be "laboratories." This commenter noted that while the definition is taken from CLIA language, there was a concern that it may be vulnerable to a similar challenge.

*Response:* CLIA specifically requires the regulation of any facility that performs tests on human beings for " \* \* \* the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings." This would include testing being done in physician offices. Moreover, the CLIA legislative history could not be more clear that one of the primary targets of that legislation was to be physician office laboratories. The statute would have to be changed to alter the regulation of these facilities.

*Comment:* We received a few comments recommending that the definition of "laboratory" be clarified to distinguish between a pathology laboratory and a clinical laboratory.

*Response:* We disagree with the commenter. The term laboratory, which is defined at section 353(a) of the PHS

Act, encompasses both clinical and anatomical services, as well as any facility that performs examination of clinical or pathological materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. The law does not make a distinction between a pathology laboratory and a clinical laboratory, but treats every laboratory equally for the purpose of defining a laboratory.

*Comment:* Several commenters asked that the regulations clarify that facilities that only draw blood specimens or collect patient samples and do not perform testing, would not be considered laboratories.

*Response:* As stated above, facilities that collect specimens, including drawing blood specimens, but do not perform testing of specimens, are not subject to CLIA requirements because they do not meet the definition of a laboratory.

*Comment:* A few commenters noted that in defining a laboratory we did not address location, control, ownership, or direction.

*Response:* The current regulations for laboratories participating in Medicare, Medicaid or interstate testing are based on the location of a laboratory and are uniform with regard to test complexity. However, CLIA requires the regulation of all laboratories according to test complexity without regard to their location. Ownership is defined in regulations concerning sanctions, which is also published today. Requirements for director and location are contained in this regulation.

*Comment:* An overwhelming number of commenters expressed concern that the definition of a laboratory was too broad and did not reflect the intent of the CLIA legislation. Commenters requested that the definition be amended to specifically exclude research laboratories, home health care services, physiological tests, private homes, forensic, police and pulmonary laboratories and public health department screening services.

*Response:* The definition of a laboratory was taken from the statute at section 353(a) of the PHS Act, which clearly defines the type of facility subject to regulation and is specific with respect to its applicability to facilities that conduct testing for the medical diagnosis, prevention, or treatment of individuals. The Basis and Scope and Applicability sections of this regulation specifically indicate entities excluded from CLIA.

*Comment:* We received a few comments objecting to the inclusion of physician office laboratories performing any tests on referred specimens in the scope of the final rule. Commenters felt that the 100 specimen exemption rule should remain in effect until a final regulation is published under CLIA.

*Response:* The statute that provided for the 100 specimen exemption is no longer in effect and has been superseded by CLIA. Therefore, we can no longer exempt laboratories from the regulations on the basis of the number of tests performed.

#### Section 493.3 Applicability

Approximately 500 individuals or organizations provided comments on this section. Approximately 27 percent of the commenters represented police/probation departments, crime laboratories and medical examiners.

*Comment:* Many commenters expressed concern that establishing regulations prior to performing the studies mandated by CLIA was not consistent with the intent of the statute. Commenters believed that proceeding with the regulations prior to the completion of these studies will result in standards developed without scientific evaluative data not supportable by the laboratory community.

*Response:* CLIA sets forth specific time frames for implementation. There is no authority in the CLIA statute to modify the effective date of those provisions by awaiting the results of the studies that the statute mandates. The Public Health Service used available scientific data and information to develop the proposed categorization of procedures and examinations based on test complexity. This regulation was developed with the suggestions and recommendations of the commenters and represents the best information and data available at this time. When the studies required by CLIA are completed, the standards will be revised accordingly if regulatory changes are needed based on the study findings.

*Comment:* Approximately 50 percent of the commenters representing law enforcement agencies, medical examiners and other State agencies indicated the regulations would have a negative impact on their ability to gather evidence for legal purposes. Commenters believed that the ability of criminal justice systems to operate breath/blood/urine screening programs would be jeopardized and emphasized that testing is not performed for the purpose of clinical treatment, medical diagnosis, health assessment or disease prevention.

*Response:* We agree with the commenters. We have determined that CLIA does not apply to such entities, provided that these entities do not conduct testing for "the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health, of human beings." This means that generally, CLIA would not apply to entities, (for example, law enforcement agencies) that conduct such testing to determine whether there is a violation of the law. In the forensic testing context, laboratory results are generated purely for the purpose of detecting illegal substances or illegal amounts of certain substances in the body that may be relevant to legal proceedings. There is no concern in such testing for developing accurate and reliable data for use by health care professionals for the purpose of diagnosis or treatment, which we believe to be the focus of the CLIA legislation. However, if the entity conducts testing for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of, human beings, the entity would be subject to CLIA. The determining factor is not the test itself, but the purpose for which the test is conducted. We have revised the regulation to incorporate these changes.

*Comment:* A few commenters strongly urged that drug testing facilities be included within the scope of these regulations. Commenters believed that although such testing may not be for the purpose of "diagnosis, treatment or prevention" of disease, the same regulatory oversight is warranted since test results are used as evidence in the court system.

*Response:* CLIA is specific with respect to its applicability to facilities that conduct testing for the medical diagnosis and treatment of individuals. Based on the CLIA law and its legislative history, we have determined that forensic testing is excluded under CLIA since forensic testing is conducted to determine if there has been a violation of the law and is not done for the purpose of providing remedial treatment. Urine drug testing that is conducted for non-forensic purposes is covered by this rule.

*Comment:* Several commenters agreed with the extension of Federal standards to all laboratories conducting tests on human specimens exclusive of National Institute on Drug Abuse (NIDA) approved testing and research laboratories.

*Response:* We are pleased that the commenters agreed with the extension of Federal standards to all laboratories, with noted exceptions. It should be noted that significant aspects of testing done by NIDA-certified laboratories will be exempt. We have specified the scope of that exemption in § 493.3(b)(3).

*Comment:* Several commenters expressed concern that the proposed rules would extend HCFA's authority over tests performed primarily for blood donor screening. Commenters indicated that these tests, already regulated under the FDA's Good Manufacturing Practices for blood components, are not performed for the diagnosis, prevention, or treatment of disease in a patient.

*Response:* It is true that FDA regulates this type of testing to some extent; however, the FDA requirements do not necessarily have the same focus as the CLIA requirements (that is, successful participation in a proficiency testing program and personnel requirements). The FDA requirements are product-related, while CLIA requirements are patient-related. Tests such as hepatitis, HIV and syphilis serology, among others, are used in donor screening to assess the health of the person donating blood, one of the activities that come within the statutory definition of "laboratory." Therefore, the performance of these tests must meet CLIA requirements.

*Comment:* Several commenters representing nuclear power companies and offshore drilling industries indicated that laboratory procedures for forensic or substance abuse testing are already subject to comprehensive regulation by the U.S. Nuclear Regulatory Commission (NRC) and the Department of Transportation (DoT). Commenters felt that the NRC and DoT regulations are consistent with and meet the objectives and requirements of these rules and should be exempt from CLIA.

*Response:* As previously indicated, these requirements do not apply to any component or function of any laboratory that is certified by NIDA to perform urine drug testing for Federal agencies. However, it does apply to all other testing conducted even in NIDA-certified laboratories.

*Comment:* Several commenters stated that there is no medical or regulatory need to require End Stage Renal Disease (ESRD) facilities to be certified as laboratories when tests are performed in conjunction with administering treatment to their own patients.

*Response:* Every facility testing human specimens "for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the

health of, human beings" is subject to these requirements. There is no provision in CLIA to exempt testing performed on a facility's own patients.

*Comment:* Numerous commenters representing State, County and local health departments strongly urged that public health laboratories should be categorized separately or exempted from CLIA regulations. Commenters expressed concern that public health service programs dependent on Federal and State funding (e.g., the Women, Infants and Children (WIC) and Early Pregnancy Screening and Diagnostic Testing (EPSDT) programs) would be adversely affected. The commenters noted that available funds would not be sufficient to meet all of the proposed requirements. Other commenters suggested that public health screening programs be exempted from the regulations when testing is performed by trained personnel.

*Response:* As previously indicated, except as noted in § 493.3 of these regulations, every facility testing human specimens "for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings" is subject to CLIA. There is no provision in the statute to exempt private dental offices or public screening programs conducted by trained personnel. However, we have revised the regulation to permit not-for-profit or Federal, State or local government laboratories that engage in limited (that is, few types of tests) public health testing to operate under one certificate.

*Comment:* Several commenters stated that home care testing and private homes should not be subject to CLIA requirements and the rule should be revised to clearly reflect this.

*Response:* Individual patients and private homes are not subject to CLIA. However, a home health agency (HHA) or hospice that performs laboratory testing on individuals for the purpose of medical treatment is subject to the requirements. On the other hand, we acknowledge that certain activities that involve testing are not within the range of concerns that the Congress had when it enacted CLIA. Specifically, we do not believe that the Congress had any wish to see us regulate, as laboratories, individuals who may be self-administering a test in their own home with an appliance that has been cleared for that purpose by the FDA. Thus, to the extent that an HHA or hospice that is providing care in an individual's home is engaged solely in assisting an individual in performing a test, we have no intent to impose a CLIA requirement

on the HHA or hospice by virtue of that activity. If these activities are performed by the individual they would be beyond CLIA's reach. Where the HHA or hospice engages in testing outside this narrow context, however, CLIA would apply.

*Comment:* Several commenters noted that research laboratories including National Institutes of Health (NIH) laboratories perform experimental tests on human specimens and may include test information in the patient's medical record for completeness. Other commenters requested that research laboratories be included in the definition of entities regulated under CLIA to assure that they can continue to receive reimbursement for tests performed.

*Response:* In the proposed rule at § 493.2 under the definition of "laboratory" we indicated that "laboratories that perform research testing on human specimens, but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of an individual patient are not considered laboratories under CLIA." However, this exception was not included in § 493.3, "Applicability." Thus, we have amended this section to reflect this exception for research laboratories. This exception is also set forth in the applicability sections of the regulation pertaining to laboratory fee collection. If the results of such "experimental" testing are used for individual treatment of the patient tested, the laboratory would be subject to CLIA requirements. Additionally, in accordance with OBRA '89, a facility must be certified under CLIA in order to receive payment under Medicare.

*Comment:* In response to our request for recommendations for development of criteria for emergency testing, we received the following suggestions and comments in support of allowing a facility to perform emergency testing, that is, testing not included on the laboratory's certificate. A few commenters indicated that the rules needed to permit exceptions to compliance with the requirements when emergency testing is necessary, but offered no specific recommendations. One commenter cautioned that the term "emergency" must be defined carefully, while another suggested that we define criteria which apply to these emergency situations and define a sub-list of tests which are used in emergency situations only. Other commenters indicated that the need to perform "emergency" testing would occur when a laboratory expands its parameters of testing (for example,

acquires new equipment) and wants to perform testing not included on its certificate. The commenters recommended that laboratories that wish to perform services not included on their certificate be granted a grace period to allow testing during the time period between which the laboratory requests revisions in its certificate and is issued a revised certificate to cover the additional testing. Other commenters expressed concern that if emergency testing were prohibited this would be in conflict with many States "Good Samaritan" laws which require a physician to do anything within his/her knowledge or abilities to aid a person in need of care. Several commenters stated that physicians should be permitted to perform direct microscopic tests (Wright or Gram stains) on an emergency basis or that physicians be permitted to perform tests in a life threatening situation provided the physician has adequate knowledge of the principles and quality assurance of the test. Such commenters felt that the intent of the law would be met if the laboratory that performed emergency tests not included on its certificate notified HCFA subsequent to the testing and immediately filed an application to include the testing on its certificate. As a final point, a commenter stated that it is cost effective and medically necessary for hospitals to perform screening tests for drug treatment facilities and emergency medical treatment. The commenter suggested that the results be reported as values obtained from a screening test with the method specified. Screening tests should be subject to appropriate quality control and PT.

Other commenters were opposed to the idea of an exemption for emergency testing. Approximately 90 percent of individuals and organizations commenting on emergency testing, opposed an exemption for emergency testing. The commenters indicated that if a laboratory is not certified to perform routine testing when the patient's life is not in danger, it should not be allowed to perform emergency testing when the patient's life is in danger. Commenters suggested that improperly performed laboratory work is probably worse than no laboratory work at all. Inaccurate results performed in the name of an "emergency situation" may lead to a more critical situation than already exists. Commenters indicated that permitting emergency testing could be used as a "loop-hole" for laboratories to circumvent the regulations. The reliability of laboratory tests performed by personnel who do not perform the

test routinely and who do not participate in proficiency testing on the emergency tests may produce results that are questionable. In addition, this would not be logical from a cost standpoint. For example, to buy all the reagents and have them sit on a shelf until they might possibly be used is costly and not practical because the reagents have a limited shelf-life. The amount of "red tape" which would have to be developed in order to prove that it was an emergency and therefore should be reimbursed (for Medicare) would be cumbersome. As a final point, in emergencies the treatment of the patient's symptoms is necessary before laboratory results are available. This would almost always be true for a non-certified one-time test where setup of equipment, reagents and control processes would be required. In very few cases would such a test result in a significant difference in patient outcome. It is possible, however, that a badly performed "quickie" test would lead to a mistake in patient care. For a physician or facility to attempt to treat an individual with an emergency condition beyond the capabilities of either the physician or facility would also be a liability nightmare.

*Response:* We never intended to prohibit emergency testing. The proposed rule asked for comments on the appropriateness and conditions under which a laboratory might perform emergency tests not listed on its certificate. In the regulation pertaining to fee collection (also published today), we have indicated that upon further review of CLIA and in response to comments raised in that regulation, a laboratory with a certificate or certificate of accreditation has up to 6 months to notify HCFA if it adds a test or examination not included on its certificate, while a laboratory with a certificate of waiver must notify HCFA prior to performing a test that is not included on the waived test list. These revisions are reflected in this regulation. Due to specific statutory references, we do not feel it is necessary to define "emergency testing."

#### *Section 493.10 Categories of Tests by Complexity*

Approximately 14,470 comments were received in response to this section of the proposed rule, with more than 95 percent opposed to the proposed categorization of tests.

*Comment:* Commenters opposed the overall design of the complexity model. A large number of commenters expressed concern that the use of the proposed model in determining specific requirements for laboratory practices

may have a negative impact on health care due to increased cost, which thus limits patient access. Over 11,000 commenters offered recommendations or alternative suggestions to the proposed categorization of tests and its applications. Some of the alternatives suggested were:

- Consider the site of testing to establish the degree of regulation;
- Create a separate level of testing or an exemption for public health screening procedures, physicians performing testing for their own patients and forensic laboratories;
- Define complexity on the basis of methodology/instrumentation;
- Create a model with only two categories or a model with more than three categories;
- Exempt from regulation or decrease the regulatory burden for testing performed using FDA "cleared" tests/devices; and
- Use a weighted matrix for test/methodology categorization.

*Response:* We agree with the commenters that a regulatory model should not unduly impede current laboratory operations or the practice of medicine, nor should the development or application of new technologies be impeded. We also agree that a complexity model should include the processes for defining levels of complexity, and assigning tests to specific categories, as well as the requirements that are derived from this categorization process. Therefore, in developing the revised model in these regulations, we have considered:

- Complexity of the analytical procedures and laboratory operations; and
- Potential impact of the regulations on the Nation's laboratories.

One organization provided a test categorization matrix and justification for the categorization, which was supported by many commenters. We took this model into consideration as we developed the revised complexity model. Rather than using a model based strictly on analyte, as was previously proposed, we have taken into consideration the methodology for test systems, assays and examinations to categorize laboratory tests as either waived, tests of moderate complexity or tests of high complexity. We believe this revised model for test categorization will not impede health care nor the services provided by any laboratory operation. Laboratories performing tests of moderate complexity will be required to conform to patient test management, quality control, proficiency testing, personnel, and quality assurance

requirements that are appropriate for tests of moderate complexity. Laboratories performing tests of high complexity will be required to adhere to more stringent requirements appropriate for tests of high complexity. Compliance with these standards will assure accurate and reliable test results through the appropriate management and use of technology and personnel having the appropriate skills, knowledge and training. If the appropriate standards are met, a laboratory should be able to continue performing any test in use at the present time.

Under these rules, eight tests now qualify as waived tests. Test categorization was based upon specific criteria outlined in § 493.15(b) of these regulations. Laboratories performing only waived tests are required to apply for a certificate of waiver and have a general responsibility to follow manufacturers' instructions for performing tests.

We have revised the criteria for tests of moderate and high complexity as listed in § 493.17(a). Using these criteria, we developed a scoring scheme for categorizing tests as high or moderate complexity. Within each criteria, tests were assigned scores of 1, 2 or 3 with the score of "1" indicating the lowest level of complexity.

The descriptions for the numerical scores within each criteria heading are as follows:

*Note:* A score of "2" was assigned to a criteria heading when the characteristics for a particular test were intermediate between the descriptions listed for scores of "1" and "3".

#### *Knowledge*

- 1—Analyst needs little, if any, information additional to the step-by-step directions to properly perform the procedure and report results
- 3—Analyst needs experience to acquire the information necessary to properly perform the procedure and report results

#### *Training and Experience*

- 1—Training specific for the procedure is all that is required
- 3—Training and experience with the total testing process is necessary

#### *Reagents and Materials Preparation*

- 1—Minimal preparation (pre-packaged or pre-measured)
- 3—Special reagents or preparation are required

#### *Characteristics of Operational Steps*

- 1—Few steps, automatic specimen processing, and timing of procedural steps, limited function checks, built-in

calibration, and minimal or no calculations required

- 3—Many steps in the procedure and some analytical procedures including calibrations are not automated or are semi-automated

#### *Characteristics of calibration, quality control and proficiency testing materials*

- 1—Calibration and control materials readily available, stable and easily incorporated into the procedure. Proficiency testing materials, when available, are stable
- 3—Calibration, control or proficiency testing materials may not be readily available or stable

#### *Troubleshooting and Maintenance*

- 1—Minimal operator intervention required
- 3—Experience required to properly troubleshoot or maintain the procedure

#### *Interpretation and Judgment*

- 1—Minimal required
- 3—Experience needed to properly perform the test because decision making is required throughout the testing process

Test systems, assays or examinations receiving scores of 12 or less were categorized as moderate complexity while those receiving scores of 13 or greater were categorized as high complexity. Laboratories performing tests of moderate complexity are required to meet the applicable requirements of the subparts concerning: Registration Certificate and Certificate of Accreditation, Participation in Proficiency Testing for Laboratories Performing Tests of Moderate and High Complexity, Patient Test Management for Moderate and High Complexity Testing, Quality Control for Tests of Moderate and High Complexity, Personnel for Moderate and High Complexity Testing (for moderate complexity testing), Quality Assurance for Moderate and High Complexity Testing, and Inspection. Laboratories performing tests of high complexity are required to meet the applicable requirements of the subparts concerning: Registration Certificate and Certificate of Accreditation, Participation in Proficiency Testing for Laboratories Performing Tests of Moderate and High Complexity, Patient Test Management for Moderate and High Complexity Testing, Quality Assurance for Moderate and High Complexity Testing, and Inspection. Laboratories performing tests of high complexity are required to meet the applicable requirements of the subparts concerning: Registration Certificate and Certificate of Accreditation, Participation in Proficiency Testing for Laboratories Performing Tests of Moderate and High Complexity, Personnel for Moderate and High Complexity Testing (for high complexity testing), Quality Assurance

for Moderate and High Complexity Testing, and Inspection.

Following publication of this rule, manufacturers of new commercial test systems, assays or examinations may submit their supporting data to FDA simultaneously with their section 510(k) and pre-market approval (PMA) submissions. The FDA, under authority of CLIA, will determine the complexity category using the previously mentioned criteria, notify the manufacturer and simultaneously inform both HCFA and CDC of the test categorization. In the case of a request for a change of category or for devices/tests that have not been previously categorized, FDA will receive the request application and determine the device/test categorization. In cases when new devices/tests cannot be easily categorized or if a manufacturer appeals an initial categorization decision by FDA, FDA will consult with CDC. Test categorization will be effective as of the notification to the applicant.

For test systems, assays, or examinations not commercially available, a laboratory or professional group may submit a written request to PHS. These requests will be forwarded to CDC for evaluation; CDC will notify the applicant, HCFA, and FDA of its decision. In the case of a request for a change of category or for tests that have not been previously categorized, PHS will receive the request application and forward it to CDC for evaluation. Test categorization will be effective as of the notification to the applicant.

Prior to categorization as provided under this rule, any laboratory test system, assay, or examination that does not appear on the list of tests published in a notice in the *Federal Register* will be considered a test of high complexity until HHS, upon request, reviews and makes a final determination of test categorization. If the request is part of the 510(k)/PMA process, determination of device/test categorization will be completed within the 510(k)/PMA time frame. If the request is not a part of the 510(k)/PMA process, the device/test categorization will be made within 120 days of the request.

Any test system, assay, or examination will be considered for recategorization not more frequently than once per year. We are creating a new § 493.17, Test categorization, which explains the categorization process for test systems, assays and examinations.

PHS will publish updates of test categorizations periodically in the *Federal Register* for comment. The following generic lists containing moderate and high complexity tests are

provided to assist laboratories in evaluating their complexity of testing. These lists may not encompass exact descriptions of all laboratory tests. However, PHS is planning to publish periodic lists of tests in the **Federal Register** which will contain specific test systems, assays and examination by test complexity category, as specified in § 493.17. (We note that published elsewhere today in the **Federal Register** as a Notice we are providing the first listing of specific tests that have been scored for purposes of categorization.)

We are specifically not providing an opportunity for comment prior to the effective date of the decision for two reasons. First, we foresee that for the many tests that will be categorized in either the moderate complexity or waiver category, it would be unfair to both laboratories and manufacturers to further extend the time that a particular test would have to be treated as one of high complexity and thus be subject to stricter regulation than is necessary. Second, by submitting the criteria for the categorization of tests to notice and comment rulemaking, as is the case with this rule, we believe that the public will have already shared in the shaping of the most critical aspect of this process.

Moderate complexity test list. The following test procedures, assays, and examinations are categorized as tests of moderate complexity unless categorized otherwise as provided under § 493.15 (a) or (c):

- (1) *Clinical cytogenetics*. No procedures.
- (2) *Histopathology*. No procedures.
- (3) *Histocompatibility*. No procedures.
- (4) *Cytology*. No procedures.
- (5) *Bacteriology*.
  - (i) Primary culture inoculation;
  - (ii) Urine culture and colony count kits;
  - (iii) Microscopic evaluation of direct wet mount preparations;
  - (iv) Isolation and presumptive identification of aerobic bacteria from throat or urine or cervical/urethral specimens;
  - (v) Isolation and confirmatory identification of aerobic bacteria from throat or urine or cervical/urethral specimens;
  - (vi) Gram stain;
  - (vii) Darkfield examination for *Treponema pallidum*;
  - (viii) Manual procedures with limited steps and with limited sample or reagent preparation;
  - (ix) Manual screening devices for bacteriuria with limited steps and with limited sample or reagent preparation; and
  - (x) Automated procedures that do not require operator intervention during

the analytic process.

- (6) *Mycobacteriology*. Direct acid fast smear.
- (7) *Mycology*.
  - (i) Primary culture inoculation;
  - (ii) Isolation of yeast with identification limited to *Candida albicans*;
  - (iii) Identification procedures for *Candida albicans* (excluding semi-automated and semi-quantitative procedures);
  - (iv) Microscopic evaluation of direct wet mount preparations;
  - (v) Tests using selective media for the presence or absence of dermatophytes;
  - (vi) Microscopic evaluation of KOH preparations;
  - (vii) Manual procedures with limited steps and with limited sample or reagent preparation; and
  - (viii) Automated mycology procedures that do not require operator intervention during the analytic process.
- (8) *Parasitology*.
  - (i) Microscopic evaluation of pinworm preparations;
  - (ii) Microscopic evaluation of direct wet mount preparations for the presence or absence of parasites;
  - (iii) Manual procedures with limited steps and with limited sample or reagent preparation; and
  - (iv) Culture devices indicating the presence or absence of *Trichomonas vaginalis*.
- (9) *Virology*.
  - (i) Manual procedures with limited steps and with limited sample or reagent preparation; and
  - (ii) Automated procedures that do not require operator intervention during the analytic process.
- (10) *Immunology*.
  - (i) Automated procedures that do not require operator intervention during the analytic process;
  - (ii) Darkfield examinations for *Treponema pallidum*; and
  - (iii) Manual procedures with limited steps and with limited sample or reagent preparation;
- (11) *Chemistry (Routine/Endocrinology/Toxicology)*
  - (i) Automated procedures that do not require operator intervention during the analytic process;
  - (ii) Automated blood gas analyses that do not require operator intervention during the analytic process (such as instruments that have an automated process for calibration, sample intake and flushing of sample lines);
  - (iii) Whole blood measurements using test strip meters, excluding glucose monitoring devices cleared by FDA

specifically for home use;

- (iv) Osmolality measurements; and
  - (v) Manual procedures with limited steps and with limited sample or reagent preparation.
  - (12) *Urinalysis*.
    - (i) Microscopic analysis of urinary sediment; and
    - (ii) Automated urinalysis procedures that do not require operator intervention during the analytic process.
  - (13) *Hematology*.
    - (i) Automated hematology procedures without differentials that do not require operator intervention during the analytic process;
    - (ii) Automated hematology procedures with differentials that do not require operator intervention during the analytic process and that do not require an analyst to interpret a histogram or scattergram;
    - (iii) Manual white blood cell differential counts when the analyst is not required to identify atypical cells;
    - (iv) Automated procedures that do not require operator intervention during the analytic process;
    - (v) Manual hematology procedures with limited steps and with limited sample or reagent preparation; and
    - (vi) Manual coagulation procedures with limited steps and with limited sample or reagent preparation.
  - (14) *Immuno-hematology*.
    - (i) Manual or semi-automated procedures with limited steps and with limited sample or reagent preparation; and
    - (ii) Automated procedures that do not require operator intervention during the analytic process.
  - (15) *Other*.
    - (i) Semen analysis for the presence or absence of sperm;
    - (ii) Occult blood on body fluids;
    - (iii) Crystal analysis on joint fluid; and
    - (iv) Viscosity.
- High complexity test list. The following test procedures, assays, and examinations are categorized as tests of high complexity unless categorized otherwise as provided under § 493.15 (a) or (c):
- (1) *Clinical cytogenetics*. All procedures.
  - (2) *Histopathology*. All procedures.
  - (3) *Histocompatibility*. All procedures.
  - (4) *Cytology*. All procedures.
  - (5) *Bacteriology*.
    - (i) Isolation and identification of aerobic and anaerobic bacteria from specimens that are not specified in moderate complexity;
    - (ii) Automated or semi-automated procedures that do require operator

- intervention during the analytic process;
- (iii) Serogrouping or typing;
- (iv) Antigen or toxin test procedures or kits requiring microscopic Avaluation;
- (v) Manual procedures with multiple steps in sample or reagent preparation or the analytic process; and
- (vi) Semi-automated nonculture urine screening devices predicting bacteriuria.
- (6) *Mycobacteriology*.
- (i) Concentration, smear, and primary culture inoculation;
- (ii) Isolation and identification techniques;
- (iii) Antimycobacterial susceptibility testing;
- (iv) Manual procedures with multiple steps in sample or reagent preparation or the analytic process; and
- (v) Automated or semi-automated procedures that do require operator intervention during the analytic process.
- (7) *Mycology*.
- (i) Isolation and identification of all fungi not specified in moderate complexity;
- (ii) Identification techniques requiring interpretative skills;
- (iii) Automated or semi-automated mycology procedures that do require operator intervention during the analytic process; and
- (iv) Manual procedures with multiple steps in sample or reagent preparation or the analytic process.
- (8) *Parasitology*.
- (i) Identification techniques requiring interpretative skills;
- (ii) Concentration or differential staining techniques;
- (iii) Antigen test procedures or kits requiring microscopic evaluation; and
- (iv) Manual procedures with multiple steps in sample or reagent preparation or the analytic process.
- (9) *Virology*.
- (i) Isolation and identification techniques;
- (ii) Antigen test procedures or kits requiring microscopic evaluation;
- (iii) Manual procedures with multiple steps in sample or reagent preparation or the analytic process; and
- (iv) Automated or semi-automated procedures that do require operator intervention during the analytic process.
- (10) *Immunology*.
- (i) Gel based immunochemical procedures;
- (ii) Electrophoresis;
- (iii) Western blot;
- (iv) Immunoassay methods requiring microscopic evaluations;
- (v) Procedures requiring cell or tissue culture techniques;
- (vi) Automated or semi-automated procedures that do require operator intervention during the analytic process;
- (vii) Cell phenotyping and analysis;
- (viii) Radioimmunoassays; and
- (ix) Manual procedures with multiple steps in sample or reagent preparation or the analytic process.
- (11) *Chemistry (Routine/Endocrinology/Toxicology)*.
- (i) Manual procedures with multiple steps in sample or reagent preparation or the analytic process;
- (ii) Atomic absorption;
- (iii) Flame photometry;
- (iv) Electrophoresis;
- (v) Gel-based immunochemical procedures;
- (vi) Blood gas analyses that do require operator intervention to calibrate the instrument, equilibrate gas supplies, introduce sample into measuring chambers or flush sample lines;
- (vii) Automated or semi-automated procedures requiring operator intervention during the analytic process;
- (viii) Anodic stripping voltometry;
- (ix) Radioimmunoassays; and
- (x) Mass spectrometry.
- (12) *Urinalysis*.
- Automated or semi-automated procedures that do require operator intervention during the analytic process.
- (13) *Hematology*.
- (i) Manual reticulocyte counts;
- (ii) Hemoglobin electrophoresis;
- (iii) Bone marrow evaluation;
- (iv) Manual coagulation procedures with multiple steps in sample or reagent preparation or the analytic process;
- (v) Manual cell counts;
- (vi) Automated or semi-automated procedures that do require operator intervention during the analytic process;
- (vii) Manual white blood cell differential counts when the analyst is required to identify atypical cells;
- (viii) Manual hematology procedures with multiple steps in sample or reagent preparation or the analytic process.
- (ix) Flow cytometry; and
- (x) Manual platelet counts.
- (14) *Immunohematology*.
- (i) Manual procedures with multiple steps in sample or reagent preparation or the analytic process;
- (ii) Semi-automated and automated procedures that do require operator intervention during the analytic process; and
- (iii) Compatibility testing, which includes any of the following when performed in the process of determining donor/recipient compatibility:
- (A) Recipient and donor ABO group/D(Rho) type/special antigen typing;
- (B) Direct antiglobulin test;
- (C) Unexpected antibody detection and identification; and
- (D) Crossmatch procedures.
- (15) *Other*.
- (i) Semen analysis (quantitative); and
- (ii) Eye bank microscopy procedures.

#### Section 493.15 Laboratories Performing Waived Tests

Approximately 4,650 comments were received in response to the proposed list of waived tests, while approximately 175 individuals and organizations provided comments on the proposed criteria for certificate of waiver test. About 670 comments were in favor of applying standards for quality assurance, quality control and personnel to certificate of waiver laboratories.

*Comment:* Many commenters suggested changing, adding or deleting the criteria for certificate of waiver. A few suggested that the criterion "no reasonable risk of harm to the patient if the test is performed incorrectly" be deleted.

*Response:* The primary criterion for placing a test on the waived list is that the test is so simple to perform, when following acceptable laboratory practices (that is, not using out-of-date materials, and following manufacturers' directions), that the likelihood of an erroneous result is extremely small. This assessment is based on our determination that the method used for testing involves a stable test system which is simple, requiring no extensive quality control or environmental control. Therefore, based on the characteristics of a waived test, we feel that there is minimal training and experience required in performing these tests and that there is minimal interpretative and judgmental skills required by the analyst.

We agree that there is no test which carries with it absolutely no risk of harm if performed erroneously. If a medical test is performed erroneously and an inappropriate action is taken, risk of harm to the patient may result. However, we do not feel that the tests on the certificate of waiver list present an insignificant risk of an erroneous result and, therefore, are exempt.

The proposed rule included tests cleared by FDA for home use as a criterion for a waived test. We have not deleted this criterion. However, it cannot be a sole criterion for qualifying as a waived test, since all home use tests may not meet the criteria for a waived test.

The criteria for waived tests are:

Test systems that are simple laboratory examinations and procedures which—

- Are cleared by FDA for home use;
- Pose no reasonable risk of harm to the patient if the test is performed incorrectly; or
- Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible.

*Comment:* A large number of commenters suggested modifications to the list of waived tests. Many recommended deleting tests and moving them to either level I or level II (now moderate and high complexity). The majority of commenters suggested moving examinations or tests that require the use of a microscope to a higher level because, according to commenters, these tests or examinations require a higher degree of training and involve independent judgement by the analyst. A very large number of physicians recommended adding to the waived test list those tests used by a physician to treat his/her own patients.

*Response:* Section 353(d)(3) of the PHS Act states that there are "simple laboratory examinations and procedures" that will not be subject to the regulations. Using the criteria outlined in the PHS Act, and in § 493.15(a) of these regulations, eight tests were selected for the waived category. The blood glucose monitors cleared by FDA specifically for home use have been placed in the waived category. Any new tests that have been determined by HHS to meet the criteria for waived tests will be placed in that category by HHS.

A number of the originally proposed 28 waived tests were removed from the list of waived tests because they did not meet the revised criteria for waived tests.

We have taken into consideration the suggestions of the commenters and modified the quality control, personnel, and quality assurance standards of the regulations for non-waived tests which will allow a laboratory currently in operation to continue to perform testing.

As previously mentioned, HHS will determine whether a new test meets or does not meet the criteria for a waived test.

*Comment:* Many commenters suggested that quality control and/or proficiency testing be required for laboratories holding a certificate of waiver. Some commenters recommended that personnel in laboratories performing only waived tests be subject to qualification requirements.

*Response:* Section 353(d)(2)(C) of the PHS Act specifies that quality assurance, quality control, personnel, proficiency testing and inspections should not be applicable to certificate of waivers laboratories. We agree with the commenters that it is the general responsibility of any laboratory performing waived tests to follow manufacturers' instructions for performing tests. This requirement is included in § 493.15(e) of these regulations.

#### *Section 493.20 Laboratories Performing Level I Tests (Now Laboratories Performing Tests of Moderate Complexity)*

Approximately 6,850 comments were received from individuals and organizations objecting to the proposed level I test list. Nearly 2,000 comments concerned the applicability of the quality control, proficiency testing and personnel requirements for level I testing. Approximately 1,250 comments were in opposition to the proposed requirement that abnormal level I screening test results for previously undiagnosed conditions be verified using a more specific level II test method.

*Comment:* Many commenters expressed concern about the proposed criteria for level I tests. A few commenters suggested changing, deleting or adding to these criteria. A few expressed the opinion that "risk of harm" is too vague and indeterminate to be used as a criterion.

*Response:* We have taken into consideration the concerns expressed by the commenters and have provided revised criteria for tests of moderate complexity as stated in § 493.17(a). The proposed rule included a "risk" criterion as well as the criterion pertaining to "the risk of erroneous results is present". These criteria have been deleted. The revised criteria for tests of moderate complexity take into consideration the analyst involvement and the complexity of the test.

*Comment:* Many commenters suggested moving tests from level I to the certificate of waiver category to allow the testing to continue in their laboratory and not interfere with patient care. Other commenters recommended moving tests from the certificate of

waiver to level I because, in their opinion, some of the proposed waived tests required training and involved some degree of judgement and interpretation by the analyst. A very large number of commenters suggested moving tests from level II to level I so as to not impede or interrupt services presently being provided to patients in doctor's offices.

*Response:* We have taken into consideration the commenters' suggestions in revising the list of tests for moderate complexity. Rather than using a model based strictly on analyte, as was previously proposed, we have taken into consideration the methodology for test systems, assays and examinations in categorizing tests.

Using the revised criteria specified in § 493.17(a) and the scoring scheme previously mentioned, some tests that were proposed as waived tests are now categorized as tests of moderate complexity. As a result of this change, performance of these tests is now subject to patient test management, quality control, proficiency testing, personnel and quality assurance standards. Other tests previously proposed as level II tests, when using the new categorization process, are now categorized as tests of moderate complexity. In most instances, these changes should allow a laboratory to continue at their present level of operation and not impede services to patients, provided the laboratory meets the applicable requirements for personnel as stated in Subpart M (Personnel for Moderate and High Complexity Testing) for tests of moderate complexity; patient test management requirements as specified in Subpart J (Patient Test Management for Moderate and High Complexity Testing); quality control standard specified in Subpart K (Quality Control for Tests of Moderate and High Complexity) and quality assurance standards specified in Subpart P (Quality Assurance for Tests of Moderate and High Complexity).

*Comment:* Many commenters opposed the personnel requirements for level I laboratories and suggested changing the personnel requirements for the director to allow specialists, such as physicians and other individuals, to qualify as director of laboratories that are located in areas where there is a shortage of personnel meeting the requirements proposed for level I laboratories. They also stated that the requirements proposed for director of a level I laboratory would unjustifiably exclude many qualified medical professionals from performing this function.

*Response:* In response to the comments, we have revised the personnel standards for laboratories performing tests of moderate complexity. A physician performing tests of moderate complexity may qualify to direct his/her own laboratory as stated in this regulation at § 493.1405(b)(2). The qualifications and responsibilities for personnel for moderate complexity testing are specified in Subpart M (Personnel for Moderate and High Complexity Testing).

*Comment:* A large number of commenters disagreed with the regulation requiring that abnormal level I screening test results be verified by a level II test method.

*Response:* We agree with the commenters and have deleted this proposed requirement, § 493.15(c), from the regulations.

**Section 493.25 Laboratories Performing Level II Tests (Now Laboratories Performing Tests of High Complexity)**

Approximately 16,230 comments suggested changes to the tests included in level II. We received nearly 2,840 comments that expressed concern about the applicability of the personnel, quality control and proficiency testing requirements to level II testing. Approximately 140 comments suggested changes in the proposed criteria for level II tests. A few comments were received concerning paragraph (d) of this section which specified that laboratories that perform level I tests would be subject to the level I personnel requirements and applicable requirements pertaining to proficiency testing, patient test management, quality control, quality assurance, inspections and computer systems.

We received a few comments in response to "whether there are specific additional *in vitro* diagnostic medical devices which should be subject to the lesser requirements of the waived or level I category rather than level II."

*Comment:* Many commenters opposed the criteria for level II tests. Commenters offered various suggestions for changing, deleting or adding criteria for level II tests. A few felt that the "risk" criterion was unclear and could not be consistently applied.

*Response:* We have considered the concerns of the commenters and we have provided revised criteria for tests of high complexity as specified in § 493.17(a). The "risk" criteria in the proposed rule have been deleted. The revised criteria take into consideration the analyst involvement and the complexity of the test.

*Comment:* many commenters recommended moving tests from level II to either the waiver or level I categories. Some commenters suggested moving tests from the waived or level I to the level II category.

*Response:* Using the revised criteria for tests of high complexity and the scoring scheme previously mentioned, many tests that were in level II have been placed in the moderate complexity category. On the other hand, tests that require specialized training, knowledge and experience that were proposed for level I or waived have been recategorized into a higher category of testing using these revised criteria.

As previously mentioned, HHS will determine whether a new test meets or does not meet the criteria for a test of high complexity.

*Comment:* Commenters opposed the personnel requirements for level II laboratories. They expressed concern that physicians in a level I laboratory performing some proposed level II tests could not direct their own laboratory. Some voiced opposition to the proposed quality control and proficiency testing requirements.

*Response:* In developing the complexity model, we have taken into consideration the concerns raised by the commenters and have revised the personnel standards for laboratories performing tests of high complexity. The qualifications and responsibilities for personnel for high complexity testing are specified in subpart M. The quality control standards for tests of high complexity are listed in Subpart K (Quality Control for Tests of Moderate and High Complexity), with the proficiency testing requirements specified in Subpart H (Participation in Proficiency Testing for Laboratories Performing Tests of Moderate and High Complexity). In addition, many of the test systems, assays, and examinations previously categorized as level II are now categorized as tests of moderate complexity. Based on the revised criteria for categorization, physicians who meet the qualifications for director of a moderate complexity laboratory will be able to perform these tests.

*Comment:* A few commenters recommended that all tests should have the same standard (level I and level II) rather than a laboratory which performs more than one level of testing to meet separate requirements for each level.

*Response:* We are retaining the requirement that a laboratory performing tests of moderate complexity will only have to meet the applicable standards for tests of moderate complexity as specified in these regulations, and a laboratory performing

tests of high complexity will have to meet the applicable standards in these regulations for tests of high complexity.

*Comment:* In the preamble to the proposed rule, we requested comments on whether there are specific additional *in vitro* diagnostic medical devices which should be subject to the lesser requirements of the waived or level I category rather than level II. A few commenters suggested that laboratory test/device categorization should be coordinated with FDA categorization and clearance of new devices, but no specific devices were suggested for placement in lower levels of testing.

*Response:* CDC, FDA and HCFA have worked together to revise the complexity model, taking into consideration the review and clearance process of FDA. HHS will serve as the primary decision making body on issues relating to test categorization and recategorization.

**Section 493.30 Determination of Test Levels and Waived Test Requirements**

We received approximately 230 comments in response to the proposed establishment of a technical advisory committee. We received about 15 comments in response to the request for suggestions on information to be submitted for test categorization or recategorization.

*Comment:* The concept of establishing a technical advisory committee was generally supported by the commenters but some expressed concern about the composition of the committee, its functions, and the frequency of meeting. Some of the suggestions were:

- Establish the committee immediately;
- Identify the types of individuals or representatives to be included in the committee;
- Specify the committee responsibilities and functions; and
- Establish a specific frequency for the committee to meet.

Individual commenters provided specific suggestions concerning who should be on the committee, its functions and meeting frequency.

*Response:* Once these rules are effective, a Clinical Laboratory Improvement Advisory Committee will be established by HHS to advise and make recommendations on technical and scientific aspects of this regulation and its provisions. HHS may designate specialized subcommittees as necessary. This committee or designated subcommittees will be composed of individuals involved in the provision of laboratory services, utilization of laboratory services, development of

laboratory testing devices or methodology and others as approved by HHS. The committee, or any designated subcommittee, at the request of HHS, will review and make recommendations concerning:

- Criteria for categorizing tests and examinations;
- Personnel standards;
- Patient test management, quality control, quality assurance standards;
- Applicability of the standards to new technology; and
- Proficiency testing standards

This committee or any designated subcommittee will meet as needed, but not less than once per year. The frequency of meeting depends on the issues referred by HHS to the committee or designated subcommittee for review and evaluation.

*Comment:* One commenter disagreed with the type of information to be submitted with requests for categorization or recategorization and questioned the value of submitting the proposed information.

A few commenters suggested revising the FDA product review process in order to establish a procedure that will initially categorize tests into the appropriate category of testing. One commenter suggested modifying the information to be submitted to include the name and description of the instrument.

*Response:* The specific information to be provided for test categorization or recategorization, as stated in the proposed § 493.30(b), has been deleted. CDC, FDA and HCFA have worked together to revise the complexity model. As previously mentioned, HHS will review and render decisions on categorization for new tests.

## Changes to the Regulation

### Section 493.2 Definitions

The definition of "challenge" is being amended to include the amount of substance or analyte measured. The definition of "referee laboratory" is being clarified to indicate that such laboratories are designated by the proficiency testing program provider and are subsequently reviewed and approved by HHS during the approval process for the proficiency testing program. A laboratory may be designated as a referee laboratory for a test or analyte as well as for an entire specialty or subspecialty. Since proficiency testing in some areas, such as compatibility testing in immunohematology, requires both donor and recipient specimens, the definition of "sample" has been modified to indicate that, for such areas of testing,

two separate vials or materials constitute a sample. Also amended is the definition of "target value" to permit the use of a "by method" or "peer group" mean and to allow ten or more laboratories to constitute a method group.

The definition of "authorized person" is being revised to delete specific reference to Medicare's definition of an authorized person. We are retaining the part of the definition to provide that an authorized person is an individual authorized under State law to order tests or receive test results.

The definition of "laboratory" is being revised to delete reference to laboratories performing research testing on human specimens. Research laboratories have been addressed under § 493.3, Applicability, of this regulation.

Definitions have been added for the terms accredited institution, performance characteristic, performance specification, reference range, reportable range, unsatisfactory PT performance, HHS, and unsuccessful PT performance.

### Section 493.3 Applicability

Excluded from CLIA are any laboratory or its component that performs testing only for forensic purposes, and research laboratories that test human specimens but do not report patient specific results for treatment or diagnostic purposes, or that are certified by NIDA and in which drug testing is performed which meets NIDA guidelines and regulations. These rules do apply to all other testing conducted by a NIDA-certified laboratory.

### Section 493.10 Categories of Tests by Complexity

We are revising the proposed three levels for categorizing tests. We have taken into consideration the methodology for test systems, assays, and examinations and have devised a model that categories all testing as either waived, tests of moderate complexity or tests of high complexity.

### Section 493.15 Laboratories Performing Certificate of Waiver Tests

- Eight tests are now included in the certificate of waiver category.
- We are adding the requirement that laboratories performing waived tests have a general responsibility to follow manufacturers' instructions for performing tests.
- We are adding the process for revisions to the list of waived tests.

### Section 493.17 Test Categorization

- We are adding this section to collectively explain the categorization

process for test systems, assays and examinations. Revised criteria for tests of moderate and high complexity, which are used for categorizing tests, are defined in this section, as well as the scoring system that we developed using each of the criteria.

- We are including in paragraph (b) the process for proposing revisions of the criteria.
- We are including in paragraph (c) the process for categorizing tests after publication of this rule.

### Section 493.20 Laboratories Performing Level I Tests (Now Laboratories Performing Tests of Moderate Complexity)

- We are deleting the test list from this section.
- We are deleting from this section the function of the technical advisory committee, now the Clinical Laboratory Improvement Advisory Committee in the categorization/recategorization of tests.
- We are deleting the requirement that all abnormal level I screening test results be verified by a level II test method.

### Section 493.25 Laboratories Performing Level II Tests (Now Laboratories Performing Tests of High Complexity)

- No substantive changes are made to this section.

### Section 493.30 Determination of Test Levels and Waived Test Requirements

- A new Subpart T, Consultation, is being created which explains the creation, responsibilities, composition and frequency of meeting of the Clinical Laboratory Improvement Advisory Committee or designated subcommittee.
- The requested information to be submitted for test categorization or recategorization, as specified in proposed § 493.30(b), has been deleted.

## Subpart B—Certificate of Waiver

### Summary of the Proposed Rule

#### Section 493.35 Application for a Certificate of Waiver

We proposed that all laboratories, performing only waived tests, must file a separate application for each laboratory location. The application must be filed on a form prescribed by HCFA and signed by the owner or an authorized representative of the laboratory. As required by section 353(d)(1)(A) of the PHS Act, the application would also describe the characteristics of the test procedures or examinations performed by the laboratory including: the total number and types of laboratory tests

and examinations performed; the methodologies for laboratory procedures and examinations employed and the qualifications of the personnel directing and supervising the laboratory and performing the tests. As also required by the PHS Act, the laboratory must agree to make records available and submit reports to HHS, as necessary.

Additionally, we proposed that laboratories performing waived tests must permit unannounced inspections by HHS, as discussed below, on a random basis to verify that they are performing only those tests specified on the waived list in § 493.15, to collect information for the addition, deletion, or continued inclusion of tests on the waived list, to evaluate complaints from the public, and to investigate when HHS has substantive reason to believe that testing is being performed in a manner that constitutes a hazard to patient health and safety.

#### *Section 493.37 Requirements for Certificate of Waiver*

We proposed that for HHS to issue a laboratory a certificate of waiver, the laboratory must meet the general application requirements as well as the specific certificate of waiver application requirements and pay the fee specified by HHS for certificate of waiver. It should be noted that laboratories performing only waived tests would not be issued registration certificates because these laboratories would not be subject to the requirements of CLIA and HHS would not need to determine compliance with the requirements of the subparts dealing with Participation in Proficiency Testing for Laboratories Performing Tests of Moderate and High Complexity, Patient Test Management for Moderate and High Complexity Testing, Quality Control for Tests of Moderate and High Complexity, Laboratory Information Systems, Personnel for Moderate and High Complexity Testing, and Quality Assurance for Moderate and High Complexity Testing. After issuance of a certificate of waiver, we proposed that laboratories, in accordance with § 493.39, must notify HHS before performing and reporting any test not listed as a waived test in § 493.15; within six months of any deletions or changes in test methodologies; and within thirty days of all changes in ownership, name and location. In addition, we proposed that laboratories issued a certificate of waiver must permit unannounced inspections by HHS:

- When HHS has substantive reason to believe that testing is being

performed in a manner that constitutes a hazard to patient health and safety;

- To evaluate complaints from the public;
- On a random basis to determine whether the laboratory is performing non-waived tests; and
- To collect information for the addition, deletion, or continued inclusion of waived tests.

We believe that certificate of waiver laboratories, while exempted from routine inspections under section 353(d)(2)(C) of the PHS Act, are nevertheless subject to extraordinary inspections in these four specific areas through our enforcement authority contained in section 353(i) of the PHS Act. This section reserves to the Secretary the right to make reasonable requests to inspect a laboratory's operations if there is cause to question whether the laboratory is operating in a lawful and safe manner. While subsection (i) speaks to certificates, it is clear from sections 353 (b) and (c) of the PHS Act that this term encompasses certificates of waiver as well. Such inspections would not be routine. Indeed, as a routine matter, certificate of waiver laboratories would not be subject to any inspections as the statute provides. We believe, however, that Congress did not wish to allow any laboratory to operate in a hazardous or otherwise unlawful manner and be beyond the reach of the statute to account for such conduct. If the laboratory fails to meet the requirements for certificate of waiver, we would propose that the laboratory's certificate of waiver be suspended, revoked, or limited in conformance with procedures in a new subpart dealing with enforcement procedures, which are to be established through another rulemaking. Also, failure to meet the certificate of waiver requirements would result in a laboratory losing its Medicare approval and having its payments under Medicare suspended or denied. Ordinarily, a certificate of waiver would be valid for no more than two years. However, in the event of a non-compliance determination, HHS would suspend or deny payments under Medicare and would initiate action to revoke or suspend the laboratory's certificate of waiver. The laboratory would be provided with a statement of grounds outlining the basis for the non-compliance determination and would be offered an opportunity for a hearing in part 498. If the laboratory requests a hearing, we would extend the expiration date of the certificate of waiver until a hearing decision is issued, unless HHS or its designee finds that conditions at

the laboratory pose an imminent and serious risk to human health. In any case, Medicare payments would be suspended or denied pending a hearing decision.

#### *Section 493.41 Requirements for a Renewal Application for a Certificate of Waiver*

To renew a certificate of waiver, we proposed that a laboratory must complete and return a renewal application to HHS not less than 9 months or more than 1 year before the expiration of the certificate of waiver. The requirements for renewal were proposed to be the same as the application requirements in §§ 493.35 and 493.37.

We proposed that the laboratory must remit the certificate of waiver fee and agree to permit unannounced inspections by HHS on a random basis to verify that they are performing only those tests specified on the waived list in §§ 493.15, to collect information for the addition, deletion, or continued inclusion of tests listed in § 493.15, to evaluate complaints from the public and when HHS has substantive reason to believe the laboratory is performing testing in a manner that constitutes a hazard to patient health and safety. If we determine that a laboratory does not meet the requirements and we do not grant a certificate of waiver, we would notify the laboratory in writing of the basis for denial, and offer an opportunity for a hearing in accordance with subpart R.

#### *Comments and Responses*

Approximately 250 individuals submitted comments on subpart B. The majority of the comments were alternative suggestions or were opposed to the content of these sections. The commenters primarily represented technologists, professional organizations, various health care entities and physicians.

#### *Section 493.35 Application for Certificate of Waiver*

*Comment:* Several commenters stated that certificate of waiver laboratories should not be involved in interstate commerce. The commenters recommended that certificates of waiver should be restricted to individual clinicians and the certificate of waiver laboratory should not be permitted to receive tests for analysis from other clinicians.

*Response:* While the PHS Act previously regulated only laboratories engaged in interstate testing, effective January 1, 1990, all laboratories in the

United States that perform tests on human specimens for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of human beings are subject to the requirements of CLIA. Soliciting or accepting specimens across State lines is no longer a criterion for regulation. Therefore, laboratories holding a certificate of waiver are not precluded from engaging in interstate testing. In addition, the statute is specific in stating that a certificate is issued to a "laboratory" (that is, a facility) rather than to individuals.

*Comment:* A few commenters recommended that as a monitoring mechanism, certificate of waiver laboratories should be required to participate in proficiency testing (PT) for tests they perform.

*Response:* Section 353(d)(2)(C) of the PHS Act states that subsection (f) (which includes participation in a PT program) shall not apply to a laboratory which has been issued a certificate of waiver. A certificate of waiver laboratory may participate in PT for its own purposes, but participation is not specifically mandated under CLIA.

*Comment:* Several physicians questioned whether pharmacies, supermarkets and shopping centers should be permitted to perform waived tests. The commenters recommended requiring that certificates of waiver only be granted to laboratories operated by physicians or other authorized individuals who order tests and receive test results for use on their own patients.

*Response:* CLIA does not restrict the performance of waived tests to physicians nor does it require routine inspections or standards, including personnel requirements, for this level of testing. In accordance with the statutory definition, procedures and examinations qualifying as certificate of waiver tests are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result. Based on the statute, we have not made the recommended revision.

*Comment:* Other commenters indicated that military facilities performing only waived tests should be exempt from CLIA. As an alternative another commenter suggested that the regulations provide for "blanket" certificates of waiver to be issued to criminal justice agencies and drug treatment facilities performing testing for patient treatment.

*Response:* Any facility conducting laboratory testing on human specimens for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment

of, or the assessment of the health of human beings is subject to CLIA requirements. If the testing conducted is limited to the tests within the certificate of waiver category, the facility would be able to apply for a certificate of waiver. The statute does not provide for "waiving" certificate of waiver requirements. If the testing performed by a military facility is limited to waived tests, then that facility must apply for a certificate of waiver. The statute also does not authorize the issuance of "blanket" certificates of waiver; however, as noted in § 493.3, if testing is conducted for forensic or research purposes, CLIA would not apply. In addition, as previously indicated, based on recent legislation, laboratories under the jurisdiction of the Department of Veterans Affairs (VA) will be subject only to regulations the VA publishes and the enforcement authority of the VA. The VA regulations are to be comparable to those issued by HHS.

*Comment:* Another commenter stated that there are existing controls which help ensure the quality of care provided by physician operated laboratories (POLs), such as malpractice liability as well as the general need to ensure patient satisfaction and the reputation of the practice, making CLIA unnecessary.

*Response:* The purpose of CLIA is to ensure that appropriate standards are established to ensure quality laboratory testing to improve the diagnosis of disease, management of care for treatment and assessment of health of patients and to avoid or eliminate test errors that might result in patient harm.

*Comment:* One commenter assumed that a certification of waiver laboratory would be exempt from the application requirements and fees associated with certification.

*Response:* The statute sets forth specific requirements for certificate of waiver laboratories at section 353(d)(2) of the PHS Act. These requirements include submission of information describing the characteristics of the laboratory examinations performed and qualifications of personnel. In addition, the statute also requires payment of fees for the issuance and renewal of certificates, except that the Secretary shall only require a nominal fee for the issuance and renewal of certificates of waiver. A separate regulation to be issued to deal with fee collection. (See 55 FR 31758, August 3, 1990 for the proposed rule and today's issue of the Federal Register for the final rule.)

*Comment:* Many commenters indicated that the requirement for a laboratory to file a separate application for each laboratory location would be

burdensome and costly for Federally funded health care clinics which operate at multiple sites under the same procedures and protocols. The commenters also recommended that "location" be defined.

*Response:* We agree with the commenters. In the above cited regulation concerning fee collection, we permit laboratories within a hospital under common direction located at the same street address to apply for a single certificate or multiple certificates. In addition, we permit not-for-profit or Federal, State or local government laboratories that engage in limited (in other words, few types of tests) public health testing to file a single application. Revised § 493.35(a) (as well as other sections) reflects this change. We also are revising the regulation to clarify that a laboratory that is not at a fixed location, that is a laboratory that moves from testing site to testing site (such as health screening fairs), or other temporary testing locations, must file a single application using the address of the home base. Mobile vans providing laboratory testing would require a separate certificate for each van which would reflect the address of the home base.

*Comment:* One commenter asked what are "other procedures" referred to in the regulation ("\* \* \* the characteristics of the laboratory examinations and other procedures \* \* \*"). The commenter was not sure what other procedures laboratories perform, other than laboratory examinations.

*Response:* We agree with the commenters that "other procedures" was vague and are revising the regulation at § 493.35(c)(3) to state "\* \* \* the characteristics of the laboratory operation and the examinations and other test procedures \* \* \*". The statute does not define "examinations or other procedures"; however, "examinations" are usually considered to be those activities related to macroscopic or microscopic evaluation of specimens. "Other test procedures" would be all other specimen analyses performed manually or by instrumentation.

*Comment:* One commenter suggested that some criteria should be set forth by HCFA to define what is meant by operating in a "lawful and safe manner" as described in the preamble with respect to inspecting certificate of waiver laboratories.

While the latitude HCFA has granted is appropriate (that is, indicating that certificate of waiver laboratories are not subject to the requirements concerning

PT, patient test management, quality control, personnel, routine inspections or computer systems), some suggested guidelines (not regulations) should be provided as to what inspectors would review for determining that a laboratory is operating in a safe and lawful manner. For instance, should records be maintained of quality control checks of reagent performance, the expiration dates of kits, or tachometer checks of centrifuges performed with established frequency?

*Response:* We are revising the regulation at § 493.15(d) to indicate that laboratories with a certificate of waiver have a general responsibility to follow manufacturers' instructions for performing the test.

*Comment:* A few commenters expressed concern that the categorization of tests listed in the proposed rule implies a static test categorization system and suggested that in light of changing technology we should not create conditions wherein we will impede or "stagnate" improvements in technology.

*Response:* We are aware that advancements in technology will impact on placing tests in a particular category. Section 493.30 sets forth the procedures that will be followed for test categorization or recategorization, and subpart T discusses the establishment of a Clinical Laboratory Improvement Advisory Committee that will be responsible for suggesting criteria for test categorization as well as evaluating data and information for recommendations to HHS on appropriateness of test categorization.

*Comment:* One commenter asked for clarification concerning the requirement that each laboratory submit "the total number of tests and examinations performed annually" and whether this number is based on the total tests performed the previous year or an estimate of the number of tests that will be performed in the current year.

*Response:* This number should be based on the total number of tests and examinations performed during the previous calendar year. However, as indicated in the final regulation on CLIA fee collection, this total should not include tests performed for purposes of quality control, quality assurance or proficiency testing. We are revising the regulations at §§ 493.35, 493.43, and 493.55 to clarify this issue.

*Comment:* One commenter suggested that laboratories performing Moh's micrographic surgery be classified under certificate of waiver until standards and methods for review of such laboratories are established. The commenter suggested that such standards could be

developed by a task force established by HCFA.

*Response:* As previously discussed, tests categorized as waived tests must meet the criteria specified in § 493.15(a). If such categorization is questioned, § 493.15(c) outlines the procedures to revise the list of waived tests.

*Comment:* Several commenters indicated that the proposed rule requires submission of qualifications of the personnel directing and supervising the laboratory and performing the examinations, as part of the certificate of waiver application process; however, there are no personnel requirements for the director or supervisor of this type of laboratory (certificate of waiver).

*Response:* It is true that there are no specific regulations pertaining to the qualifications of a director or a supervisor in a certificate of waiver laboratory. However, the CLIA statute at section 353(d)(2)(A)(i)(II) requires submission of this information by all applicants for a certificate of waiver. In addition, the application process is used to identify the individual(s) responsible for laboratory testing performed. In many instances the same individual will serve as supervisor and director in a certificate of waiver laboratory.

*Comment:* Several commenters suggested that the rule be revised to specifically exclude nursing facilities (NFs) certified under § 483.75(1) and intermediate care facilities for the mentally retarded (ICF/MRs) certified under § 483.460(m) from unannounced inspections. Inasmuch as NFs and ICF/MRs are currently subject to unannounced, routine, extended, special, complaint, and validation surveys under Medicare and Medicaid, the commenters felt that an additional unannounced inspection to investigate certificate of waiver testing would be redundant and an unnecessary expenditure of resources.

*Response:* An NF or ICF/MR which only performs those tests listed as waived tests must apply for a certificate of waiver but will not be subject to routine inspections. If an NF or ICF/MR performs tests other than those categorized as waived tests it would be subject to the requirements applicable to the level of testing conducted, including unannounced inspections. States may coordinate the Medicare/Medicaid compliance surveys for NF or ICF/MR certification with CLIA compliance activities. However, this may not be possible in all instances. In addition, inspections will be conducted on a biennial basis under CLIA rather than the more frequent intervals required for Medicare/Medicaid certification of NFs and ICF/MRs. The Medicare and

Medicaid regulations have been revised to reference the CLIA requirements for entities providing laboratory services.

*Comment:* Several commenters indicated that unannounced inspections would disrupt the daily schedule and could possibly interfere with patient care.

*Response:* Section 353(g) of the PHS Act permits the Secretary to conduct inspections on an announced or unannounced basis. In conducting inspections for Medicare program purposes, we have found unannounced inspections provide a more valid assessment of a provider's or supplier's day-to-day operations. In addition, in recent years Congress has specifically mandated that Medicare and Medicaid surveys of nursing homes be unannounced. We will make every attempt to conduct inspections in a manner that will not disrupt the facility's operations.

*Comment:* One commenter suggested that no decertification proceedings should be initiated if a laboratory fails to meet the application requirements, until an onsite review of such a facility determines why such problems exist, how they can be corrected, or that decertification is in order.

*Response:* The regulation states that if an application for a certificate of waiver is denied HHS will notify the laboratory in writing of the basis for denial of the application and an opportunity for a hearing as provided in subpart R. In addition to providing an opportunity for a hearing, the final rule concerning Enforcement Procedures for Laboratories, also published today, provides for reconsideration of actions that are initial determinations. Any laboratory dissatisfied with HHS' denial of its application may request a reconsideration. We have revised the regulation to indicate that laboratories may request an appeal, which includes a reconsideration. Since certificate of waiver laboratories will not be subject to routine onsite inspections for compliance determinations, it would serve no purpose to conduct an onsite inspection if the application for a certificate of waiver is denied.

*Comment:* One commenter suggested that certificate of waiver laboratories be exempt from the subparts concerning Administration, Participation in Proficiency Testing for Laboratories Performing Tests of Moderate and High Complexity, Patient Test Management for Moderate and High Complexity Testing, Quality Control for Tests of Moderate and High Complexity, Laboratory Information Systems, Personnel for Moderate and High

Complexity Testing, Quality Assurance for Moderate and High Complexity Testing, and Inspection. Certificate of waiver laboratories should only be required to submit information on the type of testing performed and pay the required fee.

*Response:* The regulations at § 493.35 do not require certificate of waiver laboratories to comply with the requirements of the aforementioned subparts. While certificate of waiver laboratories are not subject to routine biennial inspections, as required under the subpart dealing with Inspections, they must, in accordance with § 493.37, agree to permit unannounced inspections by HHS as specified in the subpart dealing with Inspection. Section 493.37 outlines the specific requirements for certificate of waiver laboratories.

#### *Section 493.37 Requirements for a Certificate of Waiver*

*Comment:* Several commenters suggested that if a laboratory test has no reasonable risk of harm to a patient if performed incorrectly, has a negligible likelihood of erroneous results and can be performed by anyone, then perhaps it does not need to be ordered and performed, and certainly not billed.

*Response:* Although a laboratory test may not pose a risk of harm to the patient if performed improperly, this does not diminish the importance of the testing. The categorization of a test as a waived test simply indicates that the test is simple and has an insignificant risk of an erroneous result. Moreover, the statute requires that tests falling into this category come within CLIA's scope. To the extent that the commenters are expressing an opinion about the necessity for certain kinds of testing, such considerations are beyond the scope of CLIA and this rulemaking.

*Comment:* One commenter, a State medical association, stated that criteria for placing laboratory tests within a level based on "no reasonable risk of harm to the patient if performed incorrectly" was a medically indefensible concept. The commenter stated that since virtually all testing (depending on the medical condition of the patient) has the potential to harm a patient if performed incorrectly, this criterion should be deleted from the regulations.

*Response:* Section 353(d)(3) of the PHS Act sets forth the criteria in categorizing tests as waived tests, which includes the determination that the test poses "no reasonable risk of harm to the patient if performed incorrectly." Thus, the statute does not contemplate that there be a complete absence of risk, only that the risk not be unreasonable. We believe

that the tests falling into this category in this final rule satisfy that requirement.

*Comment:* Several commenters stated that although the proposed waived tests are simple procedures to perform, there still must be assurances of accuracy and operator competence for the safety of all individuals who have laboratory tests performed. The commenters expressed concern about the lack of regulation with respect to waived tests.

*Response:* We appreciate the commenters' concern for accurate test performance. However, section 353(d)(2)(C) of the PHS Act specifically states that subsections (f) and (g) which address establishment of standards and compliance inspections shall not apply to a laboratory which has been issued a certificate of waiver. The regulations do require a certificate of waiver laboratory to permit unannounced inspections in certain instances (that is, when HHS might have reason to believe that testing is being performed in a manner that constitutes an imminent and serious risk to human health, or in response to a complaint).

*Comment:* Many commenters indicated that the proposed fees specified in fee collection proposed regulation, published in the *Federal Register* on August 3, 1990, (55 FR 31758) were prohibitive and could close operations. Commenters offered the following suggestions:

- Waive all fees for Federal departments;
- Require no fee or reduce fees (less than \$50-\$100) for laboratories of State or local public health agencies;
- Apply a single fee for the agency, not each site;
- Include only processing costs for certificate of waiver fees.

*Response:* CLIA requires that certification fees be sufficient to cover the costs of implementing and administering the program and provides for no exemptions. We recognize that some laboratories may experience more financial difficulty than others in meeting the requirements of CLIA. In developing the fees for certification and compliance determination, we considered average time estimates for determining compliance and average surveyor pay scales across the country. These estimates also considered laboratory size based on types of specialties and volumes of tests. As we gain experience in administering the CLIA program, we will review the fee schedules and revise them as necessary. The fee for a certificate of waiver represents our best estimate of the costs necessary to establish the CLIA requirements, including processing of

the application, fee collection, ongoing evaluation of tests for categorization, and a share of the costs for conducting inspections in the event of complaints as well as random inspections to gather information for PHS evaluation of waiver test performance. Commenters should review the previously cited fee collection regulation, as we have reduced fees for laboratories performing limited low volume testing by creating a new fee category for laboratories performing fewer than 2000 tests per year.

*Comment:* Several commenters suggested that the time period for a certificate of waiver be extended to 3 or 5 years; or that a permanent waiver be granted with re-application required only when new tests are to be conducted.

*Response:* Section 353(c)(2) of the PHS Act specifies that a certificate (including a certificate of waiver) is valid for a period of no more than 2 years or such shorter period as the Secretary may require. We are revising the regulation to clarify that a laboratory which requests a hearing would retain its certificate of waiver or a reissued certificate of waiver until a hearing decision by the administrative law judge (ALJ).

*Comment:* Several commenters felt it is inappropriate to suspend Medicare/Medicaid payment during an appeal of a denial of certification. Since a laboratory would be permitted to bill individual patients or carriers other than Medicare/Medicaid, this establishes two standards of care. If there is no risk to the welfare of the general patient population, the laboratory should be permitted to bill carriers until the appeal is heard. If the appeal were denied, all subsequent payments would be disallowed. As an alternative the commenter suggested an expedited decision (within 30 days) should be required of the ALJ or HHS to prevent undue financial burden on small rural hospitals.

*Response:* As we explained in the preamble of the proposed rule, although we intend for the Federal health and safety requirements to be the same for Medicare and CLIA, failure to meet the requirements for part 493 would result in different adverse actions under Medicare, as opposed to CLIA, since different statutes apply. The Medicare program has for many years required that some providers, including laboratories, not in compliance with the requirements to be subject to adverse actions under that statute before there is an opportunity for a hearing. The PHS Act specifically requires a different

result. It permits continuation of test performance until a hearing results in a revocation, suspension or limitation of the certificate, unless HHS determines there is an imminent threat to human health. The final rule concerning CLIA enforcement, issued in final elsewhere in this issue of the *Federal Register* addresses this issue in greater detail.

*Section 493.39 Notification Requirements for Laboratories Issued a Certificate of Waiver*

*Comment:* One commenter recommended that we maintain the 30-day time frame set forth in § 493.39(c) of the proposed rule for notification to HHS of any change in laboratory ownership, name or location. The commenter felt that this would contribute to stable, reliable, traceable testing histories for each laboratory site. The commenter also indicated that with the appropriate penalties, it will serve to deter short-term, ill-directed operations.

*Response:* We are maintaining this requirement for the reasons discussed by the commenter. We agree that this should contribute to good testing practices and laboratory accountability.

*Comment:* Several commenters indicated that HHS should be notified of any change in directorship or supervision within 30 days, in addition to changes in ownership or location. One commenter indicated that there are not requirements for notification in changes in the supervision of a certificate of waiver laboratory.

*Response:* We agree with the commenters to the extent that we should be notified of any change in directorship and are revising the regulation accordingly.

*Changes to the Regulation*

In addition to minor editorial changes and cross reference corrections for consistency with other CLIA regulations, the major changes to this regulation are summarized below. We also deleted § 493.41 and combined the renewal requirements with § 493.37.

*Section 493.35 Application for a Certificate of Waiver*

- We are permitting laboratories within a hospital under common direction, located at the same street address to apply for a single certificate. In addition, not-for-profit or Federal, State or local government laboratories that engage in limited testing (that is, few types of tests) can file a single application. We have revised the regulation at § 493.35(a) (as well as other sections) to reflect this change. We are also clarifying that a laboratory that is not at a fixed location, that is, a

laboratory that moves from testing site to testing site (such as health screening fairs and each mobile van), or other temporary testing locations, must file an application using the address of the home base.

- We are clarifying that the annual total number of tests and examinations performed should not include tests the certificate of waiver laboratory may run for proficiency testing or quality control purposes.

- We are revising language to more accurately reflect the statutory requirement that records must be made available and reports submitted as HHS may reasonably require to determine compliance with this section.

- We are adding a reference to § 493.15(d) which states certificate of waiver laboratories must follow manufacturers' instructions for performing the test.

- We are clarifying that certificate of waiver laboratories are subject to inspection if there is reason to believe that the laboratory is operating (rather than testing is being performed) in a manner that constitutes a risk to human health. This is being done to agree with criteria for waived tests.

*Section 493.37 Requirements for a Certificate of Waiver*

- We are revising the regulation to clarify that a laboratory which requests a hearing within the specified time frame would retain its certificate of waiver or a reissued certificate of waiver until a hearing by an ALJ unless the conditions at the laboratory pose an imminent and serious risk to human health.

- We are adding a reference to § 493.15(d) of subpart A and a reference to subpart F for remittance of fees.

- We are clarifying that laboratories receiving Medicare or Medicaid payments will have these payments suspended on the effective date specified in the notice.

- We are adding a new subparagraph (f) to include the requirements for renewal of application. This previously was in § 493.41.

- We are adding a new subparagraph (g) to address requirements for certificate of waiver laboratories that want to perform testing in addition to the waived tests.

*Section 493.39 Notification Requirements for Laboratories Issued a Certificate of Waiver*

- We are revising the regulation so that HHS is to be notified of any change in directorship. We restructured the format of this section and added language to set forth the appeals

opportunity for failure to comply with notification requirements.

- We are removing the notification requirements for deletions or changes in tests methodologies specified in § 493.15, since certificate of waiver laboratories will be able to perform all waived tests.

- We are adding the laboratory director to notification changes because, although there are no personnel requirements for a director in a certificate of waiver laboratory, we still need to know the person who is responsible for operation of the laboratory.

*Subpart C—Registration Certificate and Certificate*

*Summary of the Proposed Rule*

Under § 493.43, Requirements for initial application for provisional certificate and certificate encompassing Level I or Level II test performance or both, we proposed to require that all laboratories performing level I or level II tests, or both, file a separate application for each laboratory location. The provisional certificate was intended to be a temporary certificate that is valid for no more than two years, which would give laboratories time to comply with CLIA 88 regulations and give HHS sufficient time to determine laboratory compliance with the regulations prior to the expiration of the provisional certificate. We proposed that the application must be filed on a form prescribed by HCFA, and signed by the owner or an authorized representative of the laboratory. In addition, the application, in accordance with section 353(d)(1)(A) of the PHS Act, must also describe the characteristics of the test procedures or examinations performed by the laboratory including: The total number and types of laboratory tests and examinations performed; the methodologies for laboratory procedures and examinations employed and the qualifications of the personnel directing and supervising the laboratory and performing the tests. As required by CLIA, the laboratory must agree to make records available and submit reports to HHS, as necessary.

*Section 493.45 Provisional Certificate Requirements*

A provisional certificate is a temporary certificate that is valid for no more than two years, which gives laboratories time to comply with CLIA regulations and gives HHS sufficient time to determine laboratory compliance with the regulations prior to the expiration of the provisional certificate.

HHS would reissue a provisional certificate to any laboratory that HHS or its designee has not determined compliance prior to the expiration date of the provisional certificate. We would intend to use provisional certificates because of the practical impact of the different effective dates for the various elements of CLIA. Specifically, Congress has mandated that effective January 1, 1990, laboratories will be subject to certification requirements set forth at section 353 (b) and (c) of the PHS Act. In theory, issuance of a certificate under CLIA would reflect judgment by HHS that a laboratory has provided satisfactory assurance that it will meet the substantive requirements set forth in CLIA and that it will accede to the inspection requirements of the statute. The substantive requirements of CLIA are being implemented through this rulemaking. It will be impossible for HHS to determine anything more than simple superficial compliance with the statute's application requirements at the time certificates are issued.

Thus, while laboratories need to have CLIA certificates in order to operate lawfully, we proposed that laboratories are not in a position to represent now that they will comply with the requirements imposed by HHS under subsection (f), which are the subject of this proposed rule, and HHS is without authority to inspect most laboratories for compliance with subsection (f) requirements until July 1, 1991. As a result, we proposed that certificates be issued in provisional form to allow laboratories to test until HHS can establish standards under CLIA and inspect laboratories for compliance with these standards.

We proposed in § 493.45 that all laboratories performing level I and level II tests not currently licensed or exempt from licensure under CLIA '67 on December 31, 1988 would be issued a provisional certificate by HHS provided that the laboratory submits the appropriate information specified under the application section. Prior to issuance of a provisional certificate, we proposed to require each laboratory to:

- Comply with § 493.43, Requirements for application for provisional certificate;
- Agree to treat PT samples as it would treat patient specimens; and
- Achieve a satisfactory score for one testing event in an approved PT program in the applicable specialty or subspecialty for each test or examination it performs.

Before the provisional certificate expires, the laboratory would have to demonstrate satisfactory performance in three consecutive proficiency testing

events for each test or examination included in a proficiency testing program approved by HHS, remit the fee specified by HHS, and submit to HHS an application for a certificate from nine to twelve months before the provisional certificate expires. In addition, we proposed that an on-site inspection be conducted to determine compliance with the applicable requirements of Federal, State and local laws, proficiency testing, patient test management, quality control, quality assurance, inspections, personnel requirements and computer systems. HHS would not issue a certificate to any laboratory unless the laboratory demonstrates compliance with the applicable requirements. Therefore, if HHS or its designee has not conducted a compliance determination prior to the expiration of the provisional certificate, the provisional certificate would be reissued. We proposed that a certificate would be valid for no more than two years. However, in the event of a non-compliance determination, HHS would suspend or deny payments under Medicare and would initiate action to revoke, suspend, or limit the laboratory's certificate. The laboratory would be provided with a statement of grounds outlining the basis for the non-compliance determination and would be offered an opportunity for a hearing as provided in part 498. If the laboratory requests a hearing, we proposed to extend the expiration date of the certificate until a hearing decision is issued, unless HHS or its designee finds that conditions at the laboratory pose an imminent and serious risk to human health.

In § 493.47, Requirements for Initial Application for Certificate, we proposed that laboratories performing Level I or Level II tests, or both, meet the application requirements in §§ 493.43 and 493.45, Provisional certificate, if applicable, and permit unannounced inspections:

- To determine compliance with applicable requirements in subparts G, H, J, K, L, M, N, and P;
- To evaluate complaints from the public;
- When HHS has substantive reason to believe that the laboratory is performing any test, including those listed in § 493.15, in a manner that constitutes a hazard to patient health and safety; and
- To collect information for the addition, deletion, or continued inclusion of tests on the waiver and Level I lists.

If we find that the laboratory does not meet the requirements for a certificate, in whole or in part, we proposed to notify the laboratory in writing of the

basis for the denial, and offer an opportunity for a hearing in accordance with procedures in part 498.

In § 493.49, Requirements for a certificate, we proposed to specify that laboratories not subject to CLIA '67 on December 31, 1988 meet the applicable requirements in § 493.45 to obtain a provisional certificate. Laboratories subject to CLIA '67 on December 31, 1988 would need not obtain a provisional certificate. We proposed to require that laboratories meet the general application requirements of § 493.43 and the specific application requirements of §§ 493.47 and 493.45, as applicable, and would be issued a certificate provided compliance is achieved with the applicable requirements of subparts G, H, J, K, L, M, N, and P. We proposed that laboratories issued a certificate must comply with the notification requirements of § 493.51 to notify HHS prior to performance of any test not included on its certificate. If the laboratory performs only certificate of waiver and level I tests, we proposed to require the laboratory to notify HHS prior to performing and reporting any test not included as a waiver test or in the Level I specialty and subspecialties listed on the laboratory's certificate or any Level II tests. For laboratories performing one or more level II tests, we would require notification prior to the performance of any test or examination not included as a waiver test or included in the specialties and subspecialties of service listed on the laboratory's certificate. We proposed that all laboratories issued a certificate must notify HHS within six months of any deletions or changes in test methodologies. For administrative efficiency, we proposed to require laboratories to notify HHS within thirty days of all changes in ownership, name, location, director(s), and supervisor(s). We proposed that laboratories issued a certificate would be subject to applicable requirements of subparts G, H, J, K, L, M, N, and P and would be required to permit unannounced inspections:

- To determine compliance with the requirements of part 493;
- To evaluate complaints from the public;
- When HHS has substantive reason to believe that any tests are being performed in a manner that constitutes a hazard to patient health and safety; and
- To collect information for the addition, deletion, or continued inclusion of tests listed in § 493.15 as waived tests or § 493.20 as level I tests.

In the event of a non-compliance determination, HHS would suspend or deny payments under Medicare and would initiate action to revoke, suspend, or limit the laboratory's certificate. We proposed to provide the laboratory with a statement of grounds outlining the basis for the non-compliance determination and would be offered an opportunity for a hearing as provided in part 498. If the laboratory requests a hearing, we would extend the expiration date of the certificate until a hearing decision is issued, unless HHS or its designee finds that conditions at the laboratory pose an imminent and serious risk to human health. In any case, we proposed to suspend or deny Medicare payments pending a hearing decision.

In § 493.53, Requirements for a renewal application for a certificate, we proposed to require that within 9 months to 1 year prior to the expiration of the certificate the laboratory apply for a new certificate. To qualify for renewal of a certificate, a laboratory would continue to meet the application requirements in §§ 493.43 and 493.47, remit the certificate fee and agree to permit unannounced biennial as well as random inspections in accordance with subpart N to determine compliance with the applicable regulations, to collect information for tests listed in §§ 493.15 and 493.20, to evaluate complaints from the public and when HHS has substantive reason to believe that any tests are performed in a manner that constitutes a hazard to patient health and safety. If HHS determines that a laboratory does not meet the requirements for certificate renewal, we proposed that HHS give the laboratory a written statement of the basis for the denial, and opportunity for a hearing to be conducted in accordance with part 498.

#### Comments and Responses

Approximately 170 individuals submitted alternative suggestions or expressed opposition to the proposed requirements in §§ 493.43-493.53. The majority of the commenters for these sections represented professional organizations, and physicians of various types.

#### Section 493.43 Application for Registration Certificate and Certificate

*Comment:* A few commenters expressed concern that completing an application form will result in laboratories being issued a provisional certificate authorizing Medicare or Medicaid payment for tests performed for a period of up to two years without meeting any standards. The commenters

felt that an unscrupulous operator could follow the same procedure every year or two by changing the address or name of the laboratory and be permitted to collect payments under Medicare and Medicaid without ever being subjected to the certification process.

*Response:* A laboratory will be issued a CLIA identification number along with its registration certificate (formerly referred to as a provisional certificate). This number will be retained by the laboratory even if the laboratory undergoes a change of location or name. The laboratory is required to notify HHS within 30 days of any changes including changes in name or location (see § 493.45(a)(2)); therefore, the probability of this occurring is reduced.

*Comment:* A commenter expressed concern that the proposed rule did not establish a mechanism for issuing provisional certificates for laboratories which began operation after December 31, 1988, while it specifically mentions laboratories existing as of December 31, 1988 and new laboratories.

*Response:* In the preamble of the proposed rule, we indicated that provisional certificates would be issued initially to all laboratories not eligible for a certificate of waiver and to all laboratories not subject to CLIA '67 on December 31, 1988 (that is, not licensed for testing specimens in interstate commerce). However, as established in the regulation concerning fee collection, we will not issue registration certificates (previously called provisional certificates) or certificates of waiver until the final CLIA standards are published. This will give laboratories an opportunity to determine if they want to continue performing laboratory tests before being subject to fees.

*Comment:* Another commenter did not agree with the concept of provisional certificates and indicated that laboratories should be issued certificates only if they provide evidence of quality control and PT.

*Response:* In addition to quality control and PT requirements, laboratories must meet requirements pertaining to personnel, patient test management and quality assurance in order to obtain a CLIA certificate. CLIA requires inspections of laboratories to determine the laboratory's compliance with CLIA requirements and standards. The issuance of a registration certificate permits performance of laboratory testing until compliance can be determined by an onsite inspection.

*Comment:* A few commenters suggested that, if the number of CLIA regulated testing sites is substantial, 10-15 percent of laboratories should be

randomly selected for reinspection each year and inspections be conducted of those laboratories which exhibit substandard PT performance.

*Response:* CLIA requires that inspections of all laboratories issued regular certificates be conducted "on a biennial basis or with such other frequency as the Secretary determines to be necessary to assure compliance with such requirements and standards." The statute also indicates that certificates are valid for no longer than two years. In order to renew the certificate, the laboratory must be evaluated to determine whether it continues to meet Federal requirements.

*Comment:* Several commenters indicated that the costs involved to obtain certification (for example, enrollment in PT, hiring qualified personnel and the certificate fee) could cause laboratories to stop testing.

*Response:* The purpose of the CLIA legislation is to ensure the accuracy and reliability of laboratory testing performed on human specimens. We recognize that the costs associated with complying with CLIA may be more difficult for some laboratories than for others; however, the CLIA statute is specific in establishing that the fees imposed shall be sufficient to cover the general cost of administering the CLIA program. To the extent that the complexity of the test performed prescribes that certain requirements be met (for example, personnel standards, participation in PT) the facility may incur increased costs. However, we anticipate that meeting the requirements will benefit patients by increasing the accuracy and reliability of test results. The certificate fees are based on our best estimates of Federal costs associated with the development of the CLIA regulations, implementation, and studies. As better data become available on the costs necessary to operate the CLIA program we will adjust the fee schedules as appropriate.

*Comment:* One commenter asked for clarification concerning time frames for application for provisional certificates. The commenter also suggested that HCFA publish a chronology outlining the publication sequence of the other CLIA rules with effective dates for implementation and explain how the rules will fit together.

*Response:* By the time this final rule is published, laboratories subject to CLIA should have submitted preliminary information to HHS. Once this regulation is published and laboratories have had time to review the requirements, each laboratory that has decided to continue or initiate testing

based on the requirements of this rule will be required to complete an application for certificate of waiver, certificate, or certificate of accreditation, as appropriate. An entity that conducts only waived tests will be issued a certificate of waiver upon payment of the applicable fee. If a laboratory performs testing other than those listed as waived tests, it will be issued a certificate or certificate of accreditation, as applicable. Inspections to determine compliance will be conducted when required. If the laboratory's existing registration certificate would expire prior to the issuance of a regular certificate or certificate of accreditation, we will reissue the registration certificate, upon payment of the appropriate fees. The Background section of this preamble contains a summary of the other CLIA rulemaking activities.

*Comment:* Many commenters expressed concern about the requirement for a separate certificate for each laboratory site, believing it to be redundant and only serving to increase the cost of laboratory services, and suggested that if laboratories are part of a multi-site laboratory system, one application for a single certificate would be appropriate. A few commenters suggested that the requirements for certification, while appropriate for a central reference laboratory, are too stringent for facilities performing procedures for screening purposes, and suggested that the requirement for separate laboratory certification of each screening site be waived or eliminated for screening sites.

*Response:* As we previously indicated in § 493.35, we agree with the commenters and will permit laboratories within a hospital under common direction located at the same street address to apply for a single certificate or multiple certificates. In addition, not-for-profit or Federal, State, or local government laboratories that engage in limited public health testing can operate under one certificate. We are revising the regulation at § 493.43(a) to reflect this change. We are also revising the regulation to clarify that a laboratory that is not at a fixed location, that is, a laboratory that moves from testing site to testing site (such as health screening fairs), or other temporary testing location must file a single application using the address of the home base. Mobile vans providing laboratory testing would require a separate certificate for each van which would reflect the address of the home base. Each testing site would be subject to applicable quality control requirements

based on the testing performed or instrumentation or methodology employed.

*Comment:* Several commenters indicated that the basic differences between central and alternate site laboratories should be recognized in the regulation, as State laws recognize this distinction.

*Response:* As previously stated, we have attempted to provide flexibility to multiple site laboratories that perform limited testing for screening or treatment of individuals that are directed by not-for-profit organizations or Federal, State, or local governments by permitting them to operate under one certificate. This certificate would allow testing to be performed up to the highest level covered by the certificate for all of the testing sites. Therefore, if the central site has a certificate to perform tests of high complexity, the alternate site which may be performing waived tests under that certificate would be allowed to perform these tests without being required to have its own certificate of waiver.

*Comment:* Several commenters also indicated that issuing one certificate to an entity with multiple testing sites should not preclude each site from participating in a PT program or complying with the quality control requirements, however such a system would be less costly and disruptive to the laboratory.

*Response:* Proficiency testing requirements are applicable to a laboratory that is issued a regular certificate or certificate of accreditation. While a facility would not be precluded from voluntarily participating in more than one PT program, it must designate which site and which PT program or programs it will use to fulfill the regulatory requirements of CLIA.

*Comment:* Many commenters expressed opposition to the proposed information requirements on the certificate applications requiring laboratories to forward to HCFA personnel qualifications, techniques and methodologies employed for testing, and procedure manuals. Not only would this be burdensome, but the commenters felt that it will be impossible for HCFA to review all of the material. The commenters suggested that reviewing these records at the time of inspection should be adequate.

*Response:* Collection of information concerning personnel qualifications, techniques and methodology are required by CLIA as part of the application process. This information provides basic information on the laboratory operation and is necessary to

determine if the laboratory meets the minimum requirements in order for the application to be processed. If the laboratory does not meet our minimum application requirements, there would be no benefit to performing the initial inspection. We have attempted to design application forms that are simple to complete and that will diminish the burden of the application process.

*Comment:* Other commenters suggested that for military services' laboratories, personnel qualifications could be indicated by specialty codes rather than requiring submittal of extensive documentation. These specialty codes indicate the qualifications and training received by laboratory personnel.

*Response:* CLIA requires submission of personnel qualifications, including educational background, training and experience of personnel directing and supervising the laboratory and performing the laboratory examinations and other procedures. We have attempted to simplify the information that must be submitted on personnel qualifications and will continue to revise the forms as necessary to reduce the paperwork burden. In order for the information to be consistent we are requiring all applications to be submitted in a uniform manner.

#### *Section 493.45 Requirements for a Registration Certificate*

*Comment:* Several commenters asked for clarification concerning the role of PT during provisional certification. The commenters believe it is unreasonable to require a laboratory to successfully participate in one PT event before a provisional certificate will be issued, particularly since it can take six months or longer for the laboratory to enroll and participate in a single PT event. The commenters suggested that it would be more reasonable and feasible to revoke the provisional certificate based on the first set of results than to bar them from patient testing for such a long period of time.

*Response:* We agree with the commenters. Under the CLIA fee collection regulation (also published today), laboratories are not required to achieve satisfactory PT performance prior to issuance of a registration certificate. Similarly, under this regulation we will not require satisfactory participation in a PT program prior to the issuance of a registration certificate, and have revised the regulation to delete this requirement from § 493.45(b).

*Comment:* Several commenters agreed that successful participation in one PT

event may not be adequate; however, the proposed requirement for successful participation in three consecutive events may be difficult to achieve. As an alternative, the commenters recommended that the regulation be reworded to require successful participation in two consecutive or two of three PT events.

*Response:* Due to the phase in of PT requirements and the difficulty PT programs may have in fulfilling laboratory needs, we have removed this requirement.

#### *Section 493.49 Requirements for a Certificate*

*Comment:* A few commenters expressed concern that the fees for determination of compliance that could be in excess of \$2,000 every one or two years were excessive for certification of a level II laboratory.

*Response:* As much more fully described in the regulation pertaining to fee collection (also published in this issue of the *Federal Register*), our fee schedules reflect our best estimates of the current costs associated with implementing and operating the CLIA program. As more definitive data becomes available we will adjust the fee schedules as appropriate.

*Comment:* Several commenters disagreed with the requirement to conduct unannounced inspections since such inspections can disrupt the laboratory operation as well as compromise patient care. The commenters suggested that laboratories be given minimum notice to ensure the availability of the appropriate supervisory personnel during the inspection. Commenters suggested that 24-hour notice be provided prior to inspection. This would permit the laboratory to schedule additional staff to provide patient care while other staff employees assisted the inspector in the review of patient records, quality control data, laboratory procedures, etc.

*Response:* As previously explained, the CLIA statute authorizes the Secretary to conduct unannounced inspections and in our experience with conducting inspections for Medicare program purposes, we have found that such inspections more realistically reflect a facility's operation. In general, while initial inspections are not always announced, the schedule for such an inspection is usually known since these surveys are conducted as soon as possible following application of the laboratory. On the other hand, complaint investigations may be scheduled to ensure that appropriate staff and records are available for inspections. Whether the inspection is

announced or unannounced, every effort will be made to avoid disruption of the facility's testing activities.

#### *Section 493.51 Notification Requirements for Laboratories Issued a Certificate*

*Comment:* Several commenters supported notification of changes in ownership, name, location and directors, but did not agree that the laboratory should provide notification of changes in supervisors. Since turnover among supervisors is fairly common, they recommended that notice of changes of supervisors be provided biannually or annually.

*Response:* We disagree with the commenters' recommendation concerning the frequency in reporting changes in supervisory personnel. Such notification is necessary to ensure that the laboratory is employing appropriately qualified personnel as supervisors. We note that due to changes in the personnel standards, this is applicable only to laboratories performing high complexity testing.

*Comment:* Many commenters indicated that permitting laboratories to wait six months to report changes in test methodologies employed was too long a time period without enforcing appropriate regulations on the laboratory. They suggested revising the requirement to require notification within 30 days since this time period would coincide with the reporting requirements for changes in ownership, director, etc., and it is more important from an inspection standpoint to report changes in test performance than laboratory ownership.

*Response:* As previously stated, CLIA specifies that a laboratory has up to 6 months to notify HHS of any changes in test procedures, including changes in test methodologies. We have revised the regulation to reflect this change.

#### *Summary of Changes to the Regulation*

- We are restructuring the format of subpart C to eliminate duplicative information. We are deleting § 493.37 since it contained information also found in § 493.49. We are no longer requiring separate application for a certificate (the information from the application for registration certificate will be used), and we are deleting § 493.53 and combining appropriate information with § 493.49.

#### *Section 493.43 Requirements for Initial Application for Registration Certificate and Certificate*

- We are modifying the title of this section to more accurately reflect its contents. We are changing references to

level I and II to moderate and high complexity here and throughout the regulation. We are also changing references to provisional to registration certificate here and throughout the regulation to more accurately portray the purpose of the certificate.

- We are adding exceptions to the application requirement to permit laboratories within a hospital under common direction at the same address to apply for one certificate. In addition, not-for-profit or Federal, State, or local government laboratories that engage in limited (for example, few types of tests) can file a single application. We also clarify that each laboratory not at a fixed location must file an application using the address of the home base, including health screening fairs and each mobile van.

- We are clarifying that the annual total number of tests and examinations performed should not include tests that the laboratory runs for PT, quality assurance, or quality control purposes.

- We are revising language to more accurately reflect the statutory requirement that records and reports must be made available so that HHS may reasonably determine compliance with this section.

#### *Section 493.45 Requirements for a Registration Certificate*

- We are clarifying who must have a registration certificate, and that notification of changes in director or supervisor (applicable only to laboratories performing high complexity testing) must also be made within 30 days.

- We are adding specific reference to subpart F, Fee collections, with respect to remittance of fees.

- We are removing the requirement for successful participation in PT prior to issuance of a registration certificate or before expiration of a registration certificate.

- We are clarifying that failure to meet the requirements of this subpart will result in suspension of payments under Medicaid or Medicare.

- We are clarifying that a registration certificate is not renewable but may be reissued if compliance has not been determined by HHS prior to the expiration date of the registration certificate.

- We are restructuring the appeals discussion into a separate subsection for clarity.

#### *Section 493.49 Requirements for a Certificate*

- We are adding specific reference to subpart F with respect to fee collection.

- We are stating that an inspection may be performed if HHS has reason to believe that tests are being performed "or the laboratory is being operated" in a manner that constitutes a risk to human health.

- We are adding reference to suspension or denial of payments under Medicaid in addition to Medicare.

- We are restructuring the discussion of appeals to reflect more clearly the process set forth in Subpart R by adding separate subsections.

- We are adding new subsections (g) through (j) to discuss the renewal process that was previously addressed in § 493.53 of the proposed rule (that section has been deleted).

#### *Section 493.51 Notification Requirements for Laboratories Issued a Certificate*

- We are combining notification requirements for laboratories performing moderate and/or high complexity testing into one subsection.

- We are clarifying that supervisor change notification is applicable only to laboratories performing tests of high complexity.

- We are revising the regulation to indicate that laboratories with a regular certificate must notify HHS no later than six months after performing any tests within a specialty/subspecialty not included in their certificate.

#### *Subpart D—Certificate of Accreditation*

##### *Summary of Proposed Rule*

We proposed that subpart D would not be effective until the requirements for recognition of an accreditation program or State licensure program (developed in a separate rulemaking) are published as a final rule, become effective, and HHS has recognized an accreditation program or State licensure program. After HHS recognizes an accreditation or State program under subpart E, laboratories may choose to meet the applicable requirements of Subparts H (Participation in Proficiency Testing for Laboratories Performing Tests of High and Moderate Complexity), J (Patient Test Management for Moderate and High Complexity Testing), K (Quality Control for Tests of Moderate and High Complexity), L (Laboratory Information Systems), P (Quality Assurance for Moderate and High Complexity Testing) and Q (Inspection) by becoming accredited by an accreditation program or licensed under a State program provided the laboratory obtains a certificate of accreditation in accordance with this subpart. Laboratories that are accredited by an

approved accreditation program or licensed by an approved State program will be issued a certificate of accreditation in lieu of a certificate. A certificate of accreditation will be equivalent to a certificate.

Under § 493.55, Requirements for initial application for certificate of accreditation, we proposed to require a laboratory performing one or more Level I or Level II tests to file a separate application for each laboratory location. The application would have to be filed on a form prescribed by HHS, and signed by the owner or authorized representative of the laboratory. In addition, the application for the certificate of accreditation in accordance with section 353(d)(1)(A) of the PHS Act, would describe the characteristics of the test procedures or examinations performed by the laboratory including: the number and types of laboratory tests and examinations performed; the methodologies for laboratory procedures and examinations employed and the qualifications of the personnel directing and supervising the laboratory and performing the tests. As required by CLIA, the laboratory must agree to make records available and submit reports to HHS, as necessary.

In § 493.57, we proposed that all laboratories seeking certification through participation in an approved accreditation program or State licensure program would be issued a provisional certificate unless the laboratory holds a valid certificate issued by HHS for performance of one or more Level I or Level II tests or both. Laboratories would be issued a provisional certificate provided they comply with the initial application requirements specified in § 493.55, agree to treat proficiency testing specimens in the same manner as patient specimens, achieve satisfactory performance for one testing event in an approved PT program for each test or examination performed, and remit the provisional certificate fee specified by HHS. Prior to expiration of the provisional certificate, the laboratory must achieve successful participation, as defined in Subpart H (Participation in Proficiency Testing for Laboratories Performing Tests of Moderate and High Complexity), for three consecutive proficiency testing events in a proficiency testing program approved by HHS for each test or examination performed. In addition, the laboratory would have to file an application for a certificate of accreditation as specified in § 493.55 not less than 9 months nor more than 1 year before expiration of the provisional certificate and notify HHS with proof of its accreditation or

licensure in an approved accreditation or State program.

In accordance with the provisions of CLIA, that will be implemented as part of a separate rulemaking and located in subpart O, HHS would initiate suspension, revocation or limitation of a laboratory's provisional certificate and would deny the laboratory's application for a certificate of accreditation for failure to comply with the requirements for provisional certificate or application requirements for certificate of accreditation. A provisional certificate would not be renewable and would be valid for a period of no more than 2 years. If the approved accreditation program or State licensure program were unable to conduct an inspection to determine compliance with its requirements before the provisional certificate expires, the provisional certificate would be reissued for solely that period that is needed by the program to determine compliance with its standards.

Laboratories that do not meet the requirements for application for certificate of accreditation in proposed § 493.59 or the requirements of proposed § 493.57 for provisional certificates would be issued a denial of the application for a certificate of accreditation. In this case, HHS would provide the laboratory with a statement of grounds on which the denial is based, offer an opportunity for a hearing as provided in part 498 and notify the laboratory if it is eligible for a certificate as described in Subpart C (Registration Certificate and Certificate).

In proposed § 493.59, we specified the requirements for application for certificate of accreditation. We would require that all laboratories that perform Level I or Level II tests, or both, that are accredited by an approved accreditation organization or State licensure program meet the application requirements for a certificate of accreditation or the requirements for provisional certificate for new laboratories unless the laboratory already has a valid certificate issued by HHS. In order to meet the application requirements for certificate of accreditation, we would require laboratories to:

- Provide HHS with assurances that the laboratory would be operated in accordance with the accreditation or State program requirements;

- Agree to treat proficiency testing specimens in the same manner as patient samples;

- Authorize the accreditation or State licensure program to release to HHS the laboratory's proficiency testing results;

- Agree to permit random sample and complaint inspections as defined in the subpart on Inspection;

- Allow HHS or its designee to monitor correction of any deficiencies identified in random sample or complaint inspections; and

- Authorize the accreditation program or State licensure program to release to HHS the laboratory's survey findings whenever HHS or its designee conducts random sample or complaint inspection surveys.

If HHS determines that the application for a certificate of accreditation is to be denied or limited, HHS would notify the laboratory in writing of the bases for denial of the application, and opportunity for a hearing as provided in part 498. If the laboratory is eligible for a certificate as described in Subpart C (Registration Certificate and Certificate), HHS would advise the laboratory.

In § 493.61, Requirements for a certificate of accreditation, we would specify that laboratories must meet the requirements of § 493.55, Application for certificate of accreditation, and if applicable, § 493.57, Requirements for a provisional certificate for laboratories. We would require the laboratory to pay the certificate of accreditation fee specified by HHS. We proposed that laboratories must treat proficiency testing samples in the same manner as patient specimens; comply with notification requirements specified in § 493.63; meet the requirements of the accreditation or State licensure programs; permit random sample and complaint inspections by HHS or its designee; allow the State inspecting agency to monitor the correction of deficiencies found through the inspections; and authorize the accrediting body to release inspection findings to HHS.

In the event of a non-compliance determination, HHS would suspend or deny payments under Medicare and would initiate action to revoke, suspend, or limit the laboratory's certificate of accreditation. The laboratory would be provided with a statement of grounds outlining the basis for the non-compliance determination and would be offered an opportunity for a hearing as provided in part 498. If the laboratory requested a hearing, we would extend the expiration date of the certificate of accreditation until a hearing decision is issued, unless HHS or its designee finds that conditions at the laboratory pose an imminent and serious risk to human health. In any case, Medicare payments would be suspended or denied pending a hearing decision.

We proposed in § 493.63, Notification requirements for laboratories issued a certificate of accreditation, that laboratories performing one or more of the Level I tests or examinations listed in § 493.20 must notify the approved accrediting body and HHS before performing any test not included as a waiver test or included in the specialties and subspecialties listed on the laboratory's certificate or any Level II tests. Laboratories issued a certificate of accreditation would have to notify the accrediting or State licensure program within 6 months of changes or deletions of test methodologies of Level I or waived tests; and within 30 days of any changes in ownership, name, director(s), or supervisor(s). For laboratories performing one or more Level II tests, we would require notification to the approved accrediting body and HHS, prior to the performance of any test or examination not included as a waived test or included in the specialties and subspecialties of service listed on the laboratory's certificate of accreditation. In addition, we would specify that those laboratories performing Level II tests issued a certificate of accreditation must notify the accreditation program or State licensure program within 6 months of any deletions or changes in test methodologies and within 30 days of all changes in ownership, name, location, director(s), and supervisor(s).

In § 493.65, Requirements for renewal application for a certificate of accreditation, we would require that the laboratory apply for a new certificate of accreditation within 9 months to 1 year prior to the expiration of the certificate of accreditation. To qualify for renewal of a certificate of accreditation, the request would have to meet the requirements of § 493.55, Requirements for application for certification of accreditation and § 493.59, Requirements for application for a certificate of accreditation. We proposed that the laboratory: provide HHS with satisfactory assurances that the laboratory will be operated in accordance with the requirements of the accreditation or State licensure program; agree to treat PT samples as it treats patient specimens; authorize the approved accrediting body to release the results of the laboratory's PT samples; agree to allow random sample and complaint inspections; authorize the accrediting body to release inspection findings whenever HHS or its designee conducts random sample or complaint inspections; authorize the State inspection agency to monitor the correction of deficiencies found by the inspection; and remit the fee specified by HHS. If HHS determines that a

laboratory does not meet the requirements for renewal of a certificate of accreditation, HHS would give the laboratory a written statement of the basis for the denial, and opportunity for a hearing to be conducted in accordance with part 498.

#### Comments and Responses

Approximately 90 commenters, the majority representing physicians, technologists, and professional organizations, submitted opposing views or alternative suggestions to §§ 493.55 through 493.65.

#### *Section 493.55 Requirements for Initial Application for Registration Certificate and Certificate of Accreditation*

*Comment:* Many commenters recommended that deemed status should be given to hospital laboratories which meet the requirements of JCAHO or laboratories certified by COLA, while other commenters questioned whether JCAHO and CAP were not already recognized accreditation programs.

*Response:* CLIA establishes new requirements requiring each facility subject to its provisions to have a certificate authorizing it to perform testing. CLIA authorizes the recognition of accreditation and State programs that have standards equivalent to or more stringent than the CLIA requirements. On August 20, 1990, we published in the Federal Register a proposed rule, which sets forth the criteria for recognition of accreditation and State licensing programs. When that proposed rule is published in final, accreditation organizations and States can submit requests for review of their programs for recognition under CLIA. Programs that were previously recognized under the Social Security Act for Medicare purposes or the Public Health Service Act for CLIA '67 laboratories must reapply for recognition since laboratories are subject to new requirements mandated by CLIA.

*Comment:* Many commenters indicated that many States have certification or licensure requirements that are as stringent as those proposed in CLIA and recommended that these State programs be granted deemed status. The commenters recommended that all recognized programs should provide on-site inspection for the educational benefit of laboratory staff and for assurance of compliance with standards.

*Response:* In response to comments received on the August 20, 1990 proposed rule concerning recognition of accreditation organizations and State programs, we reexamined the statutory

provisions regarding State licensing programs. Section 353(p)(2) of the PHS Act specifies that if a State enacts laws that provide for requirements equal to or more stringent than the CLIA statutory requirements or requirements of regulations, the Secretary may exempt clinical laboratories in that State from the CLIA requirements. We are exempting from the requirements of CLIA, laboratories located in States whose licensure programs are approved by HHS. Such State-exempt laboratories will not require certification by HHS and will not be subject to fees. State-exempt laboratories will be required to permit Federal inspectors to conduct inspections to ensure that standards are being enforced in an appropriate manner. The costs for such inspections will be borne by the State licensure program.

*Comment:* One commenter questioned whether a home health agency which has a contract with a New York state licensed laboratory would be considered to have deemed status?

*Response:* If the HHA staff are not testing human specimens for "the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings \* \* \*", and such testing is performed by another entity, that entity and not the HHA would be subject to the CLIA requirements. If the HHA staff performs such testing (as opposed to specimen collection or assisting a patient in his home in performing a test), the HHA would be subject to CLIA requirements. If the HHA were licensed by an approved State laboratory licensure program or accredited by an organization for laboratory services that was approved by HHS, the HHA would be exempt from CLIA requirements or eligible for a certificate of accreditation.

*Comment:* Many commenters indicated that professional organizations have delays in scheduling inspections that result in longer time period between inspection cycles. The commenters noted that in some instances, "biennial" inspections were scheduled 36 months after the previous inspection; however, the average biennial inspection cycle is 30 months. The most common reasons given for the delays in conducting inspections were insufficient professional volunteers to participate in the inspection process, and late payment of fees to the professional agency to cover the costs of inspection and accreditation. The commenters asked how these problems would be resolved.

*Response:* As set forth in the CLIA proposed rule pertaining to

accreditation, the evaluation of the accreditation or State program will include an assessment of the accreditation organization's or State program's standards compared to the CLIA requirements and assessment of the capability of the organization or State to monitor its participants.

*Section 493.57 Requirements for a Registration Certificate*

*Comment:* A few commenters suggested that we require laboratories to notify HHS of successful participation, as defined in Subpart H (Participation in Proficiency Testing for Laboratories Performing Tests of Moderate and High Complexity, in two of the last three PT events, instead of the proposed three consecutive PT events, in a PT program approved by HHS for each test or examination performed, if applicable.

*Response:* As discussed earlier, we no longer require successful participation in a PT program prior to the expiration of the registration certificate; thus this requirement has been removed.

*Section 493.61 Requirements for a Certificate of Accreditation*

*Comment:* A few commenters stated that the fees assessed would impact on the cost of proving laboratory services, particularly since laboratories frequently change the services offered. The commenters asked about the specific costs for upgrading or reissuing a certificate.

*Response:* The actual fees to be assessed are specified in a separate CLIA User Fee Final regulation, published elsewhere in this issue of the **Federal Register**.

*Comment:* A few commenters recommended that HCFA develop a process and time frame to allow a laboratory to come into compliance prior to suspension of a certificate. This would require written notification to the laboratory detailing the specific reasons for noncompliance and recommendations for achieving compliance and provide a reasonable time frame for the laboratory to comply with the requirements. The commenters also recommended that Medicare payment not be denied while the laboratory awaits a hearing decision. If a laboratory receives a favorable judgement from a hearing or is able to reestablish compliance within a reasonable timeframe, it should not be burdened with reapplication for approval for Medicare payment.

*Response:* For a full explanation of enforcement procedures for CLIA laboratories, we refer readers to the proposed rule, which was published on

April 1, 1991 and the final rule published today.

**Changes to the Regulation**

In addition to minor editorial changes for consistency with other regulations, the major changes to this regulation are summarized below. We restructured the format of this subpart to eliminate repetitious language and deleted §§ 493.59 and 493.65, combining appropriate parts into § 493.61. We are also exempting from the requirements of CLIA laboratories located in States whose licensure programs are approved by HHS. Such State-exempt laboratories will not require certification by HCFA and will not be subject to fees.

*Section 493.55 Application for Registration Certificate and Certificate of Accreditation*

- We are no longer requiring separate application for a certificate of accreditation since information from the application for registration and accrediting body will be used.

- We are making an exception to the application requirement to permit laboratories within a hospital under common direction at the same street address to apply for one certificate.

- Not-for-profit or Federal, State or local government laboratories that engage in limited testing (i.e., few types of tests) may file a single application.

- We are clarifying that each laboratory not at a fixed location must file an application using the address of the home base, including health screening fairs and each mobile van.

- We are clarifying that the annual total number of tests and examinations performed should not include tests the laboratory runs for proficiency testing, quality assurance, or quality control purposes.

*Section 493.57 Requirements for a Registration Certificate*

- We are removing the requirement that a laboratory successfully participate in PT prior to issuance of a registration certificate or before expiration of a registration certificate.

*Section 493.61 Requirements for a Certificate of Accreditation*

- We are adding specific reference to Subpart F concerning remittance of fees.

- We are adding requirements from proposed § 493.65 (now deleted) concerning release of PT and inspection findings.

- We are adding reference to effect on Medicaid in addition to Medicare.

- We are adding discussion concerning the effect on a laboratory's

certificate if accreditation organization approval is removed.

- We are adding new subsections to discuss a renewal process that was previously addressed in § 493.65 of the proposed rule, which is now deleted.

*Section 493.63 Notification Requirements for Laboratories Issued a Certificate of Accreditation*

- We are providing that a laboratory with a certificate of accreditation must notify the accreditation program no later than 6 months after performing any test within a specialty/subspecialty not included in the certificate.

- We are revising the regulations to provide that a laboratory must notify only the accreditation program of deletions or changes in tests included in the certificate.

*Subpart G—Administration*

*Summary of Proposed Rule*

We proposed that laboratories must comply with Federal, State and local laws, and the standards of the National Fire Protection Association (NFPA).

We received comments opposing the requirement for laboratories to comply with all applicable Federal, State and local laws in Subpart G, Administration. Some commenters noted this requirement would authorize the Department to enforce regulations beyond the scope of CLIA, which is to ensure the quality of laboratory services.

CLIA neither authorizes the exemption of any laboratory from other applicable Federal, State or local laws, nor does it authorize the enforcement of regulations outside the scope of the statute. Therefore, we are deleting the requirements in this subpart as redundant.

State and local laws that are more stringent than Federal requirements take precedence over the Federal regulations. Laboratories subject to other applicable Federal laws will be required by the Federal agency with jurisdiction to comply with those laws.

*Subpart H—Proficiency Testing for Laboratories Performing Tests of Moderate and High Complexity*

*Summary of the Proposed Rule*

We proposed this subpart as, "Participation in Proficiency Testing for Laboratories Performing Level I and Level II Tests," but have renamed it to be consistent with changes in the categorization of tests under § 493.10.

Proposed subpart H contained descriptions of general requirements a laboratory must meet for enrollment in a proficiency testing (PT) program, for

testing PT samples, and for successful participation. Also described were the conditions applying to PT which must be met for certification and for reinstatement after a failure to participate satisfactorily in PT. Specific PT requirements for each specialty were proposed.

These proposed PT requirements emphasized the importance of achieving a passing score on PT samples of known content, which have been tested in the same manner as the laboratory tests patient specimens, to provide a measure of a laboratory's quality. The procedures monitored by the proposed regulatory PT program focused on tests which are commonly performed or whose results are critical in health care, or both.

In § 493.801, Condition: Enrollment and testing of samples, we proposed that a laboratory seeking certification must notify HCFA of the approved PT program in which it has chosen to enroll for each specialty and subspecialty. If a laboratory chooses to participate in more than one PT program for a specialty or subspecialty, we proposed that it must designate which program it wishes to use to comply with PT requirements. It would then have to participate in the chosen program for quarters before designating a different program for PT compliance. The laboratory must agree to allow all PT programs in which it participates to release PT performance data to HCFA. The laboratory must examine or test the PT samples in a manner as close as possible to the same manner that it tests patient specimens and must maintain records to document how PT samples were handled within its facility. We proposed that interlaboratory communications about PT results before they are reported and referrals of PT samples to another laboratory for testing be prohibited.

Section 493.803, Condition: Successful participation, would require a laboratory that does not successfully participate in PT for an analyte or test or a specialty or subspecialty be subject to termination of its certificate or intermediate sanctions.

In § 493.805 Condition: Satisfactory participation before provisional certification or revising a certificate to include additional specialties and subspecialties or services, we proposed to require a laboratory to demonstrate satisfactory performance in one PT testing event before a laboratory would be eligible for a certificate or to add a specialty or subspecialty to its certificate.

In § 493.806 Condition: Successful participation before certification, we proposed to require a laboratory to

demonstrate satisfactory performance for each specialty or subspecialty in three consecutive testing events before its provisional certificate expired.

Section 493.806 Condition: Reinstatement of laboratories performing Level I and Level II tests after failure to participate successfully, would require a laboratory whose certificate was suspended or whose Medicare approval was terminated or who had voluntarily withdrawn its certification to demonstrate satisfactory performance in three consecutive PT testing events before HCFA would consider reinstatement. In any event, the period of termination would not be less than six months.

Sections 493.821 through 493.865 contain proposed criteria for acceptable performance for each specialty and subspecialty which a laboratory would have to meet to participate successfully in a PT program. For most analytes or tests examined and for most specialties and subspecialties, a score of 80% would be considered a reasonable and achievable level of performance. However, for immunohematology, in which even one error can have serious and immediate consequences, we proposed to require a performance level of 100% for certain components of this specialty.

Sections 493.855 described the proposed requirements for successful participation in a cytology PT program for gynecologic examinations (Pap smears). We proposed that each individual engaged in the examination of gynecologic preparations be tested twice per year. One examination would be an unannounced, on-site test that was conducted annually in each laboratory, and one would be one of four off-site tests conducted annually in each State. We proposed that certain events would occur if an individual scores less than 80 percent on a test set. The laboratory would be responsible for:

- Providing the individual with immediate remedial training in the area of failure;

- Assuring the all subsequent gynecologic slides were reexamined until the individual passed a testing event; and

- Reexamining the last 500 slides (500 negative slides if the individual who failed the testing event was a cytotechnologist) examined by the individual before the failed testing event.

We proposed that if a laboratory failed to take the required remedial actions when one or more individuals failed a testing event we would initiate

intermediate sanctions, revoke the laboratory's certificate for gynecologic cytology and terminate the laboratory's Medicare approval for gynecologic cytology testing.

Due to the vast number of newly regulated laboratories expected to be enrolled in proficiency testing (PT) for the first time under this rule, PT requirements are being phased in to allow laboratories and regulatory agencies adequate time to meet requirements. These never before regulated laboratories will be required to enroll in a PT program approved under this rule by January 1, 1994. Sanctions for previously unregulated laboratories arising out of PT failures will begin on January 1, 1995.

While this phase-in period is necessary for previously unregulated laboratories (and for PT programs that will need the extra time to acquire and prepare the greatly expanded volume of samples required), its application to those laboratories that have previously been required to participate successfully in PT under Medicare/Medicaid and interstate laboratory regulations published on March 14, 1990 would be problematic. These laboratories have experience with PT and currently subscribe to PT programs that can meet their needs. Therefore, we could see no basis for exempting these laboratories from PT during the phase in period applicable to previously unregulated laboratories.

We considered two other possible approaches to the problem of how best to deal with PT requirements in previously regulated laboratories. First, we could have carried forward the PT standards from the March 14, 1990 rule until newly regulated laboratories were fully on board. This approach would have been consistent with the CLIA legislative history which contemplated the carrying forward of current standards until they could be replaced by those that would implement CLIA. Also, it would not be disruptive to currently regulated laboratories since they would carry on with their current PT participation. This approach, however, would have severe repercussions for PT providers. Specifically, carrying forward the current PT requirements for one set of laboratories, while simultaneously asking PT providers to develop other programs for the greatly expanded regulated universe that will be participating in PT on January 1, 1994, would be excessively burdensome on those programs and would ultimately slow the pace of CLIA implementation. Thus, we concluded that it would not be

productive to have current PT programs maintain the current system of four PT events per year while at the same time gearing up for production, scheduling, processing and reporting for a system of three events per year. Nor did we wish to see PT programs literally having to run two different systems during 1993.

Second, we considered applying the new PT requirements immediately to the currently regulated laboratories while permitting newly regulated laboratories the phase-in period described earlier.

We have opted for the second approach, and rejected a third possibility that currently regulated laboratories would be exempt from PT for two years. As we have explained, these laboratories are already accustomed to enrollment and participation in PT programs, and we could see no reasons to risk lowering the quality of laboratory services by dropping the PT requirement altogether until January 1, 1994. For the reasons stated above, we also rejected as infeasible and counterproductive carrying over the PT requirements from the March 14, 1990 regulations.

As a practical matter, currently regulated laboratories will be unaffected during the calendar year 1992, since they have already purchased their complete PT programs for the full year. By 1993, the PT providers will be ready to offer PT to the previously regulated laboratories using the three event schedule, while they are also gearing up for the greatly expanded PT enrollment expected by 1994 from the previously unregulated laboratories. This approach affords a smooth transition to the full implementation of CLIA PT requirements while, at the same time, maintaining PT participation by those laboratories that have been receiving Medicare or Medicaid payments and/or been engaged in interstate commerce under the March 14, 1990 regulations.

Moreover, laboratories that have been participating in PT programs under the March 14, 1990 regulations ought to be satisfied with this approach since it was clearly within our authority to maintain the current, and somewhat more rigorous, PT demands of those regulations until January 1, 1994. We wish to emphasize, however, that the substitution of three PT events for the current four annual events does not decrease our ability to identify poor laboratory performance, nor does it signal a diminution of laboratory standards since we believe that the complementary requirements of quality control, quality assurance, and patient test management provide a comprehensive regulatory scheme that

we believe should enhance the quality of laboratory services performed in this country.

The relationship between proficiency testing and the quality of laboratory testing will be examined as part of the CLIA studies. Every effort will be made to develop information on proficiency testing as quickly as possible. When the data is available, it will be used as a basis for making corrections and modifications, and to refine the proficiency testing standards in the regulations.

#### Comments and Responses

Approximately 5,700 comments were received in response to the proposed PT regulations. Of these comments, 61 percent addressed concerns about PT participation, 34 percent addressed topics related to PT program operations and logistics, and 5 percent addressed PT definitions.

About 38 percent of the comments were provided by physicians, another 32 percent were from individuals working in independent and hospital laboratories or professional organizations representing such individuals or facilities, 11 percent were from PT program providers, and the remainder were from a variety of individuals, including patients and the general public.

Comments to the proposed PT requirement for cytology were analyzed separately from those to the other specialties and subspecialties. Since the regulations in this subpart are so similar to the final rule with comment published on March 14, 1990 (55 FR 9538), we are considering comments from both that final rule and this proposed rule in making revisions in the requirements for PT in cytology.

We received a total of 2,600 letters in response to the cytology requirements in the March 14, 1990 rule. These letters contained nearly 7,000 opinions and suggestions (comments) on participation in PT (§ 493.855) and 1,500 comments on the PT program (§ 493.945). In response to the cytology requirements in this proposed rule, we received 900 letters that contained approximately 1,700 comments on cytology PT participation and 470 comments on the cytology PT program. The majority of the comments were from individual laboratory professionals, primarily pathologists, cytotechnologists and medical technologists. We also received comments from provider organizations, professional organizations, and other health care professionals.

*Comment:* Commenters recommended that the studies called for by CLIA be

completed before final regulations are written.

*Response:* The CLIA studies are extremely complex research projects and will require several years to complete. Therefore, while the results of these studies may impact future regulatory requirements, they should not delay implementation of basic good laboratory practice standards included in this regulation.

*Comment:* One commenter suggested that there is a need to allow for interim provisions for in-house blind testing and sharing specimens for histology and histocompatibility testing.

*Response:* Under Subpart P, Quality Assurance for Moderate or High Complexity Testing, or both, we have provided for determining the accuracy of tests not covered in subpart I.

*Section 493.801 Condition: Enrollment and Testing of Samples. (Previously Named, Condition: Enrollment and Testing of Samples for Laboratories performing Level I and Level II tests)*

*Comment:* Commenters recommended that we phase in PT programs over two years.

*Response:* We agree that immediately implementing PT requirements for a vast number of newly regulated laboratories would place an unacceptable burden on such laboratories as well as on PT program providers and HHS and its designees. Therefore, we have decided to allow a two-year phase-in PT for enrollment of newly regulated laboratories, but will continue to require PT participation for laboratories that were regulated under the March 14, 1990 rule. A two-year phase-in, until January 1994, for enrollment of previously unregulated laboratories will allow the PT providers time to expand their programs to accommodate the increased number of laboratories and also allow regulatory agencies sufficient time to develop processes to monitor laboratory performance and apply sanctions.

*Comment:* Commenters recommended that a laboratory be allowed to change PT programs to best meet its needs.

*Response:* Section 353(f)(3) of the PHS Act requires that laboratories issued a certificate be proficiency-tested for each examination or procedure conducted within a category of examinations or procedures for which it has received a certificate, except for examinations or procedures for which a proficiency test cannot reasonably be developed.

Recognizing the technical and administrative difficulties that would be encountered by laboratories, PT program providers, and HHS or its designees if PT were required immediately for all procedures and

examinations, we are phasing in PT. Therefore, although many external assessment programs provide evaluations of laboratory performance for a wide variety of tests, in order to guide efforts to improve laboratory performance, we have initially selected only those tests for which assessments of laboratory performance can be implemented uniformly on a national basis in a regulatory context for inclusion in the mandated PT evaluation program. We are not including in the required PT program those tests for which stable materials have not been developed, those for which the scientific community has not agreed upon what should be and can be measured, nor those tests for which we have been unable to evaluate the performance of laboratories to determine appropriate grading criteria.

For those tests that are not included in the uniform graded PT program, a laboratory must establish the accuracy and reliability of its testing procedures. A laboratory may either subscribe to an external assessment program that monitors these tests at least twice a year, or share split samples with another laboratory or incorporate known valued materials as unknowns in the testing process.

For those procedures and examinations that are included in the required uniform PT program, our interpretation of Congressional intent is that a laboratory using more than one method need only participate in PT for the test system, assay, or examination. For example, if a laboratory uses three different test systems to perform cholesterol measurements, it must participate in PT for only one of these systems in a PT testing event. This must be the method that is used as the primary system or is located at the principle site of patient testing during the time that the PT event is being conducted. We also are requiring that the laboratory establish the relationship between the results obtained with the other test systems and the system being evaluated by PT as part of the laboratory's quality assurance program.

In the same manner, a laboratory performing testing at multiple sites under one certificate must either participate in PT for each site or it must establish and maintain a fixed relationship between the results obtained at each site with those obtained at the principle site used for patient testing. In such cases, the laboratory must select the principle patient testing site as the site to be evaluated by PT.

A multiple-site laboratory, which is covered by a single certificate and elects

to participate in PT only at its principal patient testing site, must appreciate the fact that a failure in PT could lead to the revocation of its certificate for all sites, not just for the one participating in PT. Laboratories are allowed to change from one HCFA-approved PT program to another approved program after they have been enrolled for one year.

*Comment:* Some commenters recommended that we change the requirement for a laboratory to examine or test PT samples in the same manner as it tests patient specimens. These include: to delete the requirement, to add a qualifying statement "where reasonable and practical and/or possible," to place no restrictions on repeat testing of samples, to allow inter-laboratory communication after PT results are submitted, to apply the same criteria for referral of PT samples as used for referral of patient specimens, to treat documentation for PT samples and patient specimens in the same manner, and to require the regulatory agency to investigate any allegation that a PT sample might be referred to another laboratory rather than require the laboratory to report suspicious behavior.

*Response:* Since the requirement for a certified laboratory to treat PT samples in the same manner as it treats patient specimens referred to it in the ordinary course of business is specifically stated under section 353(d)(1)(E) of the Public Health Service Act, it cannot be deleted. We agree with the commenters that this requirement only applies to the extent that a PT sample is similar to a patient's specimen—that is, some PT samples are lyophilized and must be reconstituted before analysis, unlike a patient specimen. However, the intent is for the laboratory not to otherwise treat the PT samples uniquely by performing more analyses or a different type of analysis than that which would be applied to a patient specimen; repeated analysis of PT samples is not appropriate unless patient specimens are similarly tested.

We have clarified our intent under paragraph (b)(3) of this section to allow inter-laboratory communication about results after the date by which a laboratory must report results to the program for the testing event.

Under paragraph (b)(4), we indicate that PT specimen referral is not necessary for purposes of PT, since a laboratory is being evaluated on the basis of its own level of service, not on any combination of service between it and another laboratory. We understand that this violates the condition of treating the PT sample like it would treat a patient's specimen in this instance. It was the intent of paragraph

(b)(4) for the regulatory agency to investigate any allegation that a PT sample might be referred to another laboratory, but such allegations may require other laboratories to report suspicious behavior.

We concur that the intent of paragraph (b)(5) of this section is for a laboratory to treat documentation for PT samples and patient specimens in the same manner.

*Section 493.803 Condition: Successful Participation*

Approximately 1,500 comments were received in response to this section of the proposed rule. Over 95 percent of the commenters opposed the requirement to apply sanctions to a specialty or subspecialty based on the PT failure for an analyte or test within the subspecialty or specialty.

*Comment:* A large number of commenters strongly objected to losing certification for a specialty or subspecialty if a laboratory performed unsuccessfully for the challenges on a given analyte; the commenters also opposed the loss of certification in the respective specialty if the laboratory performed unsuccessfully in a given subspecialty.

Many comments provided recommendations or alternative suggestions to this regulation including the following:

- Establish a probationary period for the laboratory to investigate and clarify an event following a failure;
- Establish an appeal mechanism for failures;
- Conduct either a pilot or phase-in the PT program before implementing penalties;
- Use a training/education focus;
- Establish an "investigational status" for any laboratory that has failed PT or voluntarily withdrawn;
- Correlate suspension/termination with the instrument/method used for testing the analyte or group of analytes, since specialty/subspecialty categories may not be relevant to the state-of-the-art technology;
- Place the laboratory at risk for only the failed analyte;
- Continue testing the analyte by another method, if the analyte was performed routinely using more than one method;
- Withhold action against the laboratory until there are serious problems with several analytes in specialties/subspecialties;
- Give the laboratory the option to withdraw from testing for the failed analyte;

- Delete § 493.801(b) of this regulation and refer to paragraph (h) "Intermediate Sanctions" in the Act; and

- Base adverse actions only on true failures.

An additional suggestion provided by one commenter for the specialty of chemistry was to suspend by analyte only if the overall score for the specialty falls below 80 percent.

*Response:* We agree with the commenters that the loss or limitation of a laboratory's approval or certification for a specialty or subspecialty if a laboratory performs unsuccessfully for the challenges on a given analyte is a heavy penalty. A laboratory performing unsuccessfully for an analyte or challenge can choose to voluntarily withdraw from participation in PT, by all methods, for that analyte or challenge, thereby losing the ability to perform the test, without causing the loss of approval or certification for the entire specialty or subspecialty. In addition, we have included provisions for invoking an intermediate sanction, as opposed to loss of approval or revoking a license for the entire specialty, whenever failure is limited to an analyte or test or for a subspecialty.

We are aware of the need to provide an opportunity for a laboratory to identify and to correct unsatisfactory performance before voluntarily withdrawing service or having sanctions imposed. We are reducing the number of testing events per year from four to three in order to allow more time between testing events for corrective action before sanctions are applied.

*Section 493.805 Condition: Successful Participation Before Initial Approval of Licensure*

*Comment:* A few commenters recommended an expedited PT schedule for new laboratories awaiting a provisional certificate. One felt that this could be accomplished by allowing laboratories to request PT samples from previous PT events. Another commenter felt that a provisional six-month certificate should be issued when laboratories are awaiting PT test results, if their compliance with all other regulations has been verified. A few commenters expressed concern that this regulation will cause delay in the institution of new tests and provision should be made to allow parallel testing or split samples to verify satisfactory performance for a new test.

*Response:* We agree that the requirement for demonstrating satisfactory performance in one PT testing event before certification or revising a certificate is not necessary and have deleted it from the regulations.

*Section 493.808 Condition: Successful Participation Before Certification*

*Comment:* One commenter suggested expediting the certification process; another suggested changing this requirement so that laboratories would be obligated to pass only two consecutive or two of three PT events in order to obtain certification; and a third suggested that a laboratory not be denied certification because the PT program was not able to provide material.

*Response:* The number of testing events per year has been reduced to three. We have also eliminated the requirement that a laboratory must demonstrate satisfactory performance before issuance of a certificate.

*Section 493.807 Condition: Reinstatement After Failure To Participate Successfully*

*Comment:* Many commenters felt that a waiting period of not less than six months from the date of termination of Medicare approval or CLIA certification was too long to wait and therefore wanted the reinstatement process expedited. Many others felt that less than three PT events should be required for reinstatement because a laboratory cannot improve when it is not testing. Some felt that one on-site PT was sufficient for reinstatement, while some others felt that no on-site PT was needed since on-site PT was considered to be expensive, not cost effective, and burdensome. A few commenters felt that a special PT challenge should be provided. A few others felt that instead of the termination period the laboratory should be reinstated when it can demonstrate that the problems leading to the failure have been corrected and it is successful in two PT events.

*Response:* We feel that after a laboratory has voluntarily withdrawn from offering service or has been terminated, a requirement to demonstrate that problems have been corrected is essential before service can be resumed. A period of six months may seem excessive to some; however a failing laboratory had at least this amount of time to correct its performance problems before it failed and was unable to do so. We feel that the criteria for reinstatement should include two consecutive PT testing events to demonstrate that the problem(s) have been corrected which would require a minimum of six months.

Although an on-site PT event will not be required prior to reinstatement, we retain the right to use on-site PT, if necessary. On-site PT offers an

inspecting agency the opportunity to observe the testing process and can help to identify source(s) of error.

*Sections 493.821 through 493.865  
Proficiency Testing by Specialty and  
Subspecialty (Except § 493.855,  
Cytology)*

*Comment:* Some commenters opposed setting the score for satisfactory performance at 80 percent and were in favor of a lower passing score. An 80-percent score was viewed as an unduly harsh and unrealistic requirement. It was also considered by some to be too inflexible for some testing areas such as bacteriology. One commenter suggested that the 80-percent score should be a cumulative score for two PT events, while another recommended that the scoring be suspended until a pilot program determines an appropriate value. Another commenter proposed adopting the Commission on Office Laboratory Assessment (COLA) requirements for successful participation. Another commenter suggested a minimum passing score of 90 percent if the director is qualified as a M.D., Ph.D., or D.O. An additional suggestion offered for this regulation was that an overall score of 60 percent be used for satisfactory performance if less than 10 challenges are provided.

*Response:* We feel that a laboratory that meets acceptable standards of laboratory performance should be able to maintain at least 80 percent of its results for analytes or tests in any specialty/subspecialty within the limits of acceptable performance described in these regulations. Several factors were taken into account in establishing an 80 percent performance requirement including: A review of historical data that documented the ability of most laboratories to achieve this level of performance; the probability that a poorly performing laboratory will be identified as such; and the probability that a laboratory with acceptable performance will not be misidentified as a poor performer. This requirement does not imply that more than 20 percent of the results obtained in a laboratory that occasionally achieves a score of less than 80 percent jeopardizes patients' care. However, a laboratory that cannot achieve scores of at least 80 percent over an extended period of time does pose an added risk to the public. Therefore, we are retaining the requirement of at least an 80-percent overall score as a criterion for satisfactory PT performance in all areas.

*Comment:* A few commenters proposed 100 percent for an analyte score for diagnostic immunology, chemistry, and hematology. A few

commenters felt that the 80 percent analyte score was unduly restrictive, while another suggested an analyte score of 90 percent.

*Response:* We consider a requirement of at least 80 percent for most areas as reasonable. Since we are requiring five samples per testing event, less than an 80 percent score would mean a laboratory tests only three of five samples (60 percent) accurately.

*Comment:* A few commenters felt that flexibility should be provided in the program to allow a laboratory to continue patient testing if the laboratory's inability to submit a result is due to an unusual event such as a loss of sample(s) or a logistic breakdown in the PT system. It was further suggested that sanctions should not be imposed during the appeal process. One commenter proposed that a score of "0" should be given to laboratories that fail to participate in a particular survey regardless of their past participation, while another commenter felt nonperformance should be fineable offense rather than a "0" score. One commenter suggested a separate category for a test not performed.

*Response:* Since flexibility has been given in §§ 493.821 through 493.860 of this regulation to PT program providers to permit them to compensate for problems in the testing process, we do not feel that a laboratory will be inappropriately penalized for failure to participate.

*Comment:* Although the time frame is not specified in the regulations, two commenters replied that in small laboratories, a turn-around time of 5-7 days could be a hardship and that a turn-around time of 10-15 days would be more realistic.

*Response:* We feel that the time frame for reporting results should be determined by the PT provider(s). Since there were no comments opposing this regulation we are adopting the content of the proposed rule as final.

*Comment:* One commenter proposed the terminology "unsuccessful" rather than "unsatisfactory" with regard to immunohematology. One commenter also requested clarification of the term "appropriate" as applied to training. One suggestion, specific for microbiology and diagnostic immunology, was that the laboratory in question should investigate the problem, take corrective action, document the findings and retain the records for two years or until the next inspection, whichever is later. One commenter suggested that an outside source be consulted for technical assistance with a PT failure; another commenter requested

that the laboratory be allowed 90-120 days to correct the problem.

*Response:* The term, "unsatisfactory" relates to the failure in a PT event, while the cumulative effect of these testing event failures leads to "unsuccessful" overall performance.

The term "appropriate" refers to the level of training/technical assistance needed to correct problem(s) where failures occurred, and thus enable the laboratory to reach satisfactory status. The laboratory is free to choose its own form of remedial action, provided that it corrects the problem(s) after the first failure.

A statement or plan of corrective action may be required by the regulatory agency and any such actions must be documented. We have increased the time between testing events, which will allow more time for corrective action to occur before the next testing event.

*Comment:* In diagnostic immunology, one commenter suggested substituting "marginal performance" when a laboratory fails to "achieve satisfactory performance for the same analyte or for an overall testing event in two consecutive testing events, or two out of three consecutive testing events." One commenter suggested that unacceptable performance should only apply after failure of three consecutive testing events or three out of four testing events. Another asked that the criteria for unsuccessful performance be appropriate to the type of specimen.

*Response:* We feel that unsatisfactory performance should be corrected as soon as possible. Therefore, a plan of corrective action may be required by the regulatory agency after one unsatisfactory testing event. This permits a laboratory to correct its "marginal performance."

By reducing the number of testing events per year from four to three, we have allowed more time for corrective action to occur before the next testing event.

Specimen type has been considered in developing the PT program. A laboratory will be evaluated based on the type of specimen it ordinarily examines. As other specimen types are added to the program, appropriate criteria for unsatisfactory performance will be developed for these specimen types.

*Comment:* One commenter recommended that for microbiology and diagnostic immunology "marginal performance" be substituted for "unacceptable" in the instance when a laboratory does not score satisfactorily on two consecutive testing events or two out of three testing events. They further

recommended adding the actions that a laboratory must take to address "marginal performance". A few commenters suggested changing unacceptable performance to either three out of four testing events or four out of six testing events.

*Response:* We have taken into account concerns over "marginal performance" by allowing time for corrective action to occur. We are specifically delaying the imposition of adverse actions until a laboratory has demonstrated unsatisfactory performance on two consecutive or two out of three testing events.

*Comment:* A few commenters felt that a 100-percent performance requirement should be changed to 80 percent; one commenter felt the requirement should be "less than" 100 percent; and another commenter wanted the 100 percent performance requirement deleted. One commenter requested clarification of the concept of how "analyte" applies to "antibody identification".

*Response:* Those specialty/subspecialty tests for which a 100-percent performance standard is required are those for which mistakes in testing could have an immediate and profound effect on patient care. We will retain the 100 percent analyte score for the ABO/Rh group and compatibility testing in recognition of their importance. As indicated previously, a laboratory that achieves a score of 80 percent does not imply that 20 percent of its results jeopardize patient care. However, sustained scores of less than 80 percent indicate chronic performance problems that could affect patient care and must be corrected.

The definition for the term "analyte" under § 493.2 is applicable to "antibody identification."

*Comment:* Many commenters felt the concept that PT samples are the same as patient samples is unrealistic and consequently wanted an overall score requirement of 80 percent rather than 100 percent for ABO/Rh group, and compatibility testing. However, one commenter suggested a score of 90 percent overall; one a score of 60-80 percent, and another wanted the requirement deleted in its entirety.

One commenter suggested that if the number of challenges was increased, a 90-percent score would become acceptable.

*Response:* We disagree with the commenters. We require at least 95 percent agreement on the correct response for such tests before they are evaluated, which compensates for unrealistic samples. Given the importance of accuracy in these tests we will retain the 100 percent overall score

for ABO/Rh group and compatibility testing.

#### Section 493.855 Cytology

*Comment:* Most commenters did not object to participating in a PT program for gynecologic cytology. However, some who did object recommended that quality control and quality assurance measures be used instead of PT to identify individuals who need remediation. Several stated that the proposed regulations placed too much weight on PT as a measure of quality; some suggested that mandatory continuing education be substituted for PT. A few others recommended conducting pilot studies or initiating cytology PT on a trial basis before a national program is established.

*Response:* CLIA mandates PT for cytology. The primary purpose for PT is to identify performance problems that need correction or improvement and to ensure that good performance is maintained over time. Quality control and quality assurance, in conjunction with PT, identify performance problems. We recognize the value of continuing education, but do not think that it can substitute as a measure of performance.

PT as described in the revised § 493.855 is a means to identify individuals who need intensive remedial education to improve their performance. While pilot PT programs for cytology may be worthwhile, we believe we have developed reasonable and achievable standards based on information and implementation experience from existing State PT programs for cytology. Revisions in the requirements for PT will be based on recommendations of the Clinical Laboratory Improvement Advisory Committee. We believe that the revisions described herein provide the framework for a PT program that is reasonable and achievable.

*Comment:* An enormous number of commenters opposed the requirements under § 493.855(a) describing PT for individuals. A large number of commenters felt that the requirement for testing individuals, in particular pathologists, was tantamount to recertification and could supersede State medical licensing and medical specialty recertification prerogatives. Many suggested testing the laboratory as a whole instead of individuals. They asserted that testing the laboratory was the most cost-effective and realistic measure of day-to-day quality and would allow for the normal teamwork among pathologists and cytotechnologists. Some commenters expressed concern that individual testing measured test taking skills rather than performance ability.

*Response:* CLIA requires periodic confirmation and evaluation of the proficiency of individuals involved in screening and interpreting cytologic preparations. This evaluation is intended as a measure of performance only in the area of gynecologic cytology, and therefore does not threaten or supersede medical licensure or certification. Unlike most other laboratory subspecialties, the quality of cytology testing depends on the recognition and interpretive skills of the individual cytotechnologists and pathologists; therefore PT is focused on measuring these individual skills.

*Comment:* An overwhelming number of commenters were opposed to participating in PT twice per year as required under proposed § 493.855(a). The majority suggested changing the frequency of testing to every one or two years. Other suggestions ranged from four times per year to every five years. A few commenters suggested variable testing schedules in which testing frequency would be reduced for those individuals with successful participation and increased for those who were unsuccessful. Commenters said that biannual testing was excessive and that skills are not lost in six months. No State conducts biannual testing currently, some added. They also pointed out that there is no data to support that the frequency of PT in the proposed regulation will improve the quality of cytology laboratory test results.

*Response:* In response to these comments and other considerations, we are initially establishing the frequency for cytology testing events for each individual at once per year (unless the individual fails a testing event). We have made this change from the proposed rule on the basis of the specific cytology PT requirements at section 353(f)(4)(B)(iv) of the PHS Act. Here, the law requires that the Secretary establish "periodic" evaluation of individuals involved in screening or interpreting cytological preparations. This is in contrast to the general PT requirement for at least twice annual PT set forth at section 353(f)(3)(A) of the PHS Act. We believe that we may interpret the cytology provision as the one that governs since Congress was so specific in the law. Accordingly, we believe that we have the discretion to define "periodic" for cytology PT, and have concluded that it permits once annual PT for each individual engaged in screening or interpretation of cytological preparations.

Since there is currently no cytology PT being conducted on a national basis, the

logistics for establishing and administering such a program must be developed. We expect that the establishment of a program will take a considerable period of time, since a number of tasks must be accomplished, such as the accumulation and referencing of slides and the development of scoring and reporting systems. In addition, we anticipate that administering the program will involve coordination with State survey agencies and the establishment of systems to schedule testing events, distribute test sets and conduct on-site testing. In light of the anticipated time required for development of the program, we are allowing laboratories previously unregulated until January 1, 1994 to enroll all individuals involved in gynecologic cytology slide examination in an approved PT program.

*Comment:* A large number of commenters addressed the requirements under proposed § 493.855(a) for unannounced, on-site testing and announced, off-site testing events. Many commenters had no problem with on-site testing events, but said that they should be announced. They stated that unannounced testing will be disruptive, costly and inefficient, since many examinees may be absent on the test date. They also said there was no real benefit to totally unannounced testing since preparation for this type of test is not possible. A few commenters suggested that the week of the on-site testing be announced but not the day. A few commenters suggested that on-site testing be reserved only for remedial actions. Numerous commenters preferred a mailed PT program over on-site or off-site testing, saying that it would be more cost-effective. Some recommended regional or statewide testing instead of on-site testing and a few suggested that this off-site testing be used in combination with mail-out challenges and on-site evaluations, with the laboratory given the option of choosing sites and testing format. Other commenters recommended the elimination of off-site testing because it could not be characterized as being "under normal working conditions". Some commenters noted that off-site testing is costly in terms of travel expenses and time lost from work and that it could cause delays in reporting patient results and increase the cost of Pap smears. Some commenters stated that it would be extremely difficult for small laboratories to participate in an off-site program. A few commenters suggested a testing format based on an on-site review of random cases by outside cytology professionals.

*Response:* Standards in CLIA under section 353(f)(4)(B)(iv) of the PHS Act mandate both announced and unannounced on-site PT of individuals. Therefore, we are retaining the requirement for announced and unannounced on-site testing. We agree with commenters that in most instances announced testing is preferable. However we are retaining the option to conduct unannounced testing, if needed, in laboratories on which we have received complaints, for example. We expect that testing will typically be announced and are requiring that PT providers schedule the on-site events at least 30 days in advance. This provision should allow maximum participation in testing events since all personnel, except in unusual circumstances, should be present at the time of testing. In spite of this provision, some individuals may be unable to participate in the on-site testing event. Therefore, we are providing for off-site testing events in each region or State so that personnel who miss an on-site event, as well as those who are newly employed or those who need to be retested, can participate in a testing event within a reasonable time frame. We have specified that these off-site events must take place as necessary to provide all individuals with opportunities for testing.

While a mailed PT program may be more cost-effective, we do not think that it is appropriate for evaluating the performance of individuals, as it would be impossible to monitor in order to ensure that each individual was equitably tested. Mailed PT is more realistic as a tool for assessing the overall or collective performance of the whole laboratory.

*Comment:* A few commenters suggested changing the passing score for a PT event which was fixed at 80 percent under proposed § 493.855(b). Approximately equal numbers of commenters recommended making the passing score more than 80 percent as recommended making it less than 80 percent. Several commenters suggested adopting the scoring system used in Maryland or New York.

*Response:* We are modelling the scoring system as described in § 493.945 after that in use in the State of Maryland. To that end we have changed the minimum passing score to 90 percent. Therefore, § 493.855(b) now states that an individual is determined to have failed a testing event if he or she scores less than 90 percent on a test set. This 90 percent score, however, cannot be directly compared to the proposed 80 percent score because the point scoring system has also been changed. In

addition, at § 493.855(b), we have added a maximum time allowed for each testing event, based on the PT program in the State of Maryland. Individuals are given not more than 2 hours to complete a 10-slide test and 4 hours to complete a 20-slide test. These time limits were established to provide for equitable testing on a national scale and to allow individuals sufficient time to complete the test at their normal pace without unduly restricting or extending the time for the examination.

*Comment:* The consequences of failing a testing event as described under § 493.855(b) were a major concern to a large number of commenters. Numerous commenters suggested that individuals who fail a PT event be given the opportunity for a retest before remediation or rescreening requirements are imposed. Some noted that test anxiety is likely to be a factor for the initial examination. Many commenters suggested that retesting should occur within 30 days after the first test. One organization said that pathologists should be excluded from failure penalties because this action would preclude physicians from practicing medicine in their specialty.

An overwhelming number of commenters recommended eliminating the requirement for reexamining the last 500 slides read by an individual who fails a PT event. They said it is punitive, burdensome, has no statistical validity, and that, for small laboratories, could mean going back to pull slides from many previous months. Some commenters suggested reexamining less than 500 slides, with suggestions ranging from 50 to 250. Others recommended prorating the number of slides to be reexamined based on the size of the laboratory. A few recommended requiring a small percentage of previously read slides be reexamined by an outside reviewer.

Many commenters also opposed the requirement to reexamine all subsequent gynecologic slides until an individual passes a PT event. They said that this requirement would effectively force small laboratories to close because the individual who failed the PT event and the rescreener would both be removed from the work force. In light of the current shortage of cytotechnologists, they noted, this could have a detrimental impact on Pap smear services. Few commenters opposed requiring remedial training for individuals who failed PT as long as individuals were first given a retest. A few commenters suggested that remedial training be provided by approved cytopathology teaching centers.

*Response:* We agree with the commenters on several recommendations concerning PT failure. We are deleting the requirement for reexamination of the last 500 slides read by an individual who fails a PT event. The intent of this review was to further analyze the slide evaluation problems that an individual demonstrated in PT and to ensure that there were no significant errors in recently evaluated specimens. While we realized that the statistical probability of discovering missed cases of cancer by this retrospective rescreening was low, it was felt that even if only a few cases were discovered, the review would be worthwhile. Nevertheless, we agree with the commenters that this requirement may be burdensome and costly for some laboratories and may not accomplish the intended goals. Even though we are deleting the requirement for retrospective slide review, we expect that if a serious performance problem is identified by PT, the laboratory will take the initiative to review previous slides to further define the problem. Furthermore, laboratories must meet stringent requirements for quality control, as specified under § 493.1257, which include limits on workload and retrospective negative slide review and confirmation of abnormal results. At least 10 percent of the slides interpreted as negative by each cytotechnologist will be routinely reexamined. This ongoing program for error detection and feedback on performance should identify individual performance problems and correct them on a continuing basis.

We are providing for a series of retests for those individuals who fail PT events. Individuals who fail the annual testing event, which involves evaluation of a 10 slide test set as described in § 493.945, must be provided with a retest, using another 10 slide test set, within 45 days after the receipt of the notification of failure. Examinations must be offered as necessary within each State or region to provide sufficient opportunities to participate in a retest within this period of time. An unexcused failure to appear for a retest will result in test failure. There are no other repercussions for failure of the first testing event.

If an individual fails the first retest (the second test), the laboratory must provide him or her with documented remedial training and education in the area of failure and must assure that all subsequent gynecologic slides are reexamined until the individual is again retested and passes the testing event. If this slide reexamination is not feasible,

such as in a laboratory with few personnel, the laboratory has the option of assigning the individual duties other than gynecologic slide evaluation. Following completion of remedial training, the individual is eligible to take another retest. This second retest involves evaluating a 20 slide test set, and is thus more rigorous than the first retest.

If an individual fails the second retest (the third test) he or she must cease examining gynecologic slides. In addition, the laboratory must assure that the individual obtains in-depth training in cytology by obtaining at least 35 hours of formally structured continuing education which focuses on the examination of gynecologic preparations. Formally structured continuing education means educational activities such as those sponsored by local, regional, national or international organizations or institutions. Such programs are usually accredited by the Accreditation Council for Continuing Education, or equivalent, and provide one-for-one credit hour certification. For physicians, this training would consist of credit hours that are approved by the American Medical Association or the American Osteopathic Association for either category 1 or category 2D physician recognition award. For cytotechnologists the credit hours are approved by the International Association of Cytology or The American Society of Cytology, for example. Numerous training programs exist throughout the country which meet these criteria.

After completion of the training requirement, the individual must be retested with a 20 slide test set and achieve a passing score before he or she may resume examining gynecologic slides.

*Comment:* We received only a few comments concerning the sanctions for failure of the laboratory to take the required remedial actions after PT failure as described under § 493.855(c). The majority of these suggested that sanctions be directed at education and enhanced performance rather than punitive actions. One commenter requested clarification as to why a cytology laboratory is penalized for not providing remediation instead of for failing PT as was proposed for other laboratory subspecialties.

*Response:* We are retaining and expanding this requirement so that sanctions will be imposed on a laboratory that does not provide for individuals who fail a testing event to be retested as well as to receive remedial training after failing the first or second

retesting events. PT in other subspecialties is based on laboratory performance and sanctions are imposed on the subspecialty for repeated poor performance. Since the PT program for cytology is based on the assessment of individual performance, the effects of PT failure are designed to improve the performance of individuals, and the laboratory is sanctioned for not participating in this improvement process.

#### Changes to the Regulation

##### *Section 493.801 Condition: Enrollment and Testing of Samples*

Laboratories not previously subject to Federal regulations must be enrolled in an approved proficiency testing program on January 1, 1994. Laboratories regulated under the March 14, 1990 rule are required to enroll and participate in an approved proficiency testing program under this rule, effective July 1, 1992 for the calendar year 1993.

Since PT is no longer conducted on a quarterly basis, we are amending § 493.801(a)(3) and are requiring a laboratory to participate in an approved PT program for one year before it can designate a different PT program for compliance with requirements for PT enrollment. We are amending § 493.801(b)(2) to clarify the frequency with which PT samples may be tested and § 493.801(b)(3) to permit inter-laboratory communications about PT after the reporting date for the testing event. Section 493.801(b)(4) is modified to clarify our intent for a laboratory not to refer PT samples for tests for which it is certified to perform to another laboratory for analysis. We are also indicating that the laboratory director, rather than the PT program provider, has the responsibility to assure that a signed attestation statement is maintained for each PT event that documents that PT samples have been handled in the same manner as patient specimens. The attestation statement is part of the record of the PT event and therefore is required to be kept for a minimum of two years from the date of the PT event.

##### *Section 493.803 Condition: Successful Participation*

Provisions of this section become effective on January 1, 1995 for previously unregulated laboratories. Under § 493.803(c), we are withdrawing the proposal to suspend a laboratory's certificate or terminate Medicare or Medicaid approval for an entire specialty or subspecialty for a laboratory which fails to perform

successfully for an analyte or test. Previously regulated laboratories subject to the March 14, 1990 rule will be subject to sanctions for PT failure beginning on January 1, 1994. If a laboratory fails PT for an analyte or test, they may voluntarily withdraw service for the test or analyte, by all methods, and therefore not be subject to sanctions for the specialty or subspecialty. If they fail to withdraw, they are subject to intermediate sanctions for the analyte or test subspecialty.

*Section 493.806 Condition: Successful Participation Before Certification*

Laboratories are not required to participate in PT before a certificate or a revised certificate is issued. Therefore, we are deleting this proposed condition.

*Section 493.807 Condition: Reinstatement After Failure to Participate Successfully*

Two consecutive satisfactory PT testing events, (one of which may be on-site, if necessary), are required before a laboratory is reinstated after termination of Medicare approval or revocation of the CLIA certificate.

*Sections 493.821 through 493.865 Proficiency Testing by Specialty and Subspecialty (Except § 493.855, Cytology)*

The provisions of the proposed rule are adopted as final with the following exceptions/additions:

- In § 493.835, only overall performance is evaluated in syphilis serology.

*Section 493.855 Cytology*

By January 1, 1994, individuals engaged in the examination of gynecologic preparations must be enrolled in a PT program. Initially, each individual must participate in an annual testing event that involves the examination of a 10 slide test set. One testing event will be conducted annually in each laboratory and will be announced or unannounced. Testing events will be conducted as necessary in each region or State.

Individuals who fail the annual testing event by scoring less than 90 percent on a 10 slide test set must be retested with another 10 slide test set within 45 days of the notification of failure. Individuals who fail the retest must be provided with remedial training, and all subsequent gynecologic slides must be reexamined until the individual passes a 20 slide retest. An individual who fails the second retest must cease examining gynecologic slides and the laboratory must assure that the individual obtains at least 35 hours of continuing education

in cytology before another 20 slide retest is scheduled. Unexcused failure to appear for a retest will result in test failure.

*Subpart I—Proficiency Testing Programs for Tests of Moderate and High Complexity*

*Summary of the Proposed Rule*

We proposed this subpart as Proficiency Testing Programs for Level I and Level II Tests, but have renamed it to be consistent with changes in the categorization of tests under § 493.10.

We proposed requirements that a PT program provider would have to meet before a laboratory could use the program to meet the PT requirements of Subpart H, Proficiency Testing for Laboratories Performing Tests of Moderate and High Complexity. For each specialty and subspecialty, we described the program content, frequency of challenge, number of challenges per quarter, and process for evaluating performance.

We proposed that programs would have to offer at least five challenges per quarter for each analyte or test, except for mycobacteriology, which was to be evaluated with five challenges twice per year. Criteria for determining acceptable performance were proposed, with performance evaluations based on the scope, type, and level of services a laboratory offers.

We proposed a process for updating the PT requirements after the proposed program had been in operation for two years. We proposed to review standards for PT programs on a regular basis and to make necessary changes in the required program after giving notice of these changes to all affected individuals and groups through an expedited rule making.

In § 493.945 we proposed that test sets for cytology PT be composed of 20 glass slides which represent various types of challenges including unsatisfactory preparations, normal and various abnormal challenges. We proposed that each individual's responses would be evaluated by comparison with responses that represented an 80 percent consensus agreement of at least 5 pathologists. We proposed that premalignant and malignant slide preparations be confirmed by an 80 percent consensus agreement on the tissue biopsy. We proposed a scoring system with point values based on the significance of the relationship of the slide interpretation to a clinical condition. The point values for correct and incorrect responses would range from maximums of 2 points to -1 point, with a formula for calculating the total

points based on 100 percent. We proposed four response categories using the nomenclature developed at the National Cancer Institute Workshop in Bethesda, Maryland in 1988, known as The Bethesda System, and proposed that this nomenclature system be used by individuals to report PT results.

*Implementation of Subpart I*

The provisions of Subpart I of this rule will be applied to proficiency testing program providers seeking approval for their programs in 1993. Applicants must submit a detailed description of their program by July 1, 1992 in order to be approved as 1993 proficiency testing program providers.

*Comments and Responses*

*Section 493.901 Approval of Proficiency Testing Programs*

*Comment:* Some commenters asked that "for profit" and "duly empowered" city PT programs be permitted. A few commenters suggested using existing PT programs, such as those offered by States or by professional specialty organizations, such as the Commission on Office Laboratory Assessment. A few commenters recommended that the FDA be designated to clear and monitor the PT programs; a few others preferred that HCFA be the monitoring agency.

Many commenters asked that different PT programs be established for Levels I and II testing. A few commenters suggested that PT programs should develop PT for specific methodology/instrument combinations and be allowed time to develop test materials without subjecting laboratories to penalties. Other suggestions included the establishment of a program for eye banks and the establishment of an advisory panel of experts in PT. Some commenters suggested that we provide a customer service or complaint handling process and define the procedure in those situations where PT is not available.

*Response:* We cannot approve "for profit" PT programs because the law references only State and private non-profit organizations as approved program providers. In accordance with State law, a State may delegate responsibility for PT of a city's laboratories to a city; however, the city's PT program must meet all applicable PT program provider requirements before it can become an HHS approved PT program provider. A professional specialty organization that is non-profit can submit its program for review and approval. Approval of PT programs and monitoring the effectiveness of the

approved programs is an HHS responsibility, which could be delegated to any of the agencies within HHS. Presently, HCFA has that responsibility, but HCFA relies on the PHS to provide advice to HCFA on technical and scientific issues related to PT.

We do not propose to have different PT in terms of the frequency, number of samples, or grading for tests of moderate and high complexity. We agree that PT for less complex testing should be provided. This can be accomplished by PT providers developing PT modules to fit the testing being performed without establishing completely separate high and moderate complexity PT programs. For example, PT providers might establish a program for laboratories that only perform Gram stain testing. The phase-in period will allow the PT providers time to develop the needed modules and for laboratories to enroll in a program that most closely matches its level of service. In addition, a PT provider can provide samples that are specific for a methodology/instrument and can develop new materials before they are employed in the regulatory portion of the program.

We have reviewed the services offered by eye banks and do not feel that a unique PT program is necessary since the laboratory testing performed by eye banks fits well with existing programs. We agree with the comment that an advisory panel on PT is needed. The Clinical Laboratory Improvement Advisory Committee or one of its subcommittees can address PT concerns.

Approved PT program providers must offer technical assistance to laboratories enrolled in their PT programs. We agree that, as part of this assistance, PT providers must establish and maintain a process for resolving problems with administrative, technical, and scientific issues about program operations. Therefore, we have modified the regulation to assure this process will be available in programs offered by approved providers.

If no PT program exists, a laboratory can maintain its own internal consistency in performance by analyzing split patient or control samples with another laboratory or by incorporating known value samples as unknowns in the test procedure. However, if a PT program evaluates performance for analytes or tests which are currently not part of analytes or tests included in regulatory PT, a laboratory can use the unregulated tests to monitor its own performance for these additional tests.

*Comment:* Some commenters indicated that it should be imperative

that PT providers indicate the source, manufacturing process, possible interfering components and predictable matrix effects of all PT samples offered in their program. Providers should also arrange to include shipping and storage conditions for samples and to monitor the condition of samples on arrival at participating laboratories. A few commenters suggested that the PT materials should be compatible for each technology/instrument. It was recommended that the providers should be allowed to develop test materials without penalizing participants and that providers should be relieved of any responsibility for defending the credibility of values assigned to PT samples when the samples were used for on-site PT.

*Response:* We agree that PT program providers should be responsible for identifying any known interfering substances in the sample matrix they provide and to assist participating laboratories and kit and instrument manufacturers in identifying any unknown interferents. We are adding a provision to require approved PT program providers to have a process in place to resolve administrative, technical and scientific issues about their program. Concerns about the logistics associated with PT, such as shipping and storage conditions, etc., or about sample matrix effects for a particular technology/instrument could also be handled by this process.

We agree that PT providers should complete the development of new test materials before these materials are introduced into the regulatory program. However, PT programs must still meet the minimum requirements specified for approval, in addition to the inclusion of strictly experimental PT components.

Regarding samples used for on-site PT, the PT provider is responsible for the integrity of the samples used up to the point of the delivery of samples to a laboratory or laboratory surveyor.

*Comment:* One commenter recommended that the Food and Drug Administration (FDA) inspect and enforce 21 CFR Part 606, Current Good Manufacturing Practice (GMP) for Blood and Blood Components, and 21 CFR Part 640, Additional Standards for Human Blood and Blood Products, of the regulations since there are no provisions in the regulations for monitoring compliance with GMP. Two commenters stated that the regulations omit a relevant part of the CFR pertaining to GMP and that those practices specified in 21 CFR Part 820, GMP for Medical Devices: General, should be included. Another organization suggested that the words "when practical" be inserted

before "prepare or purchase" to avoid the need of continual regulation revision. One commenter suggested that patient specimens should be allowed for PT use.

*Response:* The FDA has the enforcement responsibility for compliance with GMP. We agree that 21 CFR part 820 should be included as a cross reference under the revised § 493.901(b)(1)(ii). We feel that the GMP rules provide sufficient flexibility to address concerns about short-lived materials.

*Comment:* A few commenters recommended that "scientifically defensible process" be defined and clarified. It was also suggested that "peer group" comparisons are the only scientifically justifiable means of comparing laboratory performance.

*Response:* A scientifically defensible process for determining the correct response for each PT challenge is one that is both technically feasible and credible. It should take into account such factors as any known and predictable causes of interference with test results due to the sample matrix as well as the accuracy, precision, sensitivity, and specificity of methods used to determine the correct response.

Peer group comparisons may be unavoidable in some instances, but should only be used when no other means of achieving comparable results across methods is possible. If bias between methods of unknown origin occurs and the sample matrix is suspected as the source, the PT program should seek to determine the reason for the bias in conjunction with the manufacturers of the method and the laboratories using the method. Comparability of data across the nation's laboratories will not be achieved unless the reasons for bias between methods and problems with the matrix of PT samples are identified and corrected, where possible.

*Comment:* Overall, the requirement for a signature block for attestation on the report form was viewed as burdensome, of little value, and one that should be eliminated. Some commenters suggested that the laboratory maintain the documentation in-house for review, at the time of a regular inspection. A few commenters requested clarification and/or better definition of the attestation statement.

*Response:* The attestation statement defines who was responsible for assuring that the PT samples were tested in the same manner as patient specimens. The PT program provider is responsible for providing a place on its report form for the attestation statement.

The laboratory director is now responsible for ensuring that the attestation statement is completed and maintained as a record as required under § 493.801(b)(5), Condition: Enrollment and testing of samples.

*Comment:* One commenter asked for clarification of the process for replacing lost or damaged samples and a few commenters suggested expanding the requirement to include a mechanism to investigate and resolve problems and complaints.

*Response:* The PT program provider must notify its program participants of the process a participant should use to replace lost or damaged samples. We agree that PT program providers need to have a process to resolve problems and have added this provision to our regulations.

#### *Section 493.903 Condition: Administrative Responsibilities*

*Comment:* It was suggested that the reporting time be extended to 60 days. One commenter asked that the data be made available "rapidly" and another indicated that PT results should be issued within 2 weeks. A third commenter would prefer cytology PT results within 7 days. Another indicated that a PT provider should be allowed 2 years from the date of the final rule publication to adjust its system to meet the new reporting requirements.

*Response:* Participants in PT programs and regulatory agencies need to receive reports of results of testing events as soon as possible. Laboratories or individuals who fail testing events must have sufficient time between testing events to take corrective action before the next testing event. Due to the large amount of information that must be computer analyzed and the many potential sources of delays in receipt of PT reports, we feel that the 45-day time frame for issuing reports may not be sufficient. After taking into account the increase in the number of newly regulated laboratories that will be participating in PT for the first time, we are requiring three rather than four testing events per year. Proficiency testing program providers must be allowed sufficient time to process data for PT events in order to provide laboratories and HHS or its designee with reports on individual laboratory performance; HHS or its designee must have sufficient time to determine which laboratories have not performed acceptably; and laboratories must be allowed sufficient time to identify the source of problems and to correct performance problems. Historically, using quarterly PT, it has not been technically feasible even with a much

smaller number of participating laboratories to allow sufficient time for all of these activities to take place before the next testing event occurs. This change permits more time for problem identification and correction between testing events and allows an increased time period for PT providers to issue reports. Under the new provisions, PT providers will be allowed 60 days to issue reports, except for cytology reports, which must be issued within 15 working days.

Regarding the comments that the PT provider be allowed 2 years to adjust its systems to meet any new reporting requirements, the phase-in period should permit time for PT providers to meet all reporting requirements.

*Comment:* One commenter suggested that the PT program reporting requirements be strengthened by requiring providers to monitor performances on a continual basis. This monitoring would include information on sample problems attributed to matrix effects and individual system biases rather than PT participant errors. One commenter recommended this regulation be deleted because the specific details of such reports and the extent of data to be collected are not specified.

*Response:* We agree that PT program providers should monitor performance problems attributed to matrix effects and individual system biases. Therefore, we have added a requirement that PT providers must report to HCFA on an annual basis any previously unrecognized sources of variability in kits, instruments, methods, or PT samples which adversely affect their ability to evaluate laboratory performance.

*Comment:* One commenter indicated that the requirement to maintain records for 5 years is "unreasonable" and an "unwarranted burden" on PT programs. The commenter stated that it should be the responsibility of HHS or its State agencies to keep records since all of the necessary data would be provided to them on a regular basis.

*Response:* Since adverse action proceedings based on failure in PT will require confirmation of PT results generated by the PT program provider, we feel that the PT provider must maintain these records for at least five years. HHS or its designee will retain copies of these reports, but will not possess originals, nor will HHS or its designee possess the type of detailed information about the samples and about the PT provider's evaluation process for the specific samples that are included in the adverse action.

#### *Section 493.907 Process for Updating PT Programs*

*Comment:* One commenter suggested that obsolete tests be deleted from PT, but that routinely well performed tests not be deleted. Data from the latter could provide HCFA with a tool to evaluate program performance. Another commenter suggested that there should be an exemption provision for "well performed" tests which have proven to be free from performance error, if documented appropriately. It was suggested that HHS should convene a panel of experts in the PT field to monitor program compliance, assess needed changes in the programs, as well as advise HHS on matters relating to PT program development.

*Response:* A Clinical Laboratory Improvement Advisory Committee, formed by HHS, will evaluate the appropriateness of applicable requirements of proficiency testing including retaining well-performed tests. HHS must publish any changes in the Federal Register and will allow proficiency testing program providers two years to incorporate the new program requirements.

As required by the Public Health Service Act, participation in PT will be required for all procedures and examinations for which PT can reasonably be developed. HHS will phase in the PT requirements for additional analytes as tests, specialties, and subspecialties and consider other revisions to program requirements based on recommendations of the Clinical Laboratory Improvement Advisory Committee concerning the feasibility of additions of analytes to the national PT program. Laboratories offering service for these analytes or tests will be required to enroll in an approved PT program by the effective date specified in the regulations for these procedures or examinations.

#### *Sections 493.909-493.959 Proficiency Testing Programs by Specialty/ Subspecialty (Formerly Proficiency Testing Programs by Specialty/ Subspecialty for Level I and II Tests)*

*Comment:* Some suggestions were made for adding and dividing specialties and subspecialties. Commenters recommended adding the specialty of flow cytometry, which would include image analysis, molecular pathology diagnostics, and nucleic acid probe technology. One commenter, however, thought that nucleic acid probe technology should be a subspecialty of microbiology. One commenter suggested adding a new specialty of

dermatopathology. Other commenters suggested adding subspecialties to specialties including direct antigen testing, lyme disease serology, viral markers, and newborn genetic screening. A few commenters suggested dividing the specialty of chemistry into subspecialties of routine chemistry, enzymatic chemistry, electrolyte chemistry, blood gas, and drug screening and dividing the specialty of hematology into hematology and coagulation. Others suggested dividing the specialty of immunology into subspecialties of immunological components, infectious disease, and non-infectious disease. Another commenter recommended that the specialty of immunology be eliminated. A few commenters recommended dividing the specialty of toxicology into subspecialties of drugs of abuse, blood alcohol, and toxic metals. An alternative that was suggested would be to reserve toxicology for drugs of abuse and create a new specialty for therapeutic drug monitoring.

There were a few suggestions that the subspecialty categorization consider variations in technology, or that testing requirements be by analyte rather than specialty. One commenter proposed that the specialty/subspecialty concept be deleted altogether and that HHS, using the assistance of laboratory representatives knowledgeable in current laboratory operations, develop a relevant, achievable and practical categorization scheme.

**Response:** We feel that the creation of additional specialty or subspecialty areas is not warranted at this time. PT results will be evaluated by analyte or test regardless of which subspecialty or specialty they are categorized under for PT purposes.

We will consider changes in specialty/subspecialty categories recommended by the Clinical Laboratory Improvement Advisory Committee. This Committee will assist HHS in determining the appropriateness of new specialty and subspecialty categories. Any necessary realignments of PT tests to correspond to new specialty or subspecialty categories will occur in conjunction with these changes.

**Comment:** For microbiology, one commenter suggested that "types of services offered by laboratories" for bacteriology, mycobacteriology, mycology, and parasitology be rewritten to reflect current technology and the wide scope of testing performed. Another commenter felt that this regulation was designed for large full-service laboratories and could not be applied to smaller, limited-service laboratories.

Others felt that organism identification to species was unnecessary and should be used only if the organism is clinically significant from the standpoint of pathogenicity or treatment. One commenter felt that laboratories should be classified in a manner similar to the College of American Pathologists system, while another said that "type of service" should be based on specimen type. A specialized program in parasitology for laboratories which determine the presence of parasites and refer them to another laboratory for identification was recommended by one commenter. One commenter felt that for bacteriology the pathogenicity of a microorganism should determine the level at which it should be tested.

For mycology PT, a few commenters expressed the opinion that PT laboratories identify yeast only to the species, while a few others suggested identification to the genus level, with species level identification optional. "Special allowance" was requested to cover a screening procedure for *Candida albicans* by germ tube for those laboratories that do bacteriology, and send out other mycology. One commenter requested a "type of service" for those laboratories only performing yeast identification. Also, a type of service was requested in mycobacteriology for those laboratories that interpret stains and culture, but send out the positive cultures for ID and sensitivity.

With regard to immunohematology, one commenter indicated that the terminology "D(Rho) group" is incorrect and that the proper terminology is "Rh typing". "Compatibility testing" should be called "Crossmatching". Correct terminology should be incorporated throughout the regulation.

**Response:** We have revised the types of service categories in microbiology to more accurately reflect the range of service offered in all types of laboratories. We have expanded the number of types of service from three to five for bacteriology, from three to five for mycobacteriology, and from two to four for mycology. We have included pinworm preparations as part of the type (a)(1) level of service in parasitology.

We have not attempted to determine or to define the clinical utility of the different levels of microbiological service being offered nor have we tried to determine the appropriateness of level of service by specimen type. The laboratory must test the PT samples to the extent to which service is offered regardless of the number of categories developed for type of service. If a

laboratory offers service for yeasts, it must enroll in PT for mycology.

In immunohematology, for PT purposes, we have amended the types of service offered to designate separately each of the components. The terminology used in this section is now consistent and appropriate for the specialty.

**Comment:** A few commenters suggested that the specific list of organisms for bacteriology, mycobacteriology, mycology, parasitology, and virology be deleted in order to permit more flexibility in each subspecialty and to meet the clinical relevance criteria of the Act. One commenter suggested adding the clause "but not limited to" in bacteriology to provide for inclusion of emerging pathogens. One commenter indicated that HHS should specify the inclusion of important viruses as opposed to determining important emergent viruses.

A few commenters indicated that only the pathogens and normal flora that are representative of the patient population and are commonly encountered by the physician should be included in PT specimens. For mycobacteriology, it was suggested that 10 percent of the samples should be mixed. A few commenters asked for clarification of the 50 percent principal organism/50 percent normal flora specimen requirement. Another suggested that the word "principal" be changed to "clinically relevant".

It was also recommended that PT challenges for organism identification be separate from those for susceptibility testing. Another recommendation was that samples for Gram stain interpretation be included along with bacteria isolation and identification. With regard to susceptibility testing, it was suggested that minimum inhibitory concentration (MIC) target values be based on "participant means" to allow for biases which exist for panels from different manufacturers. One commenter asked for an interpretation of the meaning of "predictable pattern" of sensitivity.

One commenter stated that *M. terrae* belongs in Group II (not IV); *M. fortuitum* in Group IV (not V); and that there is no Group V. Another stated that most authorities recognize only five groups of mycobacteria, not six as listed, and recommended that organisms in Groups III and IV be combined. Additional recommendations were to add challenges for nucleic acid probe technology and for antigen detection for *E. histolytica*, to add measurements for urine, bile, solid tissues, and vitreous humor in toxicology, and to include body fluids and/or tissue smears in

parasitology. Others suggested adding educational materials in parasitology, and to add PT for illegal drug screening and other forensic purposes.

With regard to hematology, one commenter suggested expanding the requirement to include current WBC identification techniques, as well as new technology. Another recommended that the WBC differential not be included at all "because of the lack of valid statistical scheme for averaging and comparing across cell lines", as well as the difficulty of producing and shipping glass slides. It was stated that the use of kodachrome transparencies has proven successful in the past.

*Response:* We believe that a specific list of organisms for bacteriology, mycobacteriology, mycology, parasitology and virology serves as a guide to PT providers about program content and assists regulatory agencies with a comparison of PT programs. The proposed rule included provisions for changes in the list of organisms to permit the addition of emerging organisms. The organisms in the PT samples are expected to be representative of those found in patient specimens. However, we recognize that those organisms included in national PT programs may not always represent those being found locally at any given time.

We support the need to have a 50-percent mixed culture distribution of samples, since the samples must be representative of those encountered in human specimens. By this we mean that samples will consist of two types: one type will be for the identification of only the significant pathogens; the other type will be for the identification of all organisms present. Of the first type one half of the samples will be pure cultures and one half will be mixed cultures. Of the second type one half of the samples will be pure cultures and one half will be mixed cultures.

We agree with the commenters regarding the classification of mycobacteria and have revised the regulation to reflect the correct groups of mycobacteria.

The term "principal" in § 493.911(b)(1) is used interchangeably with the term "significant pathogen" as defined in § 493.911(b)(1)(i). We are revising the regulations so that the terminology is used consistently throughout the regulations.

We agree with the commenter that the term "predictable" pattern is confusing and have revised the regulation at § 493.911(b)(3) to use the term "predetermined" pattern of sensitivity. One sample can be used for both organism identification and

susceptibility testing. The regulations allow PT programs flexibility as to how they establish target values for minimum inhibitory concentration (MIC). Target values for MIC can be determined using either 90 percent of 10 or more referee laboratories or 90 percent or more of all participant laboratories.

PT programs can include additional samples or challenges to address new techniques and technology for educational purposes for any test; however, HHS must be kept informed as to which samples have been designated as educational samples.

We have revised the mycology program to include *Microsporium species* and will make updates to the program at least every two years to keep it consistent with changes in technology. Approved PT program providers are charged with developing appropriate samples and challenges for their program. HHS will review data from PT programs and other sources to determine the usefulness of new approaches and materials for proficiency testing.

Since the Act specifically covers laboratories which test specimens for medical purposes, we have not included any requirements for PT for forensic purposes.

*Comment:* Suggestions regarding our proposed requirement of 5 samples per event ranged from one commenter recommending 5 or more samples/event to others wanting less than 5 samples/event. Several commenters favored 2 samples/event. One commenter stated there was no scientific rationale for using 5 samples, while another questioned the need for increasing the numbers of samples from 3 to 5 because this would increase the cost, but not the benefit. Another commenter recommended that the number of PT samples be based on the volume of tests a laboratory performs rather than requiring a minimum mandatory number, at least until a positive correlation is established between the number of PT samples and the accuracy of patient test results. For mycology, one commenter requested 10 samples twice per year.

A few commenters recommended that endocrinology, toxicology, urinalysis, and microbiology have 3 samples/event, that parasitology have 8 samples/event, and that HIV testing include 10 samples/event.

*Response:* We are retaining the 5 samples per event requirement. Five samples/event provides the best combination of high probability to rapidly identify poor performance and low probability that a laboratory which makes an infrequent mistake will fail

PT. More than 5 samples/event would increase the cost and burden of PT, without significantly improving the program's ability to separate poor from acceptable laboratory performance.

*Comment:* Suggestions regarding our proposed requirement of 5 challenges per analyte or test ranged from one commenter recommending 5 or more challenges per analyte or test to some favoring 2 challenges per analyte or test. A few suggested that 5 challenges was not supported by research or that 5 challenges had been used to accommodate the 80 percent performance requirement. An additional suggestion was to expand the number of challenges for blood gases to accommodate the number of instruments in the laboratory. There was a request for clarification of the grading system when only 4 or 5 samples could be evaluated.

*Response:* We are retaining the 5 challenges per analyte or test requirement. Five challenges provides the best combination of high probability to rapidly identify poor performance and low probability that a laboratory which makes an infrequent mistake will fail PT. More than 5 challenges per testing event would increase the cost and burden of PT, without significantly improving the ability to separate poor from acceptable laboratory performance.

While we encourage some form of assessment of the performance for every method or procedure used by a laboratory, PT is required only for the test system, assay, or examination which is the primary patient testing procedure in use during the time that PT is being conducted. The performance of other procedures used by a laboratory must be compared to the procedure evaluated by PT in order to assure consistency between laboratory measurements. Comparability of results among different methods can be achieved using split patient specimen or control samples, etc. However, PT is not required for these additional procedures.

When only four of the five challenges can be evaluated for all participants due to problems with samples or other factors beyond the participants' control, the PT program may give participants full credit for the unevaluated sample in calculating scores for the testing event.

*Comment:* We received several suggestions regarding our proposed requirement of 4 events per year (with 2 events per year for mycobacteriology). A few commenters requested less than 4 events/year, one suggested 3 events/year and a few wanted only 2 events/year. One commenter felt that

mycobacteriology should have more than 2 events/year. One asked for clarification of whether it is exactly 4 events/year or a minimum of 4 per year.

*Response:* Section 353(3)(a) of the PHS Act specifies that PT shall be conducted on a quarterly basis, except where HHS determines that, for technical and scientific reasons, a particular examination or procedure may be tested less frequently (but not less often than twice per year). We are requiring three events per year due to problems with PT providers generating and mailing results to regulatory agencies and to laboratories within the 45-day time frame specified in the March 14, 1990 rule. Four testing events per year does not allow sufficient time for a regulatory agency to receive reports, issue warning letters to laboratories who have failed a testing event, and still allow time for corrective action by the failing laboratory to take place before the next testing event. Testing triennially allows additional time between events for all of these activities to occur within a reasonable period of time.

*Comment:* One commenter indicated that any PT samples used for on-site testing must meet the same standards as mailed samples, and that any scheduled on-site testing should be made known before the start of the program year. One commenter said that on-site testing for microbiology should be deleted.

*Response:* We agree with the commenters that on-site samples must meet the same standards of quality as those required for mailed-in samples. We also agree that in some circumstances on-site PT may not be practical, particularly if such testing cannot be completed within a day or two day period while an inspector is usually present. However, in certain circumstances on-site PT offers a valuable technique for the inspecting agency. Therefore, we are retaining the requirement as specified in the regulations.

On-site PT is especially helpful in reinstatement of a laboratory that has failed PT and has had sanctions imposed. Under such circumstances the regulatory agency must make a determination of whether performance problems have been corrected before allowing testing to be resumed. Since on-site PT may be conducted either on an announced or unannounced basis, not all on-site PT can be scheduled.

*Comment:* A few commenters indicated that there should be changes in the list of analytes. Suggestions in parasitology included adding *Blastocystis hominis*, *Isospora belli*, *Taenia species*, *Schistosoma mansoni* and *hematobium*, *Plasmodia* and

*Babesia microti*. Suggestions in chemistry included: for toxicology, distinguishing between drugs of abuse and therapeutic drug monitoring and adding cocaine, amphetamines, opiates, and tobramycin, while deleting ethosuximide; adding testing for forensic purposes by placing blood alcohol and blood lead in a new subspecialty; and including samples of urine, bile, vitreous humor and tissue; for urinalysis, add nitrates, hemoglobin, specific gravity, urobilinogen, and microscopic examination of urine sediment.

In hematology, suggestions were given to add CD4 cell counts and expand cell differentiation to include cell types other than "major" abnormalities. Another recommendation was that the WBC differential not be included as a regulated analyte. In immunology, it was suggested that we add alpha-fetoprotein (AFP) as a screening test for neural tube defects. In immunohematology, we were asked to clarify the use of the terms "tests" (in § 493.959) and "subspecialties" (in § 493.857), since there are important differences in the two sections that affect scoring, certification and reimbursement.

A final suggestion was made to evaluate laboratory performance by type of procedure rather than by analyte, since for some specialties multiple analyte tests are performed using the same procedure.

*Response:* One of the tasks of the Clinical Laboratory Improvement Advisory Committee will be to review the analytes or tests that should be included in PT and to recommend to HHS any additions or deletions in the program. Since it is our intention to have the Clinical Laboratory Improvement Advisory Committee conduct a thorough review of the regulatory PT program requirements as soon as possible, we have made very few changes to the list of analytes or tests to be included in the regulatory PT program for any specialty at this time.

Once the Clinical Laboratory Improvement Advisory Committee has reviewed information about analytes or tests not currently included in the regulatory program and has recommended that specific additional analytes or tests be included in the regulatory program, a list of these additional analytes will be published along with grading criteria in a notice in the Federal Register with an opportunity for public comment. Each publication will denote the effective date for approved PT programs to incorporate these new analytes and grading criteria into their program. Laboratories offering service for these tests would be required to participate in PT for these additional

tests as soon as they are incorporated into an approved PT program.

In microbiology, we have included additional *Enterobacteriaceae* and Gram-negative bacteria, added *Microsporium species* to mycology, and added *Enterobius vermicularis* to parasitology. In chemistry, we have added tobramycin. We have included dipstick or tablet urinalysis on the list of waived tests therefore, no PT is required. Since testing conducted exclusively for forensic purposes is exempt from these regulations, PT requirements do not include forensic samples.

In hematology, we are not adding CD4 cell counts, due to problems with sample quality and stability, nor are we changing requirements for cell differentials at this time. In immunology, we are not adding alpha-fetoprotein as a screening test for neural tube defects to the list of required tests.

We agree with the commenters that for PT purposes there are no subspecialties in immunohematology, and the regulation will be changed accordingly.

*Comment:* A few commenters suggested that for hematology, referee laboratories should not be used to establish the target value. If a preponderance of referee laboratories use one method or instrument that produces results which are biased compared to other procedures, laboratories using the other procedures could be penalized or even fail PT. A few commenters recommended the deletion of all references to referee laboratories. Others suggested using both 80 percent of 10 referee laboratories and 80 percent of participants to establish the correct response. A few commenters suggested changing 80 percent to 95 percent agreement, particularly for urinalysis, hematology, routine chemistry, and toxicology. Others suggested using peer group agreements instead of a consensus process for endocrinology, routine chemistry, and toxicology.

*Response:* We are retaining the ability of a PT program provider to use referee laboratories to establish a target value. Approved PT program providers can determine whether the use of referee laboratories is scientifically valid and appropriate for the analyte or test. Performance assessments by peer group combinations of instrument/method/reagent can also be used, if necessary, in instances where a specific method has been determined by a valid scientific protocol to produce atypical results compared to patient specimens

which affect the evaluation of laboratories using the method.

We have raised to at least 90 percent the consensus required to establish a target value for qualitative analyte or tests in order to provide additional assurance that any samples which demonstrate significant variation in sample composition will not be evaluated.

*Comment:* A few commenters suggested that the penalty for reporting erroneous organisms be deleted for bacteriology, mycobacteriology, mycology, parasitology and virology. They also requested that the ambiguity regarding penalties for incorrectly identified principal organisms be alleviated. They recommended that the PT program be allowed to determine the organisms to be considered incorrect and the associated penalties.

One commenter suggested that referrals for identification be considered as a correct response for bacteriology, mycobacteriology, mycology, and parasitology. Commenters also suggested including morphology in the performance criteria for Gram stain. Another commenter expressed concern over the proposed process of evaluating a laboratory's performance in bacteriology, which was considered to allow the results from susceptibility testing to disproportionately offset an incorrect organism identification. The commenter recommended that a separate grade for identification of an organism(s) and for susceptibility testing be calculated and that these scores be averaged to obtain the score for bacteriology.

A commenter suggested changing score calculations so that varying amounts can be deducted for incorrect identifications from the "actual" instead of the "possible" number of responses. Another suggested determining a correct response for each antimicrobial agent, using criteria established by the National Committee on Clinical Laboratory Standards (NCCLS) or "other specifically accepted references as appropriate". (We note that the NCCLS only issues standards on how to test, not on which agents are appropriate to be tested.)

In the specialty of parasitology, one commenter suggested deleting the words "or concentrate and identify because in reality, not all samples require concentration.

A large number of commenters suggested using Commission on Office Laboratory Assessment (COLA) grading criteria and establishing different grading criteria for Level I and Level II laboratories. In addition, many commenters proposed changing the

criteria for acceptable performance to take into account peer group means, matrix effects, target values appropriate for dilution based tests, methodology, instrumentation, technology, and reagents.

A few commenters suggested that grading criteria should take into account clinical relevance. One commenter suggested that values within 10 percent of the target value are almost always clinically adequate and would not materially affect clinical decision making. Another suggested that PT grading requirements vary with clinical context—the more critical the test results are for diagnosis and treatment, the more stringent the PT criteria should be for acceptable performance. In this vein, another commenter recommended that the acceptable performance criteria for glucose measurements using blood glucose meters should be modified to 15–20 percent because currently available meters cannot and should not be expected to meet the criteria in the regulations.

One commenter recommended that acceptable performance criteria for many tests in routine chemistry be those currently employed in 1990 by the College of American Pathologists. Some felt that grading for enzymes should be delayed until after PT programs have been implemented and the data analyzed. Others suggested not grading an analyte when participant results show marked differences.

Concern was expressed regarding score calculations. Commenters recommended that a trial period for PT be set to allow for evaluation of the grading criteria. Many suggested changing the criteria for acceptable performance for specific tests including blood lead, cortisol, and thyroid stimulating hormone. Another commenter suggested using  $\pm 3$  SD as acceptable performance criteria for new quantitative methods. A few indicated that they considered acceptable limits for some analytes to be too broad or too narrow. Ranges were considered by one commenter to be too broad for alanine transaminase (ALT) and alkaline phosphatase. Other commenters felt that the albumin and blood urea nitrogen limits were too narrow for many methods. Others recommended retaining the use of standard deviations, however, they indicated that relying only on standard deviations could result in unreasonably narrow tolerances around the target value as technology improves and interlaboratory variation is reduced.

A commenter indicated that the target values for syphilis and for dilution-based quantitative immunology tests were not appropriately defined; the

definition of target values should be a geometric mean rather than an arithmetic mean for dilution-based tests.

A few commenters pointed out the error in the toxicology acceptable performance chart, requiring a plus sign to complete the criteria table for acceptable target ranges for toxicology.

*Response:* Since reports of erroneous organisms could contribute to mismanagement of patients, we are retaining the penalty for reporting erroneous organisms.

We disagree with comments that referrals for organism identification should be considered to be part of a laboratory's PT response. PT is being used to evaluate only the services offered by the certified laboratory, not a combination of the services offered by the certified laboratory and its referral laboratory. We also disagree that morphology should be included in the performance criteria for Gram stain.

We have amended the method of calculating the score for each sample in microbiology to permit separate scores for each of the preliminary steps leading to the final answer to be calculated and averaged to obtain the sample score. While weighing scores for each of the preliminary steps leading to a laboratory's final answer has merit, we feel that it would be difficult to implement in a regulatory PT program. Therefore, we are retaining the method of scoring calculations, but will have the CLIA committee consider the possibility of weighted scores, particularly for microbiology.

Regarding antimicrobial susceptibility testing, the NCCLS has established guidelines for performing these procedures and we have adopted these guidelines. However, if other accepted references become available they will be reviewed by the Clinical Laboratory Improvement Advisory Committee and could become acceptable alternatives.

We disagree with the commenter about deleting the words, "and concentrate and identify" because we feel that a wet mount may be sufficiently sensitive to detect small numbers of ova or parasites in a fecal specimen. Therefore, concentration constitutes good laboratory practice.

Laboratories will be evaluated on the basis of the service offered. We disagree with comments that different grading criteria should be applied for the same tests being performed by moderate and high complexity procedures. We are allowing previously unregulated laboratories to participate in PT for one year before they are held accountable to the same set of standards as previously regulated laboratories. This gives them

time to develop managerial control for these new activities.

Ideally, the criteria for acceptable laboratory performance should be based on the clinical usefulness and clinical context of the test results. However, there are no generally agreed upon medical-usefulness criteria for most tests. In the absence of consensus medical criteria, we have defined acceptable performance on the basis of the state of the practice, which presumably is sufficient to meet medical needs.

We have reviewed suggestions regarding additional ways to establish criteria for acceptable performance and have made adjustments to take into consideration some of these recommendations. We have amended criteria for acceptable performance for specific analytes or tests in general immunology, chemistry, endocrinology, toxicology, and hematology. Although we consider fixed limit criteria based on clinical relevance as the best means of performance assessment, the use of  $\pm 3$  SD seems necessary at present for some procedures and for previously unevaluated procedures.

Since both the presence or absence of antibody and the relative titer are of clinical concern and there are significant intermethod differences between enzyme linked immunoassays (ELISA) and assays based on titers, we will continue to include both qualitative and quantitative responses for immunology. We have accepted the suggestion that the  $+/-1$  dilution be based on a geometric rather than an arithmetic mean and have provided for an acceptable range of  $+/-2$  dilutions for nonsyphilis immunology tests.

The error in the table of criteria for acceptable performance in toxicology has been corrected.

#### *Section 493.945 Cytology: Gynecologic Examinations*

*Comment:* Many individuals and several organizations were opposed to the proficiency testing program content as specified in § 493.945(a). They expressed concern over the cost and the ability of program providers to acquire the quantity of high quality, referenced glass slides that would be needed to provide equivalent slide sets for a national PT program. Several commenters suggested using less than 20 glass slides, with 10 being the number favored by most. A few individuals from small laboratories noted that it would be difficult for them to discontinue their other laboratory services for the length of time required to take a test with 20 slides. A large number of commenters suggested that the program not be

restricted to glass slides and that alternative test materials, such as computer interactive video discs or Kodachromes be considered. In contrast, several commenters stressed that glass slides were preferable for PT and would be the only type of test material that could simulate daily laboratory practice.

*Response:* In response to these comments and in order to increase the feasibility of providing for a cytology PT program on a national basis we have reduced the number of glass slides per test set. As described under § 493.855, the annual testing event and the retest for individuals who fail the annual event involve 10 glass slide challenges. Test sets composed of 20 glass slides are provided to individuals who must take a second or third retest. Increasing the number of slides in a test set from 10 to 20 allows for a greater variety of challenges and, in general, increases the discriminatory power of the examination. As described under § 493.945(a) each test set should include at least one slide in each of the four response categories. We have added a requirement for test sets to be comparable so as to provide for equitable testing within and between PT providers. The exact number and type of each challenge to be included in each test set cannot be specified since this would afford the individual taking the examination the opportunity of identifying slide preparations by the process of elimination.

We have retained the requirement for glass slide challenge because we believe that testing with glass slides most closely resembles the actual examination of patient preparations. However, if other materials are developed which can be shown to be equivalent to testing with glass slides they may be considered in future regulatory revisions.

*Comment:* We received a small number of comments on the consensus agreement required for determining the correct responses for PT challenges as described in § 493.945(b)(1). A few commenters suggested that the consensus agreement be greater than 80 percent. One organization recommended 90% consensus for categorizing a slide as unsatisfactory, negative, inflammatory, reactive, or reparative. A few commenters recommended consensus agreement on the diagnosis of premalignant or malignant cytologic smears, instead of on the tissue biopsy, which they said should be used for confirmation of the smear diagnosis. In contrast, one organization and a few individuals suggested requiring only that testing material be referenced in a scientifically valid manner and

eliminating the requirement for a consensus. A few commenters suggested that the consensus panel be composed of both pathologists and cytotechnologists.

*Response:* We agree that greater than an 80 percent consensus agreement is preferred for referencing cytologic slides based both on these comments and on modifications that have been made in the scoring system as described under § 493.945(b)(3). However, increasing the consensus to a percentage between 80 percent and 100 percent requires increasing the number of slide reviewers, which would also increase the time and cost for referencing slides. Therefore, we have revised this requirement so that a 100 percent consensus agreement among a minimum of three pathologists is required for all slide preparations. We believe that this slide review is best done by pathologists since this correlates with the quality control requirements under § 493.1257 for confirmation and reporting of cytologic slide preparations. We have deleted the requirement for consensus agreement on tissue biopsies that confirm premalignant or malignant cytologic preparations and, instead, the PT program has the option of either confirming these preparations by comparison with the tissue biopsy reports or by reevaluation of the biopsy slide preparations.

*Comment:* A large number of commenters suggested changes in the methods for evaluating an individual's performance and in the scoring system as described under § 493.945(b). The majority recommended that those individuals who screen slides (cytotechnologists) should be scored differently from those who interpret them for diagnoses (pathologists). They said that scoring should be based on the daily responsibilities of the individual being tested and that cytotechnologists should be scored on their ability to separate negative cases from those that need to be reviewed by a supervisor and not on their interpretation of the degree of abnormality present. Commenters pointed out that cytotechnologists and pathologists normally work as a team to screen and interpret slides. They stated that if PT is to be conducted under conditions that normally prevail within the laboratory and samples handled the same as patient specimens, then PT should be conducted to allow for this type of teamwork.

One organization suggested changing the scoring grid so that category C includes both low and high grade lesions and category D only invasive carcinomas, similar to that used in the

State of Maryland. A few commenters recommended eliminating the "unsatisfactory" category. They said that there is no consensus on the characterization of unsatisfactory smears and that this category should not be included in testing until specific criteria can be developed by professional societies and the National Institutes of Health. Others asserted that it is unacceptable to treat specimen adequacy determination as a diagnostic category for PT purposes because determination of specimen adequacy is not comparable to diagnostic interpretation.

A few commenters said that the PT scoring system should be validated before it is implemented. One organization and a few individuals recommended that the weighted scoring system be replaced with a direct calculation of the percentage of correct responses. Several commenters, approximately equal in number, recommended adopting either the scoring system used in Maryland or New York.

*Response:* We agree with the commenters on several points and have modified the scoring system described in § 493.945(b). We have made several changes to allow for individuals to be tested in accordance with their qualifications as either a cytotechnologist or a technical supervisor. We have added a provision under § 493.945(b)(2) to allow for teamwork between technical supervisors and cytotechnologists. All cytotechnologists will be tested with materials that have not been previously reviewed. Technical supervisors who routinely examine gynecologic slide preparations only after they have been reviewed by a cytotechnologist may be tested with slides that have been reviewed by a cytotechnologist in their laboratory. Technical supervisors who routinely review slides without the assistance of a cytotechnologist must be tested with slide sets that have not been previously examined.

In addition, several changes have been made in the criteria for acceptable performance as described under § 493.945(b)(3). We have retained a weighted scoring system which is modeled after the one in use in the State of Maryland. Each slide in either a 10 or 20 slide test set has point values for responses based on both the significance of the relationship of the interpretation of the slide to a clinical condition and on whether the examinee is a cytotechnologist or a technical supervisor. There are, therefore, four scoring grids: two for a 10 slide test set

and two for a 20 slide test set, with one each for technical supervisors and cytotechnologists. The total possible points for each test, 10 or 20 slides, is 100. Consequently, each slide is worth a maximum of 10 points in a 10 slide test set and 5 points in a 20 slide test set. Point values range from -5 to 10 and -10 to 5 in the 10 and 20 slide test sets, respectively. Cytotechnologists are not penalized for being unable to differentiate between categories C and D, low grade abnormalities or high grade abnormalities and carcinoma. Technical supervisors, however, lose points for incorrectly identifying challenges in these two categories. All individuals fail an examination (score less than 90%) if they incorrectly identify one high grade abnormality or carcinoma (category D) as a negative/normal (category B).

We have retained the four category delineations, including the unsatisfactory category. We think that it is appropriate to include unsatisfactory slides in proficiency testing since laboratories are required under § 493.1257 to identify, report and keep statistics on slides that are unsatisfactory for diagnostic interpretation. We have retained the separation between categories C and D as being between low grade and high grade squamous cell abnormalities. This point of separation is in keeping with the weighting of the scoring system and, we believe is more readily discernable than the separation between high grade abnormalities and carcinoma. We have added a table in § 493.945(b)(3)(ii)(A) which defines and describes the four categories. We acknowledge that the professional community has not reached a consensus on the criteria for unsatisfactory preparations, however, for proficiency testing purposes, we have defined three criteria that are to be used for classifying slides as unsatisfactory. These criteria are scant cellularity, air drying and obscuring material. We believe that by defining each of the categories in this table, rather than referring to The Bethesda System of nomenclature, we have alleviated the confusion that commenters expressed over the classification.

*Comment:* While some commenters supported the use of The Bethesda System for reporting cytopathology PT results, a larger number were opposed to requiring its use. Some suggested delaying or phasing-in this requirement. Others recommended that individuals use the terminology they normally use in practice, either alone or in conjunction with The Bethesda System. They said that it was inappropriate and premature

to require the use of terminology that is not widely used or accepted and with which many cytotechnologists and pathologists are unfamiliar. One commenter suggested the use of a simpler reporting system that does not have such fine differentiation among the various abnormalities. A few commenters pointed out that requiring the use of The Bethesda System for reporting PT results, if the laboratory does not normally use it, is inconsistent with the requirement that PT samples be treated like patient samples.

*Response:* We agree with the commenters and have deleted this requirement. Proficiency testing results are to be reported using the four categories previously described. While these categories are delineated based on The Bethesda System of nomenclature, the PT program may supplement the category descriptions with other terminology, if desired. We will evaluate the PT program on an ongoing basis, and may consider changes in the format and terminology for reporting results in the future.

#### Changes to the Regulation

In addition to editorial and clarifying changes, we have made the following specific changes to this subpart:

- We are renaming this subpart as Proficiency Testing Programs for Tests of Moderate and High Complexity to reflect the changes in the categorization of tests under § 493.10.

- Under § 493.901, we are amending the requirement to prepare PT samples in accordance with good manufacturing practices by adding a requirement to follow 21 CFR part 820.

- We are retaining the requirement for PT program providers to include an attestation statement with the report form for each PT testing event and have made the completion of an attestation statement and its documentation the responsibility of the laboratory director.

- We are including a requirement in § 493.901 that PT program providers develop and maintain a process to resolve administrative, technical, and scientific problems associated with program operations.

- We are revising § 493.903 to require providers of PT programs to issue reports within 60 days of the testing event, except for cytology PT for which reports must be issued within 15 working days. In order to improve the exchange of information about problems with PT, all approved PT providers will be required to provide HCFA with an annual report which identifies any previously unrecognized sources of variability in kits, instruments, methods,

or PT samples, which adversely affect the programs' ability to evaluate laboratory performance.

- We are deleting § 493.907 since these requirements have been incorporated elsewhere in this rule.
- In §§ 493.909–493.959 (except for § 493.945), the provisions of the proposed rule are adopted as final with the following exceptions/additions:
  - All specialty and subspecialty testing must be conducted at least three times per year, at approximately four month intervals, with the exception of mycobacteriology, which must occur at least twice per year.
  - Formulas for calculating testing event scores have been amended throughout this subpart to clarify the grading scheme.
  - For tests requiring quantitative results, provision has been made to allow target values based on a "peer" or "by method" group when the PT provider has determined by a valid scientific protocol that a specific method's results are atypical compared with results on patient specimens, and the bias would adversely affect the evaluation of laboratory performance if an all-method target value had been used. PT program providers must report the circumstances which require such variations on an annual basis to HCFA. Since the use of standard deviation limits for acceptable performance could unduly penalize very precise method groups when "by method" assessments are employed, fixed-limit criteria for acceptable performance have been added, where possible, for quantitative tests.
  - In order to assure that a laboratory's evaluation process is fair for qualitative responses, a 90% agreement is required in the determination of the correct response before laboratories are evaluated.
  - For microbiology, a laboratory's evaluation is determined by its final answer, which is based on the type of service it offers. Scores for any preliminary analyses leading to the final answer are not included in the averaging of results to calculate a laboratory's score for each sample.
  - The procedure for calculating scores for antigen tests has been clarified.
  - For the subspecialty bacteriology, five types of laboratory services are now recognized. Laboratories are required to report the principle pathogen rather than the significant pathogen in designated samples. Four additional *Enterobacteriaceae* and two additional Gram-negative organisms have been added to the list of organisms to be included in approved PT programs over time. A predetermined rather than a

predictable pattern of resistance to common antimicrobial agents as determined by a NCCLS guideline procedure or a reference method approved by HCFA is being required for antimicrobial susceptibility testing.

- For mycobacteriology five types of laboratory service and for mycology four types of laboratory service are now recognized. The types of mycobacteria now reflect the five groups suggested by most authorities. *Microsporium species* have been added to the list of organisms to be included in approved PT programs over time.
- For parasitology, *Enterobius vermicularis* (pinworm) has been added to the list of parasites that might be included in an approved program.
- In toxicology, acceptable performance limits for blood lead have been narrowed to reflect both improvements in the analytic state of the practice and the need for better accuracy and precision due to the recognition that lower concentrations of lead can cause adverse health effects in children. Also, tobramycin is now included in toxicology.
- For hematology, standard deviation limits have been replaced with fixed criteria for determining acceptable performance.
- We are revising § 493.945 to require that cytology proficiency testing programs provide: (1) 10 slide test sets for the annual testing event for each individual and for the retest for those who fail the annual test; and (2) 20 slide test sets for the second and subsequent retesting events. Each test set must include at least one slide in each of the four response categories and test sets should be comparable. All slide preparations included in each test set must be referenced by obtaining 100 percent consensus agreement of a minimum of 3 anatomic pathologists. Premalignant and malignant slide preparations must be confirmed by either comparison with the reported tissue biopsy results or with the reevaluation of the tissue biopsy slide material.
- An individual qualified as a technical supervisor may be tested with a test set after it has been screened by a cytotechnologist in the same laboratory if he or she routinely examines prescreened slides. Technical supervisors who work without a cytotechnologist must be tested with an unevaluated test set.
- There are separate scoring systems for cytotechnologists and technical supervisors. The maximum point value for each slide is 10 in a 10 slide set and 5 in a 20 slide set. One major undercall (reporting category B for a slide in

category D) results in a failing score (less than 90 percent) in both the 10 and 20 slide test sets. Proficiency test results are to be reported using the four categories as defined.

#### *Subpart J—Patient Test Management for Moderate or High Complexity Testing, or Both*

##### Summary of the Proposed Rule

We proposed this subpart as Patient Test Management For Level I and Level II, but have renamed it to be consistent with changes in the categorization of tests under § 493.10. Proposed § 493.1101 Condition: Patient Test Management for Level I and Level II Testing (now Patient Test Management for Moderate or High Complexity Testing, or both) was substantially unchanged from the final rule with comments published on March 14, 1990, at 55 FR 9536. At § 493.1101(e), Standard; Referral of specimens, the proposed rule was slightly reworded to reflect the site-neutrality direction of CLIA and section 6141 of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89), Public Law 101-239, which requires laboratories participating in the Medicare program to comply with CLIA requirements. Specifically, the requirements in the March 14, 1990 final rule for CLIA licensed laboratories to refer specimens only to other CLIA licensed laboratories, and Medicare approved laboratories to refer specimens to other Medicare approved laboratories has been removed. The proposed rule required laboratories to refer specimens only to a laboratory certified to perform testing for the appropriate level of testing.

##### Comments and Responses

Almost 250 comments were received on this subpart. The comments were divided almost evenly between commenters who opposed portions of the proposed requirements and commenters who basically agreed with the intent of the subpart, but offered alternative suggestions.

*Comment:* Several comments were received from individuals associated with nursing homes and other inpatient facilities that perform bedside laboratory testing. Commenters believed that the requirements of this subpart were burdensome and not appropriate to this type of testing. These commenters requested that the regulations be modified to accommodate laboratory testing when specimens are analyzed at the source of collection (i.e., patient's bedside).

At these facilities, the patient and specimen information is on the patient's

chart or medical record and test results are recorded directly on the chart or medical record. The commenters believed that they would be required to use additional formal requisitions and report forms.

*Response:* We agree with the need for revision as suggested by the commenters. However, every laboratory must implement a system that maintains the pertinent patient and specimen information required to assure reliable and accurate test orders, testing, and reporting of test results for each patient. Due to the diversity of laboratory settings that will be subject to these regulations, and in response to the comments received, we have modified the regulation to allow facilities flexibility in devising and implementing such a system. The regulations allow a laboratory to receive test requests and report test results directly in the patient's chart or medical record. While testing may be done at the bedside, written procedures describing patient preparation, specimen collection and handling and test reporting policies would still be required, as would the applicable requirement for record retention.

*Comment:* A number of commenters suggested that the requirements of the subpart addressing specimen integrity and record keeping should be applicable to waived tests.

*Response:* We agree with the commenters that specimen integrity and record keeping are an essential component of good laboratory practice. We expect that any laboratory committed to reporting accurate and reliable results would institute a policy that includes these components. However, section 353(d)(2) of the Act specifically exempts those laboratories that perform only waived tests from meeting the Federal health and safety standards.

*Comment:* Most commenters agreed with the requirements for specimen collection. Several commenters requested that the standards for specimen collection and submission be applicable to all entities, including those facilities that only collect specimens for testing.

*Response:* We agree with the commenters, but the requirements in CLIA apply only to those facilities that meet the definition of a laboratory; that is, a facility that performs tests on human specimens for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of human beings. Facilities that perform no testing and only collect specimens do not fall into this category.

It is the laboratory's responsibility to establish criteria for acceptance or rejection of specimens and to provide their collection sites and/or clients with the instructions needed to meet these criteria.

*Comment:* A few commenters suggested that we require the facility that collects specimens to label the specimen container and the request slip with a unique patient identification number as part of the labeling requirements to assure positive patient identification.

*Response:* The regulations provide laboratories the flexibility to establish a system that ensures positive patient identification through each step of specimen accession, storage, testing and reporting of test results. This may include a system that involves labeling the specimen container and request slip with a unique patient identification number, but does not preclude the use of other mechanisms to assist in patient identification and tracking of specimens throughout the testing and reporting processes. The choice remains with the laboratory.

*Comment:* A few commenters expressed concern about the requirement for laboratories to make written instructions available to patients for specimen collection, including patient preparation, and suggested that an oral explanation is often more effective.

*Response:* We agree with the commenters that oral instructions to patients for specimen collection, including patient preparation, may be more effective in some cases. We are modifying the regulations to add a number of additional sections. New § 493.1103 is entitled, "Standard; Procedures for specimen submission and handling." At § 493.1103(c), we include a provision for a supplemental oral explanation of instructions to patients for specimen collection, if the laboratory desires to do so. This does not replace the requirement that a laboratory have written instructions for specimen submission which include patient preparation as warranted.

*Comment:* A few commenters noted that facilities performing testing for organ transplants (e.g. eye banks) do not initiate testing as a result of direct authorization or requisition by a patient's physician. Commenters suggested that the final rule provide for testing of organ specimens.

*Response:* We agree with the commenters. The definition of "authorized person" has been broadened to cover their concern. An "authorized person or entity" now may request the testing required by organ

agencies. However, the organ agencies are required to follow their respective State regulations for testing authorization.

*Comment:* A few commenters suggested that electronic test requests should be accepted as an alternative to written requests.

*Response:* The regulations do not preclude the use of electronic requests. As previously stated in § 493.1101(b), now at § 493.1105, Standard; Test requisition, the laboratory must perform tests only at the written or electronic request of an authorized person.

*Comment:* Many commenters offered alternative time frames, both shorter and longer, for a laboratory to obtain written verification of oral requests, and some believed written verification was not necessary at all.

*Response:* Written verification of oral requests is necessary to prevent the unauthorized ordering of tests. We have retained the provision of proposed § 493.1101(b), now located at § 493.1105. That provision requires written verification of oral test requests within 30 days as a reasonable time frame within which to comply. Electronically signed documents are acceptable in lieu of written authorization.

*Comment:* Some commenters disagreed with the requirements for retaining the test requisition for two years. Commenters believed that the two year requirement was too long.

*Response:* All records related to testing, including documentation of the tests requested and that tests were ordered by an authorized person, are a necessary part of a laboratory's recordkeeping. We also note that CLIA directs biennial certification and we plan biennial inspections, not annual inspections, as had been the case for previously regulated laboratories. We are retaining the requirement at proposed § 493.1101(b), relocating it to § 493.1105. The requirement directs laboratories to retain the test requisition or the test authorization for a minimum of two years. This period may be longer if other Federal or State regulations are applicable.

*Comment:* Several commenters suggested that in physician office laboratories the patient chart could serve as the test requisition.

*Response:* We agree with the commenters that a patient's chart or medical record could serve as the test requisition provided that it includes all the information relevant and necessary to assure accurate and timely testing and reporting of test results. Specifically required is the patient's name or other unique identifier, the name and address

or other suitable identifier of the authorized person requesting the test, the test(s) to be performed, the date of specimen collection, and for Pap smears, the last menstrual period, the patient's age or date of birth, and indication of whether the patient had a previous abnormal report, treatment or biopsy. Additional information may include the patient's age, sex, current medications, the time the specimen was collected, diagnosis, the type of specimen to be tested, (i.e., serum versus urine, etc.) if relevant and necessary to the testing to be performed. This would be determined by the laboratory. The patient's chart or medical record used for this purpose must be available to the laboratory at the time of testing, available to HCFA upon request, and must be maintained in lieu of a separate form for at least two years.

*Comment:* A number of commenters felt that too much information was required on the requisitions, and that much of it was really not necessary for proper test performance.

*Response:* We agree with the commenters that the requirements at proposed § 493.1101(b)(1-8), now at § 493.1105(a)-(f), were overly prescriptive in some instances and have revised them to allow laboratories to develop their own system of determining the information relevant and necessary for proper specimen identification and handling, and to assure accurate and timely test performance and reporting of test results. The laboratory must, however, include on the requisition the name of the authorized person ordering the test and, if appropriate, the individual responsible for utilizing test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person. In addition, the requisition must include the test(s) to be performed and the date of the specimen collection. In the event a question arises concerning specimen integrity or if a life-threatening or panic level result is obtained, the requesting individual or entity must be notified.

*Comment:* Numerous commenters stated that it would be unfair to the patient and adversely affect patient health to require the rejection of cytology specimens that are submitted without the required information provided on the test requisition. Some suggested that the laboratory document its attempts to obtain required information.

*Response:* We have not specified the conditions under which specimens should be rejected. Each laboratory must establish its own criteria for specimen acceptability or rejection and

specify these criteria in its procedure manual as required in subpart K, Quality Control at § 493.1211(b)(1). It is our intent that the laboratory make provisions for obtaining patient information, and demonstrate reasonable attempts to obtain the information.

*Comment:* A few commenters felt that the determination of which information is pertinent should be left to the individual ordering the test.

*Response:* We agree with the commenters that the individual ordering the test may be qualified to determine the relevance of clinical information. However, in many instances the technologist or laboratory director will be aware of clinical conditions that may affect testing while a clinician, nurse practitioner, or even a patient who may order a test may not have such knowledge. The laboratory must determine the information it requires to assure proper and reliable test performance and result reporting. A laboratory must make a reasonable attempt to obtain such information. The laboratory can solicit specific information from the authorized person ordering tests by specifying or identifying specific areas on a test request form. If specific information is required by the laboratory in order to perform or report the test, and it is not supplied by the test requester, direct communication is warranted.

*Comment:* Several commenters noted that pertinent clinical information may include HIV testing status or the presence of risk factors for AIDS and may conflict with patient confidentiality requirements.

*Response:* "Pertinent clinical information" pertains to the patient information that may be required by the laboratory for the proper performance of the required test procedure. Only the information that the laboratory determines is necessary for testing must be obtained. We have reworded this requirement to state that, "any additional information relevant and necessary to a specific test to assure accurate and timely testing and reporting of results." Since all patient information is considered confidential, the laboratory must ensure patient confidentiality for all the information it collects.

*Comment:* Several individuals and organizations expressed concern about the requirement to obtain information as to whether a patient is at risk for developing cervical cancer or its precursors. Some stated that many clinics are successful in obtaining Pap smears because of the assurance of patient confidentiality and this

requirement might reveal confidential patient information. Other commenters stated that the majority of American women fall into one or more high risk categories so there would be no point in providing this information.

*Response:* We agree with the commenters and have deleted the requirement, formerly at § 493.1101(b)(8), requesting information as to whether a patient is at risk for developing cervical cancer or its precursors.

*Comment:* A significant number of commenters expressed concern about the requirement for laboratories to have records of each step in the processing and testing of patient specimens, stating that such records could be voluminous.

*Response:* We agree with the commenters regarding the burden implied by this requirement; that is, the recording of every step in the processing and testing of patient specimens. We have removed the requirement to document each step in the processing of patient specimens. We have, however, added the requirement that records must identify the personnel performing the testing procedure. The complexity model consists of waiver, moderate, and high complexity tests and dictates the personnel qualifications required for performing each level of tests. Documentation of the identity of the personnel performing the test procedure is a mechanism for determining compliance with the regulations. These records must be maintained for at least two years.

*Comment:* A few commenters stated that the language in § 493.1101(c) should be clarified to indicate that instrument printouts must be retained for 2 years.

*Response:* We agree with the commenters that instrument printouts must be maintained for two years. We are revising the requirement proposed at § 493.1101(c), and locating it in a new § 493.1107, Standard; Test records, to state that records of patient testing, including, if applicable, instrument printouts, must be retained for at least two years.

*Comment:* Several commenters suggested that assigning accession numbers was not necessary in very small laboratories.

*Response:* We agree with the commenters. It was never our intent to require the laboratory to utilize accession numbers. The system used must assure proper identification of the specimen throughout the testing process. The requirement, which has been relocated to § 493.1107(a), is being reworded for clarification to include the patient identification number, accession

number, or other unique identification of the specimen. The patient's name may be used as part of the identification system. However, the patient's name must be linked with another identifier to assure positive identification between patients with like or similar names.

*Comment:* Numerous commenters opposed the requirement for retention of copies of all test reports, including preliminary reports, for two years or longer. Most of the commenters were concerned about maintaining copies of preliminary microbiology reports.

*Response:* The laboratory's recordkeeping system must include copies of all results that have been reported and potentially acted upon by the clinician. Preliminary reports generated in microbiology are often used by the clinician to initiate treatment and must be retained.

*Comment:* A few commenters questioned the meaning of the phrase "legally reproduced record".

*Response:* The questions raised by the commenters have prompted a more clearly worded requirement. Rather than using the phrase "legally reproduced record", we are changing the regulation as proposed at § 493.1101(d), and are incorporating the provision in a new § 493.1109(h), Standard; Test report. We are requiring laboratories to retain an "exact duplicate" of the original report. The exact duplicate of the test report may be a manually written report or a report generated by an electronic system, one maintained on microfilm, etc., provided it contains all of the information that was on the original test record or report. The duplicate copy does not necessarily have to be reproduced in the exact format of the original test record or report.

*Comment:* Several commenters suggested revisions to proposed § 493.1101(d)(1), which required that systems used to report results ensure the confidentiality of those results when appropriate. The commenters stated that "when appropriate" should be changed to "when appropriate as determined by the laboratory director".

*Response:* The confidentiality of patient results should be insured to the best of the laboratory's ability and in areas over which it has control. All patient information, as well as test results, are confidential. The decision to determine which portions of patient information are or are not confidential cannot be made in the laboratory. We have modified the requirements in proposed § 493.1101(d)(1), and relocated them to § 493.1109(a). As modified, they state that the laboratory must have adequate systems in place to report results in a timely, accurate, reliable and

confidential manner, and ensure patient confidentiality throughout those parts of the total testing process that are under the laboratory's control.

*Comment:* Many commenters stated that it was unreasonable to expect laboratories to be able to retrieve stored records within a two hour time frame.

*Response:* A specific time frame was not mandated in the proposed regulations nor are we including such a requirement in the final rule. The laboratory must be capable of retrieving records in a timely fashion and making these records available when requested to do so during the inspection process.

*Comment:* A few commenters noted that proposed § 493.1101(d)(3), which states that the results or transcripts of laboratory tests must be released only to authorized persons, restricts release of results to authorized individuals and may impede patient care in emergency situations if the physician is not available.

*Response:* We agree with the commenters and we have modified proposed § 493.1101(d)(3), relocating it at § 493.1109(e) and requiring that results or transcripts of laboratory tests or examinations be released to authorized persons or the individual responsible for utilizing test results. This allows results to be released to an authorized person other than the person who ordered the test. In addition, the reporting of potentially life-threatening test results to an individual or entity that requested the test as proposed at § 493.1101(d)(5), is being revised and relocated to § 493.1109(f) to include reporting results to the individual responsible for utilizing the test results, when any test result indicates an imminent life-threatening laboratory result.

*Comment:* Several commenters pointed out that life threatening results could not be immediately reported to the individual responsible for utilizing test results unless the regulations were revised to require that a laboratory referring test include on the test request the name, address and telephone number or other means of contacting the authorized person who ordered the test or is responsible for utilizing test results.

*Response:* We agree with the commenters that a mechanism is needed to report life-threatening or panic value test results when a specimen is sent to a referral laboratory. At § 493.1109(f), we now require that the laboratory immediately alert the authorized person or entity requesting the test or the individual responsible for utilizing the test results whenever a test result is imminently life-threatening. In addition, we have modified proposed

§ 493.1101(b)(2), now relocated to § 493.1105(b), to include on the requisition, as applicable, a contact person to enable the reporting of imminent life threatening laboratory results or panic values. The laboratory is responsible for establishing a reporting system to ensure that this information is reported to the appropriate person.

*Comment:* A few commenters were opposed to the requirement that a laboratory make available to clients data on test sensitivity, specificity, and interferences, pointing out that "volumes" have been written on these subjects. A small number of commenters stated that the rules should stipulate to what extent manufacturer's literature can be used to comply with the requirements for laboratories to provide data on sensitivity, specificity, interferences, etc. A few commenters stated that it was unreasonable to require laboratories to make available "information that may affect the interpretation of test results". They also stated that, for many tests and diseases, sensitivity and specificity data are not available.

*Response:* We agree with the concerns of the commenters regarding the requirement for laboratories to make available specified information on test characteristics. We have modified proposed § 493.1101(d)(7), now relocated at § 493.1109(g), by removing exact requirements and are making the regulation more general. The laboratory must make available, upon request, the performance specifications as required under § 493.1213, Standard; Method performance verification, if applicable, of each test method used. This information may include the manufacturer's data supplied, dependant upon whether the method is used according to the manufacturer's instructions. In addition, the laboratory must make available, upon request, information that may affect the interpretation of test results, such as test interferences. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.

*Comment:* Several commenters expressed concern about the requirement for the name and address of each laboratory performing tests to be included on report forms, noting that some reports are already crowded and additional information could make the reports confusing.

*Response:* The potential for the individual requesting and/or utilizing the test results to require additional test

information to aid in result interpretation and treatment of patients is of much greater importance to patient care than report format. If a laboratory determines that its reports are crowded and confusing to the test requester and/or utilizer, it has complete latitude to reorganize the report in the manner necessary to correct the problem. In addition, it is a Medicare requirement to include this information on result reports if the laboratory participates in and receives payment from the Medicare program. The final rule maintains the requirement at § 493.1101(d)(8), now located at § 493.1109(b), to include the name and address of the laboratory location at which the test was performed. In addition, we have added that the test performed, the test result, and if applicable, the units of measurements also be included on the test report.

*Comment:* A few commenters stated that the requirement to refer specimens only to CLIA laboratories should be modified to include Medicare certified laboratories.

*Response:* CLIA requires HHS to establish certification requirements for any laboratory performing tests on human specimens for diagnosis, prevention, treatment of disease or impairment, or health assessment purposes and to certify through issuance of a certificate that those laboratories meet the requirements. The Omnibus Budget Reconciliation Act of 1989 (OBRA '89) required that all laboratories participating in the Medicare program comply with CLIA requirements. Only laboratories that have a current unrevoked and unsuspended certificate issued by HHS under CLIA will be eligible for reimbursement in the Medicare or Medicaid programs, or both. Due to the passage of OBRA '89, it is no longer necessary for the distinction to be made between Medicare approved laboratories and CLIA certified laboratories for referral of specimens since a laboratory, in order to be approved by Medicare, must meet the applicable CLIA requirements. Therefore, the requirement proposed at § 493.1101(e), is retained at § 493.1111 and states that a laboratory may refer specimens for testing only to a laboratory possessing a valid certificate authorizing the performance of the service for the level of complexity in which the referred test is categorized, and does not mention Medicare approval.

*Comment:* A few commenters suggested the deletion of the requirement at proposed § 493.1101(e)(2) for a referring laboratory, which revises

results in any way, to notify both the testing laboratory and the authorized person who ordered the test of the changes made. Other commenters stated that the requirement should be eliminated by revising the regulation to prohibit alteration of results by a referral laboratory.

*Response:* We agree with the commenters who suggested the elimination of the requirement at § 493.1101(e)(2). We have modified the regulations, now at § 493.1111(a), to state that the referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory.

#### Changes to the Regulation

We have made several editorial and clarifying changes to this subpart to provide more flexibility to the diverse variety of testing entities now subject to the final rule. We also have renamed the subpart as Patient Test Management for Moderate and High Complexity Testing, or Both and have renumbered and added sections § § 493.1103 to 493.1111 to accommodate changes in the regulations. Specific changes to the regulations are as follows:

- Under § 493.1103(c), we are allowing laboratories to provide oral explanations of instructions to patients as a supplement to written directions.
- Under § 493.1105, we are allowing laboratories to receive test requests directly in the patient's chart or medical record.
- Under § 493.1105(b), we are adding the option to include a contact person and/or the name and address of the person utilizing test results on the test requisition.
- Under § 493.1105(c), we are requiring that the test(s) to be performed be included on the test requisition.
- We are modifying the test requisition standard under § 493.1105(f) to allow laboratories to develop their own system of determining the information relevant and necessary for proper specimen identification and handling, and to assure accurate and timely test performance and reporting of test results.
- We are deleting from the test requisition standard the requirement requesting time of collection, source of specimen and test requested, age and sex of patient, and pertinent clinical information.

- For Pap smears, we are removing the requirement that the requisition request information as to whether a patient is at risk for developing cervical cancer or its precursor, but requiring that the form indicate the patient's age or date of birth.

- We are removing the requirement that the test record document each step in the processing and testing of patient specimens.

- Under § 493.1109, we are allowing laboratories to report test results directly in the patient's chart or medical record, which must be readily available to HHS upon request.

- We are requiring that the test record identify the person who performed the test and that the laboratory retain instrument printouts for at least two years.

- We are requiring that the test performed, the test results and, if applicable, the units of measurement be included on the test report.

- We are removing the option for a referring laboratory to revise test results received from a testing laboratory.

#### *Subpart K—Quality Control for Tests of Moderate or High Complexity, or Both*

##### Summary of the Proposed Rule

We proposed this subpart as "Quality Control for Level I and Level II Testing," but have renamed it to be consistent with the changes made in this subpart.

With the exceptions described herein, the quality control requirements in the May 21, 1990 proposed rule were the same standards as specified in the final rule published March 14, 1990. We sought comments on the applicability of those proposed requirements to new technology.

In § 493.1203, Standard; Facilities, we proposed to add the requirement for laboratories that perform non-waived tests to provide for adequate ventilation to ensure proper removal of toxic fumes and that air exhausted from areas in which infectious materials are handled is appropriately filtered before discharge into the atmosphere.

Also in § 493.1203, we proposed to add a requirement for laboratories to have and maintain a stable electrical power source.

We proposed to add to § 493.1211(a)(12), Standard; Procedure Manuals, a new paragraph requirement to ensure that appropriate specimen storage criteria be included in each test procedure.

In § 493.1217, Standard; Frequency of quality control, we proposed to specify in paragraph (e) that the laboratory include only one control in each electrophoresis cell rather than include two controls with each test run. In addition, we proposed at § 493.1249, Standard; Toxicology, for drug abuse screening using thin layer chromatography, that each plate be spotted with at least one calibrator

containing all drugs identified by the thin layer procedure and that at least one control be included in each chamber and processed through every step of patient testing.

In the proposed regulations, we proposed no substantial changes to the special quality control requirements specified in the final rule published March 14, 1990. In the preamble to the proposed rule, we requested the public to consider and comment on the following statements that could be included in several future regulations:

#### HIV-1 Antibody Testing

A reactive screening test for HIV-1 antibody must be followed up with a more specific supplemental test before issuing a final report.

#### Urine Drug Testing for Drugs of Abuse

A positive screening test for drug(s) of abuse must be followed up with a more specific confirmatory test before issuing a final report.

Although we proposed no substantive changes to § 493.1257, Standard; Cytology, from the cytology regulations published on March 14, 1990, to provide clarity to the proposed requirements we are providing an overview of the proposed cytology regulations.

The proposed requirements for quality control in cytology provided for a comprehensive program to detect errors and assure accurate diagnoses. To ensure satisfactorily stained slide preparations and to prevent specimen cross-contamination during staining, we specified that a Papanicolaou stain be used, that stains be filtered or changed between staining gynecologic and nongynecologic specimens, and that body cavity fluids be assessed for their potential to cross-contaminate. We also proposed that no diagnostic interpretations be reported on unsatisfactory slide preparations.

We proposed that each individual examining slides by nonautomated technique examine no more than 120 gynecologic and nongynecologic slides in a 24 hour period, irrespective of the site or laboratory. No more than two thirds of this slide limit, up to a maximum of 80 slides, could be unevaluated slides. We proposed that the technical supervisor establish a slide limit for each individual based on performance and that the limit be documented and reassessed monthly. In addition, we proposed that the laboratory require each individual to account for any slides he or she examined for the laboratory or any other laboratory or employer. Each laboratory would have to maintain a record of the number of slides examined by each individual within each 24 hour

period. We also proposed that the maximum number of 120 slides be examined in no less than 6 hours and proposed a formula for prorating the slide limit for individuals who worked part-time.

We proposed that all premalignant and malignant gynecologic smears and all nongynecologic preparations be reviewed and confirmed by a technical supervisor in cytology. In addition, we proposed that the technical supervisor provide for feedback to cytotechnologists on premalignant and malignant cases and on the results of the reexamination of negative or normal cases. This feedback was to be part of a documented performance evaluation for each cytotechnologist.

To provide for the detection of errors and for further performance evaluation, we proposed that each laboratory establish an error detection program. This program was to include the rescreen of at least 10 percent of all gynecologic cases interpreted to be negative for premalignant or malignant conditions by each individual not qualified as technical supervisor. We proposed that this 10 percent rescreen include cases from patients identified as having a high probability of developing cervical cancer. We also proposed that laboratories compare premalignant and malignant gynecologic cytology results with histology results, available either in the laboratory or from the State health department, and that all normal or negative specimens from the previous 5 years be reexamined when a new malignant or premalignant case is identified. In addition, we proposed that laboratories establish and document an annual statistical evaluation of their case mix with respect to several variables and compare the case reviews of each individual with the overall laboratory statistics, documenting and evaluating any discrepancies.

We proposed several requirements for the laboratory report to specify information that would assist the ordering physician in interpretation of the results. Additionally, we requested comments on whether we should require The Bethesda System for reporting Pap smear results.

We proposed that cytology slides be retained for 5 years if reported as normal, negative or unsatisfactory and 10 years if reported as premalignant or malignant. We proposed to provide for laboratories to donate slides to approved cytology proficiency testing programs in lieu of retaining them for the 5 or 10 year period if authorized by HCFA.

We also proposed that laboratories report all malignant and premalignant

gynecologic cases to their respective State health departments.

#### Comments and Responses

Approximately 1400 comments were received on § 493.1201 Condition: General quality control; tests of moderate or high complexity, or both. About one-half of the commenters were opposed to the proposed quality control requirements, while about one-fifth of the commenters were in support of the proposed requirements. Alternate suggestions were submitted by many of the commenters. Comments received from a few individuals indicated that they had misinterpreted or misread the proposed requirements.

In response to commenters concerns, language has been added to this subpart to allow a two-year phase-in for the development and implementation of a FDA clearance process which will determine if instruments, kits, and test systems developed by manufacturers for in-vitro diagnostic use are in compliance with the CLIA requirements for general quality control.

CDC, FDA, and HCFA have worked collaboratively to revise the complexity model, taking into consideration the responsibility for regulating the products used in the clinical laboratory under the Medical Device Amendments to the Food Drug and Cosmetic Act and these regulations. Although the FDA mandate and regulatory activities have a different focus than does the legislation underlying these proposed rules, we agree that it would benefit both the laboratory and the manufacturer for FDA to consider the CLIA regulations during the review process for products used in the clinical laboratory. Therefore, exercising its authority under both the Federal Food, Drug and Cosmetic Act and CLIA, FDA will develop guidelines for manufacturers to follow in preparing their supplementary data to support their performance claims and recommended quality control procedures for laboratory users of both moderate and high complexity tests. FDA will review this data and, if found to be in compliance with CLIA regulations, will allow the manufacturer to market "cleared" products as meeting the quality control requirements for performing tests of either moderate or high complexity. The laboratory performing these tests in accordance with their labeling instructions, and complying with the requirements of this subpart that are unique to the laboratory facility, will be considered in compliance with the requirements of this subpart. With respect to notifying laboratories that compliance with the

quality control instructions specified in the labeling for the product will constitute compliance with CLIA, the regulations provide that a laboratory cannot rely on a manufacturer's quality control instructions unless the manufacturer, in addition to obtaining FDA clearance of its quality control instructions, also includes the following statement in the quality control instructions: "Unless this device is modified by a laboratory, compliance with these quality control instructions satisfies 42 CFR 493.1201 through 493.1221 and 493.1223 through 493.1285, as applicable, implementing the Clinical Laboratory Improvement Amendments of 1988." The inclusion of such a statement in the quality control instructions without FDA review and clearance will be considered a violation of 21 U.S.C. 352(a) and applicable provisions of Title 18, including 18 U.S.C. 1001. Manufacturers should be advised that HHS will continue to regard any other statements concerning FDA review and clearance of devices to violate 21 U.S.C. 301(1) or 352(a).

Except for the discussion listed below under § 493.1201 which explains the addition of §§ 493.1202 and 493.1203 concerning the applicability and the effective dates of the quality control requirements, the comment and response section does not include the two year phase-in implementation nor does it include any equivalent procedures that will be specified in the State Operations Manual and may be used by laboratories to meet the requirements specified in this subpart.

*Section 493.1201 Condition: General Quality Control; Level I and Level II Testing (General Quality Control for Tests of Moderate or High Complexity, or Both)*

*Comment:* Many commenters believed that quality control (QC) activities are an essential component of good laboratory practice and supported subpart K as written, stating that the quality control requirements should apply to all testing facilities, including those laboratories that perform only waived tests. Many other commenters expressed general disagreement with subpart K stating that it was too rigid and did not allow laboratories the flexibility needed to meet basic QC requirements. Many of these commenters suggested that the regulations be more outcome-oriented as opposed to listing prescriptive requirements. Other commenters felt that the requirements were excessively burdensome and would lead to significant increases in laboratory cost

without substantially improving quality and benefiting patient care.

*Response:* We agree with those who felt that QC activities are an essential component of good laboratory practice. The development, performance, and documentation of QC protocols enables the laboratory to assure the quality of patient test results and reporting. We cannot, however, impose QC requirements upon laboratories that perform only waived tests because the Act specifically exempted laboratories performing only waived tests from all standards, including those of quality control.

The QC requirements established in subpart K are designed to assure the accuracy and reliability of patient test results by monitoring and detecting variations in the performance of test systems using calibration and control materials. We have amended this subpart to clarify the intent of the various sections describing QC requirements and have restructured portions of the subpart to provide a more logical flow to these requirements.

For laboratories that perform tests of moderate complexity using any instrument, kit or test system cleared by the FDA through the premarket notification (510(k)) or premarket approval (PMA) process for *in-vitro* diagnostic use, we have added § 493.1202, Standard; Moderate or high complexity testing or both: Effective from September 1, 1992 to September 1, 1994, which allows a two year phase-in of some of the quality control requirements. Specifically, during this two year period, these laboratories must: Follow manufacturers' instructions for instrument or test system operation and test performance; have a procedure manual describing the processes for testing and reporting patient test results; perform and document calibration procedures at least once every six months; perform and document control procedures using at least two levels of control materials each day of testing; perform and document applicable specialty and subspecialty control procedures; and perform and document that remedial action has been taken when problems are identified.

When laboratories perform tests of high complexity or perform tests of moderate complexity using a method developed in-house or using an instrument, kit or test system cleared by the FDA through the 510(k) or PMA that has been modified by the laboratory there is no phase-in for quality control requirements. For these tests,

laboratories must meet all applicable standards of this subpart.

We have added § 493.1203, Standard; Moderate or high complexity testing, or both: Effective beginning September 1, 1994, which addresses requirements in effect after the 2 year phase-in period. Laboratories must either follow the instructions in package inserts or operator manuals supplied with instruments, kits, and test systems that have been cleared by the FDA as meeting the CLIA requirements for general quality control and comply with requirements of this subpart that are unique to the laboratory and cannot be met by manufacturers' instructions; or they must meet all applicable quality control requirements specified in this subpart. If, on September 1, 1994, a laboratory is performing a test of moderate or high complexity using an instrument, kit or test system that has not been cleared by the FDA as meeting the CLIA requirements for general quality control, the laboratory will be expected to meet all applicable requirements of this subpart.

The FDA has analyzed the potential number of 510(k) submissions likely to be received from manufacturers during the phase-in period for implementation of the General Quality Control standard, based on the very limited data available. The agency estimates that an initial, non-recurring bolus of between 3,000 and 9,000 existing applications could potentially be resubmitted for review, most within the first two years of the effective date of the rule, along with the 1,000 new 510(k) or PMA applications the agency usually receives annually. The estimates of reapplications vary widely as a result of the fact that the revised review process is new to both the FDA and to manufacturers, and because the submission of reapplications for devices already in use will depend on market factors which are complex and inherently difficult to anticipate.

The FDA is concerned about its ability to process all applications received within the 2-year phase-in period. The agency's ability to handle this early, greatly-expanded workload of premarket submissions will depend on the actual numbers and timing of submissions received, as well as on the availability of the additional resources necessary to fully accommodate the projected workload. While a moderate number of applications can be accommodated, if the early submissions received are in the higher range of estimates, FDA may well have difficulty in completing its review of all

reapplications during the 2-year phase-in period.

The agency anticipates that CLIA user fees will be available to support additional staff and services needed to develop and implement an expanded 510(k) process. However, there are practical limits on the number of additional technical staff that can be hired and trained within a short period of time, particularly when the need for these staff is temporary. In any case, subject to user fee generated resources, FDA management will be monitoring submission activity very closely and will take all possible steps to anticipate and meet the challenges presented.

*Comment:* Many commenters felt that comprehensive QC programs were fully justified for large laboratories but too costly for small limited-service laboratories that perform only Level I tests. Commenters suggested that QC requirements should be commensurate with the scope of testing performed and compatible with the instruments and methodologies used for testing. A few commenters suggested that built-in computers in many of today's instruments would handle most QC requirements.

*Response:* We agree that QC programs should be commensurate with the scope of testing performed. The regulations have been amended to provide all testing facilities performing tests of moderate and high complexity a framework within which to develop a QC program that will provide accurate and reliable patient test results. In addition, an option is provided for laboratories to be in compliance with these regulations by using instruments, kits and test systems that have been cleared by the FDA as meeting the CLIA requirements for general quality control.

We agree that many instruments provide computer assisted QC monitoring and data processing; however, the interpretation of these data, and the decisionmaking process concerning whether quality control results are acceptable or require remedial action, and the final decision regarding the release of patient test results are functions which require trained laboratory personnel.

We recognize that these requirements will increase the costs in some testing facilities that have practiced little or no QC to date, but we feel that these QC requirements are essential to ensure quality patient testing. Therefore, the benefits associated with these requirements outweigh any costs imposed and burden associated with their implementation.

*Comment:* Several commenters felt that the extensive requirements in

subpart K would have a negative impact on the development of tests for the diagnosis of uncommon or rare diseases and on the development of new technologies, methodologies, and equipment. Many commenters identified specific types of equipment or devices that they felt had sufficient control mechanisms recommended by the manufacturer and should not be subject to additional Federal requirements. Several commenters felt that manufacturers should be required to provide products which meet the Federal QC requirements. If so, laboratories would only be required to comply with manufacturers' instructions for QC.

*Response:* We appreciate the commenters' concerns. The requirements in subpart K were established to provide a basic framework within which all testing facilities can develop policies and protocols which will assure accurate and reliable test results. As previously described, we have amended the requirements to permit greater flexibility by allowing laboratories performing tests of moderate complexity, for a two year period after the effective date of the regulation, to be in compliance with the QC provisions of this subpart by meeting minimal QC requirements and following manufacturers' instructions, as long as the laboratory has not modified the instrument, kit, or test system's procedure. During this two year period, the FDA will implement a thorough review and clearance process for manufacturers' products to assure that QC claims and instructions conform to these regulations before products are marketed. If existing manufacturer's claims for products presently on the market do not conform to these regulations, manufacturers may choose to collect and submit, to FDA for review and acceptance, quality control data to support claims presented in their instructions. After the manufacturer's QC claims and instructions have been cleared by the FDA, a laboratory may meet the QC requirements by following the manufacturer's product instructions. With these changes, we feel that the regulations will not impede the development of new technologies. If, however, a future technological advancement would warrant existing quality control requirements to be revised or amended, the Clinical Laboratory Improvement Advisory Committee (CLIAC) would be requested to undertake such a review. The request for review of new technology may be sent to HHS by an organization, a manufacturer or an individual. The

CLIAC and its functions are described in subpart T.

CLIA is specifically applicable to laboratories, not manufacturers. Manufacturers may recommend QC practices, but the laboratory is responsible for their performance, documentation, and QC data interpretation.

*Comment:* Several commenters requested that Home Health Agencies and Ambulatory Surgical Centers not be subject to this subpart.

*Response:* If a Home Health Agency or an Ambulatory Surgical Center performs " \* \* \* examinations of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease \* \* \*" as stated in section 353(a) of the Statute, that agency or center is defined by law as a laboratory. Unless these facilities perform only waived tests, they would be subject to the applicable quality control requirements in this subpart.

*Comment:* Several commenters felt that the QC standards of organizations such as the College of American Pathologists (CAP), the Commission on Office Laboratory Accreditation (COLA), the American Association of Family Practitioners (AAFP), and the American Society of Internal Medicine (ASIM) should be acceptable alternatives to Federal requirements.

*Response:* Section 353(e) of the statute allows for the deeming of non-profit organizations such as CAP, COLA, AAFP, and ASIM, provided they apply for HHS approval of their accreditation program and have standards that are equal to or more stringent than those of the final rule. If an organization is recognized as an approved accreditation program, its QC standards would be deemed to be equivalent to or more stringent than the quality control standards described in this rule.

In a separate rule, we are establishing the criteria for approval of accreditation bodies and State programs that have standards equivalent to or more stringent than the final regulations.

*Comment:* Several commenters were concerned about public access to the interpretive guidelines published in Appendix C of the HCFA State Operations Manual.

*Response:* State Operations Manual publications are available through the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161. The phone number is 1-800-336-4700.

*Section 493.1203 Standard; Facilities (This Section Has Been Redesignated as § 493.1204)*

*Comment:* Several commenters recommended that safety requirements be added to this section.

*Response:* We agree with the commenters that safety is an important factor, and have added § 493.1204(b), which states, "Safety precautions must be established, posted, and observed to ensure protection from physical hazards and biohazardous materials."

*Comment:* Several commenters considered the term "adequate ventilation" to be too vague. The commenters indicated that the costs associated with adding a ventilation system would be prohibitive, and suggested that this requirement not apply to laboratories doing simple bacteriology.

*Response:* While we agree with the commenters that the term "adequate ventilation" is vague, laboratories should defer to applicable Federal, State and local laws regarding ventilation to determine what is "adequate" for their facility. The regulation has been reworded to provide a framework that will allow the laboratory to determine what requirements are necessary to ensure proper performance and accurate reporting of tests. We do not agree that laboratories performing simple bacteriology testing should be exempt from this requirement, since laboratories performing any test procedure that may adversely affect the health of laboratory personnel must employ appropriate safeguards. We have added § 493.1204(b), which requires the laboratory to establish, post, and observe safety precautions to ensure protection from physical hazards and biohazardous materials.

*Comment:* A few commenters noted that the preamble contained language which would require all air exhausted from areas where infectious materials are handled to be "appropriately filtered before discharge into the atmosphere." They expressed concern about the expense involved and the types of materials which would be considered infectious.

*Response:* A laboratory should defer to Federal, State and local laws, including those regulations provided by OSHA and EPA, concerning the requirements for the discharge of infectious materials into the atmosphere. Laboratories must establish, post, and observe safety precautions to ensure protection from physical hazards and biohazardous materials. In laboratories where hazardous specimens are handled and processed, such as cultures for

tuberculosis and systemic mycoses, we would expect these activities to be performed in a properly maintained biological safety hood.

*Comment:* Many commenters felt that the phrase to "ensure an adequate, stable electrical source" is too vague and compliance with such a requirement would be costly. It was suggested that it would be more appropriate to require preventive measures such as voltage regulators, surge suppressors, and uninterruptible power supplies.

*Response:* We agree with the commenters that the proposed language was not well defined. Our intent is to detect circumstances when proper test performance or accurate reporting of test results are adversely affected. The laboratory must then identify and document remedial actions taken to correct the problems. The facility would determine the mechanisms needed to achieve the desired outcome of proper performance and reporting of results. This requirement has been rewritten and now appears § 493.1205(c)(2).

*Comment:* Several commenters suggested that the electrical sources of existing facilities by "grandfathered." Other commenters requested that manufacturers of laboratory equipment not be held responsible for electrical power conditions, associated problems, and their resolution.

*Response:* We disagree with the commenters. If electrical sources were always constant and never changed, "grandfathering" of existing testing facilities might be a viable recommendation. Unfortunately, neither the source nor its use is predictable, and either could adversely impact testing.

We agree it would be impractical to hold manufacturers of equipment responsible for areas beyond their control. Manufacturers may and usually do recommend to equipment purchasers the necessary power requirements needed for optimum instrument performance; however, electrical power usage and stabilizing power problems, such as fluctuations, are the responsibility of the equipment user when such conditions impact adversely on patient testing.

*Section 493.1205 Standard; Adequacy of Methods and Equipment (Now Renamed Standard; Test Methods, Equipment, Instrumentation, Reagents, Materials, and Supplies)*

*Comment:* Several commenters believed that HCFA should be required to register and regulate all equipment.

*Response:* The Act does require each laboratory to designate the methods and procedures it uses for testing. The Act requires standards for laboratories using

equipment, instruments or systems for testing human specimens to assure that they are functioning appropriately to provide accurate and reliable test results. FDA is responsible for regulating all of the equipment described in this standard.

*Comment:* Several commenters suggested adding linearity testing to parts (b) and (c) of this section.

*Response:* We disagree with the commenters. The subject of linearity has been addressed under § 493.1213, Establishment and verification of method performance specifications. Laboratories that are required to verify or establish their reportable range for patient test result could perform a linearity determination for new testing procedures. In addition, the calibration verification procedure described in § 493.1217, Calibration and calibration verification procedures, requires that the laboratory verify the reportable range for patient test results a minimum of once every six months. This does not preclude the laboratory from performing additional linearity checks to verify the reportable range for methods in use.

*Comment:* A few commenters stated that it is impossible to perform tests in a manner that ensures "freedom from interference" as stated in § 493.1205(c).

*Response:* We agree with the commenters and have deleted the requirement. However, as part of the establishment or verification of the method performance specifications, under § 493.1213(b)(2), for methods developed in-house, a modification of the manufacturer's test procedure, or a method that has not been cleared by the FDA as meeting the CLIA requirements for general QC, we expect a laboratory to identify specific interfering substances and include these substances in the procedure manual as a limitation in methodology as directed under § 493.1211(b)(9).

*Section 493.1207 Standard; Temperature and Humidity Monitoring (The Contents of This Section Have Been Incorporated in Section 493.1205, Standard; Test Methods, Equipment, Instrumentation, Reagents, Materials and Supplies Under Paragraph (c))*

*Comment:* Many commenters believed that it was not necessary to monitor humidity and requested that the requirement be deleted. Others asked how humidity should be monitored and with what frequency. Others asked for definitions of "acceptable ranges" for temperature and humidity.

*Response:* We have revised the requirements at § 493.1205(c) to state that the laboratory must, when

applicable, define criteria for humidity only as it applies to proper test performance and storage of reagents and specimens and document corrective actions taken when there is a failure to meet the acceptability criteria. The laboratory location, test method, instrumentation, procedure, and reagent storage requirements will determine the necessity for establishing an acceptable range and monitoring and modifying humidity, as necessary. The method used for measurement of humidity, where applicable, is the responsibility of the laboratory.

*Comment:* Several commenters expressed concern about controlling climatic conditions of transported specimens, specifically the integrity of specimens that are placed in containers for specimen pickup prior to transporting the specimens to a reference laboratory for testing.

*Response:* We share the commenters' concern about specimen integrity during storage prior to transport. We would expect a laboratory to establish policies and procedures for specimen transport, storage, and evaluation of specimen acceptability for testing and monitor the acceptable operation of this system as required in Subpart J, Patient Test Management and Subpart P, Quality Assurance.

*Comment:* Numerous commenters expressed concerns about possible increased matrix effect upon proficiency testing samples and proper control material reconstitution if improper diluent was used by the laboratory.

*Response:* We have included requirements at § 493.1205(c) which requires the laboratory to define the criteria for those conditions which are essential for proper storage of reagents and specimens, and accurate and reliable test system operation and test result reporting. Water quality is a condition that may affect test performance. The presence of possible contaminants in impure water, such as tap water, may compromise the integrity of a proficiency testing sample or control sample and procedure interference sufficient to cause inaccurate results.

*Section 493.1209 Standard; Labeling of Testing Supplies (The Contents of This Section Also Have Been Incorporated in § 493.1205 Under Paragraphs (d) and (e))*

*Comment:* Many commenters believed that the regulations should allow laboratories to use certain rare and expensive antigens, antibodies, stains, and other materials beyond their expiration dates as long as the performance of these materials is closely monitored. One commenter

asked for a list of products exempted from the dating requirements by the FDA.

*Response:* While we understand the concerns expressed by the commenters regarding the use of rare and expensive material beyond their expiration dates, these dates have been established to assure that materials will perform properly when used for patient testing. For licensed biological products, product dating requirements specified in FDA regulations at 21 CFR 610.53 and at 21 CFR 809.10 for all other *in-vitro* diagnostics must be met. Any exceptions to these product dating requirements for licensed biological products must be approved by FDA in accordance with 21 CFR 610.53(d). No exceptions are approved for other products. FDA does not publish a list of exempted products.

*Comment:* A few commenters noted that HCFA does not recognize that calibrator and control sera are often packaged in containers too small to enable the manufacturer or user to fully label the container, whereas FDA provides an exemption for small containers.

*Response:* Laboratories may choose to store small containers in larger containers that are suitable for proper labeling or develop another method or system that would ensure that materials are properly identified and labeled.

*Comment:* Several commenters considered the requirement prohibiting the interchange of kit components to be "too rigid" and suggested only applying this rule to those "critical" components of a kit when interchanging these components might not produce acceptable and reliable results.

*Response:* The performance specifications of a particular kit are established by the manufacturer based on the reactivity of the reagents in the kit to provide the most accurate and reliable test results. Alterations, such as substituting components of other lot numbers, may adversely affect the test results. The testing facility must follow the manufacturer's recommendations for using the kit components unless the laboratory chooses to establish (not verify) the performance specifications for the modified kit as described in § 493.1213(b)(2). Therefore, no changes were made in the regulation as proposed.

*Section 493.1211 Standard; Procedure Manual*

*Comment:* A few commenters requested that procedure manuals for small laboratories be developed by DHHS, several suggested using package inserts, and many commenters wanted

the National Committee for Clinical Laboratory Standards (NCCLS) identified as a reference for developing procedure manuals. A few commenters recommended that textbooks and literature references or product materials supplied by manufacturers not be accepted in lieu of a procedure manual.

*Response:* A procedure manual is the testing facility's written instructions and descriptions related to its own unique operation. The regulations provide a framework for which each laboratory may tailor its manual, where applicable. Manufacturer's package inserts or operator manuals are acceptable for use by the facility in place of separate, rewritten step-by-step instructions for test performance provided they meet the requirements of the regulation. Specifically, manufacturer's package inserts or operator manuals may be used, when applicable, to meet the requirements of § 493.1211 (b)(1) through (b)(13). However, any of the items under paragraphs (b)(1) through (b)(13) not provided by the manufacturer must be provided by the laboratory. We believe that laboratory directors will have to spend only a minimum of time writing procedure manuals and, as a result, the regulatory impact analysis estimates only a small cost for this provision.

Laboratories may use a number of reference resources when establishing a procedure manual, including the NCCLS publication.

*Comment:* A few commenters believed that a procedure for referring specimens to another laboratory should be included in the procedure manual.

*Response:* We agree with the commenters and have added this requirement at § 493.1211(b)(16).

*Comment:* Several commenters noted that the requirements for the procedure manual did not include step-by-step instructions for performing examinations.

*Response:* We agree with the commenters and have added these requirements at § 493.1211(b)(3).

*Comment:* One commenter noted the term "Quality Control" under Procedure Manual was too general and needed to be clarified by adding requirements for identification, number, and frequency of control specimens.

*Response:* We agree with the commenter and have revised the title of subparagraph 493.1211(b)(7) to "Control procedures" which will allow the testing facility to develop policies and procedures identifying the type and number of controls, the frequency of use, etc. and any other pertinent directions.

*Comment:* A few commenters noted that Subpart M, Quality Assurance, adequately addressed quality assurance policies and it is redundant to require that quality assurance instructions be in the procedure manual.

*Response:* We agree with the commenters. We have removed the requirement for quality assurance protocols to be included in the laboratory's procedure manual.

*Comment:* Several commenters noted that in § 493.1211(b) it would not be possible for the current director to "initially approve" a procedure if that person was not director at the time the procedure was instituted. Another commenter suggested deleting the term "initially."

*Response:* We agree with the commenters. Since all procedures must be approved by the laboratory director, we have deleted the term "initially" from the section that is now at § 493.1211(d). In addition, we have added § 493.1211(e) which requires that procedures be re-approved, signed and dated if the directorship of the laboratory changes.

*Comment:* Many commenters suggested changing § 493.1211 (b) and (c) to allow laboratory personnel qualified in the particular specialty or subspecialty to approve, sign, and date procedure manual changes.

*Response:* We disagree with the commenters. The laboratory director is ultimately responsible for the overall management of the testing facility and \* \* \* must assure that tests, examinations and procedures are properly performed, recorded and reported \* \* \*. In addition, in laboratories that perform no high complexity testing, only a director and an analyst may be employed. Therefore, we are retaining the requirements, now at § 493.1211 (d), (e) and (f) for documentation of the director's approval of the procedure and reapproval of each change in a procedure.

*Comment:* Several commenters requested adding "reviewed annually by the director" to § 493.1211(c).

*Response:* We disagree with the commenters and therefore, have not included a requirement for an annual review of the procedure manual. The requirements at § 493.1211 (d), (e) and (f), which require approval of the procedure manual by the director and re-approval when changes occur in procedures, accomplishes the same function without requiring the repetitive annual reviews.

*Comment:* A few commenters suggested that § 493.1211(d) be changed to require laboratories to retain copies

of discontinued procedures for five years rather than for two years.

*Response:* We have retained the requirement, which is now addressed in § 493.1211(g), for a laboratory to retain records for two years as a minimum requirement. Laboratories may choose to retain records for longer periods of time. Under State law a laboratory may be required to maintain records for a longer period than the Federal regulations stipulate.

#### *Section 493.1213 Standard: Equipment Maintenance and Function Checks*

*Note:* This section has been moved to § 493.1215, Standard; Validation of methods.

*Comment:* Many commenters supported following manufacturers' preventive maintenance instructions and one suggested using this requirement as a "model" throughout the regulation. A few commenters requested that laboratories be allowed to deviate from manufacturers' suggested maintenance schedules. Several commenters recommended simplifying § 493.1213(a) to read: "The laboratory must document the existence of and adherence to a preventive maintenance program." A few commenters requested that laboratories be allowed to omit some maintenance requirements providing they could document that they served no useful function.

*Response:* We agree with the commenters who suggested using the manufacturer's instructions as a "model" for the testing facility's equipment maintenance policy. We have modified the regulations now at § 493.1215(a) to clarify this point. Laboratories using manufacturers' equipment, instruments, or test systems cleared by the FDA as meeting the CLIA requirements for general QC must perform maintenance as defined by the manufacturer. We disagree with the commenters who suggested omitting "unnecessary" maintenance requirements and have retained the requirement for following the maintenance instructions with at least the frequency suggested by the manufacturer to avoid inaccurate and unreliable test performance and result reporting as a consequence of improper equipment maintenance.

*Comment:* Many commenters objected to the requirement for performance checks on certain pieces of equipment. Some were confused about the terms "function checks," "rechecking," "calibrating," and "recalibrating."

*Response:* The terms "function checks", "rechecking", "calibrating," and "recalibrating" are the terms most

often used by manufacturers when describing the activities needed to be performed, prior to patient testing, to assure accurate and reliable test results. Function checks are activities performed regularly to ensure that an instrument, device, or test system is performing properly. These activities are usually described by the manufacturer and may include such things as evaluating electrical levels, optical alignment, background counts, etc. Function checks must be performed as stated in § 493.1215(b) to assure proper equipment, instrument and test system performance and accurate and reliable test results. Calibration is the process of testing and adjusting an instrument, kit, or test system to provide a known relationship between the measurement response and the value of the substance that is being measured by the test procedure. Recalibration is the repeat performance of the calibration procedure after a certain time period or when an event has occurred which may have caused a shift in test values. Rechecking may involve using another group of samples of known concentration or activity to verify that the procedure is operating properly.

*Comment:* Several commenters suggested requiring function checks less frequently than each day of use if "specified by the manufacturer."

*Response:* If the laboratory uses equipment, instruments, or test systems cleared by the FDA as meeting the CLIA requirements for general QC, the laboratory must adhere to the manufacturer's specifications to assure that the equipment, instrument, or test system is performing at the optimum levels. If the manufacturer's instructions state that function checks may be performed at less than daily frequency, the laboratory may follow that schedule.

*Comment:* One commenter requested deleting the requirement at § 493.1213(b)(1), which requires rechecking, calibrating, or recalibrating each day of use because they were included in § 493.1217, Standard; Frequency of quality control. Other commenters suggested deleting § 493.1213(b)(1) if function checks are performed.

*Response:* We agree with the commenters. We have revised § 493.1215 to describe a laboratory's responsibility to perform equipment maintenance and function checks and § 493.1217 was revised to describe a laboratory's responsibility for calibration and calibration verification.

*Section 493.1215 Standard; Validation of Methods (Redesignated as Section 493.1213 and Renamed Establishment and Verification of Method Performance Specifications)*

*Comment:* Numerous commenters agreed that validation of methods was important, but recommended that the validation performed by the manufacturer or other authoritative sources should be accepted in lieu of a validation performed by each laboratory for every method. Many commenters believed that validation of a method would not be necessary if a laboratory followed the manufacturer's instructions and had not altered the method, but the commenters agreed that laboratories should validate methods that had been altered or developed "in-house." Commenters stated that in-house laboratory validation was expensive, not feasible for all laboratories, unnecessary, and too complicated for many laboratories to perform. A few commenters stated that laboratories should be allowed to use manufacturers' validation studies if the laboratory follows the manufacturer's calibration scheme and instrument maintenance schedule, particularly if the manufacturer provides evidence of following the NCCLS protocols for linearity, precision, accuracy, and interference claims. These commenters suggested that manufacturers be encouraged to follow the NCCLS validation protocols. Several commenters recommended deleting all validation requirements while others proposed maintaining only parts of the requirements. Many commenters suggested this requirement be changed to read "evidence of validation."

*Response:* We agree with the commenters who stated that testing facilities should be allowed to use manufacturers' established validation studies for methods used strictly according to the manufacturer's specifications. Laboratories introducing a new procedure for patient testing using an instrument, kit, or test system cleared by the FDA as meeting the CLIA requirements for general QC must demonstrate, prior to patient testing, that it can obtain performance specifications for accuracy, precision, and reportable range of patient test results comparable to those established by the manufacturer. The laboratory must also verify that the manufacturer's reference range is appropriate for the laboratory's patient population.

Laboratories that use in-house methods, a modification of the manufacturer's test procedure, or an instrument, kit or test system that has

not been cleared by the FDA as meeting the CLIA requirements for general QC, must verify or establish the performance specifications for the applicable performance characteristics such as: Accuracy; precision; analytical sensitivity; analytical specificity to include interfering substances; reportable range of patient test results; reference range; and any other performance characteristic required for test performance. This requirement is not retroactive for testing facilities not previously subject to the regulations or test procedures in use prior to the effective date of the regulations.

*Comment:* Several commenters questioned the acceptability of validations performed by parent laboratories for their satellite laboratories. Some of these commenters suggested that the validation studies conducted by a parent laboratory not be accepted for satellite locations. Others suggested that all satellite laboratories perform at least a minimum verification of a parent facility's validation.

*Response:* As previously described, each laboratory must verify the performance specifications of each test method before patient test results can be reported. If the satellite laboratory uses the same method, equipment, and reagents, and the performance specifications have already been verified by the parent laboratory, the satellite laboratory may use this verification in lieu of its own, but should confirm that equivalent data is being produced which can be accomplished through performing tests using common control materials or patient specimens. If the satellite laboratory serves a different patient population, it must confirm that the parent laboratory's verification or establishment of the reference range is valid for the satellite laboratory. In addition, in situations where a patient may have the same test performed by both the parent laboratory and satellite laboratory the comparability of the test values must be defined as required at § 493.1709, Standard; Comparison of test results.

*Comment:* Numerous commenters were unclear about what was expected of a laboratory under the method validation requirements. One commenter was pleased to see a change in the regulation from "linear reportable range" to "reportable range." Commenters requested clarification of validation requirements for the following: Applicability to microbiology procedures; determination of the linear reportable range; whether clinical trials are required; and the applicability of validation to a small limited-service

laboratory that might be unable to collect data to verify performance characteristics. In addition, commenters inquired whether validation records should include lot numbers of reagents and dates of testing and asked for specific guidance to ensure that inspectors uniformly interpret the validation requirements.

*Response:* In order to meet the requirements for establishment and verification of method performance specifications, a testing facility must have documentation of its claims for each method used. If the instrument, kit, or test system has been cleared by the FDA as meeting the CLIA requirements for general QC and is used by the testing facility in accordance with the manufacturer's instructions, the testing facility must demonstrate it can obtain results comparable to those obtained by the manufacturer for accuracy, precision, and reportable range of patient test results. In addition, the laboratory must verify that the manufacturer's reference range is appropriate for the laboratory's patient population. In most cases, clinical trials are not required to validate the performance characteristics of a test method. However, if the laboratory establishes an in-house method, alters a manufacturer's described test methodology, or uses an instrument, kit or test system not cleared by the FDA as meeting the CLIA requirements for general QC, verification or establishment of the performance specification must be performed and documented as previously described.

A laboratory's verification or establishment of microbiology procedures' performance specifications is expected to demonstrate the ability to isolate and identify the organisms that the laboratory claims to be capable of isolating and identifying.

To document method verification activities performed by the laboratory, records of dates of testing and of the reagents employed must be maintained. Lot numbers of reagents need not be recorded when performing method verification, but are required when lot numbers of reagents are changed during routine use of the procedure.

*Comment:* Several commenters suggested that § 493.1215(d) be deleted, specifically the requirement for laboratories to determine the sensitivity and specificity of a method, because it was considered too time consuming and not possible for a laboratory to routinely and consistently establish these parameters for all tests and disease states. A few commenters suggested adding the word "analytical" before the

words sensitivity and specificity to clarify that we were not referring to diagnostic sensitivity or specificity.

*Response:* We understand the commenters' concerns about the extent to which a testing facility must determine and provide documentation of precision, accuracy, sensitivity and specificity. While we are retaining this requirement, we have modified it as previously explained in response to other commenters' concerns about method performance verification. We have added the word "analytical" before the words sensitivity and specificity.

*Comment:* One commenter requested clarification of the data required at § 493.1215(e) of the proposed rule, requiring the laboratory to maintain documentation verifying that test systems perform according to the laboratory's specifications. The commenter stated that this was a reasonable requirement if the data was limited to performance characteristics, such as bias and precision that are measurable, and the rationale for selecting reporting limits.

*Response:* We agree in part with the commenter. We have changed the requirements, now in § 493.1213, to reflect that if the testing facility utilizes an instrument, kit, or test system that has been cleared by the FDA as meeting the CLIA requirements for general quality control according to a manufacturer's specifications, it must demonstrate and document that it can obtain results comparable to the manufacturer's performance specifications for accuracy, precision, and the reportable range of patient test results, and verify that the manufacturer's reference range is appropriate for the laboratory's patient population. However, if the testing facility develops its own in-house method, alters a manufacturer's method, or utilizes an instrument, kit, or test system not cleared by the FDA as meeting the CLIA requirements for general QC, it must verify or establish, and document the method's accuracy, precision, reportable range of patient test results, reference range, analytical specificity and sensitivity and other performance specification required for test performance. The data collected by the laboratory during the establishment and verification of method performance specifications process, must be available to the authorized person ordering tests or receiving test results.

*Comment:* Several commenters stated that it is not possible for each laboratory to establish reference ranges for all methods as required under § 493.1215(f). Commenters recommended that

laboratories be permitted to use reference ranges published in the literature or established by the manufacturer provided the laboratory has documentation of the source. One commenter requested clarification of this requirement to indicate how a laboratory is to establish a reference range. Other commenters noted the nationally established reference range for cholesterol. A few commenters indicated that this requirement would be appropriate for procedures with significant variability like coagulation.

*Response:* We appreciate the commenters' concerns. We have modified the language in the regulation now at § 493.1213(b) to state that testing facilities must verify or establish their reference ranges before reporting patient results. Verification of the reference range can be accomplished by testing a random sample of (normal) patient specimens and comparing the results with the reference range established by the manufacturer or documented in related literature. Laboratories using instruments, kits, and test systems that have been cleared by the FDA as meeting the CLIA requirements for general quality control must verify that, prior to patient testing, the manufacturer's reference range is appropriate for the laboratory's patient population.

*Section 493.1217 Standard: Frequency of Quality Control (Now Separated Into Two Sections, Section 493.1217 Standard; Calibration and Calibration Verification Procedures, and Section 493.1218 Standard; Control Procedures)*

*Comment:* Many commenters felt that § 493.1217 should be revised to allow laboratories latitude in testing quality control samples. The commenters felt that the frequency of testing controls should vary depending upon the amount of testing performed and the types of procedures and instruments employed. They were critical of the prescribed frequencies and claimed that some of these frequencies were excessive, contributed to higher costs, and did not improve the quality of patient testing. Many commenters recommended that § 493.1217(a)-(f) be replaced with the requirement that "laboratories perform calibration, calibration verification, or recalibration of each automated and manual procedure as specified by the manufacturer." Several commenters asked for clarification concerning the definition of a run and how often controls and/or calibrators would have to be tested. Several commenters suggested that laboratories be allowed to follow the manufacturer's recommendation regarding the number

of calibrators and controls per run or be allowed to use a less stringent protocol if supported by proper documentation. Some commenters suggested more frequent calibration while other commenters suggested less frequent calibration.

*Response:* We appreciate the concern of the commenters regarding frequency of calibration and control procedures. While we have retained certain minimum requirements necessary to alert analysts to unsatisfactory analytical performance, we have made some changes in the regulations. The laboratory must perform the calibration procedure specified by the manufacturer and with at least the frequency recommended by the manufacturer. In addition, we maintained the requirement for laboratories to verify calibration every six months and whenever testing conditions are altered. We are allowing the testing facility to determine the frequency of testing control samples with each run based on its evaluation of instrument and reagent stability and operator variance, although we are requiring at least two levels of control to be included with each run of patient specimens. We are defining "run" as an "interval within which the accuracy and precision of a testing system is expected to be stable, but must not exceed a period of 24 hours and must not be less frequent than the manufacturer's specifications of including controls and calibration materials."

*Comment:* While some commenters favored calibration every six months, many believed it increased the cost of testing without improving the quality of test results. Many commenters asked for exact definitions of calibration, calibration verification, and recalibration.

*Response:* We disagree with the commenters who consider verification of calibration at least every six months to be an unreasonable requirement. We have defined calibration, recalibration and calibration verification of a procedure as follows:

*Calibration*—is the process of testing and adjusting an instrument, kit, or test system to provide a known relationship between the measurement response and the value of the substance that is being measured by the test procedure.

*Recalibration*—is the repeat performance of the calibration procedure after a certain period of time or when an event has occurred which has caused a shift in values.

*Calibration Verification*—is the assaying of calibration materials in the same manner as patient samples to confirm that the calibration of the

instrument, kit or test system has remained stable throughout the laboratory's reportable range of patient test results.

*Comment:* Many commenters felt that verifying calibration of different shipments of reagents was unnecessary if the reagents were the same lot number.

*Response:* We appreciate the commenters' concerns. The laboratory must perform calibration verification of each automated and manual procedure when commercially prepared reagents of the same lot number are received in different shipments to ensure that reagents have not been adversely affected during shipment and to verify that parallel results are obtained with the new reagents. However, we have modified the requirement, now at § 493.1217(b)(2)(ii)(C)(1), to allow the laboratory to waive this requirement if it can demonstrate that changing lot numbers does not effect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes.

*Comment:* Several commenters felt that the phrase in § 493.1217(a)(1)(iii) "Controls begin to reflect an unusual trend," was not defined, difficult to determine and should be deleted. A few commenters agreed with this part as written. Many commenters believed that recalibration should not be the first and only solution required when control values exceed acceptable limits and a few commenters suggested that the laboratory staff should decide how to troubleshoot a problem.

*Response:* We disagree with the commenters who indicated that one cannot identify when "controls begin to reflect an unusual trend." A number of QC "rules," have been developed to help detect and monitor trends in QC testing and decision rules have been developed for situations which may indicate an analytic problem.

We have modified the regulation, now at § 493.1217(b)(2)(ii)(C)(3), to allow testing facilities to correct unacceptable control values by other means rather than requiring calibration verification of an instrument, kit or test system.

*Comment:* A few commenters suggested changing the term calibrators to "standards."

*Response:* The term "standard" usually refers to a primary reference material that is of fixed or known composition, which can be used to establish a reference point for all measurements. Secondary reference materials may also be used to perform calibration activities. These secondary materials are of many types and varieties, including calibrators. In some

instances, where costs are not prohibitive, a "standard" may be employed as a calibrator. For this reason we have decided to use the term "calibration materials(s)" instead of calibrator(s) or standard(s).

*Comment:* Although several commenters agreed with a full range calibration check, many commenters felt that requiring calibrators to cover the entire range of patient values was excessive and unnecessary for linear tests. Commenters claimed that four point calibration was unnecessary and offered suggestions when fewer calibration points could be used. Several commenters were concerned that this requirement increased costs and four calibration materials are not always available to calibrate linear methodologies on each instrument. Several commenters suggested that the number of calibrators should be no fewer than the number recommended by the manufacturer.

*Response:* Although we recognize that calibration materials may not be available to cover the manufacturer's reportable range, we believe that a laboratory must confirm the calibration over the laboratory's reportable range of patient test results. The laboratory must follow the manufacturer's instructions for calibration and verify calibration using additional calibration materials to check the upper and lower limits of the laboratory's range of reporting patient test results. We have amended the number of calibration materials required to verify calibration throughout the laboratory's range of reporting patient test results to include a minimum value or zero, a mid-point value, and a maximum value at the upper limit of that range.

*Comment:* Several commenters suggested adding linear reportable range verification to the calibration and recalibration requirements contained in § 493.1217(a).

*Response:* We have clarified the regulation, now at § 493.1217(b)(2)(B)(2), stating that the calibration materials used for calibration verification must cover the laboratory's range of reporting patient test results. The required calibration verification will then verify the laboratory's range of reporting patient test results.

*Comment:* Several commenters objected to the requirement at § 493.1217(a)(4) that patient values above the maximum calibration point or below the minimum calibration point be reported as greater than or less than the calibration point. They felt this requirement was too restrictive and that other factors such as test linearity, manufacturers' specifications, and

patient clinical history needed to be considered.

*Response:* We agree with the commenters that felt that this requirement was too restrictive and have deleted the requirement. However, if a laboratory reports patient results that are outside of the laboratory's reportable range of patient test results, it must be able to provide evidence that the procedure used yields accurate and reliable results as specified in § 493.1219, Remedial actions.

*Comment:* Several commenters recommended deleting "operator variance" from the requirement § 493.1217(b) for determining quality control frequency noting that it is impractical and unnecessary.

*Response:* We disagree with the commenters. Variance between individuals performing a test may occur in both automated and manual systems. Operator variance is a significant factor in test systems that are dependent on technique. Therefore, the ease of use and the amount of training and experience of the analyst must be considered when determining the frequency of quality control checks.

*Comment:* A few commenters cautioned that the rule should require that the controls be run by the operator who performs the testing.

*Response:* We appreciate the concerns of the commenters and we agree that there are test methods where the operator who runs the controls should be the operator doing the testing for that run. However, this is not the case for all procedures. We have defined "run" as an interval within which the accuracy and precision of a testing system is expected to be stable, which must not exceed 24 hours, but must be no less frequent than the manufacturer's specifications. Also, in § 493.1218(b), we require that "for each procedure, the laboratory must evaluate instrument and reagent stability and operator variance in determining the frequency of testing quality control samples with each run."

*Comment:* Two commenters felt that § 493.1217(d) needed clarification. They suggested changing the requirement to allow the laboratory to use some combination of calibration materials, control samples, linearity standards, and other standards that monitor both the abnormal and normal range of reportable patient values. Other commenters indicated that many analyses cannot be characterized as having "normal" and "abnormal" ranges and that this section should be changed to read " \* \* \* and monitor appropriate clinical ranges of reportable patient

values." Other commenters suggested changing the language to read " \* \* \* ranges that approximate both the abnormal and normal \* \* \* "

*Response:* We agree with the commenters and have changed the regulation, now at § 493.1218(b), to require that testing facilities monitor the performance of their testing systems using calibration materials, control materials, or a combination thereof.

*Comment:* One frequently expressed comment was to amend the wording of the section to specify "abnormal high, abnormal low, and normal daily controls."

*Response:* We disagree with the commenters because control or calibration materials are not always available to check the abnormal low, abnormal high and a normal range of reportable patient values for each test. We have amended this requirement, now at § 493.1218(b), from " \* \* \* "must use the calibrator samples, the control samples, or combinations thereof, and monitor both the abnormal and normal range of reportable patient values" to " \* \* \* "must monitor test performance using calibration materials, control materials, or combination thereof."

*Comment:* Two commenters felt that § 493.1217(d)(2) is too restrictive and recommended deleting the sentence that reads: "Two separate dilutions \* \* \* must be used."

*Response:* We agree with the commenters and have deleted this requirement from the regulations.

*Comment:* Many commenters suggested that § 493.1217(f) be revised by adding "where appropriate" to provide for those tests in which either the positive or negative control is not necessary. Several other commenters suggested adding "or as recommended by the manufacturer" to permit laboratories to follow the manufacturer's instructions regarding control materials.

*Response:* We disagree; assaying positive and negative controls provides assurance that all phases of the test procedure have been performed appropriately. Controls are required to monitor the test procedure in order to detect the deterioration of the reagents, improper use or sequence of reagent additions, incorrect incubation time, etc., so that the testing facility can be assured that it reports accurate and reliable test results. This requirement is now at § 493.1218(b)(1). Any exceptions to the requirements are specified in §§ 493.1223 through 493.1255 of this subpart.

*Comment:* A few commenters suggested changing § 493.1217(g) by removing the requirement to verify

assayed values previously determined by the manufacturer; several commenters supported the requirement as written.

*Response:* We agree with the commenters who supported the requirement, however, for clarity we reworded the regulation, now at § 493.1218(d)(1), to specify that "the stated values of an assayed control material may be used as the target values provided the stated values correspond to the methodology and instrumentation employed by the laboratory and are verified by the laboratory."

*Comment:* Several commenters felt that the requirement in § 493.1217(k) for daily testing of positive and negative controls for direct antigen systems should be changed to the "frequency recommended by the manufacturer."

*Response:* Control materials are tested to assure proper reagent reactivity throughout all phases of the system. Positive and negative control materials (organism or antigen extract) for direct antigen systems must be run each day of testing to evaluate the detection phase. When an extraction phase is included, the system must be checked each day of use using a positive organism. Clarification will be provided in the State Operations Manual concerning the appropriate controls to be employed with antigen systems used to identify viruses. If the manufacturer recommends more frequent use of control samples, the testing facility must follow the manufacturer's recommendation. This requirement is now at § 493.1218(b)(4).

*Comment:* One commenter believed that § 493.1217(1) should be changed to simply accept the manufacturers' results of quality control testing of media. Another commenter indicated that it was unclear whether all media tested by the manufacturer would need to be retested by the laboratory. One commenter felt that some media, identified in the NCCLS Guidelines, are unstable and should be rechecked.

*Response:* The regulations, now at § 493.1218(f)(4), allow the testing facility to accept the manufacturers' quality control checks on media if the testing facility has documentation to verify that the manufacturer has used the quality assurance practices that have been cleared by the FDA as meeting the National Committee for Clinical Laboratory Standards (NCCLS) for media quality control. The testing facility must document that the physical characteristics of the media are not compromised. However, the laboratory must perform quality control checks of the media having a high quality control

failure rate. A testing facility may wish to perform additional quality control testing of media, but it must document the results and any corrective action taken.

*Comment:* A few commenters recommended that § 493.1217(n) be modified to allow the director of the laboratory to report some critical results for patient care purposes even when control results do not meet the laboratory's quality control criteria.

*Response:* We appreciate the commenters' concerns regarding § 493.1217(n), now at § 493.1218(e). However, it is the responsibility of the laboratory director to establish policies under which test results may be reported even though the control results do not meet the laboratory's established criteria for acceptability, to avoid compromising patient care if results are not reported. Such occurrences should be rare and be documented. Any affected patient specimen should be retested, if possible, once control has been reestablished.

#### *Section 493.1219 Standard: Remedial Actions*

*Comment:* A few commenters believed the requirement to notify the ordering individual when specimens cannot be tested within the laboratory's established time frame is impossible, inefficient, and troublesome to the practitioner. One commenter suggested a time frame of 24 hours. Another commenter suggested that the laboratory have contingency plans, including back-up testing for emergency procedures.

*Response:* We appreciate the commenters' concerns and have revised the regulations at § 493.1219(c) to allow the testing facility to establish and document a plan of action based on the urgency of the patient test results for patient management. They may refer specimens to another certified laboratory for testing or store specimens until testing can be resumed. The need to notify the person who would utilize the test results depends on the urgency of the test request, whether results are needed immediately or can be delayed.

*Comment:* One commenter suggested adding to § 493.1219(a) a requirement that remedial action be documented when quality control results exhibit a trend as reflected on a Levy-Jennings graph or defined by multi-rule systems, such as those of Westgard, *et. al.*

*Response:* The regulations at § 493.1219, now at § 493.1219(b), require the testing facility to document actions taken in response to control and calibration results that fail to meet the

laboratory's criteria for acceptability. It is the responsibility of the testing facility to determine its criteria for evaluating and accepting quality control results and define the remedial action necessary to correct out-of-control situations.

*Comment:* One commenter requested clarification about the type of format that must be used to notify the "authorized person ordering a test or utilizing test results." Specifically, the commenter asked whether electronic notification would be adequate.

*Response:* The regulation permits flexibility in determining the format or mechanism to be used for notification. Electronic notification, as well as other mechanisms, would be acceptable provided that records are maintained to document that the appropriate person was contacted.

*Comment:* A few commenters requested changing the word "copies" to "records" in the requirement that a laboratory "maintain copies of the original report as well as the corrected report for two years."

*Response:* The regulation at § 493.1219(d)(3) has been modified to state "exact duplicate" in keeping with previous language used in the regulation.

*Comment:* A few comments were received on § 493.1219(a)(3). One commenter suggested that the requirement for a laboratory to document remedial action taken when "test results that are outside of the laboratory's reportable range" be changed to "test results that are outside of the laboratory's linear reportable range." Two commenters suggested eliminating the requirement and another commenter stated that reportable ranges are established by methodology, maximum and minimum concentration values of linearity, repetitive testing, and well-defined population test studies, not based on maximum and minimum calibration values.

*Response:* In response to the commenters' concerns, we have revised the requirement now at § 493.1219(a)(2). The laboratory must document remedial action taken when patient test values are outside of the laboratory's reportable range of patient test results.

#### *Section 493.1221 Standard: Quality Control Records*

*Comment:* Several commenters found the record retention requirement in § 493.1221(b) to be unrealistic, time-consuming and a storage problem. The commenters suggested that the requirement exceeded the need to ensure quality laboratory results. In § 493.1221(b), one commenter asked for

clarification of the words "each step in" while other commenters suggested deleting "each step in" from the requirement or deleting § 493.1221(b) entirely.

*Response:* We agree with the commenters who requested the removal of the phrase "each step in" from the regulations. We have modified the regulation to state that "records of all quality control activities" are retained. This modification removes the burden of documenting unnecessary steps in the testing of quality control specimens while requiring the testing facility to maintain quality control data to verify the performance of accurate and reliable test results for a minimum of two years, except in immunohematology where record retention is required for no less than five years, in accordance with 21 CFR part 606, subpart I.

#### *Section 493.1223 Condition: Quality Control, Specialties and Subspecialties (Now Condition: Quality Control—Specialties and Subspecialties for Tests of Moderate or High Complexity, or Both)*

We proposed this section as Quality control—specialties and subspecialties but have renamed it Quality control—specialties and subspecialties for tests of moderate or high complexity, or both, because this terminology better describes the quality control that is applicable for tests of moderate and high complexity.

Approximately 250 comments were received concerning § 493.1223, Condition: Quality control, Specialties and Subspecialties. One hundred twelve were opposed to the requirements as proposed, 23 were positive and 124 made alternate suggestions. The majority of comments were received from technologists, followed by dermatologists and pathologists, respectively. The summary of comments received concerning the quality control requirements for cytology are listed under § 493.1257.

In response to commenters' concerns, language has been added to §§ 483.1202 and 493.1203 to allow a 2 year phase-in for the development and implementation of an FDA clearance process which will determine if instruments, kits, and test systems developed by manufacturers for in-vitro diagnostic use are in compliance with the CLIA requirements for quality control.

Effective September 1, 1994, a laboratory that performs tests of moderate or high complexity, or both, as applicable, will be in compliance with this section if it meets quality control requirements specified in this subpart or follows manufacturer's instructions

when using products cleared by FDA as meeting the CLIA requirements for general quality control, as well as specialty and subspecialty quality control.

*Comment:* Several hospitals and one professional organization expressed the concern that a laboratory could possibly lose its certification for an entire specialty or subspecialty or testing because of quality control problems with only one test in the specialty or subspecialty category.

*Response:* Certification is not granted on a test-by-test basis but by specialty or subspecialty of testing. Therefore, if a laboratory has quality control problems related to only one test or one analyte in the specialty or subspecialty and the laboratory fails to correct those problems it could jeopardize its certification for that specialty or subspecialty area. In all instances, a laboratory would be notified in writing of the quality control deficiencies found during a survey and be given an opportunity to correct the deficiencies. If the laboratory is unable or refuses to correct the deficiencies, its certification could be cancelled and an intermediate sanction could be imposed or certification could be limited, suspended or revoked as specified in Subpart R—Enforcement Procedures.

*Comment:* One organization has recommended the addition of more specialty categories such as flow cytometry and molecular pathology to § 493.1223.

*Response:* We agree that eventually additional specialty areas will be needed. As more laboratories performing a wider array of services are regulated, HHS will need advice on how to most effectively certify laboratories for these procedures. However, we are deferring changes in certification categories until we have established the Clinical Laboratory Improvement Advisory Committee. This committee will assist us in determining not only new specialty and subspecialty areas but also the appropriate quality control requirements, personnel qualifications, recordkeeping, proficiency testing and quality assurance requirements that apply in the new areas.

*Comment:* Numerous commenters found the requirement at § 493.1225 Condition: Microbiology, to be unclear about what was expected of a laboratory for method validation. One commenter was pleased to see a change in the regulation from "linear reportable range" to "reportable range." Commenters requested clarification of validation requirements for the applicability to microbiology.

*Response:* A laboratory's validation of microbiology procedures is expected to demonstrate its ability to accurately and reliably isolate and identify each organism that the laboratory claims to be capable of isolating and identifying. Susceptibility testing procedures are validated according to the guidelines published by the National Committee for Clinical Laboratory Standards (NCCLS). Commercial test systems including those for biochemical identification, antigen and antibody detection, and nucleic acid detection should be validated by using a range of controls that verify the qualitative and quantitative performance claims of the manufacturer in accordance with the applicable requirements at § 493.1218, Standard; Control procedures.

*Comment:* A few commenters suggested that the frequency of performing quality control checks for beta-lactamase testing should be each day of use and included in § 493.1227, Standard; Bacteriology, at paragraph (a)(1).

*Response:* We agree with the commenters that reagents such as beta-lactamase should be quality controlled each day of use to check for proper positive and negative reactivity. We have revised § 493.1227(a)(1) to also include beta-lactamase testing.

*Comment:* One professional organization contended that the regulation at § 493.1227(a)(1) was excessive in the testing frequencies required for catalase, coagulase, and oxidase, and that ONPG needs testing by lot only. The commenters also stated that there was no need for a negative catalase control, while other commenters noted that a negative control is not required for catalase testing of anaerobes.

*Response:* Unstable reagents (such as catalase, coagulase, and oxidase) that are used in the routine testing of patient specimens for microbiological identification must be checked for proper positive and negative reactivity each day of use. In the case of ONPG, checking for positive and negative reactivity each week of use is considered a minimum time interval for verifying the reactivity and stability of this reagent. A negative catalase control is required for aerobic microorganisms to assure proper reactivity of the catalase reagent, however, a negative control is not required for anaerobic microorganisms. The Clinical Laboratory Improvement Advisory Committee will periodically review the quality control and quality assurance standards for test performance and will make recommendations to HHS for revisions to the current regulations. We

are retaining the requirement at § 493.1227(a)(1) until the Clinical Laboratory Improvement Advisory Committee advises HHS a change is warranted.

*Comment:* A manufacturer recommended that the same positive and negative control requirements should be applied to DNA probe methods as are applicable in other Microbiology areas.

*Response:* We agree with the commenter. The requirement to check DNA probes each day of use for positive and negative reactivity using control organisms is included under § 493.1227(a)(1).

*Comment:* A few commenters noted that there is no known available organism for a negative control for XV discs, and recommended that other important stains, such as flagella, be included under § 493.1227(a)(2), which requires weekly quality control.

*Response:* We agree with the commenter regarding the negative control for XV discs and are revising the regulation at § 493.1227(a) to require that laboratories check positive reactivity with a control organism each week of use. The quality control requirements for flagella stains and other stains not specified in this subpart require a positive and negative control each day of use. The frequency of quality control for these stains are covered under paragraph (f)(2) of the general quality control requirement at § 493.1218, Standard; Control procedures.

*Comment:* A professional organization recommended the regulation at § 493.1227(a)(3) be revised to require antisera quality control checks each six months instead of each month.

*Response:* Antisera used in aerobic culture identification that will directly impact on patient care (i.e. Salmonella and Shigella) should be quality controlled with the opening of each new vial and at least monthly thereafter using an organism that produces a positive reaction and an organism that produces a negative reaction. Antisera used for epidemiological categorization beyond routine testing should be quality controlled with the opening of each new vial and quarterly until further review by the Clinical Laboratory Improvement Advisory Committee.

*Comment:* Various commenters suggested that the time frames for quality control of antibiotic sensitivity testing under § 493.1227 (c)(1) and (c)(2) be revised. They suggested time frames ranging from daily to quarterly as well as initially when the test is placed into routine use. However, the majority of

commenters suggested testing quality control organisms on a weekly basis.

*Response:* We agree with the majority of commenters who recommended weekly control of susceptibility test procedures. However, we are retaining the regulation at § 493.1227(c)(2) which requires daily quality control checks for antibiotic sensitivity testing unless the laboratory complies with the options specified in § 493.1223. Once a laboratory establishes that it can meet the accuracy and precision limits established by NCCLS and adopted by HCFA, it may test control strains on a weekly basis.

*Comment:* A few commenters recommended that a minimum length of time (6 weeks) for holding negative mycobacteriology cultures be included in the regulations under § 493.1229, Standard; Mycobacteriology.

*Response:* We appreciate the commenters' concerns for the accurate testing of mycobacterial specimens. While we agree that an extended incubation for negative mycobacterial cultures is good laboratory practice, we do not feel that specific instructions for the incubation of mycobacterial cultures or any other specimen types should be specified in the regulation. It is the laboratory's responsibility to develop and validate procedures to accurately and reliably isolate and identify organisms for which service is offered.

*Comment:* Several commenters questioned why the regulation at § 493.1229(a) specifically addressed the iron uptake test while quality control regulations did not address less-reproducible tests such as catalase, niacin, tween hydrolysis and nitrate. A few commenters suggested this section be rewritten by deleting references to specific tests and adding generic instructions for quality control testing for labile reagents (catalase) and stable reagents/test (iron uptake).

*Response:* Section 493.1229(a) specifically addresses the iron uptake test. By using an acid-fast organism that produces a positive reaction and an organism that produces a negative reaction, the laboratorian has a reference for making a distinctive color determination. All other tests such as catalase, niacin, tween hydrolysis, and nitrate only need to be checked with an acid-fast organism that produces a positive reaction. For these tests, negative control checks can be performed as good laboratory practice using uninoculated media or other organisms that would produce a negative reaction. We are retaining as written the requirements at § 493.1229(a) for checking these tests each day of use.

*Comment:* A few commenters felt that the requirement for daily testing of fluorochrome stain with controls each day of use in § 493.1229(b) was inconsistent with the requirement under § 493.1229(c) for checking acid-fast stains each week of use.

*Response:* We agree with the commenters. Quality control for fluorochrome acid-fast stains must be checked weekly since this is not a fluorescent antibody procedure and we are revising the regulation at § 493.1229(b) to reflect this change.

*Comment:* A few commenters stated that the quality control requirements in § 493.1229(b) for fluorochrome acid fast stains are inconsistent with the CDC manual "Quality Control in Microbiology," 1987, p. 64, which requires controls to be tested each time of use.

*Response:* The CDC publication, "Quality Control in Microbiology" is currently under review for possible revision. The regulation at § 493.1229(b), which has been modified to require the testing facility to check fluorochrome acid-fast stains weekly, reflects the latest revision to the requirements for quality control in microbiology.

*Comment:* A few commenters stated that for safety and standardization purposes the *Mycobacterium tuberculosis* control strain for susceptibility tests should be specified as H37Rv in § 493.1229(d).

*Response:* We agree with the commenters that for safety and standardization purposes a susceptible control strain of *Mycobacterium tuberculosis*, such as H37Rv, should be used. In addition, we are revising the requirement at § 493.1229(d) to state that for susceptibility test performed on *M. tuberculosis* isolates, the laboratory must check the procedure each week of use with one strain of *M. tuberculosis* susceptible to all antimycobacterial agents tested. While we have specified the use of H37Rv as an example, we are not precluding the use of other appropriate control strains of *M. tuberculosis*.

*Comment:* A few commenters suggested that the regulation at § 493.1231, Standard: Mycology, be rewritten to include instructions for the commonly performed or more variable tests (i.e., germ tube, yeast morphology media, and nitrate).

*Response:* The regulations contain minimum quality control requirements for laboratories to use in determining that its results are within its established control limits. It is up to each individual laboratory to determine which test methodologies it will use in performing laboratory testing and to establish a

mechanism to determine whether the results obtained from testing are accurate and reliable. In § 493.1218, Standard; Control procedures, under paragraph (f), laboratories are required to check each batch or shipment of reagents, discs, stains, antisera and identification systems when prepared or opened for positive and negative reactivity.

Under § 493.1231, specific requirements are listed for checking nitrate reagent, acid-fast stains and susceptibility test procedures. In order to be consistent with other microbiology requirements and for clarification, we are adding to this section a requirement that reagents used for biochemical tests and other test procedures be checked each week of use with a positive control organism.

*Comment:* In § 493.1233 Standard: Parasitology, several commenters felt that concentrated and permanent mount techniques are not necessary for the identification of fecal parasites and that wet mount preparations were sufficient to identify fecal parasites.

*Response:* A wet mount preparation may not be sufficiently sensitive to detect small numbers of ova or parasites in fecal specimens, or to render a final species identification. However, the regulations at § 493.1233 do not require the use of concentrated and permanent mount techniques to identify fecal parasites. It is the laboratory's responsibility to assure that it can accurately and reliably identify the organisms it claims to be able to identify, to specify on the test report the method employed by the laboratory for screening fecal specimens and upon request provide information to clients that may affect the interpretation of test results, such as test interferences, if known, and detection limits, if applicable.

*Comment:* An organization recommended that § 493.1233(a) require the use of a standard textbook as a reference in lieu of slides, photos or gross specimens.

*Response:* We disagree with the commenters and are retaining the regulation as written in § 493.1233(a) which requires a laboratory to have available a reference collection of slides, or photographs, and if available, gross specimens for use in the identification of parasites. This allows the laboratory the flexibility of having a standard textbook with photographs as their reference source, or other applicable reference materials with which to make appropriate comparisons for identification.

*Comment:* Several commenters requested that § 493.1233(c) be revised

to require more frequent quality control requirements for staining materials. Other commenters wanted controls to be required daily and when any staining component is changed.

*Response:* We disagree with the commenters and are retaining the regulations at § 493.1233(c) which specify a minimum requirement that permanent stains be checked each month of use using a fecal sample control that will demonstrate staining characteristics. If desired, a laboratory may establish a quality control procedure to check staining materials at a more frequent interval than required by the regulations.

*Comment:* In § 493.1235, Standard: Virology, a few commenters considered paragraph (a) to be overly broad in requiring laboratories to have available host systems and test methods for the identification of viruses that cover the "entire range of viruses" that are etiologically related to clinical diseases for which services are offered. Also, laboratories should be able to offer testing for the isolation of herpes virus only.

*Response:* We disagree with the commenters. The intent of the regulations at § 493.1235(a) is for the laboratory to have methodologies available to isolate and identify the viruses it claims to be able to isolate and identify that are etiologically related to the clinical disease for which services are offered. That means, that if a laboratory offers services only for *Herpes* testing, it must have available host systems for the isolation and/or test methods for the identification of the *Herpes* virus.

*Comment:* A few commenters noted that there are no time frames specified in § 493.1235 for performing virology quality control.

*Response:* Frequency of testing for quality control specimens is addressed in the general quality control section, § 493.1218, Standard; Control procedures.

*Comment:* Several commenters recommended that under § 493.1235(c) a positive control could be "cell culture cells infected with the specific virus" while a negative control could be "uninfected cell culture cells from the same batch as the specific virus-infected cells."

*Response:* We agree with the commenters. A laboratory may use cell culture cells infected with the specific virus as a positive control and uninfected cells culture cells from the same batch as the specific virus infected cells as a negative control to meet the requirement.

*Comment:* In § 493.1239, Standard: Syphilis Serology, several commenters believed that § 493.1239(c) applies only to complement fixation procedures and that only positive and negative controls are needed for all other tests.

*Response:* We disagree with the commenters. Controls which evaluate all phases of the test system would be applicable to complement fixation procedures as well as Microhemagglutination Treponema pallidum (MHATP) and the Fluorescent Treponemal Antibody Absorption (FTA-ABS), a multiple step indirect immunofluorescence procedure. We are modifying the regulation at § 493.1239(c) to clarify the requirement that controls which evaluate all phases of the test system must be used to assure reactivity and uniform dosages.

*Comment:* In § 493.1241, Standard: General Immunology, several physicians considered the requirement under § 493.1241(a) for running a positive and negative control with qualitative RA and Mono tests to be a waste of expensive reagents and that a negative control should be run only if the patient is positive.

*Response:* We disagree with the commenters and are retaining § 493.1241(a), which requires the concurrent testing of patient specimens with positive and negative controls. Concurrent testing of positive and negative controls with each batch of patient specimens is necessary to ensure proper testing performance and reactivity of the test system. It is the laboratory's decision to determine the frequency with which it performs testing in order to limit usage of control materials.

*Comment:* Several commenters stated that serology procedures using EIA do not need controls beyond those in the kit and the requirements under § 493.1241(b) should not apply.

*Response:* Laboratories using test kits which include controls are expected to test those controls in the same manner as patient specimens. The control materials provided in each kit are acceptable provided they are subjected to the same procedures as patient specimens such as dilution, extraction, incubation, washing, etc. and evaluate all phases of the test system.

*Comment:* Several commenters thought that § 493.1241(d) should differentiate between HIV and Hepatitis tests performed on autologous units as opposed to testing of other blood and blood products for transfusion.

*Response:* We are adopting the FDA requirements referenced at § 493.1241(d) for testing of HIV and hepatitis which are required along with syphilis testing

for all homologous blood or blood products, that is blood or blood products processed for transfusion to a recipient other than the original donor. There have been numerous questions concerning the applicability of testing requirements to blood collected for autologous transfusion. The FDA published a memorandum in January, 1990, clarifying their position on the testing requirements for autologous blood. While the performance of these tests is recommended, an exception to the HIV-1 and hepatitis testing requirement, as well as syphilis testing for autologous blood or blood components, can be made when the establishment collects and uses these blood products only for the autologous donor, these products are used at the site of collection, and all products not used by the donor are destroyed. However, establishments that routinely ship autologous units interstate must be licensed by the FDA, the units fully tested and appropriately labeled, and any autologous units that are used homologously must come from a donor who meets all donor suitability requirements at 21 CFR 640.3 and whose products meet all test requirements at 21 CFR 640.5, 610.40 and 610.45.

*Comment:* In response to requesting comments from the public on adding the requirement that "a reactive screening test for HIV-1 antibody must be followed-up with a more specific supplemental test, before issuing a final report," many commenters supported this new requirement. Several commenters stated that the proposed language appeared to disallow the reporting of initial screening results for HIV until the confirmatory testing was performed, that the terminology " \* \* \* reactive screening \* \* \* " should be changed to read " \* \* \* repeatedly reactive \* \* \* " and a few commenters stated that if the initial test for HIV meets the criteria for a confirmatory test, no further testing is needed.

*Response:* We appreciate the commenters response to our request for comments concerning the reporting of HIV results. We have determined that laboratories should not be required to perform confirmatory tests for reactive HIV-1 antibody tests. Each laboratory must be responsible for providing accurate and reliable test results and ensuring that the test report clearly indicates the test procedure performed. It is up to the authorized person who requested the test or the individual responsible for utilizing the test results to determine whether additional testing is required.

*Comment:* In § 493.1245, Standard: Routine chemistry, many commenters

felt that the requirements under paragraphs (a) and (b) pertaining to blood gas analyses, were too restrictive, already obsolete and the time frames for recalibration of blood gas analyzers were unrealistic. A few commenters suggested that these sections be deleted from the regulation and added to the State Operations Manual.

*Response:* While we are retaining the section on blood gases at § 493.1245, we are modifying the regulations at § 493.1245(a) to allow laboratories to use manufacturer's specifications for calibration with at least the frequency recommended by the manufacturer. These requirements are based on the guidelines of the National Committee for Clinical Laboratory Standards (NCCLS) and are minimum standards with which a laboratory must comply when performing blood gas analyses. We are modifying the regulations at § 493.1245(b) to clarify the requirement that one sample of controlled material be used each eight hours of testing. We are adding, at § 493.1245(c), that a combination of calibration and control materials, which include both low and high values, must be used each day of testing to monitor the reportable range.

*Comment:* Concerning § 493.1249, Standard: Toxicology, a few commenters objected that the regulation specifies quality control requirements only for thin layer chromatography for drug abuse testing. Other commenters expressed concern over the non-availability of a calibrator that contains all of the drugs that the system detects and the requirement for the inclusion of a control on the same chromatography strip as the patient specimen. Several comments suggested that the regulation at § 493.1249(b) is obsolete and that a control for each chamber is not necessary, if one calibrator for each drug is included on each plate.

*Response:* We disagree with the commenters and are retaining, with modification, the requirement at § 493.1249(a) that each thin layer chromatography plate be spotted with a minimum of one calibrator that contains a representative of each drug group for which the laboratory reports results in order to assure proper performance of the test system. We are adding the word "groups" due to commenters concerns over the nonavailability of a calibrator that contains all of the individual drugs that the system detects. Calibrators are available and widely used which detect the major drug groups being tested for abuse. In addition, each testing chamber must contain a control which is processed through each step of patient testing, including the extraction

procedures. Quality control requirements for gas chromatography and GC-MS are included in the general quality control section under § 493.1218(b) which states that the laboratory must evaluate instrument, reagent stability, and operator variance in determining the frequency of testing quality control samples with each run.

*Comment:* A few commenters wanted to replace the word "calibrator" in § 493.1249(a) with "primary standard."

*Response:* We disagree with the commenters. A primary standard is a reference material that is of fixed or known chemical composition and capable of being prepared in essentially pure form. It is the gold standard by which similar materials should conform. Secondary reference materials are often commercially prepared and are less expensive to use in performing calibration activities while still retaining a certain condition of accuracy. These secondary materials are of many types and varieties and should be traceable to a National Institute for Standards and Technology (NIST), if possible. For this reason we are using the term "calibration material(s)" instead of calibrator(s) or standard(s).

*Comment:* In response to our request for comments on whether confirmatory tests should be required for positive urine drug screening results, several commenters wanted the decision for ordering a confirmatory test left to the physician for those tests used for counseling purposes or emergency medical treatment. Several suggested that drug testing for patient care purposes be excluded from requirements for confirmatory testing and maintenance of chain of custody records since such requirements would unnecessarily increase costs.

Several hospitals and drug treatment facilities wanted to be able to use screening test results for inpatient counselling without having to confirm the results. A few commenters supported requiring confirmatory testing using a test procedure that employs a methodology different from the methodology used for screening purposes.

*Response:* We appreciate the commenters response to our request for comments concerning whether confirmatory tests should be required for positive urine drug screening results. We have determined that laboratories should not be required to perform confirmatory tests for positive urine drug screening tests that are used for patient care purposes. However, NIDA certified laboratories which perform testing under "Mandatory Guidelines for Federal Workplace Drug Testing

Programs" (Federal Register, Vol. 53, No. 69, April 11, 1988) must comply with requirements including confirmatory testing. Each laboratory must be responsible for providing accurate and reliable test results and ensuring that the test report clearly indicates the test procedure performed. It is up to the authorized person who requested the test or the individual responsible for utilizing the test results to determine whether additional testing is required.

*Comment:* Concerning § 493.1253, Condition: Hematology, many individuals believed that the frequency of testing hematology quality control materials as required under paragraph (a) should be revised to reflect the same frequency as chemistry controls, i.e., no less frequently than once every 24 hours, since it is the hematology quality control material that is unstable rather than the instrumentation.

*Response:* We disagree with the commenters. Hematology controls generally do require fastidious handling in order to maintain the accuracy of their control properties. However, the requirement to run controls every eight hours is necessary to effectively detect shifts or trends in instrumentation of this type that may potentially lead to problems resulting in inaccurate and unreliable patient results. We are retaining the requirements to test hematology control materials a minimum of every eight hours of operation as specified in § 493.1253(a) to ensure the accuracy and reliability of patient test results. These are the existing minimum standards which laboratories currently regulated under Federal requirements must meet. A patient specimen may be used to meet the requirements for a control, provided that the patient specimen was verified in the same run with the assayed material. The patient specimen must have a range of acceptable performance limits established for the difference between duplicates. We have included automated differential counters, manual cell counts and automated coagulation as well in this requirement.

*Comment:* Other commenters suggested that the quality control checks at § 493.1253(a) for manual cell counts should be more frequent than those required for automated systems use in hematology.

*Response:* We believe the regulation to test control materials for manual cell counts a minimum of every 8 hours is sufficient to ensure accurate and reliable patient results. We are revising the regulation at § 493.1253(b) (formerly § 493.1253(a)), for the manual cell count, to require one control material to be tested each eight hours of operation. We

have also included the requirement to perform manual cell counts (using a hemocytometer) in duplicate.

*Comment:* Several individuals were concerned that § 493.1253 did not include a requirement for checking the stain quality of differential blood films. The commenters also felt that the regulation should include quality control requirements for manual and automated differentials.

The instability of automated differential instruments, and the importance of verifying abnormal differential tests results was emphasized by the commenters.

*Response:* The quality control regulations for stains are included in § 493.1218(f) (1) and (2), which require initial quality control testing of each batch of stains and thereafter testing of control materials each day of use to verify staining properties. We agree with the commenters that automated differential counters should be included in the quality control regulations for hematology and we are clarifying this position by requiring hematology controls on automated differential counters in the regulation at § 493.1253(a). The laboratory must establish policies and procedures which specify decision making criteria for repeating or verifying abnormal test results, as appropriate, as well as defining remedial action to follow when controls are out of the laboratory's established limits.

*Comment:* Several commenters felt that it was not necessary to require duplicate testing of patient specimens for manual coagulation tests as required under proposed § 493.1253(c)(2).

*Response:* We disagree with the commenters and are retaining the provision which requires that patient and control specimens be tested in duplicate. This provision is now located at § 493.1253(d)(2).

#### Section 493.1257 Standard: Cytology

Comments in response to both the March 14, 1990 final rule with comment period and the May 21, 1990 proposed rule were considered for making revisions in the cytology quality control requirements. A total of 2600 letters were received in response to the cytology requirements in the March 14 rule. These letters contained nearly 2000 opinions and suggestions (comments) on quality control. In response to the cytology requirements in the May 21 rule, 900 letters were received, which contained nearly 1100 comments on quality control.

*Comment:* A few individuals disagreed with the regulation at

§ 493.1257(a)(1) which requires gynecologic cytology specimens to be stained using the Papanicolaou staining method saying that such a requirement would inhibit development of new technology and impede research. A few said that it restricted the laboratory from choosing a stain that may be optimal for their situation. Some commenters suggested changing the requirement to specify the use of a modified Papanicolaou stain or a Papanicolaou type stain since the original Papanicolaou stain is rarely used.

*Response:* Our intent is not to impede research, but to assure that routine gynecologic specimens are stained using the best stain for differentiation of the morphology of cells to ensure quality slide evaluations. Therefore, we are retaining the requirement at § 493.1257(a)(1) with the added clarification for using either a Papanicolaou or a modified Papanicolaou technique. Other staining methods may be used as adjuncts, but not as a replacement for a Papanicolaou staining procedure.

*Comment:* Several commenters felt that the regulation at § 493.1257(a)(2) requiring changing or filtering stain solutions between staining gynecologic specimen batches and nongynecologic batches was not needed since cross contamination is more prevalent when staining nongynecologic specimens.

*Response:* We are revising the regulation at § 493.1257(a)(2) so that the laboratory must establish effective measures to prevent cross-contamination between gynecologic and nongynecologic specimens. The laboratory would thus have the option of filtering or changing stain solutions after staining nongynecologic specimens prior to staining gynecologic specimens or using some other method to prevent cross-contamination.

*Comment:* A few commenters objected to the requirement that body cavity fluids be evaluated for their potential for cross-contamination as required under § 493.1257(a)(3). Rather than making this evaluation, one recommendation was that staining solutions be filtered after they are used to stain any specimens highly suspicious of having abnormal cells. Another recommendation was that body cavity fluids should be stained in separate staining jars and the stain solutions should be filtered or discarded after staining each specimen.

*Response:* We are changing this requirement to address all nongynecologic specimens, such as body cavity fluids, which have a high potential for cross-contamination. It is

up to the laboratory to determine which specimens fall into this category. These specimens are to be stained separately from other nongynecologic specimens and the stains filtered or changed after use.

*Comment:* Many commenters were opposed to one or more of the requirements under § 493.1257(b)(1) specifying workload limits. Many said that the workload limit of 120 slides per 24 hours was too high, whereas other commenters remarked that the limit was too low and did not allow flexibility for exceptional screeners. Of those who suggested a lower limit, the most favored numbers ranged between 80 and 100 slides per day. One professional organization recommended a limit of 100 slides per 24 hours. Some commenters recommended that no specific limit be designated and that the establishment of a workload limit be the responsibility of the laboratory supervisory staff who could make allowances for the different slide screening abilities of cytotechnologists. Additionally, a large number of commenters recommended eliminating the separate workload limit on unevaluated slides and leaving it to the discretion of the laboratory how to divide the unevaluated and previously evaluated slides (quality control, quality assurance and proficiency testing slides). Several commenters believed that cytotechnologists should be allowed to examine slides for longer periods of time than the standard eight hour day. Some thought that the workload limit should be specified for 8 hours instead of 24 hours or that it be set as an hourly rate. A few commenters felt that the workload limit should apply only to cytotechnologists and not technical supervisors.

*Response:* CLIA requires the establishment of "the maximum number of cytology slides that any individual may screen in a 24-hour period." In accordance with the law, the workload limit is based on 24 hours, not a standard 8-hour work day. We established the workload limit of 120 slides, with a maximum of 80 unevaluated slides, based on the suggestions and recommendations that we received from professional organizations and individuals. However, since the commenters were overwhelmingly opposed to the differentiation between unevaluated and previously evaluated (quality control, etc.) slides, we have deleted this distinction. Also, in response to the comments, we are reducing the workload limit to 100 slides per 24 hours. Accordingly, there is now one workload limit of 100 slides (gynecologic, nongynecologic, or both)

and the laboratory has the flexibility to establish for each individual how many unevaluated slides can be screened per day. This 100-slide limit represents an absolute maximum number and is not intended to be used as a performance target for each individual. We recognize that all individuals do not possess the same capabilities with respect to slide examination, and that every laboratory's caseload is different with respect to degree of difficulty in interpretation and to numbers and types of gynecological and nongynecological preparations processed. Therefore, in each laboratory, the technical supervisor must evaluate each individual's performance and establish the individual's actual workload limit based on performance. We are specifying that laboratories must evaluate their own operation and determine appropriate workloads that do not exceed 100 slides per 24 hours for each individual. This includes the technical supervisor in cytology when he or she performs initial gynecological or nongynecological interpretations and/or participates in the rescreen of cases interpreted to be negative for reactive, reparative, atypical, premalignant or malignant changes.

*Comment:* A number of commenters suggested that the workload limit separately address one-slide gynecologic cases, two-slide gynecologic cases and nongynecologic cases. A few thought that the workload limit should not include nongynecologic slides. One organization suggested prorating slides from nongynecologic cases and counting them up to a maximum of 3 slides/case as done in New York State.

*Response:* CLIA requires the establishment of the maximum number of cytology slides that any individual can screen, therefore the workload limit includes both gynecologic and nongynecologic cytology slides. Since workload is counted by the number of slides, one-slide and two-slide gynecologic cases are counted as either one slide or two slides. We recognize that some types of slide preparations have smaller cell areas to be evaluated than others, and therefore have added a new provision at § 493.1257(b)(2), which allows for a variance in slide counting for certain gynecologic and nongynecologic slide preparations. Each slide made using automated, semi-automated or other liquid-based preparatory techniques that results in cell dispersion over one-half or less of the available slide area may be counted as one-half slide toward the workload limit. For example, two nongynecologic slides prepared using a filter and

centrifugal technique would be counted as one slide for workload calculations. Additionally, if instrumentation currently under development for use in preparing cytology slides is approved by the FDA for use with gynecologic preparations, and an individual evaluates, by manual microscopic technique, only slide preparations made by this type of instrumentation which produces preparations as described above, the effective absolute workload limit would be 200 slides per 24 hours. It must be noted that this limit and method for calculating workload only apply to slide preparations evaluated by nonautomated microscopic technique. We are not addressing slide evaluation done by automated methods (e.g., image analysis or other computerized systems) in this regulation.

*Comment:* A few commenters thought that the requirement at § 493.1257(b)(2) for maintaining records of the number of slides read by each individual during each 24 hours should be the responsibility of the individual rather than the laboratory. They felt that this requirement is a recordkeeping burden for the laboratory.

*Response:* It is the laboratory's responsibility to ensure that each individual keeps records of the number of slides read and the number of hours spent reading slides during each 24 hour period, irrespective of the site or laboratory. These records must be available in the laboratory. The responsibility for keeping these records is also stated under §§ 493.1451, 493.1471 and 493.1485 which list the technical supervisor, cytology general supervisor and cytotechnologist responsibilities, respectively. Each individual is responsible for keeping records of his or her slide screening activities.

*Comment:* Several organizations and individuals felt that the time limit of 6 hours specified in § 493.1257(b)(2)(i) for examining the maximum number of 120 slides and the formula for prorating the part-time workload limit under § 493.1257(b)(2)(ii), which is based on 8 hours, were inconsistent. Some thought that the time for examining the maximum number of slides should be changed to 8 hours.

Others suggested that the maximum slide limit should be adjusted for individuals working full-time based on the actual time spent evaluating slides during an 8 hour workday. Some were concerned that the 6 hour limit may have an adverse effect on quality as some laboratories may make 6 hours a target time period for cytotechnologists to screen the workload maximum.

*Response:* Because of the concern that some laboratories will compel individuals to read the maximum number of slides in 6 hours on a routine basis and to provide consistency, we are changing the requirement now at § 493.1257(b)(3)(i) to require that the maximum of 100 slides can be read in no less than an 8 hour workday. In addition, for individuals working less than 8 hours per day examining slides, either those who work part-time or those who work full-time and carry out other duties not related to slide examination, the formula now at § 493.1257(b)(3)(ii) should be used to calculate the individual's slide limit. We emphasize again that this is an absolute maximum and is not to be construed as a target number of slides for every individual.

*Comment:* Comments on § 493.1257(c)(1) indicated that the technical supervisor's responsibilities for diagnostic confirmation of gynecologic smears should be expanded. One professional organization suggested that all cases that are interpreted as abnormal or atypical be reviewed by a technical supervisor before they are reported.

*Response:* We agree with the commenters and are adding the requirement at § 493.1257(c)(1) that all gynecologic smears interpreted to be showing reactive or reparative changes or those of atypia of undetermined significance be confirmed by a technical supervisor. This requirement is in addition to the review and confirmation by a technical supervisor of gynecologic smears interpreted to be premalignant or malignant and confirmation of all nongynecologic preparations as described under § 493.1257(c)(2).

*Comment:* Most commenters supported the requirements specifying that the technical supervisor evaluate and document the slide examination performance and establish and document a workload slide limit for each individual as required under §§ 493.1257(c)(3) and (4). Several felt, however, that the requirement to reassess each individual's workload on a monthly basis, as specified under paragraph (c)(4)(ii), was excessive. They recommended an annual or semi-annual reassessment, saying that monthly evaluations are burdensome and not necessary since an individual's ability does not change in a month's time.

*Response:* We are modifying § 493.1257(c)(3), which formerly required slide examination performance evaluation and feedback on normal, negative, premalignant and malignant cases to additionally require evaluation and feedback on cases which show

reactive, reparative, or atypical changes. We are making this change to correspond to the addition made in paragraph (c)(1) requiring that slides showing these conditions be confirmed. Paragraph (c)(4)(i) in this section was revised to require that each individual's workload limit be established based on this performance evaluation. We agree with the commenters that monthly workload limit evaluation is unrealistic and have changed this requirement to allow for workload limit reassessments not less frequently than every six months. This does not preclude more frequent workload limit evaluations. If adjustments to workload limits are needed before the six month interval for reassessment, they should be made as necessary.

*Comment:* A large number of commenters were opposed to the requirement under § 493.1257(d)(1) specifying that at least 10 percent of all gynecologic cases interpreted by cytotechnologists as negative for premalignant or malignant conditions be reexamined. Many recommended eliminating this requirement and several recommended that rescreening be focused on those patients who have been identified as high risk or who belong to a population group identified as high risk. Commenters stated that a random rescreening of negatives was nonproductive and that the statistical probability of identifying false negatives by this method was remote. Several published articles were cited and one organization provided statistical analyses to support this conclusion. On the other hand, some commenters supported the random 10 percent rescreen and felt that it was the best available method for evaluating the ability of cytotechnologists to identify normal or negative conditions. One organization recommended deleting the requirement that slides be reviewed before reporting patient results, because they felt that such a requirement would cause significant delays in reporting patient results. Another commenter suggested that any individual authorized by the laboratory to examine cytologic preparations should be able to rescreen slides, not necessarily a supervisor. One commenter asked for clarification as to whether the inclusion of negative cases from patients identified as having a high probability of developing cervical cancer meant that all of these cases must be rescreened or just those that would be needed to obtain a total of 10 percent of all negative cases. A few commenters recommended replacing the rescreening requirements with a requirement for inserting blind

abnormals into the routine workload. They said that this is a more effective method for determining false negative rates.

*Response:* The reevaluation of 10 percent of gynecologic cases interpreted as negative for malignant or premalignant conditions has been a longstanding quality control practice in cytology. Several published statistical analyses have shown that, depending on the cervical cancer prevalence rate for the laboratory, the number of slides that are typically rescreened does not detect a significant number of missed cases of cancer. Rescreening slides, however, is a method that is readily available for assessing an individual's ability to correctly interpret negative cases. Additionally, misinterpretations may be detected for conditions other than those that are classified as malignant or premalignant. Therefore, we are retaining the requirement for reevaluating at least 10 percent of the cases interpreted by individuals not qualified as technical supervisors which would not otherwise be reevaluated. The cases to be included for reexamination are those found negative for reactive or reparative changes and atypical cells of undermined significance, as well as premalignant and malignant conditions. This would include cases reported as negative or normal or showing infections other than HPV. Cases for this review must be selected at random from the total caseload and include some cases from patients or groups of patients which can be identified as having an increased risk for developing cervical cancer (high risk cases). If a laboratory evaluates a large number of cases from high risk populations that account for more than 10 percent of its caseload, all of these do not need to be reexamined, however we hope that the laboratory would determine if more than 10 percent of these cases need to be reevaluated based on its own performance statistics.

To ensure that this review is done in a timely manner, we are retaining the requirement that it must be completed before reporting patient results. For clarification, we added that this refers only to those cases selected for review. Laboratories should be able to develop a routine system to accomplish this review so as not to result in significant delays in reporting. Also, we are retaining and clarifying the requirement that the slide reexamination be done by a cytotechnologist who meets the qualifications of cytology general supervisor or by the technical supervisor. For clarification, we have listed who can perform this review; a

technical supervisor in cytology, a cytology general supervisor, or a cytotechnologist who has the experience specified for a cytology general supervisor. This does not mean, therefore, that only those individuals designated as the laboratory's supervisors can perform this slide review, but any cytotechnologist who meets the experience qualifications for cytology supervisor can do so.

The insertion of blind controls into the workload is another method to evaluate performance, but, at this time, cannot be routinely achieved in most laboratories. Therefore, we are not specifying the use of this method; however, a laboratory that is able to perform this type of slide review is encouraged to continue to do so in conjunction with other quality control and quality assurance measures.

*Comment:* Several commenters objected to the requirement for comparing all premalignant and malignant cytologic results with the histopathology report, if available in the laboratory or through the State health department as described in § 493.1257(d)(2). The primary concern noted by most individuals and organizations is requiring the laboratory to obtain reports from State health departments. They said that this will be extremely burdensome for both the laboratories and the health departments, especially since many laboratories receive specimens from multiple States and patients may change residency from State to State.

A few commenters suggested that the requirement be revised to require only in-house report comparison. One commenter noted that interpretations of histopathology reports are as variable as cytology Pap smear reports and that it will be difficult to determine the causes for discrepancies.

*Response:* We recognize that discrepancies between histopathology and cytology results may be due to the subjective nature of the interpretations or to sampling differences. However, the laboratory's comparison of histopathology and cytology results is a valuable quality control activity and when discrepancies are found, useful information can be generated. We are retaining this requirement, therefore, with one modification. We agree with the commenters that at this time, many State health departments are not equipped to retrieve tissue reports and, therefore, are deleting this requirement.

*Comment:* There were a number of objections to the requirement under § 493.1257(d)(3) for review of gynecologic specimens from the last five years for current malignant and

pre-malignant cases. Commenters objected to both the time frame for this review as well as the inclusion of some premalignant conditions. Suggestions ranged from leaving the review to the discretion of the technical supervisor to changing from the previous 5 years to the previous one or two years or the previous one or two slides. Commenters said that it was improbable that abnormal cells would be missed consistently over 5 years. Some organizations and individuals recommended that this review should be conducted only for newly diagnosed cases with high grade lesions or worse. They stated that it would be very time consuming and could result in the review of a large number of cases to comply with this requirement for low grade or condylomatous lesions and that the effort would have no clinical value or benefit to patients. A few commenters asked what the laboratory was supposed to do with the results of this retrospective review. They contended that this activity is to be used as an educational tool for quality assurance purposes and recommended that if a missed positive slide is found, the laboratory should only issue an amendment report if it would impact on patient management or treatment.

*Response:* The primary purpose for this retrospective slide review is to evaluate the slide examination performance of individuals. We agree with the commenters that this review should be limited to current cases showing high grade intraepithelial lesions or worse, which includes moderate dysplasia or CIN-2 or above, and have modified the requirement accordingly. Although we were interested in decreasing the 5 year time period, we were prevented from doing so by the statutory requirements for reviewing all prior available specimens. Since slides must be held for 5 years, available specimens should date back through that time period. We are not requiring that laboratories issue amended reports of results found on this retrospective review that have minor differences from the original report that would have no impact on patient care. However, if significant discrepancies are found that would effect patient care the laboratory must notify the patient's physician and issue an amended report.

*Comment:* The annual statistical evaluation requirement under § 493.1257(d)(4) was opposed by a few commenters. Some felt that specific requirements should not be defined and that the development of a credible evaluation system should be the responsibility of the technical

supervisor. Some thought that these recordkeeping requirements were burdensome and that some items should be deleted, such as the number of cases for which histology results were unavailable. Others were concerned about the ability of some laboratories, especially those that do not have automated information management systems, to provide this documentation. A few commenters wanted clarification on the requirement for documenting the number of unsatisfactory specimens per physician and wondered whether this information should be maintained only in the laboratory or sent to the individual physicians.

*Response:* The goal of this annual statistical evaluation is for each laboratory to obtain data which describes its overall case mix with respect to specimen types and diagnoses as well as the general false negative rate. These data can then be used as a baseline to compare the case reviews of each individual as specified under § 493.1257(d)(5). We recognize that if a laboratory does not have a mechanism in place to collect and analyze this information the initial implementation may take time. However, once a system is in operation, these statistics will provide invaluable to the laboratory in assessing its performance and the performance of individuals. With the exception of records for unsatisfactory specimens, we are retaining this requirement as proposed.

The intent for requiring records for the annual number of unsatisfactory specimens submitted by each physician or laboratory was to enable the laboratory to recognize trends. The laboratory then would have the option of sending these statistics to individual physicians or notifying them in some other manner of improper specimen collection or preparation. We recognize that laboratories without computerized record systems may find this requirement difficult to meet, and have therefore deleted it. However, we have included under the documentation of the volume of cases reported by diagnosis, the number reported as unsatisfactory for diagnostic interpretation. Therefore, the laboratory should have annual overall statistics on the total volume of specimens submitted for each specimen type that were determined to be unsatisfactory.

*Comment:* A few commenters objected to § 493.1257(d)(5), which requires the laboratory to compare the case reviews of each individual examining slides with the overall laboratory statistics and document discrepancies. One commenter felt that

this review and documentation should only be necessary for individuals who are poor performers.

*Response:* The comparison of each individual's case reviews with the laboratory's overall statistics is intended to provide a mechanism for evaluating each individual's performance and to assure that poor performance is identified. It is not meant as a punitive or remedial measure. Therefore we are retaining this requirement.

*Comment:* A small number of comments were received on the laboratory report requirements as listed under § 493.1257(e). A few individuals noted that there is no consensus agreement in the cytology community on the definition for smears that are unsatisfactory for diagnostic interpretation. One organization suggested that endometrial cells should be reported if present and not only if "present out of cycle" as stated under § 493.1257(e)(3). Another organization felt that the ordering physician should determine the appropriate follow-up actions and that the requirement for a follow-up recommendation on the report as specified under § 493.1257(e)(5) should be eliminated.

In addition, in response to our request for public comment on requiring The Bethesda System to report Pap smear results, several commenters were in support of such a requirement, but most commenters, while they supported its use, were opposed to requiring it. Some thought that, if required, it should be phased-in or delayed to give everyone time to become familiar with it and for the system to be standardized and accepted. Several organizations said that The Bethesda System was still evolving and not yet widely used, and a few were concerned that requiring its use at this time may impede its further development. A few commenters suggested requiring the use of descriptive terminology, such as The Bethesda System or other nomenclature, giving the laboratories the option to choose.

*Response:* We are changing § 493.1257(e) to reflect recommendations made by commenters. We are not requiring the use of The Bethesda System, but are specifying that the laboratory report must contain narrative, descriptive nomenclature for all results. While we are in support of using The Bethesda System to report patient results, other terminology is acceptable, as long as it is descriptive. The Papanicolaou numerical classification system is not acceptable. Since a descriptive report is required,

we have deleted specific requirements for reporting endometrial cells, viral infections and follow-up recommendations. The presence of endometrial cells and viral infections are part of descriptive reporting and laboratories should determine when follow-up recommendations are appropriate. We are retaining the requirement for reporting unsatisfactory smears as mandated by CLIA. The laboratory must define its criteria for categorizing smears as unsatisfactory and notify physicians if they receive specimens which are unsatisfactory for diagnostic interpretation.

*Comment:* A few commenters were opposed to the slide retention requirements under §§ 493.1257 (g) and (h). Some recommended that all slides be retained for 5 years, rather than 5 years for negatives and 10 years for premalignant or malignant cases, adding that there was no significant advantage to retaining abnormal slides longer than negative slides, since they automatically initiate patient management. A few commenters suggested retaining negative slides for only 2 or 3 years in order to reduce the amount of storage space required and a few suggested retaining all slides indefinitely.

*Response:* We are revising and combining the slide retention requirements under § 493.1257(g) to require that all slides be retained 5 years. This change should simplify the slide filing system for laboratories while assuring that slides are available for review with the tissue reports of a follow-up biopsy. Laboratories have the flexibility of retaining slide preparations for longer time periods if they feel this will aid in the provision of better patient care.

*Comment:* One organization and a few individuals objected to the requirement for cytology laboratories to obtain HHS approval for donating slide preparations to an approved proficiency testing program as required under § 493.1257(i). They said that requiring HHS approval would impede contributing slides to a program.

*Response:* We agree with this comment and are deleting the requirement that a laboratory must obtain HHS authorization to loan slides to an approved proficiency testing program. Instead, a laboratory may loan slides to any proficiency testing program, without regard to whether the program has been approved by HHS. This revision was made to allow PT programs to collect the slides needed to assemble test sets which must be done prior to seeking HHS approval. If slides have been retained by the laboratory

less than 5 years, the laboratory must have written acknowledgment from the proficiency testing program of the slide transfer. This requirement has been combined with the requirement for slide retention under § 493.1257(g). In addition, we have added a provision for laboratories that loan or refer slides for purposes other than PT to maintain documentation of the loan or referral, and that all slides must be retrievable upon request.

*Comment:* An overwhelming number of individuals and organizations were opposed to the requirement at § 493.1257(j) that the laboratory must report all malignant and premalignant gynecologic cases to its State health department. The majority of commenters recommended deleting this requirement, noting concerns with feasibility, cost, and maintenance of patient confidentiality. Several State health departments questioned the reason for this reporting and they, along with other commenters, noted that many State health departments have no mechanism in place to receive these reports and most have no resources to establish such a registry. Some recommended that the wording of the regulation be changed, adding "if so directed by the State." One commenter recommended that if the purpose for this requirement is to set up a data bank, then it should be done on a national level with a central registry at the CDC.

Additionally, some commenters noted that a large volume of cases would be reported if premalignant conditions such as dysplasia and HPV infection are included. Several laboratories suggested that the physician should report premalignant and malignant cases to the State since the physician would have more information on the patient's status and usually would be practicing in the State in which the patient resides. Several physicians stated that this requirement infringes on the right of privacy and would compromise patient confidentiality. A few commenters noted that the requirement should be clarified to address how laboratories should report interstate cases, specifically those situations in which the laboratory reports results to the State in which it is located but the patient is a resident of another State. A few States pointed out that they have no interest in test reports of nonresidents whose specimens were examined within their State.

*Response:* We recognize the difficulties associated with this requirement and agree with many of the comments. Therefore, we are deleting § 493.1257(j)

*Comment:* A few commenters indicated that the regulations, at § 493.1259 Standard: Histopathology, should be applicable to the laboratory that prepared the slides not the individual examining the slides.

*Response:* CLIA requirements apply only to those facilities that perform " \* \* \* examinations of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease \* \* \*" and does not apply to facilities that prepare specimens for examinations. It is the responsibility of the laboratory to ensure that the specimens it receives are properly labeled, processed and stained for examination, and are transported to it in a manner that assures safe and intact receipt of the specimen.

The requirements for specimen submission procedures for referral specimens are in subpart J, Patient Test Management.

*Comment:* A few commenters felt that it was not necessary to document control slide results as required under § 493.1259(a).

*Response:* We disagree with the commenters. All quality control staining procedures in histopathology must be performed and documented in accordance with the requirements at § 493.1218(f) (1) and (2) of this subpart and with the requirement here at § 493.1259(a). Documentation of quality control performance is necessary to provide records of the performance of the quality control, to determine if there is a problem with the staining materials or procedures, or to alert the laboratory to an unsatisfactory trend in quality control results. We are retaining the requirement at § 493.1259(a) which requires documentation of the reaction of the control slides with each special stain used.

*Comment:* Several pathologists and a professional organization recommended that the time frame for maintaining paraffin tissue blocks be changed from 2 years, as required under § 493.1259(b), to 10 years.

*Response:* Section 493.1259(b), which requires laboratories to retain paraffin tissue blocks for at least 2 years from the date of examination, is a minimum requirement. A laboratory may be required under State law to retain paraffin tissue blocks for longer time periods or the laboratory may choose to retain paraffin tissue blocks for longer periods of time.

*Comment:* Several pathologists and a professional organization objected to the retention of surgical specimens "in a fixative solution" as required in

§ 493.1259(c). A few commenters noted that there were times when fresh tissue material is better if refrigerated and that some fixative solutions were deemed hazardous by OSHA and EPA.

*Response:* We agree with the commenters that the requirement for surgical specimens to be retained in a fixative solution was prescriptive and may pose a safety hazard. The requirement is intended to assure that tissue fragments are satisfactorily preserved in the event they are needed for further examination. We are revising § 493.1259(c) to state that remnants of tissue specimens must be retained in an appropriate manner that results in the preservation of the tissues until the portions submitted for microscopic examination have been examined and a diagnosis made by an authorized individual.

*Comment:* A few commenters recommended that § 493.1259(e) be clarified or deleted because there is no specific system of histopathologic terminology and they did not want to rely on one particular nomenclature for reporting tissue results. Several hospitals indicated that this reporting requirement is a duplication of activities normally performed by the medical records department.

*Response:* We did not specify under § 493.1259(e) the type of terminology that a laboratory must use to report tissue pathology results. This requirement requires laboratories to use "acceptable terminology of a recognized system of tissue nomenclature" and does not restrict the laboratory to any one particular nomenclature.

*Comment:* Numerous commenters objected to the mandatory reporting of all biopsy-confirmed cases of cervical cancer by the laboratory to its State health department and requested the deletion of § 493.1259(f). Several commenters stated that many State health departments have no tumor registry of this type and no resources for its establishment. A few noted that many localities already have tumor registries to which these cases are reported and reporting to the State health departments would be a duplication of effort. A few commenters said that this reporting should be the responsibility of the patient's clinician, not the laboratory, and many were concerned about the effect of this requirement on patient confidentiality. Several commenters said that the requirement should be clarified to specify procedures for handling cases in which the laboratory is located in a State that is different from the one in which the patient resides.

*Response:* This requirement was established to assist laboratories in tracking and obtaining follow-up biopsies from client physicians who submit Pap smears to one laboratory and biopsy specimens to another. We believed that a central repository in each State containing laboratory reported biopsy results would provide a mechanism by which all laboratories could make comparisons between cytology and histology results as required in § 493.1257(d)(2). However, we recognize the logistical complications involved in this type of interactive tumor registry, and, since many States are unable, at this time, to comply with this requirement, we are deleting it from the regulations.

*Comment:* Several commenters stated that radiobioassay in § 493.1263 is not one of the established specialty areas and that this specialty of testing essentially was part of chemistry, the only difference was the qualifications of the technical supervisor.

*Response:* Radiobioassay as a category of testing was established to include those tests that involve the in vivo administration of radioactive materials to a patient and the subsequent measurement of radioactivity in body fluids in order to evaluate body functions, and is a separate specialty area from chemistry.

*Comment:* A professional organization recommended changing the wording of proposed Condition: Histocompatibility, § 493.1265(a)(6) to read "make every reasonable attempt and effort to obtain and have available the appropriate serum samples from all potential renal transplant recipients."

*Response:* We agree with the commenters that this requirement is too restrictive and not practical. Thus, we are requiring that laboratories document their efforts to reasonably obtain serum specimens for all potential transplant recipients at initial typing, for periodic screening, pretransplantation crossmatch, and following sensitizing events. We are including this change at § 493.1265(a)(2)(ii).

*Comment:* Several commenters questioned whether proposed § 493.1265(a)(10) and (a)(18)(ii) apply only to renal transplant recipients or if they apply to all types of organs. The commenters were concerned about the cost of complying with these requirements.

*Response:* This provision applies to renal as well as non-renal solid organ transplants, especially to sensitized recipients. Monthly antibody screening of recipient serum can be beneficial in regulating the dosage of the immunosuppressive drug(s) as well as

providing retrospective data to monitor any problems that may arise. For non-sensitized patients, monthly screening may not be necessary, but it is desirable. We are including this provision at § 493.1265(a)(6)(i) and (a)(8)(i)(B).

We are modifying § 493.1265(b)(1) to accommodate living donor liver and pancreas transplants, a procedure that has been performed for the last 18 months. In these instances, the mixed lymphocyte culture test, while listed as an exception to the requirement at § 493.1265(b)(1), is helpful and is one of the compatibility testing options stated in § 493.1265(a)(10) (formerly § 493.1265(a)(20)). Section 493.1265(b)(1) now states that "for transfusions and other non-renal transplantation, excluding bone marrow and living transplants all the requirements specified in this section, as applicable, except for the performance of mixed lymphocyte cultures must be met."

*Comment:* Several individuals noted that renal transplant compatibility testing does not frequently incorporate DNA analysis and suggested that this be deleted from proposed § 493.1265(a)(20).

*Response:* We disagree with the commenters. DNA analysis is an applicable procedure for renal and non-renal transplants. In renal transplants it could be used for compatibility testing as an alternative to the mixed lymphocyte culture test.

*Comment:* Several commenters suggested that proposed § 493.1265(a)(12) be revised to require verification of the efficacy of those immunologic reagents used to remove contaminating cells during the isolation of lymphocytes.

*Response:* We agree with the commenters. Based on commenters' suggestions, we are including reagents other than ABO antisera. The regulation now states "If the laboratory utilizes immunologic reagents such as antibodies or complement to remove contaminating cells during the isolation of lymphocytes or lymphocyte subsets, the efficacy of the methods must be verified with appropriate quality control procedures." We are including this change at § 493.1265(a)(12).

*Comment:* A professional organization suggested that "or proficiency testing program" be added after "regional cell exchange" in proposed § 493.1265(a)(24).

*Response:* We disagree with the commenter. We have not yet established requirements for approval of proficiency testing programs, however, the histocompatibility proficiency testing program currently offered by CAP/ASHI is considered an acceptable cell exchange program.

*Comment:* Many commenters stated that § 493.1265(b)(3) should not be applicable to non-renal solid organ transplants because it would significantly increase the amount of time required to perform the transplant and with the application of immunosuppressive drugs, many recipients are transplanted successfully.

*Response:* Although we disagree with the commenters, we are modifying § 493.1265(b)(3) to permit life saving non-renal solid organ transplants to be performed prior to completion of the final crossmatch provided records document the emergency basis for the transplant. The short term viability of liver, heart, and pancreas organs after removal from the donor is often insufficient time for the laboratory to complete the crossmatch. However, for those individuals that exhibit presensitization, we are continuing to require the crossmatch prior to transplant. When transplants are performed prior to the crossmatch for emergency situations or at the discretion of the patient's physician, we are requiring that the laboratory document the reason(s) if provided by the patient's physician.

*Comment:* Several commenters felt that several requirements in § 493.1265 do not apply to disease-associated studies or parentage testing as required under § 493.1265(c). They felt that the requirements concerning crossmatching or antibody screen do not apply.

*Response:* We agree with the commenters that crossmatching and antibody screening do not apply to parentage testing and disease-associated studies. Therefore, we are modifying § 493.1265(c) to exclude antibody screening and crossmatching along with mixed lymphocyte cultures.

*Comment:* Many commenters felt that § 493.1265(d), which requires the laboratory to assure the donor is tested for HIV reactivity, places an unrealistic responsibility on the histocompatibility laboratory and that this should be the responsibility of the Organ Procurement Agency or the transplant center.

*Response:* We agree with the commenters that it is not appropriate to require histocompatibility laboratories to assure HIV testing of donors. Therefore, we are modifying § 493.1265(d) to require those histocompatibility laboratories that perform HIV testing to meet the requirements of § 493.1241.

*Comment:* Several laboratories did not feel that they should have to perform HIV testing as required under § 493.1265(d). Several individuals stated that it would cause delays in

transplantation and given the condition of the patient, HIV testing should not be required.

*Response:* We agree with the commenters and are revising § 493.1265(d) to require that any laboratory performing and reporting HIV reactivity testing on organ donors must meet the requirements at § 493.1241.

*Comment:* A few commenters disagreed with the HCFA Common Procedures Coding System (HCPCS) list categorization of HLA B27 testing in the certification category of histocompatibility since the commenters believe that the histocompatibility testing quality control requirements are not applicable to HLA B27 testing.

*Response:* We disagree with the commenters. We are retaining disease associated antigen testing in the specialty of histocompatibility because we believe that the expertise of the technical supervisor is necessary for performing this test.

*Comment:* A few commenters said that the word "adequate" appeared in three of four explanatory paragraphs under § 493.1267 Condition: Clinical Cytogenetics, but was never defined.

*Response:* In accordance with § 493.1213, Standard; Establishment and verification of method performance specifications, the laboratory will define the number of cells to be examined for X and Y chromatin counts and the number of karyotypes prepared for each patient that it determines to be adequate in order to meet the laboratory's stated performance specifications. We are retaining § 493.1267 (a) and (b) as written. However, we are replacing the word "adequate" in § 493.1267(c) with the words "accurate and reliable" to be consistent with the language used in subpart J, Patient Test Management.

*Comment:* Other individuals noted that many parts of § 493.1201 to § 493.1221 do not apply to cytogenetics such as the inclusion of positive and negative controls.

*Response:* The regulations at § 493.1201 to § 493.1221 have been written to apply to a wide variety of testing facilities. The laboratory must adhere to those requirements applicable to the scope of testing it performs.

If the inclusion of positive and negative controls with each run of specimens is not applicable to cytogenetics, then the laboratory need not comply with that requirement, as stated in the first paragraph of § 493.1267.

*Comment:* Several health care providers suggested that §§ 493.1269, Condition: Immunohematology, and 493.1285, Standard; Investigation of

transfusion reactions, be deleted and replaced with reference to the appropriate parts of 21 CFR.

*Response:* The regulations promulgated by FDA and HCFA are based on different laws. The FDA regulations are directed towards establishments which collect blood and blood components in other than emergency situations, perform therapeutic collection or apheresis with no destruction of resulting product or prepare frozen deglycerolized, washed, rejuvenated, or leucocyte-poor red blood cells and/or recovered human plasma. HCFA is responsible for regulating transfusion service facilities and laboratories performing HIV, hepatitis and syphilis testing for registered blood establishments. FDA regulations are product oriented while HCFA regulations are patient oriented. For this reason, we are retaining §§ 493.1269 and 493.1285 as a supplement to those published by the FDA, but whenever possible we have adopted the FDA regulations for blood and blood products.

*Comment:* A few commenters said that the requirements for immunohematology under §§ 493.1269 and 493.1285 were too specific, while others wanted more specifics for testing the Du variant.

*Response:* We are retaining the requirements under §§ 493.1269 and 493.1285 since they are compatible with the FDA requirements. Except where noted, the intent of this regulation is to allow laboratories the flexibility to determine the appropriate tests for their patient population and scope of operation. For this reason, the requirement at § 493.1269(c) does not address when Du variant testing be performed. However, as with all test procedures, when Du variant testing is performed, it must be in accordance with manufacturer's instructions and the applicable quality control requirements of this subpart. We are making supplemental changes to the regulations requiring positive identifications of the blood products recipient at § 493.1273(d) and monitoring and inspection of the blood products refrigerator at § 493.1275(a) and (b).

*Comment:* Several technologists noted that the requirement under proposed § 493.1283, Standard: Retention of Transfused Blood, does not set retention time frames nor does it reference other standards that should be observed. Other commenters wondered if the intention of this regulation was that all components and retained specimens were to be stored in an alarmed system.

*Response:* The intent of this regulation is to allow laboratories the flexibility to

determine an appropriate length of time to retain samples of transfused blood in the event that post-transfusion testing becomes necessary. The regulation did not intend to require that these samples be retained in an alarmed system. There was no mention of alarmed systems at § 493.1283. We are retaining the regulation at § 493.1283 with a modification only to the paragraph title where we have added the word "samples" which changes the title to "Standard; Retention of Samples of Transfused Blood."

*Comment:* A few commenters suggested that in § 493.1285, Standard: Investigation of Transfusion Reactions, the words "Where appropriate and possible" be added to the second sentence to read "Where appropriate and possible, the facility must (change to should) document that all necessary remedial actions are taken to prevent future recurrences of transfusion reactions" as many reactions are unavoidable and not under the control of the laboratory.

*Response:* We disagree with the commenters because transfusion reactions are potentially life threatening events and we expect that every laboratory involved in transfusion services will treat them as such. Therefore, we are retaining the language at § 493.1285, which states that "The facility must document that all necessary remedial actions are taken to prevent \* \* \*". This language allows the laboratory some flexibility in determining appropriate action to be taken when a transfusion reaction occurs. If the investigation reveals that action must be taken to prevent future recurrences then appropriate policies must be established and the corrective action must be documented.

#### Changes to the Regulation

##### *Section 493.1201 Condition: General Quality Control*

We are revising this condition to clarify that procedures HCFA approves as equivalent will be specified in appendix C of the State Operations Manual.

##### *Section 493.1202 Standard; Moderate or High Complexity Testing, or Both*

Effective from September 1, 1992 to September 1, 1994.

We are adding this standard to explain the applicability of the quality control requirements from September 1, 1992, to 2 years thereafter. This standard is providing a 2-year phase-in of quality control requirements for laboratories performing tests of moderate complexity

using an instrument, kit, or test system cleared by the FDA through the 510(k) or PMA process.

*Section 493.1203 Standard; Facilities*

The contents of this section are being redesignated as § 493.1204, with the exception of electrical power variances, which are now covered in § 493.1205(c) and revised to eliminate the requirement for laboratories to maintain an adequate, stable, electrical source for laboratory equipment.

We are adding a requirement for the laboratory to establish, post, and observe safety precautions to ensure protection from physical hazards and biohazardous materials.

*Section 493.1203 Standard; Moderate or High Complexity Testing, or Both*

Effective beginning September 1, 1994. This standard is being added to explain the applicability of the quality control requirements effective September 1, 1994. We are revising §§ 493.1213, 493.1215, 493.1217, and 493.1218 to differentiate between laboratories using an instrument, kit, or test system that has been cleared by the FDA as meeting the CLIA requirements for general QC, and those laboratories using a method developed in-house, a modification of the manufacturer's test procedure, or an instrument, kit, or test system that has not been cleared by the FDA as meeting the CLIA requirements for general QC. Section 493.1205 Standard; Adequacy of methods and equipment; Section 493.1207 Standard; Temperature and humidity monitoring; and Section 493.1209 Standard; Labeling of testing supplies.

These standards are being combined into § 493.1205 Standard; Test methods, equipment, instrumentation, reagents, materials and supplies. We are reorganizing the section to incorporate the principal components of the three proposed standards.

Since the laboratory is required to identify specific interfering substances and include these substances in the procedure manual as a limitation in methodology, we are deleting the requirement to perform test procedures or examinations in a manner that ensures "freedom from interference."

We are adding "as applicable" to the requirement for laboratories to define criteria for the conditions essential for proper storage of reagents and specimens, and accurate and reliable test system operation and test result reporting. Also, we are adding water as an essential condition for test performance.

*Section 493.1211 Standard; Procedure Manual*

We are adding the following requirements to this standard:

- Manufacturers' package inserts or operator manuals that include the information in § 493.1211(b) (1) through (13) may be used in addition to or in lieu of preparing a separate manual;
- Instructions for the step-by-step performance of the procedure;
- Reportable range for patient test results;
- Reference range (normal values);
- Panic values;
- Criteria for the referral of specimens; and
- Reapproval of procedures whenever directorship of the laboratory changes.

We are deleting the requirement for quality assurance protocols to be included in the procedure manual and the requirement for the director to "initially" approve procedures.

*Section 493.1213 Standard; Equipment Maintenance and Function Checks*

This standard is being moved to § 493.1215.

Laboratories using equipment, instrument or test systems cleared by FDA as meeting the CLIA requirements may follow manufacturers' instructions for maintenance and function checks.

Laboratories using equipment, instruments, or test systems not cleared by FDA as meeting the CLIA requirements, or equipment, instruments, or test systems that have been modified or developed in-house, must establish their own maintenance and function check protocols.

We are deleting the requirement to recheck, calibrate or recalibrate each instrument, device, or test system at least once each day of use, and perform baseline or background checks each day of use.

*Section 493.1215 Standard; Validation of Methods*

This standard is being redesignated as § 493.1213, renamed, "Establishment and verification of method performance specifications," and revised to emphasize that the requirements in this section are not retroactive.

We are adding language that permits laboratories using test methods established and validated by a manufacturer whose product has been cleared by the FDA to meet these requirements by using the manufacturer's performance specifications, provided they can obtain comparable results.

The requirement for laboratories to retain documentation of method validation is being deleted to eliminate redundancy with the quality control records retention requirement at § 493.1221.

We are revising the terms sensitivity and specificity to include the word "analytical."

We are consolidating the documentation requirements formerly in paragraphs (c), (d), and (e) into a new paragraph (c).

We are deleting the requirement for making method validation records available to the authorized persons ordering or receiving test results since it is already covered in Subpart J, Patient Test Management.

*Section 493.1217 Standard; Frequency of Quality Control*

This section is being divided into two sections, § 493.1217 Standard; Calibration and calibration verification, and § 493.1218 Standard; Control procedures.

Under the new § 493.1217 Standard; Calibration and calibration verification, we are making the following revisions:

- We are adding language that permits laboratories using a manufacturer's product that has been cleared by the FDA as meeting the CLIA requirements, to meet these requirements by using the manufacturer's instructions for calibration and calibration verification.
- For those laboratories using a method that is developed in-house, is a modification of the manufacturer's test procedure, or is a manufacturer's product that has not been cleared by the FDA as meeting the CLIA requirements, we are revising this section to distinguish between the calibration and calibration verification requirements.
- Under the calibration requirements, the laboratory may meet the requirements by either following, as a minimum, the manufacturer's instructions for calibration or developing its own criteria for calibration that includes calibration materials appropriate for the methodology.
- Under the calibration verification requirements, the laboratory must use calibration materials appropriate for the methodology to verify the adequacy of the calibration over the laboratory's reportable range for patient test values.
- We are adding an option for laboratories to waive calibration verification for a complete change of

reagents, if the laboratory can demonstrate that changing reagent lot numbers does not affect the range to report patient test results and control values are not adversely affected.

- Rather than requiring calibration verification whenever controls reflect an unusual trend or shift or exceed the laboratory's acceptable limits, we are adding language to permit laboratories to employ other means of correcting unacceptable control values. Calibration verification is required whenever these measures fail to correct the problem.
- We are reducing the number of calibration materials required to verify calibration from three points and a zero to two points and a zero. Also, we are no longer distinguishing between linear and nonlinear methods.
- We are deleting the requirements specifying the procedures to follow when patient values are above the maximum calibration point or below the minimum calibration point.

• Under the new § 493.1218 Standard; Control procedures, we are making the following revisions:

- We are adding language to this section to permit laboratories using a manufacturer's product that has been cleared by the FDA as meeting the CLIA requirements, to meet these requirements by using the manufacturer's instructions for control procedures. In addition, these laboratories must test control samples in the same manner as patient samples, have statistical parameters for calibration and control materials, and control results must meet the laboratory's criteria for acceptability prior to reporting patient test results.
- We are requiring those laboratories using a method developed in-house, a modification of the manufacturer's test procedure, or a method that has not been cleared by the FDA as meeting the CLIA requirements, to meet the requirements in this section.
- We are deleting the reference to using two separate dilutions from a stock calibrator and using a sample spiked with a calibrator to meet these requirements.
- We are revising the direct antigen system control procedure requirements to clarify that controls must check, when applicable, both the detection and extraction phases.

#### *Section 493.1219 Standard; Remedial Actions*

We are reorganizing this section to correspond to the sequence of laboratory testing and reporting of results.

We are incorporating the contents of paragraph (b) into paragraph (c), which is being revised to allow the laboratory to establish and document a plan of action when it cannot report patient test results within its established time frames. It allows the laboratory, based on the urgency of the patient test(s) requested, to determine whether to notify the appropriate individual of the delay in testing. We are moving the requirement located at proposed paragraph (e), which required a laboratory to have remedial action policies and procedures when proficiency test results are unacceptable or unsatisfactory, to Subpart P, Quality Assurance. The requirement for the laboratory to evaluate for accuracy and reliability all patient test results obtained in an unacceptable test run or since the last acceptable test run, and take remedial action as necessary, is being revised for clarity and moved from Subpart P, Quality Assurance, to this section.

#### *Section 493.1221 Standard; Quality Control Records*

We are deleting the requirement for the laboratory to maintain records of each step in the processing and testing of quality control samples. We are deleting the reference to maintaining records reflecting that control samples were tested in the same manner as patient specimens since this requirement is already included in § 493.1218(c).

#### *Section 493.1223 Quality Control—Specialty and Subspecialties for Test of Moderate and High Complexity*

We are adding other options for quality control procedures. We are adding that effective September 1, 1994, a laboratory that performs tests of moderate or high complexity, as applicable, will be in compliance with this section if it meets quality control requirements specified in this subpart or follows manufacturer's instructions when using products (instruments, kits, or test systems) cleared by the FDA as meeting the CLIA requirements for general quality control and, as applicable, specialty and subspecialty quality control. We are adding the requirement that the laboratory document all quality control activities. This requirement was formerly located at § 493.1221 and has been transferred to all standard requirements and, where applicable, to condition requirements. We are requiring the laboratory to establish and follow "written" policies and procedures for an acceptable quality control program.

#### *Section 493.1227 Bacteriology*

We are adding the requirement for beta-lactamase testing to be checked each day of use for positive and negative reactivity.

We are revising the requirement for checking XV discs or strips to require that the XV discs or strips be checked each week of use with only a positive control organism.

#### *Section 493.1229 Mycobacteriology*

We are changing the frequency for testing quality control specimens for fluorochrome acid-fast stain from each day of use to each week of use. We are revising this section to require the use of a strain of *Mycobacterium tuberculosis* which is susceptible to all antimycobacterial agents each week antimycobacterial susceptibility testing is performed.

#### *Section 493.1231 Mycology*

We are adding a requirement that reagents used with biochemical tests and other test procedures be checked each week of use with a positive control organism.

#### *Section 493.1233 Parasitology*

We are clarifying that the ocular micrometer be calibrated prior to its use.

#### *Section 493.1235 Virology*

We are clarifying the requirement that a laboratory must "simultaneously culture" uninoculated cells or cell substrate controls as a negative control to detect erroneous results.

#### *Section 493.1239 Syphilis Serology*

We are deleting the reference to Appendix C of the State Operations Manual (HCFA Pub. 7) because the items referenced are not applicable to syphilis serology. We are clarifying that controls which evaluate all phases of the test system must be used to assure reactivity and uniform dosages. For clarification, we are stating that the laboratory may not report test results unless the predetermined reactivity pattern "of the controls" is observed.

#### *Section 493.1241 General Immunology*

We are clarifying that controls which evaluate all phases of the test system must be used to ensure reactivity and uniform dosages. For clarification, we are adding that the laboratory may not report test results unless the predetermined reactivity pattern "of the controls" is observed.

#### *Section 493.1245 Routine Chemistry*

We are revising this section, for blood gas analyses, to allow laboratories to

use the manufacturer's specifications for calibration. We are specifying that one sample of control material be used each eight hours of testing.

We are adding that a combination of calibration and control materials, which include both low and high values, be used each day of testing.

For clarification, we are adding that "one sample of a calibration material" or control be included each time patients are tested unless automated instrumentation verifies calibration.

#### *Section 493.1249 Toxicology*

We are clarifying the requirement by using the words "calibration material" instead of "calibrator" or "standard" because in many instances a secondary reference material is used.

We are modifying the requirement that a calibration material contain a representative of each drug "group," instead of each drug, since calibration materials are available which detect the major drug groups being tested for abuse.

#### **§ 493.1253 Hematology**

We are revising this section to include the use of controls with automated differential counters. The words "automated" hematology "testing systems" are used to clarify this requirement.

We are adding the requirement that manual cell counts, using a hemocytometer, must be tested in duplicate. We are adding, for clarity, the words "automated" coagulation "testing systems."

We are revising this section, for manual coagulation testing, to require two levels of controls each time there is a change of reagent.

#### *Section 493.1257 Cytology*

- We are clarifying that slide preparations must be stained with a Papanicolaou or modified Papanicolaou stain and have given laboratories flexibility in establishing procedures that prevent specimen cross-contamination.

- We are adding that all cytology slide preparations must be evaluated on the laboratory premises.

- We are deleting the workload limit on unevaluated slides and have established one maximum of 100 slides per 24 hour period.

- We are specifying that the limit of 100 slides is not a performance target for each individual but an absolute maximum limit. The technical supervisor must establish the actual workload limit for each individual and this limit must be reassessed and documented at least

every six months, rather than monthly, as proposed.

- We are specifying that the maximum of 100 slides can be read in no less than an 8 hour workday, rather than 6 hours, as proposed. In accordance with this change, the formula for prorating slides is now based on the time spent reading slides for both full-time and part-time employees.

- We are adding a provision for establishment of workload limits for individuals examining gynecologic slides by nonautomated technique that are prepared using automated, semi-automated or other liquid-based preparatory methods. Each slide prepared by these methods that results in cell dispersion over one-half or less of the total available slide area counts as one-half slide for purposes of workload calculation.

- We are adding a requirement for the confirmation of all gynecologic smears interpreted as showing reactive or reparative changes or atypia of undetermined significance by a technical supervisor in cytology.

- We are specifying that for each patient with a current high grade intraepithelial lesion or worse moderate dysplasia or CIN-2 or above, the laboratory must review all normal or negative gynecologic specimens from the previous 2 years, or slides from the most recent 2 specimens, whichever is less. If significant discrepancies are detected in this retrospective slide review between previously reported results and current evaluations that would affect patient care, the laboratory must notify the patient's physician and issue amended reports.

- We are retaining the requirement for gynecologic cytology/histology correlations, but are deleting the requirement for laboratories to obtain histology results from the State health departments. These comparisons are to be done only if the histopathology reports are available in the laboratory. In conjunction with this modification, we are deleting the requirement for reporting premalignant and malignant gynecologic cytology results to the State health department as well as biopsy-confirmed cases of cervical cancer as was required under the histopathology quality control section.

We are deleting specific requirements for the laboratory report and specifying that the laboratory report all results using narrative, descriptive nomenclature. We are not requiring use of The Bethesda System for gynecologic results.

We are changing the slide retention requirement for malignant and premalignant slides to 5 years. The

requirement now states that all slides must be retained for 5 years. We are modifying the requirement for loaning slide preparations to PT programs to allow for slide donation to programs regardless of their approval status and to require that written acknowledgement of the receipt of slides by the PT program is maintained by the laboratory in lieu of slides if the slides are less than 5 years old, and therefore, still subject to the retention requirement.

#### *Section 493.1259 Histopathology*

We are revising this section to require that remnants of tissue specimens are retained in a manner that assures their proper preservation. We are deleting the requirement that the laboratory report results of biopsy-confirmed cases of cervical cancer to the State health department.

#### *Section 493.1265 Histocompatibility*

We are revising the requirement that laboratories document their efforts to reasonably obtain serum specimens for all potential transplant recipients at initial typing, for periodic screening, pretransplantation crossmatch and following sensitizing events. We are revising this section to accommodate living donor transplants by including the performance of the mixed lymphocyte culture test.

We are revising the requirement to require a laboratory to verify the efficacy of immunologic reagents used to remove contaminating cells during the isolation of lymphocytes.

We are modifying the requirement for laboratories performing histocompatibility testing for bone marrow transplantation and living transplants to meet all the requirements of this section, including the performance of mixed lymphocyte cultures. We are adding the alternative requirement to perform other augmented testing to evaluate class II compatibility to accommodate new technology emerging in this specialty of laboratory testing.

We are clarifying the requirement not to limit life-saving non-renal solid organ transplants prior to completion of the final crossmatch if records document the emergency basis for the transplant.

We are including antibody screening and crossmatching as exceptions for HLA typing for disease-associated studied and parentage testing.

We are revising the requirement that laboratories performing and reporting HIV reactivity testing on organ donors must meet the requirements at § 493.1241.

*Section 493.1267 Clinical Cytogenetics*

We are adding the words "accurate and reliable" in clarifying the procedures for patient identification.

*Section 493.1273 Immunohematological Collection, Processing, Dating Periods, Labeling and Distribution of Blood and Blood Products*

We are clarifying that the testing laboratory must meet the applicable requirements of part 493. We are adding the requirement that policies be available, followed, and documented to assure positive identification of the blood product recipient.

*Section 493.1275 Blood and Blood Products Storage Facilities*

We are adding the words "Blood products" to the section title in order to include proper storage for blood products.

We are requiring that an audible alarm system monitor proper blood and blood product storage temperature over a 24 hour period.

We are requiring that inspections of the alarm system be documented.

We are requiring that blood storage facilities document that storage conditions are appropriate.

*Section 493.1283 Retention of Samples of Transfused Blood*

We are adding the word "samples" to the paragraph title for clarity.

*Section 493.1285 Investigation of Transfusion Reactions*

We are revising the requirement that the facility must investigate all transfusion reactions occurring in all facilities for which it has investigational responsibility.

*Subpart M—Personnel Standards*

## Summary of the Proposed Rule

In accordance with CLIA, the proposed rule was designed to establish uniform personnel requirements based on the complexity of testing performed. The proposed personnel standards in §§ 493.1401–493.1445, proposed as subpart M, were site neutral and were not to be applicable to laboratories possessing a certificate of waiver. The proposed rule specified requirements for laboratories that perform Level I or Level II testing, or both. Specifically, the personnel requirements contained in the proposed rule were the following:

- For laboratories performing less complex Level I tests, we proposed that the laboratory director be a physician with four years of laboratory training and experience, have a doctoral degree

and four years of laboratory training and experience or be currently qualified under Federal regulations. We proposed that the director be qualified to serve as the technical and general supervisor, or the director could delegate the functions of the general supervisor to an individual qualified as a general supervisor of Level II testing. Since Level I tests were less complex, we proposed that the individual performing the testing be a high school graduate or equivalent, as long as the director provided assurance that the individual had appropriate training commensurate with the testing performed. In addition, we proposed that the director be responsible for assuring that testing personnel were evaluated for competency on an ongoing basis.

- For laboratories performing Level II testing, we proposed that the director requirements be essentially the same as for Level I testing. The proposed education, training, and experience requirements to qualify as a director, technical supervisor, general supervisor, technologist, technician, or cytotechnologist for laboratories performing Level II tests were based on the current personnel requirements for independent laboratories.

Responsibilities were specified for the director, technical supervisor, general supervisor, technologist, technician, and cytotechnologist. We proposed that the director be responsible for assuring that testing personnel had appropriate training and were evaluated for competency on an ongoing basis. We proposed that qualified supervisors monitor performance of testing personnel through direct observation of the testing personnel's performance. We proposed that a general supervisor be required to be on the premises during all hours of testing in laboratories performing Level II tests. However, we proposed to reduce the number of years of experience required for a general supervisor from six to three years.

- Since Level II test procedures were more complex, we proposed to require specific education, training, and experience credentials. The qualification requirements for individuals performing Level II testing were differentiated based on the proposed proficiency testing specialty/subspecialty categories. In general, we proposed that technicians with specific specialty/subspecialty training and experience were qualified to perform the majority of Level II laboratory tests. We proposed that tests not currently included in the proficiency testing specialty/subspecialty categories be performed by a technician with one year of experience in the subspecialty category or by a

technologist until the tests had been categorized through a formal review process. In cytology, microbiology, and immunohematology, in which testing involves independent judgment or when erroneous results are critical to patient health and safety, we proposed personnel qualified as cytotechnologists and technologists, respectively. The proposed rule contained current cytotechnologist qualification requirements but solicited comments on three options for qualifying individuals who did not meet the proposed requirements for cytotechnologists. The options we proposed were: Option 1, extend the July 1, 1989 period for qualifying individuals under the "grandfather" provision located at appendix E; Option 2, recognize an accrediting agency's credentials; and Option 3, administer an examination to qualify cytotechnologists.

The proposed rule acknowledged the paucity of scientific data correlating education and experience qualifications with test performance and asked for recommendations to establish appropriate, reasonable and cost-effective personnel requirements which assure quality testing.

## Comments and Responses

*General summary of comments on proposed personnel requirements.*

Approximately 23,200 comments were received in response to the proposed personnel requirements. The majority of the commenters were opposed to the proposed provisions, while a small percentage of the commenters expressed support for the proposed requirements. About 28 percent of the comments received demonstrated that the commenters had misinterpreted the proposed requirements and almost 25 percent of the commenters offered alternative suggestions to the proposed personnel regulations.

Of the comments received, physicians provided about 42 percent, technicians and technologists submitted approximately 11 percent, respiratory care practitioners provided about 25 percent, and the remaining comments on personnel were provided by a variety of health care professionals, organizations and groups. The following is a summary of these comments.

*Comment:* Approximately 2,450 commenters provided general comments that were nonspecific and not related to a particular section. Of these comments, nearly 60 percent generally were opposed, 30 percent offered alternative suggestions and the remainder either misinterpreted or offered some support

for the proposed personnel requirements.

A number of medical technologists commented that education, training and experience qualifications of testing personnel represent the single most important factor in quality laboratory testing. On the other hand, several manufacturers contended that with the advances in instrumentation and technology, pathologists and medical technologists are not needed to operate a laboratory.

Many commenters expressed concern about the job security of those currently employed laboratory workers who would not have the education necessary to meet the proposed requirements. Many commenters recommended that the final rule contain a "grandfather" provision to qualify all currently employed laboratory personnel.

Some commenters expressed the view that the proposed personnel requirements should be uniform for all levels of testing in all settings ranging from a large hospital laboratory to a small physician office laboratory performing waiver tests. However, a large number of commenters expressed the view that the proposed personnel requirements, if finalized, would limit patient access to laboratory services, since only a few facilities will have personnel with the qualifications required for certification.

Numerous commenters stated that there is an insufficient number of technologists to meet the requirements and facilities will experience difficulty in recruiting technologists and will be in competition for limited technologist resources. Some commenters from rural areas suggested that the personnel standards be waived in underserved or rural areas if a laboratory can document that "good faith" efforts were made to acquire and retain qualified laboratory personnel.

A large number of commenters suggested using the current Medicare hospital requirements to require that the director, a physician or individual with a doctoral degree, assume responsibility for the overall competency and supervision of the staff, and not specify qualification requirements for testing personnel. Some commenters recommended modifying the proposed personnel requirements for laboratories performing the most complex tests to allow a physician to serve as the laboratory director and technical supervisor of his or her own laboratory, and require no detailed personnel standards for other laboratory personnel.

A few commenters suggested maintaining the proposed requirements

for director of a laboratory performing Level I testing but eliminating the qualification requirements for technical and general supervisor and for testing personnel. Some commenters recommended establishing more flexible personnel requirements until the shortage of qualified laboratory personnel is alleviated with some suggesting that individuals be allowed to qualify through "alternate routes" rather than requiring a specific degree or academic course work.

A small number of commenters suggested Federal funding be appropriated to support medical technology training programs to ensure the availability of qualified personnel to meet the proposed Federal requirements. A number of commenters suggested HHS recognize certification examinations administered by a variety of credentialing organizations (i.e., ASCP, ISCLT, NCA, AMT, etc.) to qualify individuals as technologists and technicians.

Numerous commenters recommended reinstatement of the HHS technologist proficiency examination formerly offered as an alternative mechanism to qualify individuals who are unable to meet the Federal requirements for education and training. Commenters suggested allowing individuals to qualify as technologists if they are able to pass any part of the examination, but test performance should be limited to those areas in which a passing grade was achieved. Many commenters recommended that all laboratory workers be required to pass a competency-based examination as well as participate in a specific amount of continuing education.

Numerous technologists of all registries decried the lack of a career ladder while those individuals with associate degrees believed that their training was ignored by the framers of the proposed regulation. A number of commenters objected to the absence of requirements for histotechnologists, medical laboratory technicians and supervisory histotechnologists. A group of commenters suggested that HHS complete the studies mandated in the CLIA statute prior to establishing laboratory personnel standards.

A number of commenters supported the proposed personnel requirements and recommended that they be retained in final regulations.

*Response:* In response to commenters concerns, we re-evaluated the proposed criteria for categorizing non-waived tests, the procedures included in the moderate and high complexity categories, and the personnel

requirements for laboratories performing non-waived tests. As previously discussed under § 493.10, the names of non-waived test categories were changed from Level I and Level II to moderate complexity and high complexity testing, respectively.

In establishing the personnel requirements, we complied with section 353(f)(1)(C) of the PHS Act, which requires HHS to establish personnel qualification standards which " \* \* \* take into consideration competency, training, experience, job performance, and education \* \* \*". In our opinion, many individuals currently working in laboratories, as a function of their employment, have gained valuable experience in testing operations. In most instances in this rule, we are acknowledging the value of this experience, by allowing those individuals, who do not meet the qualification requirements in these regulations, to continue their laboratory employment while acquiring the education or training necessary to meet the requirements. The net effect of the personnel standards will be to permit a preponderance of personnel presently working in laboratories to continue their employment while they are upgrading their credentials to meet the national standards for laboratory personnel specified in this rule.

In the future, we anticipate that college curricula and laboratory training programs will be geared to meet these education and training requirements and sufficient personnel will be available and qualified to perform the laboratory testing needed for patient diagnosis and treatment. Moreover, the personnel qualification requirements are being established in concert with other standards that contain additional safeguards to ensure quality laboratory services. We are requiring laboratory personnel at all levels to meet rigorous responsibility requirements. Testing personnel are required to demonstrate their testing skills prior to performing tests on patient specimens and thereafter on an ongoing basis to ensure their continued competency in patient testing. In addition, we are establishing other standards under proficiency testing, recordkeeping/patient test management, quality control and quality assurance that will serve as a mechanism for the laboratory to assess and evaluate its testing performance and personnel capabilities. Requirements in this rule will be imposed on a large number of laboratories never before subject to Federal regulation. These formerly unregulated laboratories in many cases

have not implemented internal or external programs to assess the quality of laboratory services provided by their laboratories and to monitor the testing capabilities of their laboratory employees.

We believe that these regulations will provide the framework to guide laboratories in the establishment of quality control practices that will result in improved laboratory testing for the nation's laboratories. We determined that for each personnel position specified in these regulations, the education and training or experience required are appropriate for the performance of tests of moderate and high complexity; however, these qualifications are intended to be the minimum standards. In many laboratories, individuals with higher qualifications may be needed to perform the functions that may be unique to their testing operations and necessary to comply with the responsibility requirements in this rule. In addition to the minimum personnel requirements contained in this rule pertaining to all laboratories, the regulations require the laboratory director to assure that the individuals working in his or her laboratory have the appropriate education, training or experience to perform the specific responsibilities assigned to the individual.

For those individuals currently employed in laboratories subject to Federal regulations, we determined that the records of these individuals, reflecting acceptable performance abilities, serve to demonstrate their competency in laboratory service activities. Therefore, under this rule we have established a provision to allow those individuals who qualified under the March 14, 1990, rule to continue to qualify under the requirements for laboratory director or general supervisor of high complexity testing as well as testing personnel for performance of high complexity testing. In addition, those individuals who qualified as a director under the March 14, 1990, rule will continue to qualify as a director of a laboratory performing tests of moderate complexity.

We agree with the majority of commenters that personnel standards for laboratories should be based on the complexity of the tests performed. As a result, we have separated non-waived testing into two categories describing test complexity and have linked the responsibilities and qualifications of personnel to these categories.

We agree that the current number and location of medical technologists would not permit staffing of all of the nation's laboratories with such individuals. We

also agree that rural areas, and even some urban areas, would have difficulty recruiting medical technologists to staff their facilities. Therefore, we have amended the personnel requirements to qualify individuals who are involved in providing health care and, in addition, perform laboratory services, provided they can meet the responsibilities associated with the testing performed. Such provisions should allow flexibility in selection of qualified individuals to fulfill the personnel requirements. We agree that the laboratory director has the responsibility of assuring the competency of the laboratory staff and have specifically designated this as one of the director's functions.

We agree that a physician who meets the training and experience requirements can serve as both the director and the technical supervisor in a laboratory performing tests of high complexity. However, in order to assure that all of the laboratory's test responsibilities are met, other laboratory staff must also meet the training and experience requirements specified for their positions.

We agree that the responsibilities of the general supervisor can be met by the laboratory director in a laboratory that performs only tests of moderate complexity. Therefore, we are not requiring a general supervisor for such laboratories. However, we have concluded that a technical consultant will be required for tests of moderate complexity, and that the laboratory director may function as the technical consultant provided he or she possesses the amount of training or experience required in the specific specialty and subspecialty for which service is offered.

We have established requirements which allow personnel from many diverse backgrounds to qualify to supervise and to perform laboratory testing. However, all personnel must be able to meet the responsibilities required by their position. We have recognized several professional credentialing organizations as a means of assuring that personnel meet standards of practice established by such groups.

Because of the many pathways that are open to individuals wishing to qualify, we have not proposed to reinstate the HHS exam as an alternative to qualify individuals. Assuring staff competency has been included as one of the laboratory director's responsibilities. Therefore, we are not proposing to provide competency exams.

Continuing education and training opportunities are offered by many

manufacturers of laboratory products and by professional societies as well as by the Federal Government. Laboratory personnel who take advantage of these opportunities will be prepared to climb a career ladder by taking advantage of the expanding universe of laboratory testing.

Since testing in histopathology consists of the interpretation of tissue specimens which must be performed by a physician qualified in histopathology, we have not proposed specific personnel requirements for histotechnologists.

#### Laboratories Performing Level I (Moderate Complexity) Testing

##### *Sections 493.1403-493.1407 Laboratory Director, Qualifications and Responsibilities*

Approximately 2,700 comments were received concerning the qualifications and responsibilities of the director of a laboratory performing Level I tests. Over half of the commenters mistakenly interpreted the proposed rule to require that a pathologist serve as director of a laboratory performing Level I tests. Approximately 8 percent of the commenters supported the proposed director requirements, while 20 percent expressed opposition to these provisions and 6 percent offered alternative suggestions. Around 88 percent of the comments were submitted by physicians operating their own office laboratories.

*Comment:* A number of commenters objected to allowing physicians to qualify as laboratory directors since they lack formal laboratory training and/or experience. Commenters noted that physicians generally do not receive clinical laboratory training in medical school or during their internship or residency. Commenters were particularly concerned about physicians serving as laboratory directors, since the proposed rule did not specify education and experience qualification requirements for personnel performing Level I testing.

Several commenters were opposed to the "grandfather" provision that would permit a person, who qualified as a laboratory director prior to 1971, to serve as a director of a laboratory performing Level I tests. Some commenters agreed that an individual, who is qualified under State law to direct a laboratory in the State in which the laboratory is located, should be qualified as a director of a laboratory performing Level I services.

A number of health professionals, including registered nurses, nurse practitioners, physician assistants, podiatrists, naturopathic physicians and

chiropractors, suggested that they be qualified to direct Level I laboratory services if they are authorized to perform this function under State law. Alternatively, many commenters suggested that the regulations permit individuals with a bachelor's or a master's degree and appropriate experience to serve as the director of Level I laboratory services.

Commenters representing public health laboratories expressed concern about employing personnel with the credentials specified in the proposed rule to serve as directors of laboratories performing Level I testing, since hiring such individuals would present a severe economic hardship to their local health departments.

A few physicians requested that the regulations be expanded to include certification by other boards. Some commenters indicated that the proposed personnel standards for Level I testing personnel were not stringent enough, while the requirements for director and supervisor were overly stringent and place an unnecessary burden on laboratories in rural areas.

Several commenters recommended that the regulations be revised to differentiate directorship on the basis of services performed. One suggestion was to define "laboratory director" as the director of a laboratory performing only single specialty or subspecialty services whereas "director of laboratories" would be the director of a laboratory performing tests in multiple specialty/subspecialty areas. The commenters indicated that different credentials should be required depending on the types of services performed, with a physician trained in anatomical or clinical pathology being the most qualified to serve as director of a multi-specialty laboratory. Other commenters suggested the regulations distinguish between administrative director and medical director.

Several commenters objected to the proposed requirement in paragraph (a)(3) of § 493.1407, Standard; Laboratory director responsibilities, requiring the establishment of a process for reviewing test results prior to issuing patient reports. Commenters representing physician group practices objected to a laboratory director reviewing test results of other physicians' patients.

Many commenters disagreed with the requirement for all abnormal Level I screening tests for previously undiagnosed conditions to be referred to an appropriately certified laboratory for verification by a more specific Level II method citing increased costs and delay in patient diagnosis and treatment.

One commenter disagreed with the requirement for the laboratory director to assure that personnel performing and reporting tests have appropriate training. The commenter suggested that persons performing Level I testing meet higher personnel standards promulgated by the American Society of Medical Technologists.

*Response:* We agree with the commenters who suggested that the director qualification requirements be more flexible and have expanded the requirements in § 493.1405, Standard; Laboratory director qualifications, to permit individuals with a bachelor's or master's degree to serve as directors of laboratories performing moderate complexity testing provided they have laboratory training or work experience and, in addition, have supervisory experience. Also, since moderate complexity testing is more extensive than testing proposed for Level I, we have added a requirement for physicians to have laboratory training or experience in order to qualify as a laboratory director. This training or experience can be gained in one of three ways. Physicians with at least one year of experience directing or supervising non-waived testing can qualify and this experience may be gained while directing or supervising their laboratories, while simultaneously engaged in providing diagnosis, treatment, or other services to patients. Physicians who do not have this experience must have laboratory training which can be gained either during residency training or by completing at least 20 hours of continuing medical education in laboratory practice commensurate with the responsibilities of the laboratory director as detailed in § 493.1407. This training should include principles and theory of laboratory practice and hands on laboratory testing. Those physicians having laboratory training and experience acquired during their residency training programs for specialty certification will be qualified under these regulations to direct a laboratory performing moderate complexity testing. For example, a board certified hematologist or hematologist/oncologist would meet the training or experience requirements to direct a laboratory performing moderate complexity testing. Physicians have one year from February 28, 1992 to obtain the continuing education credit hours and during that year can function as a laboratory director.

We are retaining the qualification requirement for individuals with a doctorate degree who are certified by a national accrediting board acceptable to

HHS to qualify and, to provide consistency with the laboratory director qualifications in high complexity testing, we are adding the American Board of Medical Laboratory Immunology. We are modifying the experience requirement for individuals with a doctorate degree who are not board-certified to have one year of experience directing or supervising non-waived testing.

Individuals with a master's degree must have at least one year of laboratory training or experience and at least one year of experience as a laboratory supervisor. Individuals with a bachelor's degree must have two years of laboratory training or experience and two years of supervisory experience. These revisions permit medical technologists and other health care professionals (i.e. nurses and physician assistants) to serve as directors of moderate complexity testing provided they have the requisite degree in science and can meet the laboratory training, experience and supervisory requirements. In addition, individuals, who either were qualified or could have been qualified as a laboratory director under previous Federal regulations, will be qualified under this rule. Also, we will allow those individuals to qualify as director if, on the date of publication of these regulations, they are qualified under State law as a laboratory director. This is a "one-time" recognition of those individuals who have qualified under State law as a director. In this rule, we are not authorizing states to continue to set standards that in the future will automatically qualify individuals under State law to function as director when those cannot meet the director qualifications contained in this rule.

In our view, these requirements are the minimum qualifications necessary to perform the functions of laboratory director. We expect laboratories to evaluate their own testing activities to determine whether additional knowledge, training or skills are required to fulfill the director responsibilities.

The laboratory director responsibilities in § 493.1407 are being revised to more accurately define the duties of the director and to clearly specify that the director has overall responsibility for all laboratory operations and testing personnel. The director may delegate some of his or her responsibilities but retains the responsibility for ensuring that all of the director responsibilities are properly performed. For consistency with the director requirements for high complexity testing, we are limiting the

number of laboratories that an individual can direct to five laboratories. Since we did not propose to place a limit on the number of laboratories that an individual can direct, we are inviting comments on this requirement.

We have eliminated the requirement for abnormal Level I screening tests for previously undiagnosed conditions to be confirmed by a more specific Level II method. Also, we deleted the requirement for the director to establish a process for review of patient test results prior to reporting.

*Sections 493.1408 Standard; Technical Supervisor (Sections 493.1409-493.1413 Technical Consultant, Qualifications and Responsibilities)*

A total of 168 comments were received on the proposed requirements for technical supervisor of a laboratory performing Level I testing, proposed as § 493.1408. Approximately 60 percent of the commenters were opposed to these proposed provisions, nearly 30 percent of the commenters offered alternative suggestions and the balance of the commenters either misinterpreted or were in support of the proposed requirements for technical supervisor. Most of the comments were provided by technologists who either disagreed with the proposed requirements or offered alternative suggestions.

*Comments:* A number of commenters mistakenly interpreted the proposed regulations to require a pathologist to serve as technical supervisor of a laboratory performing Level I testing. Several commenters were of the opinion that physicians who direct their own laboratories performing Level I testing on their own patients should be exempt from personnel requirements for technical supervision. Several commenters representing public health laboratories disagreed with the requirement that an M.D. or Ph.D. serve as director and technical supervisor since hiring such individuals would be cost prohibitive for the volume and complexity of procedures performed in these laboratories. Another commenter recommended that the current proposed requirements for director and supervisors be waived for public health facilities.

Numerous commenters indicated that a consultant medical technologist would be qualified and capable to function as the technical supervisor of a laboratory performing Level I testing. One commenter recommended expanding the qualification requirements for technical supervisor to permit individuals with two years of general laboratory training and experience to qualify. Other

suggestions for technical supervisor qualifications included: allowing individuals to qualify with a master's or higher degree in a laboratory related field of study or laboratory management, or qualifying those individuals having certification as a clinical laboratory director by a recognized certifying agency plus two years of general laboratory training and experience. One commenter was opposed to allowing individuals who were approved as laboratory directors prior to 1970 (i.e., grandfathered) to be technical supervisors.

One commenter suggested requiring technical and general supervisors to be available by phone whenever Level I testing is performed. One commenter requested that proposed § 493.1408(c)(1) include a definition of the phrase "regular in-service training and education appropriate for the type and complexity of the laboratory services offered." A commenter questioned the procedures to be used for evaluating the performance of the testing personnel under § 493.1408(c)(2) and recommended that the technical supervisor annually certify the competency of those individuals performing Level I testing. Another commenter expressed concerns about the recordkeeping required to document the competency assessment of each employee's testing of previously assayed samples. Finally, a commenter expressed concerns about the cost of retesting previously assayed samples and suggested deleting this requirement because of the increased proficiency testing standards.

A number of commenters were opposed to the requirement in proposed § 493.1408(c)(3) for the technical supervisor to evaluate the performance of individuals performing tests at least quarterly during the first year the individual tests patient specimens and thereafter semiannually. They considered this requirement to be excessive and recommended evaluation and documentation of employee performance initially during orientation training followed by annual evaluation.

*Response:* The regulations for technical supervisor qualifications and responsibilities proposed at § 493.1408 have been revised and recodified. We have changed the name from technical supervisor to technical consultant to more closely reflect the functions related to moderate complexity testing that may be provided by one or more individuals on a consultative basis. We created a condition level requirement at § 493.1409, Condition: Laboratories performing moderate complexity testing; technical consultant, to encompass the qualifications and responsibilities of the

technical consultant. At § 493.1411, Standard; Technical consultant qualifications, we have defined the technical consultant qualification requirements, and we created a standard at § 493.1413, Standard; Technical consultant responsibilities, to contain the specific responsibilities of the technical consultant. Specifically, the regulations authorize pathologists to function as the technical consultant of any moderate complexity testing service. Physicians may function as the technical consultant in any area in which the physician has at least one year of laboratory training or experience. The specialty/subspecialty training or experience may be acquired simultaneously in more than one specialty or subspecialty. For example, those physicians who have obtained laboratory training or experience during their medical residency training programs will be able to qualify as a technical consultant of any specialty or subspecialty area related to their residency training or experience. In other words, a board certified hematologist or hematologist/oncologist will be qualified as a technical consultant of all examinations and test procedures included in the specialty of hematology.

Individuals with a doctoral or master's degree in a chemical, biological or clinical laboratory science or medical technology and one year of laboratory training or experience may serve as the technical consultant if the training or experience was in the specialty or subspecialty area of moderate complexity testing performed by the laboratory. In addition, individuals with a bachelor's degree in the sciences may serve as technical consultant provided they have at least two years of laboratory training or experience in the specialty and subspecialty services of moderate complexity testing performed by the laboratory. The training or experience in more than one specialty or subspecialty may be acquired concurrently as noted in the regulation. These changes are somewhat similar to the changes made in the qualification requirements for director of a laboratory performing moderate complexity testing; therefore, many medical technologists and other health care professionals will be able to meet the qualifications necessary to function as technical consultants of laboratories performing moderate complexity testing. We believe that the qualifications specified for technical consultant will ensure the provision of technical oversight needed to monitor the laboratory's testing activities.

The proposed technical supervisor responsibility requirements were revised to require the technical consultant to be accessible to the laboratory to provide on-site or telephone consultation on an as needed basis. The competency evaluation of testing personnel has been revised to require semiannual evaluations the first year the individual tests patient specimens, and thereafter, annual evaluations are required unless there are changes in test instrumentation or methodology, in which case performance must be evaluated initially prior to reporting patient results. The use of proficiency testing samples to evaluate employee test performance was proposed as an option, not a specific requirement. Since it is essential to evaluate testing personnel performance based on the ability to test specimens, we have retained the requirement as proposed and allow the laboratories the flexibility of deciding which specimens to use in the evaluation. Laboratories must maintain records to document that the evaluations have been performed.

*Section 493.1409 Standard; General Supervisor*

A total of 208 comments were received concerning the qualifications and responsibilities for general supervisor of a laboratory performing Level I tests that were proposed as § 493.1409. Slightly over 51 percent of the commenters were opposed to the proposed requirements, nearly 35 percent of the commenters offered alternative suggestions and 13 percent of the commenters either supported or misinterpreted the proposed requirements for general supervisor.

*Comment:* Several commenters suggested deleting the general supervisor requirement for a laboratory performing Level I testing, while other commenters did not see the need for both a technical and general supervisor. Several commenters stated that the proposed qualification requirements for general supervisor were too stringent for Level I screening procedures, and registered nurses should be permitted to supervise Level I test performance.

A number of commenters from rural health clinics suggested waiving the requirement for a general supervisor if the facility performs only Level I tests and meets the Medicare requirements for rural health clinics located at 42 CFR part 491. Another commenter proposed that nurse practitioners be allowed to supervise rural health clinics when a physician is not readily available. One commenter objected to allowing a person who qualified under State law as

a director to qualify as a general supervisor of a laboratory performing Level I tests.

A few commenters agreed with the requirement that a technologist have three years of experience in order to qualify as a general supervisor of a laboratory performing Level I testing, while a small number of commenters objected to lowering the experience requirement from 6 to 3 years. About 20 commenters suggested that technicians be permitted to serve as general supervisors due to the shortage of registered medical technologists. Several commenters expressed concern about the difficulty in recruiting medical technologists willing to supervise Level I testing.

Several commenters expressed concern about the national shortage of qualified laboratory personnel, especially in rural areas. A number of commenters were concerned that there would not be enough qualified general supervisors to provide supervision during all hours that a laboratory would perform Level I testing. Several commenters were opposed to the requirement that a supervisor be on-site during all hours of testing in a laboratory performing Level I testing. Several commenters suggested requiring a consultant medical technologist to fulfill the general supervisor requirements. A commenter suggested that non-accredited hospitals performing Level I testing be required to have a general supervisor on the premises only during one shift and, on the other shifts, the general supervisor could be available by phone.

Several commenters requested a definition of the term "accessible" relative to the general supervisors' location and availability. Other commenters objected to the requirement for on-site supervision. Specifically the commenters disagreed with requiring individuals qualified under paragraphs (b)(1), (2), (3), (4), or (6) of § 493.1427, Standard; General supervision, to be on-site while allowing the director functioning as the general supervisor to be accessible to the staff rather than on-site. Some commenters recommended that a physician not be permitted to serve as supervisor of his own office laboratory since a physician would not be readily available to provide general supervision to the staff. One commenter suggested that a physician director not be permitted to serve as both technical and general supervisor. Other commenters recommended that persons qualifying as general supervisor under proposed § 493.1405, Standard; Laboratory director qualifications,

should have at least two years of full-time general laboratory training and experience.

Several commenters suggested that in laboratories performing Level I testing, if the director is not always on-site, monthly consultation by an individual meeting the qualifications of a general supervisor should be required. A few commenters suggested revising the general supervisor requirements to specify "experience at the management level".

*Response:* We agree with the commenters that the responsibilities that were proposed for the technical and general supervisor overlap in a laboratory performing moderate complexity testing. To reduce confusion and provide clarity to the personnel standards, we have eliminated the requirement for general supervision of moderate complexity testing. The duties proposed for the general supervisor have been incorporated into the revisions made in the responsibility requirements for the laboratory director and technical consultant.

*(Sections 493.1415–493.1419 Clinical Consultant, Qualifications and Responsibilities)*

*Comment:* A number of commenters recommended that for laboratories performing Level II testing, requirements should be established for an administrative director and a medical director/advisor. The commenters expressed the view that a medical technologist is qualified to handle the administrative responsibilities while a physician should serve as a medical director/advisor to evaluate test results for medical intervention or decision-making concerning patient diagnosis and treatment.

*Response:* We agree with the commenters. However, we believe that clinical consultation is needed for moderate as well as high complexity testing to ensure proper oversight of the total testing process from test selection through analysis and test result reporting and interpretation. Therefore, we are including provisions requiring each laboratory performing moderate complexity testing to have access to clinical consultant services. At § 493.1415, Condition: Laboratories performing moderate complexity testing; clinical consultant, we are creating a condition for clinical consultation to encompass the qualifications and responsibilities required for the clinical consultant. Revised § 493.1417, Standard; Clinical consultant qualifications, contains the specific qualifications required for the clinical

consultant. The clinical consultant responsibilities are defined at § 493.1419, Standard; Clinical consultant responsibilities. The addition of these requirements should enable the laboratory to provide to its' clients clinical consultation whenever needed for the utilization of specific laboratory test results in the diagnosis and treatment of patients and to assist in the interpretation of particular test results with individual patient conditions.

*Sections 493.1410–493.1411 Testing Personnel (Sections 493.1421–493.1425 Testing Personnel, Qualifications and Responsibilities)*

Approximately 450 comments were received in response to the proposed requirements for testing personnel (which were proposed at §§ 493.1410–493.1411). About 45 percent of the commenters expressed opposition to these sections, with some indicating that the requirements were too stringent and others stating that the proposed requirements were not stringent enough. Around 25 percent of the commenters misinterpreted the requirements, 23 percent of the commenters offered alternative suggestions and 8 percent of the commenters agreed with the proposed requirements for testing personnel.

*Comment:* Although a number of commenters agreed that the proposed standards for personnel performing Level I testing were appropriate for the limited testing categorized as Level I, many commenters strongly advised HHS to modify the proposed qualifications for personnel performing Level I testing to require specific laboratory training. The commenters stated that studies show there is a correlation between the qualifications of testing personnel and the quality of the results. Commenters were concerned that the minimal personnel qualification requirements proposed would result in laboratory errors and decreased quality of testing affecting patient diagnosis and treatment. In addition, some commenters suggested that if a physician functions as the director, technical supervisor and general supervisor of Level I testing, the individuals performing testing should meet the qualifications specified in § 493.1441 for Level II test performance. On the other hand, several commenters suggested that regulations for physician office laboratories should permit lesser trained personnel to perform Level I testing.

A number of commenters mistakenly interpreted the proposed regulations to require a registered technician to perform of Level I testing. Other

commenters suggested that only medical laboratory technicians or clinical laboratory assistants be allowed to perform Level I testing. These commenters stated that high school graduates, or equivalent, do not have the background and training necessary to perform Level I testing. On the other hand, a few commenters were opposed to any proposed regulations that would require laboratory technicians for test performance. The commenters cited the personnel shortage and the expense associated with hiring personnel with these qualifications. The commenters expressed the opinion that the quality of the testing could be monitored by proficiency testing that is reviewed by the laboratory director.

Several commenters suggested that HHS establish uniform standards for testing personnel for all laboratories performing non-waived tests. Other commenters were concerned that the regulations were unclear about whether physicians and nurses were qualified to perform Level I tests. One commenter from a rural health clinic suggested that the requirements for testing personnel be eliminated and these clinics be allowed to continue to provide laboratory services if they meet the rural health clinic requirements located at 42 CFR part 491.

A few commenters proposed that standards for personnel performing Level I testing focus on performance rather than on education, with several commenters suggesting that HHS develop a competency-based examination for all personnel performing Level I testing. Several commenters suggested that the Level I testing personnel requirements permit high school graduates with formal training in laboratory testing to perform testing only when a supervisor is on-site. Alternatively, numerous commenters suggested that each laboratory performing Level I testing be required to have a consultant medical technologist to provide orientation and training to employees, assist in the selection of test methodology and development of quality control and quality assurance programs, and monitor testing personnel performance. Other commenters noted that the proposed personnel requirements for Level I test performance are not appropriate for some of the procedures, specifically gram stain interpretations, microscopic examinations, and semen analysis. Several commenters recommended expanding personnel requirements to create a Level IA to include higher personnel standards for performance of certain tests.

Several commenters suggested that if Level I testing is performed by a high school graduate, the high school curriculum should include biology and chemistry courses. Other commenters questioned the necessity of requiring a high school diploma, and suggested qualifications be based on individual competency. Some commenters suggested that there be a "grandfather" provision in this section to allow persons without a high school diploma to perform tests. These commenters noted that the proposed requirements for technician under Level II test performance contained a "grandfather" provision which was formerly used to qualify individuals without a high school diploma and asked that a similar "grandfather" provision be included for Level I testing.

Several commenters suggested adding to the training requirements for testing personnel language that would require individuals to have an "understanding of the basic principles surrounding each test and be able to identify problems, using preset criteria" or "understanding of reagent preparation, stability and storage and factors that influence test results, and test system stability".

*Response:* In response to comments, the proposed regulations for testing personnel were modified and recodified. At § 493.1421, Condition: Laboratories performing moderate complexity testing; testing personnel, we are creating a condition level requirement to encompass testing personnel qualifications and responsibilities. Testing personnel qualification requirements are now located at § 493.1423, Standard; Testing personnel qualifications. A new standard, Standard; Testing personnel responsibilities, has been created at § 493.1425 to contain the responsibility requirements for testing personnel. As previously discussed under § 493.20, the criteria for categorizing tests as moderate complexity were revised resulting in more uniform and appropriate test/methodology categorization. The criteria were closely analyzed for proper linkage with testing personnel requirements resulting in the following revisions to the proposed requirements.

Section 493.1423 was revised to clearly reflect that physicians and individuals who possess a doctoral, master's, bachelor's or associate degree in science would be qualified to perform moderate complexity testing. In addition, we have modified the requirements to ensure that any individual who has military training in laboratory procedures and is qualified

as a Medical Laboratory Specialist would be qualified to perform moderate complexity testing. We have retained the requirement for testing personnel to have a high school diploma, or an equivalent, to ensure that individuals have basic skills in reading and comprehension. We believe that the qualifications specified for testing personnel are appropriate for the performance of moderate complexity testing but are placing the responsibility on the laboratory director and consultant(s) for assessment of these individuals' competency and abilities specifically related to the types of testing performed. At § 493.1423, we have more clearly defined the training needed for high school graduate testing personnel, and in § 493.1425 we have established specific responsibilities for any individual performing testing.

#### Laboratories Performing Level II (High Complexity) Testing

##### *Sections 493.1413-493.1417 (Sections 493.1441-493.1445) Laboratory Director: Qualifications and Responsibilities*

Almost 7,000 commenters responded to the proposed qualification requirements for director of a laboratory performing Level II testing. Over half of the commenters misinterpreted the proposed requirements, about 26 percent of the commenters were opposed to the proposed requirements, 17 percent of the commenters offered alternate suggestions and nearly 2 percent of the commenters were in support of the proposed requirements for director of Level II testing.

Over 4,000 of the commenters mistakenly interpreted the proposed regulations to require a pathologist to serve as director of a laboratory performing Level II testing. These commenters noted the increased costs associated with employing such individuals and the shortage of pathologists available to serve as laboratory directors. Many of these commenters also assumed that the proposed rule required a pathologist to be present whenever Level II testing is performed. A small number of commenters suggested that the director requirements for laboratories performing Level II testing should be the same as the proposed requirements for director of Level I testing. Some commenters recommended that current Medicare hospital requirements be adopted as the qualifications required for director of Level II testing, in particular rural hospitals appeared to be in favor of employing either a consultant pathologist or a person with a doctoral

degree in a biomedical area to function as the director of Level II testing.

A number of commenters suggested that only physicians who have appropriate training in laboratory test methodology and technology be permitted to serve as directors of laboratories performing Level II testing. On the other hand, many commenters suggested that the proposed regulations be modified to allow physicians to serve as directors of office laboratories performing Level II testing, provided the laboratories perform tests only on the physicians' own patients. A number of physicians serving as directors of laboratories performing tests on their own patients, stated that current technology and instrumentation provides test results that are sufficiently accurate and reliable to preclude the need for specific qualification requirements for the director of Level II testing. Several of these commenters felt that approval to perform Level II testing should be based upon proficiency testing performance.

Many commenters noted that requiring a pathologist or individual with a doctoral degree to serve as director would result in a "figurehead" director, since these individuals were not necessarily trained or skilled in quality control, management or quality assurance, whereas medical technologists were capable of performing the management and administrative functions of the laboratory director. Some commenters felt that the laboratory director standards of Puerto Rico (i.e., medical technologists with 5 years of experience) should be adopted. Some commenters were opposed to allowing individuals to direct Level II testing if they met the "grandfather" provision in current Federal regulations, which previously permitted individuals to qualify as a director if they directed a laboratory prior to July 1, 1971. Conversely, a few commenters were in favor of retaining the "grandfather" provision, while numerous commenters stated that final regulations must contain a liberal "grandfather" clause to allow individuals currently serving as directors of Level II testing to continue to serve.

A few commenters stated that board eligibility was not sufficient, that directors should be required to pass the board examination. Other commenters suggested approving additional boards, such as the American Board of Forensic Toxicology and the American Board of Medical Laboratory Immunology. A large number of comments from physicians and other allied health

professionals suggested that board certification or speciality training should be acceptable to qualify individuals as directors of laboratories performing specific Level II tests. The professionals and the services they felt qualified to have performed in laboratories they direct included:

Dermatopathologists—mycology, histopathology  
 Mohs micrographic surgeons—histopathology  
 Rheumatologists—chemistry, serology  
 Allergists/immunologists—chemistry, serology  
 Endocrinologists—chemistry  
 Podiatrists—Level II testing  
 Naturopathic physicians—Level II testing  
 Ophthalmic pathologists—ophthalmic histopathology  
 Hematologists—hematology  
 Oncologists—chemistry, hematology  
 Pulmonary physicians and anesthesiologists—blood gasses  
 Urologists—chemistry, microbiology  
 Psychiatrists—Level II tests  
 Pediatricians—microbiology, serology, hematology  
 Psychiatrist—Level II testing  
 Physician with a master's degree in public health—all public health testing

Many comments were received from respiratory care practitioners, specifically pulmonary physicians or anesthesiologists, suggesting that they be qualified to serve as laboratory directors of Level II testing. As an alternate suggestion, they recommended recognizing their boards to qualify individuals as directors of blood gas laboratories. A few commenters stated that the proposed experience requirements needed to be more specific and recommended requiring that the director of Level II testing have three years of post-doctoral experience in all phases of clinical laboratory testing. Some commenters were concerned that the proposed rule established no limit on the number of laboratories performing Level II testing that an individual could direct.

*Response:* Qualification requirements for director of Level II testing, now high complexity, that were proposed in § 493.1415 are now located at § 493.1443, Standard; Laboratory director qualifications. We have retained the requirement for the director to be a pathologist, physician, or have a doctoral degree but are changing the training or experience required for physicians or individuals with doctoral degrees. Physicians are required to have at least one year of laboratory training during medical residency. This training should include principles and theory of laboratory practice and hands on laboratory testing. This medical residency laboratory training may be

acquired in conjunction with obtaining specialty certification. In other words, a board certified hematologist or hematologist/oncologist would meet the training or experience required to qualify as a director of a laboratory performing high complexity testing. In addition, physicians may qualify to direct a laboratory performing high complexity tests if they have two years of experience directing or supervising high complexity testing. Physicians may use the experience gained directing or supervising their own laboratories, or co-directing or sharing in the supervision of a group practice laboratory while simultaneously engaged in patient care, provided this experience is in high complexity testing. Physicians currently operating their own laboratories, who do not have one year of laboratory training or two years of experience directing or supervising high complexity testing on September 1, 1992, will not be qualified as a director. In order to perform high complexity testing, such physicians must obtain the services of an individual qualified under § 493.1443 until the requirement for laboratory training or experience is met.

We are retaining the requirement for individuals with a doctoral degree to be board-certified as a prerequisite to meet the director requirements. We have added the American Board of Medical Laboratory Immunology to the list of board recognized under the regulations because its certification requirements are similar to the American Board of Medical Microbiology. We did not include certification by the American Board of Forensic Toxicology because these regulations are applicable to clinical testing, not forensic procedures. For individuals with a doctoral degree, we are modifying the proposed four-year laboratory training or experience requirements to require that two of the four years include experience directing or supervising high complexity testing. We are also specifying that these individuals must obtain certification by an approved Board within two years after September 1, 1992. We have made a provision to allow those individuals who are qualified or could have qualified as director under the March 14, 1990 regulations, to qualify as director of high complexity testing. We are specifying that individuals will be qualified as laboratory directors, if on the publication date of these regulations, they previously qualified under Federal regulations as a laboratory director or are qualified under State law as a laboratory director. This is a "one-time" recognition of those individuals who have qualified under State law as a

director. In this rule, we are not authorizing states to continue to set standards that in the future will automatically qualify individuals under State law to function as director when those individuals cannot meet the director qualifications contained in this rule. These qualification requirements are consistent with current Federal regulations and we believe they are appropriate for the direction of laboratories performing the test procedures or examinations now categorized as high complexity tests.

The director responsibility requirements that were proposed in § 493.1417 are now located at § 493.1445, Standard; Laboratory director responsibilities. They are being revised to more accurately define the duties of the director of a laboratory performing high complexity testing. We are specifying that the director has overall responsibility for all laboratory operations and testing personnel. The director may delegate some of his or her responsibilities but retains the responsibility for ensuring that all of the director responsibilities are properly performed. In response to commenters concerns, we are limiting the number of laboratories that an individual can direct to five laboratories. Since we did not propose to place a limit on the number of laboratories that an individual can direct, we are inviting comments on this requirement.

*Sections 493.1419–493.1423 (Sections 493.1447–493.1451) Technical Supervisor, Qualifications and Responsibilities*

Approximately 1,250 comments were received on the proposed requirements for technical supervisor. Almost half of the commenters were opposed and a small percent of the commenters were in agreement, 40 percent offered alternative suggestions and about 10 percent of the commenters misinterpreted the proposed requirements for technical supervisor. Physicians provided 42 percent and dermatologists submitted 26 percent of the total comments received on these sections. A large number of physician commenters misunderstood the proposed requirements and mistakenly assumed that only pathologists or individuals having a PhD would be qualified to function as technical supervisors of their office laboratories performing Level II testing.

A number of commenters suggested that physicians be permitted to serve as technical supervisors of their own laboratories. Other commenters requested expanding the proposed technical supervisor requirements to

permit medical technologists to qualify for these positions based on either demonstrable expertise in a subspecialty or specialty of services or on their overall laboratory training and experience. In addition, commenters suggested that the criteria for qualifying technical supervisors be expanded to relieve current laboratory personnel shortages and include nurse practitioners or nurses having a master's degree or individuals with bachelor's degrees who are certified or eligible for certification in a particular specialty. A few commenters suggested allowing existing laboratory supervisors to qualify by passing an examination such as the examination formerly administered by HHS in the 1970s.

Several commenters objected to the proposed regulations citing the shortage of trained personnel available in rural areas and suggested eliminating the requirements for a technical supervisor. One commenter noted that under the proposed regulations, nearly 25 percent of the rural hospitals in his State would be unable to find qualified persons to provide technical supervision of chemistry and immunohematology services. A few commenters suggested substituting the current Medicare or Joint Commission accreditation requirements for hospital laboratory director for the proposed technical supervisor requirements.

Some commenters proposed that the technical supervisor requirements be revised to qualify those individuals who have been certified by a nationally recognized certifying body at the specialist level or higher in clinical and/or public health microbiology, to relieve the shortage of qualified personnel available to work in public health laboratories. A few commenters recommended allowing a "medical technologist with appropriate experience" to meet the qualification requirements for technical supervisor in chemistry, while other commenters suggested that an individual who has a bachelor's degree in science and certification or is eligible for certification and has four years experience in chemistry, should be qualified as a technical supervisor in chemistry.

A large number of pulmonary physicians and respiratory therapy practitioners objected to the proposed requirements for technical supervisor in chemistry and suggested that credentialed respiratory therapy practitioners be qualified to serve as technical supervisors in blood gas laboratories. Many comments received from hematologists/oncologists

indicated that they misinterpreted the proposed regulations and thought that they would be prohibited from serving as technical supervisors in their own office laboratories performing Level II testing.

A large number of comments on the proposed regulations for technical supervisor were received from dermatologists, who objected to the proposed provisions which would prohibit them from examining skin biopsies and performing a number of Level II tests on their own patients. Some dermatologists suggested that any test or examination performed by a dermatologist should be categorized as a waived test. Other dermatologists suggested that the requirements of § 493.1421(g) be changed to include the following: " \* \* \* for tests in dermatopathology, the individual is certified in dermatopathology by the American Board of Pathology and American Board of Dermatology."

A number of commenters representing physicians who perform Mohs micrographic surgery, proposed that physicians performing such procedures " \* \* \* be accredited as an Associate Member or Fellow of the American College of Mohs Micrographic Surgery and Cutaneous Oncology, or possess qualifications equivalent to those required for accreditation as an Associate Member or Fellow status \* \* \*" A number of commenters practicing ophthalmic pathology recommended revising the proposed requirements for technical supervisor at § 493.1421(g) to include a new paragraph (4) as follows: "For tests in ophthalmic pathology, the individual—

- (i) Meets the requirements of paragraph (a) of this section;
- (ii) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology; or
- (iii) Is certified by the American Board of Ophthalmology (or eligible for such certification) and has successfully completed a minimum of one year of formal post-residency fellowship training in ophthalmic pathology." Other commenters recommended adding to the requirement, the phrase " \* \* \* is recognized as an ophthalmic pathologist upon the recommendation of the AAOP, a subspecialty group affiliated with the American Academy of Ophthalmology".

A few commenters agreed with the proposed requirements for technical supervisor of histocompatibility services and indicated that histocompatibility testing requires more evaluation and judgement than most other areas of laboratory medicine; therefore, additional training and experience are necessary to acquire the requisite

specialized experience. Some commenters suggested that the requirement for technical supervisors of histocompatibility to have four years of experience in immunology, two of which have been in histocompatibility testing, should be revised to allow individuals having four years of training or experience in histocompatibility testing to qualify. Commenters also suggested that the proposed rule be revised to require experience in "human" histocompatibility testing.

A few commenters objected to the technical supervisor responsibility requirements. The commenters were particularly opposed to requiring the technical supervisor to evaluate personnel on a quarterly basis. They recommended requiring initial training and competency evaluation of each individual performing testing at the time the individual is hired with subsequent performance evaluation required only when new procedures are introduced or changes in procedures occur.

*Response:* The proposed condition of technical supervision of Level II (now high complexity) testing formerly located at § 493.1419 has been relocated to § 493.1447. The qualification requirements for technical supervisor that were proposed at § 493.1421 have been revised and recodified and are now at § 493.1449, Standard; Technical supervisor qualifications. In response to the commenters' concerns, we reevaluated the qualification requirements. We had proposed that, at a minimum, technical supervisors of hematology and radiobiology have a bachelor's degree in science. In this regulation, we have revised the requirements for technical supervision to permit an individual, who has a bachelor's degree and four years of laboratory training or experience in the specialty/subspecialty, to provide technical supervision of high complexity testing not only in hematology and radiobiology, but also the subspecialties of microbiology, immunology, and chemistry. For individuals with a master's degree in a science, we have reduced the proposed requirement for laboratory training and experience from four years to two years. We had proposed that physicians be qualified as technical supervisors of all specialty/subspecialty areas, provided they had the required certification or specialty/subspecialty experience. Under this rule, we are retaining the requirement permitting physicians without pathology specialty certification to serve as technical supervisors in all specialty/subspecialty areas, except cytology and histopathology. To serve

as technical supervisor, we proposed that each individual have training and experience in the specialty/subspecialty area; we revised the requirement to qualify those individuals who either have training or have experience in the specialty/subspecialty area. For physicians and individuals with a doctoral degree, we have reduced the specialty/subspecialty training or experience required to one year, except for the specialties of histocompatibility and clinical cytogenetics. Those physicians, who are not pathologists but have medical residency laboratory training and experience acquired during their training programs for specialty certification, will be qualified under these regulations as a technical supervisor of any specialty or subspecialty area related to their residency training or experience. For example, a board certified hematologist or hematologist/oncologist will be qualified as a technical supervisor of all examinations and test procedures included in the specialty of hematology.

In response to recommendations from medical schools, we are revising the cytology technical supervisor qualification requirements to allow physicians in their final year of residency training in anatomic pathology to perform some of the responsibilities of the cytology technical supervisor. These individuals are expected to perform duties in cytology as part of their training and are qualified to perform the duties of the cytology technical supervisor.

We agree with the commenters that dermatologists and ophthalmic pathologists should be permitted to perform tissue examinations and have added provisions to allow dermatologists and ophthalmic pathologists to qualify as technical supervisors of dermatopathology and ophthalmic pathology, respectively.

In response to recommendations from commenters that we permit residents in anatomic pathology training programs to perform histopathology services, we have added provisions to the technical supervisor requirements for histopathology, dermatopathology, ophthalmic pathology and oral pathology to permit pathology residents to perform tissue examinations in these subspecialty areas.

We agree with the commenters who suggested that in histocompatibility testing the experience should be in "human" histocompatibility. The technical supervisor qualifications require laboratory training or experience. According to the CLIA statute, a laboratory is defined as a

facility performing testing on " \* \* \* materials derived from the human body \* \* \* ", therefore it is not necessary to specify that the experience be in "human" histocompatibility. In response to commenters suggestions, we have revised the training or experience requirement to allow individuals, who have four years of training or experience in histocompatibility, to qualify as technical supervisors of histocompatibility.

We believe that the changes made in the qualification requirements for technical supervisor represent a more uniform set of standards across laboratory specialty and subspecialty service areas and are consistent with the knowledge and skills needed to monitor the technical aspects of laboratory testing for high complexity procedures or examinations.

We agree with the commenters that the proposed requirement for the technical supervisor to perform quarterly evaluations of personnel the first year of testing and thereafter semiannually is excessive and burdensome. We have revised the standard to require semiannual evaluations of personnel during their first year of testing and annually thereafter. If there are changes in test methodology or instrumentation, semiannual evaluations are required for an additional year.

*(Sections 493.1453-493.1457 Clinical Consultant, Qualifications and Responsibilities)*

*Comment:* A number of commenters recommended that for laboratories performing Level II testing, requirements be established for an administrative director and a medical director/advisor. The commenters expressed the view that a medical technologist is qualified to handle the administrative responsibilities but a physician should serve as the medical director/advisor to evaluate test results for medical intervention or decision-making concerning patient diagnosis and treatment.

*Response:* We agree with the commenters. Therefore, we are including provisions requiring each laboratory performing high complexity testing to have access to clinical consultant services to ensure proper oversight of the total testing process from test selection through analysis and test result reporting and interpretation. At § 493.1453, Condition: Laboratories performing high complexity testing; clinical consultant, we created a condition for clinical consultation to encompass the qualifications and responsibilities required for the clinical

consultant. Section 493.1455, Standard; Clinical consultant qualifications, contains the specific qualifications required for the clinical consultant, and the clinical consultant responsibilities are defined at § 493.1457, Standard; Clinical consultant responsibilities. The addition of these requirements should enable the laboratory to provide clinical consultation to its clients whenever needed for the utilization of specific laboratory test results in the diagnosis and treatment of patients and to assist in the interpretation of particular test results with individual patient conditions.

*Sections 493.1425-493.1429 (Sections 493.1459-493.1463) General Supervisor, Qualifications and Responsibilities*

Approximately 950 comments were received on the proposed requirements (proposed at §§ 493.1425-493.1429) for general supervisor of a laboratory performing Level II testing. About 66 percent of the commenters were opposed and almost 5 percent were in support of the proposed requirements, 27 percent offered alternate suggestions and 3 percent misinterpreted the proposed requirements. Technologists submitted 25 percent and physicians submitted 30 percent of the total comments received on these sections.

In the proposed rule, the qualification requirements for the general supervisor of Level I testing were cross-referenced to the requirements for general supervisor of Level II testing. Therefore, many of the comments concerning the requirements for general supervisor were previously summarized under our discussion of proposed § 493.1409.

*Comment:* Several commenters felt that the proposed requirements for general supervisor were overly stringent and personnel would not be available to provide supervision of Level II testing. These commenters expressed the view that the proposed regulations would increase the cost of testing specimens and noted that it has not been demonstrated by scientific studies that the proposed personnel requirements will improve the quality of Level II testing. Additionally, the majority of the physicians, who commented on these sections, indicated that their test costs would increase if they were required to have a general supervisor with the qualifications listed in the proposed rule.

A number of commenters suggested that hematologists, rheumatologists and registered nurses be qualified as general supervisors of laboratories performing Level II tests. On the other hand, several commenters expressed the view that only a registered medical technologist

should be qualified as a general supervisor. Many medical technologists contended that physicians do not have training or experience in laboratory management, quality control, instrument calibration, maintenance or trouble shooting; therefore, physicians need to employ a medical technologist to fulfill the responsibilities of a general supervisor.

Several histotechnologists objected to the proposed requirement that would permit only a physician certified in anatomic pathology, or equivalent to serve as general supervisor of histopathology. Other commenters recommended recognizing those individuals trained in respiratory therapy, who are either credentialed by the National Board for Respiratory Care or licensed by a State to practice respiratory therapy, as meeting the qualifications of a general supervisor.

Several commenters suggested eliminating the academic and experience requirements and focusing on the competency of personnel as a mechanism for meeting the general supervisor qualifications. A few commenters suggested that HHS developed an examination to qualify individuals currently employed as supervisors who could not meet the proposed requirements.

Many commenters objected to requiring a general supervisor to be on the laboratory premises during all hours of testing. Numerous commenters observed that there are not enough qualified people available to serve as general supervisors of all laboratories performing Level II testing. Commenters from rural areas expressed concerns about the hardships associated with hiring individuals who have the qualifications necessary to meet the proposed general supervisor requirements. One commenter estimated that if the proposed regulations were finalized, 65 percent of the hospitals in his state would be unable to have a qualified general supervisor on all shifts.

Some commenters recommended that a technologist supervisor be required if more than one person is employed in the laboratory. Numerous commenters suggested that if testing is performed by qualified technologists, a general supervisor should not be required to be on-site during test performance. One commenter, reflecting the view of many commenters, suggested that the requirements be changed to read " \* \* \* the general supervisor is on the premises during the majority of scheduled hours in which test are being performed, provided the individual that is performing tests is qualified to perform

such tests and the supervisor responsible for the results reviews them within 24 hours and a record is maintained to reflect the actual review."

Several commenters were opposed to the proposed requirement that would allow a physician or doctoral scientist with only one year of experience to qualify as a general supervisor performing Level II testing. They suggested the a minimum of two years experience be required to qualify as a supervisor of a laboratory performing Level II testing in multiple specialties or subspecialties of service. Other commenters recommended that three years of experience be required.

Many commenters agreed with the proposed requirements that would allow a medical technologist with three years of experience to qualify as a general supervisor. However, a number of commenters recommended reducing the experience requirement from three years to one year, while several other commenters supported the current Federal regulations for independent laboratories that require six years of experience to qualify as a general supervisor.

*Response:* In response to the comments, we have clarified the general supervisor qualification requirements to specify that physicians are qualified to function as the general supervisor if they have at least one year of laboratory training or experience in high complexity testing. Physicians may acquire the one year of laboratory training or experience during medical residency training programs for speciality certification. For example, a board certified hematologist or hematologist/oncologist would meet the training or experience required to serve as a general supervisor of high complexity testing. Also, individuals who are qualified as a director or technical supervisor of high complexity testing, are qualified to function as the general supervisor. In addition, we are revising the proposed rule, which would have required individuals with a master's degree to have two years of laboratory experience and individuals with a bachelor's degree to have three years of laboratory experience, to require one year of laboratory training or experience to be consistent with the requirement for physicians to have one year of laboratory training or experience. This will permit nurses and other allied health professionals to qualify as general supervisors. We have revised the requirements to allow individuals with an associate degree in laboratory science or medical technology to qualify as general

supervisors provided they have at least two years of laboratory training or experience in high complexity testing. We are permitting those individuals, who are qualified or could have qualified as a general supervisor under Federal regulations published on March 14, 1990, to qualify as a general supervisor of high complexity testing. Also, we have added a provision to qualify as general supervisors of blood gas analysis, those individuals with a bachelor's degree in respiratory therapy and one year of training or experience in blood gas analysis, and those individuals have an associate degree related to pulmonary function and two years of laboratory training or experience in blood gas analysis. In establishing standards for general supervisor of high complexity testing, we carefully evaluated the personnel qualifications in conjunction with tests now categorized as high complexity and believe that the education and experience requirements are reasonable and appropriate for individuals responsible for the day-to-day supervision of laboratories performing the most complex procedures and the direct supervision of high school graduates performing high complexity testing.

We understand and agree with the commenters concerns that it may not always be feasible to have a general supervisor in the laboratory during all hours of testing. Therefore, we have revised the requirements to generally require day-to-day, but not necessarily on-site, supervision of testing personnel. However, direct, onsite supervision is required when high complexity testing is performed by a high school graduate who does not meet the other qualification requirements for testing personnel. In other cases, the general supervisor must be accessible to the laboratory to provide on-site, telephone, or electronic consultation on an as needed basis.

In response to the histotechnologists comments that the general supervisor requirements should be expanded to allow histotechnologists to function as a general supervisor of histopathology, we have not changed the proposed requirement because we are permitting only pathologists and pathology residents to perform histopathology testing i.e., gross and microscopic examinations of tissue. However, the regulations do not preclude a director from appointing a histotechnologist to supervise specimen handling, i.e., tissue processing and staining of slides.

*Section 493.1427(b)(5) (Sections 493.1467-493.1471) Cytology General Supervisor*

*Comment:* Several commenters recommended that the experience requirement for qualifying as a cytology general supervisor be expanded to include teaching experience or other experience that was field related, not just laboratory experience. Many commenters objected to requiring the general supervisor of cytology to be on the premises when nonsupervisory cytotechnologists examine cytologic preparations, unless a technical supervisor of cytology was present. They said that it is not necessary to have a cytology general supervisor on-site when slides are examined because the examination of slides is not generally an emergency procedure and laboratories must employ qualified cytotechnologists to examine cytologic preparations.

*Response:* We agree with the commenters that the cytology general supervisor qualification requirements should be expanded to include experience obtained in performing various duties, including evaluating slide preparations, teaching or clinically oriented cytology research. Therefore, we have modified this requirement to qualify those cytotechnologists who have 3 years of full-time experience within the preceding 10 years as a cytotechnologist. We agree that supervisory personnel do not need to be on the premises at all times when nonsupervisory personnel are reviewing slides and are revising the proposed requirement. The revision states that the cytology general supervisor is responsible for the day-to-day supervision of the overall laboratory operation and must be accessible to provide on-site, telephone, or electronic consultation to resolve technical problems. In addition, we have expanded the list of responsibilities for the general supervisor to be consistent with the duties listed under the cytology quality control regulations, including documentation of the number of cytology slides examined or reviewed.

*Sections 493.1437-493.1439 (Sections 493.1481, 493.1483 and 493.1485) Cytotechnologist, Qualifications and Responsibilities*

*Comment:* In response to our request for comments on optional cytotechnologist qualification requirements, recognition of an accrediting agency's credentials for qualifying cytotechnologists was the preferred option of the majority of those

who commented on the options for cytotechnologist qualifications. The majority of commenters were in favor of recognizing the American Society of Clinical Pathologists' (ASCP) Board of Registry of qualifying cytotechnologists who do not meet existing regulations. To qualify as a cytotechnologist, ASCP currently requires a baccalaureate degree (in cytotechnology or a biological science) from an accredited university, graduation from a school of cytotechnology approved by the Committee on Allied Health Education and Accreditation (CAHEA) or five years of experience as a cytotechnologist, and ASCP certification. A few commenters suggested that certification by the American Society of Cytology should be recognized by HHS for qualifying cytotechnologists, while others suggested that cytotechnologists from foreign countries be qualified on the basis of certification by the International Academy of Cytology (IAC). A few commenters working in hospitals expressed fear of losing their jobs if the IAC certification examination is not recognized.

Many commenters felt that the existing qualification requirements for cytotechnologists should not be changed because they represent the appropriate qualifications necessary for examination of cytology preparations. Due to the shortage of cytotechnologists in the field, a few commenters felt the educational requirements for cytotechnologists were either unnecessary or too stringent and should be removed from the regulations. These commenters felt they should be allowed to qualify through an examination that would be made available to all individuals.

Many commenters made recommendations to ensure that individuals currently working as cytotechnologists would not be disenfranchised and would be given an opportunity to qualify based on demonstrated competency. These recommendations included: Use proficiency testing to ensure that individuals are competent; require attestation of competency by the technical supervisor; establish a time frame for all currently working cytotechnologists to sit for a recognized examination; and designate a date by which individuals must meet qualification requirements. A few commenters requested the establishment of new training programs for cytotechnologists. One commenter suggested a nationwide training program

similar to the training programs offered during the 1950s and 1960s.

Many individuals and organizations offered suggestions on the option of extending the "grandfather" clause. These suggestions included extending the time period for qualifying individuals under the "grandfather" clause until the implementation date of the regulations and considering as qualified all individuals who have functioned in the capacity of a cytotechnologist whether or not they have the specific education or training in cytology. Many commenters indicated a variety of entry methods for becoming certified as cytotechnologists have been available over the past 20 years and both employers and individuals performing cytology services should have been aware of these opportunities, therefore an extension of the time period in which to qualify individuals was not necessary.

A variety of comments were received about the option of establishing an examination to qualify cytotechnologists. A few commenters indicated they did not agree with qualifying cytotechnologists on the basis of a single examination. Several commenters indicated an additional examination was both unnecessary and inefficient since similar examinations already exist or did at one time.

Under the cytotechnologist responsibility requirements, one commenter suggested daily documentation of the amount of time spent in the cytopreparatory laboratory and/or on clerical duties.

*Response:* We are adopting the option favored by the majority of the commenters and are adding to the qualification requirements for cytotechnologists a provision to recognize certification by a certifying agency approved by HHS. In addition, we are adding a provision to qualify those individuals who have graduated from a school of cytotechnology accredited by the Committee on Allied Health Education and Accreditation (CAHEA). Depending on the school, these individuals may or may not have a bachelor's degree, but they will meet education requirements that we feel are appropriate for performing the duties of a cytotechnologist. We are not establishing new training programs for cytotechnologists, but, if there is a need for new programs, we encourage their development.

Our intent is not to disenfranchise individuals currently working as cytotechnologists but to provide standards for cytotechnologist qualifications that will ensure quality of

service and be in the best interest of public health. We realize, however, that some currently employed cytotechnologists may not be able to qualify under the new requirements described above. Therefore, in addition to these new provisions for qualifying as a cytotechnologist, we are permitting individuals to qualify who, as of September 1, 1992 meet qualification requirements specified under previous Federal regulations. Accordingly, those individuals who are able to qualify under the requirements that were published on March 14, 1990, will be qualified, including those who have recent experience and can meet the grandfather clause contained in prior regulations for Medicare approval and interstate license of laboratories. These individuals would be qualified based on training and experience acquired before January 1, 1969 provided they have had at least 2 years of full-time experience as a cytotechnologist within the preceding 5 years.

In spite of our efforts to develop standards that will qualify most individuals currently working as cytotechnologists, there may be some individuals who are unable to meet these requirements. Therefore, we are adding provisions to allow up to 2 years for individuals who do not meet the new qualification standards or those in previous regulations, to either complete a CAHEA-approved program in cytotechnology or obtain certification credentials. Individuals seeking to qualify by this route must have at least 2 years of full-time experience or equivalent as of September 1, 1993. In addition, we are providing a second year for those individuals who meet the experience requirement to either complete formal training in a CAHEA-approved school or to become certified as a cytotechnologist. Prior to September 1, 1994, HHS will assess the status of these individuals and consider modifications to these requirements.

Because of its limited scope, we do not think that proficiency testing for gynecologic cytology, as described under §§ 493.855, Standard; Cytology: Gynecologic cytology, and 493.945, Cytology: gynecologic examinations, is a suitable means for qualifying cytotechnologists. However, proficiency testing will test the competency of all individuals who are able to qualify as cytotechnologists under the provisions described above. We believe that proficiency testing, along with standards in quality control, such as limitations on workload, rescreening of negatives, feedback on abnormal and other cases, and performance evaluations will

provide and maintain quality performance in cytology.

Under the cytotechnologist responsibility requirements, we are retaining requirements for documentation of workload needed to meet the standards under the cytology quality control section; that is, documentation, for each 24-hour period, of the number of slides examined or reviewed and the number of hours spent examining slides for all laboratories in which the individual is employed. We do not agree that it is necessary for each cytotechnologist to document the amount of time spent on duties other than slide examination. However, if a cytotechnologist has other duties not directly related to slide examination, his or her workload limit must be prorated based on the formula given in the cytology quality control section.

*Sections 493.1431, 493.1441, 493.1443 and 493.1445 Technologist, Technician and Technician Trainee Qualifications and Responsibilities (Sections 493.1487-1495 Testing Personnel, Qualifications and Responsibilities)*

About 1,500 comments were received concerning the proposed regulations for testing personnel. Approximately 54 percent of the commenters were opposed, while about 5 percent were in support of the proposed requirements. About 9 percent of the commenters misinterpreted the proposed requirements and nearly 31 percent of the commenters offered alternative suggestions. Approximately 37 percent of the comments were from physicians, while 33 percent of the comments were from technologists and respiratory care personnel.

*Comment:* Many physicians and numerous commenters representing rural hospitals expressed the view that the proposed qualifications for testing personnel were too stringent and could not be met due to the severe shortage of technical personnel and the financial burden associated with employing such individuals.

Many commenters mistakenly interpreted the proposed rule to require all Level II testing personnel to have at a minimum an academic degree and, therefore, requested regulatory revisions to allow test performance by non-degree individuals. They expressed concern about laboratory personnel shortages and noted that the performance of tests using highly automated equipment does not require specialized expertise. However, a number of commenters agreed with the proposed requirements for personnel performing Level II testing, while several commenters recommended more

stringent requirements for testing personnel such as requiring that all testing be performed either by certified medical technologists or medical laboratory technicians.

Numerous commenters disagreed with the proposed qualifications for technicians, since a high school graduate with two years of laboratory experience was considered equivalent to a medical laboratory technician having an associate degree. A few commenters suggested Federal funding to support technician and technologist training programs to avoid critical personnel shortages.

Several commenters from States having personnel licensure laws suggested that testing personnel either be licensed or certified by examination, while other commenters recommended that HHS reinstate the proficiency examination as a mechanism to qualify individuals as technologists. One professional organization recommended establishing a competency-based, credentialing examination to qualify individuals as technologists and technicians. The organization proposed three levels of personnel qualifications. Another organization recommended that the proposed qualifications for technologists be modified to recognize certifying organizations approved by HHS.

A few commenters suggested that, in addition to the studies mandated under CLIA, HHS conduct a study to evaluate the equivalency of alternative mechanisms for qualifying as technologists those individuals who do not have a baccalaureate degree. Some commenters noted that the proposed requirements did not include any requirements for histotechnologists or histologic technicians. These commenters suggested that histotechnologist qualifications be included in proposed § 493.1433, and that histotechnician qualifications be included in proposed § 493.1441. One commenter suggested recognizing the American Society of Clinical Pathologists certification for histotechnologists. Other commenters recommended that individuals performing histocompatibility testing possess a bachelors degree in a biological science, which includes courses in immunology and genetics, and complete a 3-6 month training program in histocompatibility.

Numerous commenters suggested that the "pertinent full time laboratory experience" should be in an approved laboratory. A few commenters voiced concerns about the quality of the training programs for laboratory technicians and were opposed to for-

profit laboratory technician training programs.

*Response:* We are adding provisions to clarify that physicians and individuals with a doctoral or master's degree in a science are qualified to perform high complexity testing in specialty areas other than pathology. We are including a provision to allow individuals who were qualified or could have qualified as a technologist under the March 14, 1990 regulations, to now qualify to perform tests of high complexity. Additional specifications were provided in the responsibility requirements to insure that testing personnel are aware of all of the duties related to test performance.

#### *Section 493.1442 Personnel Qualifications for Test Performance*

Approximately 6,100 commenters responded to the proposed personnel qualifications required for performance of specific categories of Level II tests. Approximately 65 percent of the commenters to this section were opposed to the proposed requirements, primarily because they misunderstood the qualification requirements, while around 34 percent offered alternative suggestions.

*Comment:* Nearly 85 percent of the comments received were from respiratory care practitioners (primarily respiratory therapists), who believed that the proposed regulations precluded them from performing and supervising blood gas analysis and other laboratory tests. They felt that restricting respiratory therapy practitioners from performing blood gas analysis would have an adverse impact on patient care that could be life threatening. A large number of respiratory therapists expressed the view that they were qualified to perform laboratory testing by virtue of their training in an American Medical Association (AMA) approved program and certification by the National Board for Respiratory Care. These commenters strongly suggested that credentialed respiratory therapy practitioners and pulmonary function technologists be qualified to serve as technologists/technicians in blood gas laboratories. A much smaller number of respiratory therapists felt that they were not prepared to operate laboratory equipment and instruments and should be limited to interpretation of blood gas reports rather than performance of blood gas analyses.

A few commenters did not understand that the proposed requirements would permit physicians to perform laboratory tests. Several comments were received from dermatologists, who perform Mohs

micrographic surgery as well as clinical laboratory tests in their offices, suggesting that they be qualified to perform these procedures on the basis of their training, experience and board eligibility and/or certification. Other commenters asked that hematologists, oncologists, and ophthalmic pathologists be exempt from the requirements contained in § 493.1442.

Many comments from individuals employed in rural physician office laboratories and nurses working in home health agencies, clinics and hospitals, were in opposition to the proposed regulations because the commenters incorrectly assumed that only credentialed laboratory personnel would be permitted to perform Level II testing. They recommended revising the proposed requirements to allow non-credentialed laboratory personnel to perform Level II testing, provided the proficiency testing and quality control requirements were met.

A number of commenters thought that the proposed rule would have to be revised in order to permit hospital nursing personnel to perform Level II tests at the patient's bedside, while other comments received from perfusionists indicated that they should be qualified to perform blood gas analysis and electrolyte determinations.

Some commenters agreed with the requirement that all testing personnel be licensed as required by the State but other commenters indicated that only medical technologists should be qualified to perform Level II testing. On the other hand, several commenters expressed the view that the proposed personnel qualification requirements would severely limit the ability of State and local clinics to provide epidemiology testing and health fairs to offer screening services. In addition, numerous commenters expressed concern that the requirement permitting only technologists to perform tests in microbiology and immunohematology was overly stringent, without scientific basis and would cause severe problems in rural hospitals that do not have personnel who could meet the proposed qualifications. Many commenters representing rural hospitals stated that, if the proposed regulations were implemented, their hospitals would no longer be able to perform blood bank services due to the shortage of qualified technologists.

A few commenters suggested adding the phrase "or equivalent education and/or experience" to all personnel qualification standards, especially in the specialty/subspecialty areas of cytogenetics, histocompatibility, and virology because qualified medical

technologists are not always available to perform the testing and personnel having equivalent education and experience should not be restricted from testing in these areas. A few commenters felt that "trained" persons rather than "credentialed" individuals should be qualified to perform *in vitro* allergy tests.

Many commenters expressed the view that medical laboratory technicians with an associate degree are qualified to perform the same level of testing as medical technologists, although a much smaller number of commenters suggested that technicians be allowed to perform Level II tests only under the supervision of technologists. A few commenters claimed that there were no studies, conducted in the past or currently in process, to support the proposed technician and technologist testing categories. Other commenters felt that the addition 30 semester hours of course work required for a degree in medical technology did not necessarily ensure competency in laboratory testing and was not justified for performance of the proposed testing categories. Numerous commenters objected to the proposed requirement for medical laboratory technicians to have additional experience in order to perform Level II testing, since their training programs prepare graduates to perform the Level II tests listed under § 493.1442(a). They indicated that the additional experience is not needed and suggested that medical laboratory technicians be allowed to perform all Level II tests, except cytology. On the other hand, some commenters recommended that technicians be required to gain additional experience and training prior to performing toxicology, complex electrophoresis testing and gas chromatography/mass spectrophotometry tests. Other commenters suggested requiring technicians to have additional experience of from three months to one year prior to performance of tests in general immunology, endocrinology, mycology, virology, immunohematology, mycobacteriology and toxicology. One organization cited an inconsistency in requiring work experience for technicians performing Level II tests listed in § 493.1442(b), but not requiring work experience for technologists performing Level II tests listed in § 493.1442(a). The commenter suggested requiring technologists to have a minimum of one year experience before qualifying to perform the tests listed in § 493.1442(a).

A number of medical laboratory technicians expressed concerns that the requirements for technicians fail to

differentiate between individuals who complete a formal associate degree training program for medical laboratory technicians, and high school graduates with on-the-job training.

A number of commenters suggested that § 493.1442 be deleted. The commenters were of the opinion that it is the laboratory's responsibility to establish personnel qualifications required for test performance and monitor the competence of individuals. Many commenters felt that the director should have responsibility for determining which individuals are qualified to perform specific tests.

A few commenters noted the difficulty in inspecting laboratories for compliance with the proposed requirements, since different personnel qualifications would be required for Level I and Level II test performance on the same specimen.

A few commenters asked for clarification of "full-time experience". Others suggested that "testing" be defined in the definition section. The commenters noted that testing does not include clerical or support tasks and, for the purpose of defining personnel qualifications requirements, testing should be defined as the functions performed on a specimen that changes it in some significant or substantial way.

One commenter noted that in the table under § 493.1442(a), immunohematology procedures were incorrectly referenced to § 493.950 instead of § 493.959.

**Response:** The respiratory therapy practitioners misinterpreted the proposed requirement that would have permitted a high school graduate with two years of testing experience to perform laboratory tests, including the performance of blood gas analysis. To clarify that respiratory therapy practitioners are qualified to perform blood gas analyses, we are adding a provision under § 493.1489, Standard: Testing personnel qualifications, specifically authorizing blood gas analysis by individuals who have a bachelor's degree in respiratory therapy or an associate degree related to pulmonary function.

We agree with the commenters that the qualification requirements for testing personnel need to ensure that individuals have the knowledge and skills necessary to process specimens, perform testing and report test results. Since the test categorization criteria were revised, only the most complex text procedures now are categorized as high complexity. At a minimum, individuals performing high complexity testing must have an associate degree in

science in order to perform high complexity testing without direct, on-site supervision by a general supervisor. For five years after the effective date of the regulations, we will allow high school graduates to perform high complexity testing under the on-site, direct supervision of a general supervisor. During the five year period, we expect that these individuals will complete the course work necessary to obtain an associate degree in laboratory science or medical laboratory technology to continue to qualify to perform high complexity testing. An individual qualified under § 493.1489 to perform high complexity testing is authorized to perform testing in all specialties and subspecialties, except histopathology and cytology. In our view, the qualifications required for testing personnel are appropriate for individuals performing high complexity testing provided they have been appropriately oriented and trained to perform the tests and the director specifies in writing that the individual is authorized to perform the specific tests or examinations. In addition, we have provided for these individual's testing skills to be evaluated prior to performing test on patients, and thereafter on an ongoing basis to ensure continued competency in test performance.

The requirements that were proposed at §§ 493.1442 are being deleted, since we have revised the director responsibilities to require the director to specify in writing the responsibilities of each consultant, supervisor, and individual performing tests. In addition, the director must determine the procedures each individual is authorized to perform, whether supervision of testing is required and whether a supervisor or director must review test results prior to reporting.

#### Changes to the Regulation

*Moderate complexity testing—*Laboratory director. We are changing the qualification requirements for laboratory director for moderate complexity testing (previously Level I) so that physicians who are not pathologists must have laboratory training or experience. This training or experience can be acquired by directing or supervising non-waived testing for at least one year or by obtaining 20 continuing medical education credit hours in laboratory practice commensurate with the responsibilities for laboratory director of moderate complexity testing or equivalent training obtained during a residency training program. Physicians have one year from [the publication date of the regulations] to obtain the continuing education credit hours. In addition, individuals who have

a doctoral degree, if not Board certified must have at least one year of experience directing or supervising non-waived testing. We have added the American Board of Medical Laboratory Immunology to the list of Boards that are accepted by HHS to meet this requirement. We are expanding the director qualifications to include individuals with a master's or bachelor's degree in the sciences with one or two years of laboratory training or experience and one or two years of supervisory laboratory experience, respectively. In addition, individuals who were previously qualified or could have qualified as a laboratory director under the Federal regulations published on March 14, 1990, will be qualified as laboratory director for moderate complexity testing. Also, we are adding a provision to permit individuals, who on the date of publication of these regulations are qualified under State law as a director, to qualify as a director of a laboratory performing moderate complexity testing.

We are expanding the responsibilities for laboratory director to be more comprehensive and represent the functions required for directing moderate complexity testing, which is more extensive than the testing proposed for Level I. Thus, responsibilities have been added and are listed under § 493.1407, Standard; Laboratory director responsibilities.

*Technical consultant.* We are renaming technical supervisor to technical consultant to reflect changes in functions related to moderate complexity testing that may be provided on a consultative basis. The qualifications for technical consultant are listed under § 493.1411, Standard; Technical consultant qualifications, and are not the same as those for director as specified in the proposed rule for technical supervisor. The qualifications are:

- Physician certified in anatomic or clinical pathology;
- Physician or individual with a doctoral or master's degree in the sciences and at least one year of laboratory training or experience in the specialty or subspecialty areas for which the consultant is responsible; or
- Individual with a bachelor's degree in the sciences and at least two years of laboratory training or experience in the specialty or subspecialty for which the consultant is responsible.

We are modifying the technical consultant responsibilities somewhat from those proposed for the technical supervisor and are listed under § 493.1413, Standard; Technical

consultant responsibilities. The technical consultant must be accessible to the laboratory to provide on-site or telephone consultation on an as needed basis to resolve technical problems and perform the other responsibilities listed. We are changing the frequency for evaluating and documenting the performance of testing personnel to semiannual during the first year the individual tests patient specimens and annually thereafter, unless test methodology or instrumentation changes, in which case performance must be evaluated initially prior to reporting patient results.

*Clinical consultant.* We are adding a requirement for clinical consultant. The qualifications for clinical consultant are met by the laboratory director when the director is a physician or has a doctoral degree with Board certification. In addition, the clinical consultant may be a physician without pathology certification or laboratory training or experience as specified under the director requirements. The clinical consultant is responsible for providing consultation regarding appropriateness of the testing ordered and interpretation of results. Specific responsibilities are listed under § 493.1419, Standard; Clinical consultant responsibilities.

*General supervisor.* We are deleting the requirement for general supervisor for moderate complexity testing.

*Testing personnel.* We are revising the qualifications for testing personnel to clearly reflect that physicians and individuals who possess a doctoral, master's, bachelor's or associate degree in the sciences are qualified to perform moderate complexity testing. In addition, we are modifying the requirements so that individuals who have military training in laboratory procedures and are qualified as a Medical Laboratory Specialist can qualify. Individuals who possess a high school diploma or equivalent can qualify if they have had training appropriate for the testing performed prior to analyzing patient specimens. The requirements for this training have been modified and are listed under § 493.1423, Standard; Testing personnel qualifications.

We are adding a new § 493.1425, Standard; Testing personnel responsibilities, which lists the testing personnel responsibilities.

*High complexity testing.—*Laboratory director. We are modifying the qualification requirements for director of high complexity testing (formerly Level II) to require physicians who are not pathologists to either have one year of laboratory training during medical residency, or have at least two years of

experience directing or supervising high complexity testing. For individuals with a doctoral degree in science, we are adding the American Board of Medical Laboratory Immunology to the list of boards required for certification. Also, individuals who were previously qualified or could have qualified as a laboratory director under Federal regulations published March 14, 1990, will now qualify as a laboratory director of high complexity testing. In addition, we are adding a provision to permit individuals, who on the date of publication of these regulations are qualified under State law as a director, to qualify as a director of a laboratory performing high complexity testing.

We are revising and expanding the responsibility requirements for laboratory director under § 493.1445, Standard; Laboratory director responsibilities, to more closely correspond with the functions required to direct a laboratory performing the examinations and procedures now categorized as high complexity testing.

Technical supervisor. We are modifying the qualification requirements for technical supervisor to require physicians and individuals with a doctoral degree to have at least one year of laboratory training or experience in high complexity testing in the specialty or subspecialty of service for which the individual is providing technical supervision. For individuals with a master's or bachelor's degree, laboratory training or experience in high complexity testing in the specialty or subspecialty of service is required for a period of two or four years, respectively. In addition, in the subspecialties of microbiology located at § 493.1449 (c)-(g), the technical supervisor is required to have at least six months of experience in the subspecialty of service.

We are revising the technical supervisor qualification requirements for cytology formerly located at § 493.1421(f), now § 493.1449(k). We are adding a provision to permit physicians in their final year of residency training in anatomic pathology to perform some of the functions of the cytology technical supervisor. In addition, we are expanding the technical supervisor's responsibilities in cytology to include duties listed in the quality control section and the responsibility for ensuring that each individual examining gynecologic cytology slide preparations participates and achieves a passing score in a gynecologic cytology testing program. To the qualifications for technical supervisor of histopathology, we are adding provisions at

§ 493.1449(1)(2) to qualify those individuals, who are certified in dermatology by the American Board of Dermatology, to serve as technical supervisors of dermatopathology testing. Likewise, we are revising § 493.1449(1)(3) to allow a physician certified in ophthalmic pathology by the American Board of Ophthalmology to qualify as a technical supervisor of ophthalmic pathology. In addition, we are adding provisions to the technical supervisor requirements for histopathology, dermatopathology ophthalmic pathology and oral pathology to permit residents in anatomic pathology to perform tissue examinations.

Under the responsibility requirements for technical supervisor located at § 493.1451, Standard; Technical supervisor responsibilities, we are revising the requirements to require technical supervision on an as needed basis and expanded the responsibilities to correlate with the technical functions to be performed by the individual providing technical supervision. The frequency for performing evaluations of testing personnel was revised to require semiannual evaluations the first year the individual tests specimens and annual evaluation thereafter unless test methodology or instrumentation changes, in which case performance must be evaluated initially prior to reporting patient results.

At § 493.1451(c), we are expanding the specific responsibility requirements for the technical supervisor in cytology to provide for internal consistency within the regulation. Now included are those duties listed in the cytology quality control section, such as establishing and documenting workload limits and review and confirmation or cytologic preparations.

Clinical consultant. At § 493.1455, Standard; Clinical consultant qualifications, we are adding a requirement for a clinical consultant. The qualifications for clinical consultant may be met by the laboratory director provided the director is qualified as a physician or has a doctoral degree with Board certification. Alternatively, the laboratory may employ a physician without pathology certification or laboratory training or experience as specified under the director requirements to fulfill the responsibilities of the clinical consultant. The clinical consultant is responsible for providing consultation regarding the appropriateness of the tests ordered and interpretation of results. Specific responsibilities for the clinical consultant are listed under

§ 493.1457, Standard; Clinical consultant responsibilities.

General supervisor. We are revising the qualification requirements for general supervisor to clearly specify that an individual functioning as the technical supervisor could qualify to provide general supervision. We are adding to the general supervisor requirements the phrase "day-to-day supervision" to distinguish the role of the general supervisor from that of the technical supervisor. We are changing the qualification requirements at § 493.1459, Condition: Laboratories performing high complexity testing; general supervisor, to allow individuals with a master's or bachelor's degree to serve as general supervisors if they have at least one year of laboratory training or experience. Additionally, we are adding a provision to allow individuals with an associate degree in medical laboratory technology and two years of laboratory training or experience to qualify as general supervisors. Also, we are specifying that on the date of publication of these regulations, individuals who previously qualified or could have qualified as general supervisors under Federal regulations published March 14, 1990 will qualify under these regulations as a general supervisor. For blood gas analysis, we are adding a provision to permit individuals, who have a bachelor's degree in respiratory therapy and one year of training or experience in blood gas analysis or an associate degree related to pulmonary function and two years of training or experience in blood gas analysis, to qualify as general supervisors. Under paragraph (d) of § 493.1461, Standard; General supervisor qualifications, we are adding ophthalmic pathology to the histopathology subspecialties in which the general supervisory requirement is met by the technical supervisor performing tissue examinations, to correspond with the addition of ophthalmic pathologists to the technical supervisor qualification requirements.

Under the general supervisor responsibilities at § 493.1463, Standard; General supervisor responsibilities, we are specifying that the general supervisor must be accessible to the testing personnel at all times testing is performed to resolve technical problems. However, if high complexity testing is performed by a high school graduate who does not possess at least an associate degree in laboratory science or medical laboratory technology, the general supervisor must be onsite to provide direct supervision.

Cytology general supervisor. At § 493.1469, Standard; Cytology general supervisor qualifications, we are revising the qualification requirements for cytology general supervisor so that various types of experience as a cytotechnologist can be applied toward the 3 year experience requirement. In addition, at § 493.1471, Standard; Cytology general supervisor responsibilities, we are replacing the proposed requirement that the cytology general supervisor be on the premises when nonsupervisory cytotechnologists examine cytologic slide preparations, with the requirement that the cytology general supervisor be accessible to provide on-site, telephone, or electronic consultation to resolve technical problems. We also are expanding the list of responsibilities listed at § 493.1469 to be consistent with those duties for the general supervisor that are listed under the cytology quality control requirements in § 493.1257.

Cytotechnologist. We are establishing a new condition at § 493.1481, Condition: Laboratories performing high complexity testing; cytotechnologist, to encompass the qualification and responsibility requirements for cytotechnologists. We are relocating the cytotechnologist qualification requirements to § 493.1483 and cytotechnologist responsibility requirements are now at § 493.1465. We are adding to the qualification standards for cytotechnologists to require that individuals either have graduated from a CAHEA-approved school of cytotechnology or have been certified as a cytotechnologist by an HHS-approved certifying agency. Individuals who meet the qualifications for cytotechnologists under previous Federal regulations, prior to September 1, 1992, will also be qualified. In addition, for those individuals currently working as cytotechnologists who do not meet any of these standards, we are phasing-in the requirements so that a one year period from the effective date of the regulation is provided to obtain the experience requirement of 2 years of full-time or equivalent experience and a two year period is provided for either completing training in a CAHEA-approved school or obtaining certification.

We are deleting from the cytotechnologist responsibilities, the requirement for documenting the numbers of slides examined for initial interpretation, quality control, quality assurance and proficiency testing to correspond with the deletion under the cytology quality control section for a separate workload limit for different

types of slides. In addition, we are removing the requirement for the laboratory to employ a sufficient number of cytotechnologists from the cytotechnologist responsibilities section. This requirement is now under the laboratory director responsibility requirements located at § 493.1407, Standard; Laboratory director responsibilities, where it is more appropriate.

Testing personnel. Under § 493.1489, Standard; Testing personnel qualifications, we are revising the qualifications for testing personnel to clarify that physicians and individuals with a doctoral or master's degree in a science are qualified to perform all high complexity testing, with the exception of pathology. For blood gas analysis, we are adding a provision to qualify individuals having a bachelor's degree in respiratory therapy or an associate degree related to pulmonary function. We are including a provision to qualify all individuals who, on the date these regulations are published, were previously qualified or could have qualified as a technologist under Federal regulations published March 14, 1990. The minimum qualification requirement for individuals performing high complexity testing without onsite direct supervision by a general supervisor, is an associate degree in laboratory science or medical laboratory technology. We are adding a provision to allow a high school graduate to perform high complexity testing for a period of five years before such individuals would be required to obtain, at a minimum, an associate degree in medical laboratory technology or laboratory science.

*Subpart P—Quality Assurance for Moderate or High Complexity Testing, or Both*

**Summary of the Proposed Rule**

This subpart was proposed as Subpart M—Quality Assurance for Level I and Level II Testing. It has been renamed to reflect changes previously discussed. We proposed that the requirements in subpart M, established in the final rule on March 14, 1990, apply to all laboratories not issued a certificate of waiver. This subpart was previously applicable only to laboratories licensed under CLIA '67 and/or participating in Medicare. We proposed that the subpart would apply to laboratories performing any Level I or II tests.

**Summary of Comments and Responses**

Approximately 700 comments were received on this subpart. Thirty percent of the comments supported the

requirements as written, 45 percent were opposed to the proposed regulations and approximately 25 percent offered alternative suggestions.

*Comment:* Several commenters expressed concern that certificate of waiver laboratories were excluded from quality assurance requirements. They felt that quality assurance activities are necessary to insure the validity and accuracy of the test results reported.

*Response:* We agree with the commenters that quality assurance is an essential component of good laboratory practice and anticipate that any laboratory committed to accurate, reliable and prompt reporting of test results would institute a quality assurance program. However, the statute exempts certificate of waiver laboratories from compliance with certain CLIA standards including quality assurance, quality control, proficiency testing, personnel records and biennial inspections.

*Comment:* A small number of physicians commented that since the regulations did not define quality assurance, a laboratory might assume that quality assurance requirements could be met by complying with the quality control requirements. Other commenters confused quality assurance standards with proficiency testing requirements and assumed these requirements were the same.

*Response:* We agree with the commenters that the proposed rule did not clearly define quality assurance or differentiate between quality assurance activities and quality control activities. In this final regulation, we are defining quality assurance (QA) as an ongoing process for monitoring and evaluating every step of the laboratory's testing operation including pre-analytic, analytic and post-analytic processes.

QA extends to the laboratory's interactions with and responsibilities to patients, physicians, other laboratories, and other departments of the facility, organization, or institution of which it is a part. A QA program must: Evaluate all established policies and procedures for their effectiveness; identify and correct problems; assure accurate, reliable and prompt test reports; and assure the adequacy and competency of the staff. This encompasses the entire testing process from patient preparation and specimen collection, through test analysis and finally, to test result reporting.

To clarify QA requirements, we are adding language to the condition requiring the laboratory to have a QA program that monitors and evaluates the ongoing and overall quality of the total

testing process. This clarification was previously in the regulatory guidelines and is now being placed in the regulations at § 493.1701, Condition: Quality Assurance for Moderate or High Complexity testing or both. In addition, when appropriate, the standards of this subpart have been revised to emphasize that the laboratory must evaluate the effectiveness of its policies and procedures and, as necessary, revise policies and procedures based upon the results of its evaluation.

While quality control (QC) and proficiency testing (PT) are components of the total testing process that often identify problems in the analytic phase of testing, they may not necessarily identify problems in the pre- or post-analytic phase of the testing process. For this reason, we are adding § 493.1703, Patient test management assessment, which requires that the laboratory have an ongoing mechanism for monitoring and evaluating the systems under Subpart J, Patient Test Management. We believe the addition of this requirement addresses QA activities in the pre- and post-analytic processes which were not adequately addressed in the proposed rule.

*Comment:* Several commenters agreed that laboratory tests performed in a doctor's office should fall under a quality assurance program; however, the requirements should be appropriate for the complexity of the testing performed. The commenters also believed that quality assurance regulations for physicians' office laboratories should be different from the requirements for laboratories in which the attending physician is not directly involved with the laboratory testing. Other commenters felt that the regulations were appropriate and that the quality assurance standards should not be lowered. Some commenters stated that a quality assurance program that allows for the evaluation of services and performance indicators is the ideal basis for construction of a site-neutral and criteria based model of laboratory operations.

*Response:* We agree with the commenters who expressed the view that the quality assurance standards that were proposed in these regulations should be maintained. The standards in Subpart P, Quality Assurance for Moderate or High Complexity Testing, or Both, provide guidance for a laboratory in establishing a QA program that monitors and evaluates the overall quality of its total testing process. A laboratory should use the regulations as a guide while designing a QA program that is appropriate for the complexity of

the testing performed and the unique practices of the testing entity. The extent of a laboratory's quality assurance program should be proportional to the laboratory's test volume, scope and complexity of operations. We are broadening the language of § 493.1701 to clarify that the laboratory must meet the standards of this subpart as they apply to the services offered, complexity of testing performed and the unique practices of each testing entity.

*Comment:* A few commenters recommended that employee training, quality control and quality assurance functions should be the responsibility of the manufacturers. The commenters believed that the manufacturers could provide these services at little cost to the physician's office laboratory.

*Response:* It is true that many manufacturers provide services and reference materials to assist with the training of laboratory personnel who will be operating the instrumentation purchased. Some manufacturers also assist the laboratory to develop its quality control policies and procedures. However, it is ultimately the responsibility of the laboratory, through its director, to assure that personnel are adequately trained and quality control and quality assurance programs are established and implemented.

*Comment:* Several commenters noted that laboratories performing only Level I testing will not have qualified personnel capable of establishing and monitoring a quality assurance program. The commenters felt that Level I testing personnel would not have the education and experience necessary to understand the implications of pathologic conditions on specimen testing, or to assess/correlate patient test results.

*Response:* Although all laboratory personnel must be involved in quality assurance activities, the laboratory director, regardless of the laboratory's level of testing, is ultimately responsible for the overall management of the laboratory QA program. The director must establish and implement QA policies and procedures according to the standards contained in subpart P, including devising a system to monitor the QA program, assess and document problems that may arise, and perform and document the corrective actions taken to prevent recurrences.

*Comment:* A few commenters were concerned that the proposed regulations were too comprehensive for their laboratories to implement without extensive revision of their present hospital based quality assurance programs.

*Response:* We believe that the revised final regulations would not require extensive revisions to existing QA programs. Current hospital regulations require a facility-wide QA program that must include laboratory services. CLIA requires every laboratory performing non-waived tests to maintain a QA program adequate and appropriate for the laboratory's total testing process. These final regulations establish minimum requirements for a laboratory to follow in devising its own QA program, and are no more comprehensive than those presently required for laboratories currently participating in Medicare or Medicaid or testing specimens in interstate commerce.

*Comment:* A small number of commenters noted that in proposed paragraph (a) of § 493.1501, Condition: Quality Assurance; Level I and Level II, the word "ongoing" was excessive and that a laboratory would be consumed with continual monitoring of quality assurance activities. A few commenters suggested that § 493.1501(a), which requires the laboratory to evaluate test results against the laboratory's stated performance criteria including sensitivity, specificity, validity and adequacy, be deleted because these characteristics are not analytical attributes but instead refer to the clinical application of test results. Other commenters requested that laboratories be allowed to use manufacturers' test performance criteria to satisfy the requirement. A few commenters requested a definition of the terms validity and adequacy.

*Response:* We disagree with the commenters who felt that the word "ongoing" was excessive. Quality assurance is a comprehensive process that must be performed on a continuing basis to monitor and evaluate the laboratory's test performance and identify and correct problems in a timely manner to assure accurate and reliable test results. The determination and monitoring of a laboratory's performance specifications for precision and accuracy, are quality control issues and are addressed in Subpart K, Quality Control at § 493.1213, Standard; Method performance verification and § 493.1219, Standard; Remedial actions. For this reason, we are deleting proposed § 493.1501(a) as being repetitive and are adding § 493.1705, Standard; Quality control assessment, which addresses the evaluation of the effectiveness of corrective actions taken under § 493.1219. This addition correlates with the QA activities previously described and required by the condition of this

subpart. The terms validity and adequacy, as used in proposed § 493.1501(a), have not been included in § 493.1705.

*Comment:* We received several comments regarding the establishment of reporting times by the laboratory. A suggestion was made that, as part of the quality assurance program, reporting times should be periodically evaluated for all testing priorities (for example, emergency and routine).

*Response:* We agree with the commenters and are rewording the requirement proposed at § 493.1501(b) (now at § 493.1703(e)) to state that the laboratory must have an ongoing mechanism, based on testing priorities (STAT, routine, etc.) for monitoring and evaluating the timely reporting of test results.

*Comment:* Several commenters noted that repeating a control which was outside of the laboratory's acceptable range could be the first step in assuring the validity of patient results before reevaluating and reporting patient results. Several other commenters felt that it was unreasonable to expect that patient test results not be reported in every instance that a control is outside of its acceptable range particularly when multiple controls are in use and suggested that the regulation be modified to allow for review and release of test results by the technical supervisor.

*Response:* We agree with the commenters that there is more than one action a laboratory can take when a control is outside of the laboratory's acceptable range to assure the validity of data before reporting patient results. This subject has been addressed in subpart K, Quality Control at § 493.1211(b) (7) and (8) which addresses the establishment of the laboratory's own control procedures that would provide flexibility for determining the criteria for releasing test results, and at § 493.1218(e) which addresses the laboratory's established criteria for reporting patient results when control values are outside of the laboratory's acceptable limits. We are removing proposed paragraph § 493.1501(c)(2) as being repetitive.

*Comment:* A commenter noted that the requirement in proposed § 493.1501(c)(3) to evaluate patient test results analyzed in the same run before a failure in quality control or since the last acceptable quality control would be applicable only to batch processing of specimens and could not be applied to random access analyzers. Several commenters were concerned that laboratories may not have samples available for retesting patient specimens

and felt that it was not necessary to repeat all patient samples when a failure in quality control is identified. Another commenter suggested that the requirement at proposed § 493.1501(c)(3) should be revised to delete the words "before reporting" since this would require laboratories to test quality control materials before and after each run. The commenter noted that reports would be excessively delayed until the testing of quality control materials was completed. The commenters further noted the lack of consensus on the definition of an analytical run.

*Response:* A run, as defined in subpart K, Quality Control at § 493.1218(b), indicates a period of time within which the accuracy of the test system is expected to be stable. The regulation does not specify the quantity of test specimens per run and does not make any distinction between test systems as to the length of a run. Also, the regulations here do not mandate that all patient specimens be retested when a failure in quality control is identified but that the laboratory must evaluate those test results involved and, based on this evaluation, take the necessary action to correct any problems identified and issue corrected reports as appropriate. Actions necessary after correction of the problem may include the retesting of all patient specimens, but are not restricted to that. We have determined that the requirement specified in proposed § 493.1501(c)(3) should be included in the laboratory's remedial actions policies and procedures and are removing this paragraph from this subpart and inserting it into subpart K—Quality Control, § 493.1219 Remedial Actions. The regulation is being reworded to state that the laboratory must employ the remedial action necessary to ensure that accurate and reliable patient test results are reported.

*Comment:* A small number of commenters believed that testing quality control material before any patient testing is performed is a form of self-regulation.

*Response:* Quality control testing is performed by the laboratory as a check of the testing system's stability and to assure that the test results reported are accurate and reliable. A laboratory regulates itself through its QA program, part of which is the monitoring and evaluating of the effectiveness of corrective actions taken for problems identified in the review of calibration and control data to substantiate that the laboratory is meeting its specified performance criteria.

*Comment:* An overwhelming number of commenters requested that proposed § 493.1501(c)(5) be deleted.

*Response:* We agree with the commenters and are deleting § 493.1501(c)(5).

*Comment:* Several commenters requested that the regulation be revised to require that the laboratory's test report contain pertinent notation concerning the condition of the patient specimen when testing is performed on an unacceptable specimen.

*Response:* The requirement that the laboratory must indicate on the test report any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability is addressed at § 493.1109(c), Standard; Test Report, in subpart J, Patient Test Management. The language of proposed § 493.1501(e), now at § 493.1703(c), has been revised to state that the laboratory's QA program must have an ongoing mechanism for monitoring and evaluating the use and appropriateness of the criteria established for specimen rejection. This revision correlates with the QA activities previously described and required by the condition of this subpart.

*Comment:* Many commenters agreed that the patient data requirements in proposed § 493.1501(f) would be useful and may be pertinent to testing. However, commenters were concerned that the laboratory frequently has little knowledge or access to a patient's actual diagnosis or condition and that this information is often confidential. In addition, it is believed that it is the responsibility of the physician to evaluate test results to determine if they are inconsistent with the patient's condition.

*Response:* We agree with the commenters that the laboratory frequently is not provided with the diagnosis or other pertinent patient information and are adding the words "when provided" to the requirement at § 493.1711(c). The laboratory is responsible for making reasonable attempts to obtain the information necessary for the performance of accurate and reliable testing and for determining whether the test results are consistent with any patient data provided. However, it is ultimately the responsibility of the physician to evaluate the test results received for consistency with the patient's condition. Since many laboratories perform the same test using different methodologies, instruments, or at multiple testing sites, it is essential that the laboratory assure consistency among patient test measurements regardless of the methodology, instrument or testing site. The physician's interpretation of the test

result and subsequent treatment of the patient must not be hampered by a lack of correlation between the laboratory's methodologies, instruments or testing sites. For this reason, we have added § 493.1709, Comparison of test results, which requires the laboratory, twice a year, to establish and define the relationship between the test results obtained using different methodologies, instruments, or testing sites. In addition, if a laboratory performs tests that are not included under subpart I, Proficiency Testing Programs, the laboratory must have a system for verifying the accuracy and reliability of its test results at least twice a year. One of the ways this may be accomplished is by split sample testing as previously described in the Proficiency Testing regulations and the preamble discussion of Proficiency Testing.

This standard requires that laboratories have a mechanism in place which would help to detect misidentified specimens and gross errors by using whatever data is available to the laboratory. As an example, if a positive pregnancy test result is obtained and the patient is male, the laboratory must take steps to be sure that the specimen is not mislabeled; it may be necessary to repeat the test to be certain that the correct result was obtained. It is a very useful quality assurance tool for the laboratory, and is considered good laboratory practice.

*Comment:* A few commenters were concerned that more sophisticated computer software would be necessary to comply with the requirement in proposed § 493.1501(g) to assess breakdowns in communication.

*Response:* The regulation at proposed § 493.1501(g) (now at § 493.1715, Standard; Communications) is not intended to require the use of computers to resolve communication problems and is applicable to manual as well as automated laboratory information systems. The requirement is now worded to clarify that a laboratory does have flexibility in establishing a system for documenting and correcting breakdowns in communication that is appropriate for the type of information system the laboratory employs.

*Comment:* Many commenters objected to the two methods specified in proposed § 493.1501(h) for evaluating employee competency. Most of the commenters felt that a laboratory should have the flexibility to develop its own mechanisms to evaluate staff performance. The majority of the commenters objected to evaluating employee performance through an additional external proficiency testing program. Commenters indicated that

this requirement is repetitive and would dramatically increase costs over and above the proficiency testing required in subpart H. A few commenters believed that proficiency testing and quality control requirements were sufficient to measure the competency of cytotechnologists and that using blind proficiency test samples for evaluating employees may cause problems in record keeping and test reporting. While several commenters felt that direct supervisory observation of employees is sufficient to assure adequate performance of staff, others believed that evaluating individuals in this manner would be disruptive to the performance and reporting of tests.

*Response:* We agree with the commenters who felt that a laboratory should have the flexibility to develop its own mechanism to evaluate staff performance. This is now addressed under subpart M, Personnel Standards, under Director, Technical Consultant/Supervisor responsibilities. We are revising the paragraph at § 493.1501(h) (now at § 493.1713, Standard; Personnel) to require that the laboratory must have an ongoing mechanism to evaluate the effectiveness of policies and procedures instituted for assuring the competency of employees and, if applicable, consultants. This revision correlates the QA activities previously described and required by the condition of this subpart.

*Comment:* A few commenters felt that clarification was needed for the statement, under proposed § 493.1501(h)(2), suggesting that cytology laboratories insert blind samples into the workload or exchange slides with another laboratory. They questioned whether this would necessitate establishing an additional quality assurance program for each individual or whether the other requirements such as rescreening and comparing individual performance statistics with laboratory performance statistics satisfy this requirement. One commenter recommended that the requirement state that the laboratory must define an employee performance evaluation system and maintain documentation allowing the laboratory to develop its own program.

*Response:* This statement for assuring employee competency and monitoring performance in cytology was not intended to require the development of additional programs to those specified in § 493.1257, Standard; Cytology, but was given as an example of ways in which to accomplish performance evaluation. To avoid confusion, we are deleting this statement.

*Comment:* Concerning proposed § 493.1501(j), commenters requested clarification regarding whether this requirement applies to manual reporting systems as well as computer systems. In addition, commenters were concerned about the required frequency of this activity and suggested that continuous verification was not necessary for automated systems. Several other commenters suggested that § 493.1501(j) be expanded to include security systems and confidentiality safeguards and eliminate proposed subpart P, Computer Systems for Level I and II Testing.

*Response:* Section 493.1501(j), now at § 493.1703(f), applies to both manual and automated test reporting systems. We have removed words that would be specific to automated systems so as not to preclude users of manual systems. We are requiring that the laboratory evaluate its test reporting, storage and retrieval systems on a continuing basis. We have not mandated how a laboratory should evaluate these systems or the frequency with which the evaluation must be done, however, documentation of this quality assurance activity is required and must be made available to HHS. We agree with the commenters who suggested we eliminate the proposed subpart P, Computer Systems for Level I and II testing. The standards of the proposed subpart P are covered in the appropriate subparts of the final rule such as Patient Test Management, Quality Control and Quality Assurance.

*Comment:* A few commenters were concerned about documenting all complaints and problems reported to the laboratory since such documentation would be extremely time consuming and unrealistic. Commenters suggested replacing the word "all" with "substantive" or "significant" or "pertinent".

*Response:* We disagree with the commenters. We are not removing the requirement, formerly at § 493.1501(k) and now at § 493.1717, to document all complaints and problems reported to the laboratory. We have, however, provided flexibility in this requirement by adding "when appropriate", to "Investigations of complaints must be made \* \* \*" to allow for the laboratory to decide when and to what extent an investigation will be made based on its established policies and procedures.

#### Changes to the Regulation

As previously described, the regulations have always been applicable to the total testing process. Language has been added to the subpart which has been redesignated as subpart M and

renamed Quality Assurance for Moderate or High Complexity Testing, or Both to clarify that QA activities extend throughout the total testing process and include an evaluation of the effectiveness of the laboratory's policies and procedures.

We have added § 493.1709, Comparison of test results, which requires, twice a year, that the laboratory evaluate and define the relationship between test results obtained using different methodologies, instruments, or testing sites, and verify the accuracy and reliability of test results obtained using tests that are not included under subpart I, Proficiency Testing Programs.

We are clearly defining quality assurance and differentiating between quality assurance activities and quality control activities.

We are adding § 493.1703, Patient test management assessment, which requires that the laboratory have an ongoing mechanism for monitoring and evaluating the systems under subpart J, Patient Test Management.

Section 493.1705, Quality control assessment, is being added and requires that the laboratory have an ongoing mechanism for evaluating corrective actions taken under subpart K, Quality Control.

We require the laboratory to have an ongoing mechanism, based on testing priorities (STAT, routine, etc.) for monitoring and evaluating the timely reporting of test results.

We are removing proposed paragraph § 493.1501(c)(2) as being repetitive of § 493.1211(b) (7) and (8) which concerns the establishment of the laboratory's own control procedures that would provide flexibility for determining the criteria for releasing test results, and § 493.1218(e) which concerns the laboratory's established criteria for reporting patient results when control values are outside of the laboratory's acceptable limits.

We are moving the requirement specified in proposed § 493.1501(c)(3) concerning the laboratory's remedial actions policies and procedures to subpart K—Quality Control, § 493.1219, Remedial Actions.

We are deleting proposed § 493.1501(c) (1) and (4) because these are QC issues and have been addressed in subpart K, Quality Control and subpart M, Personnel.

We require the laboratory to evaluate the effectiveness of corrective actions taken, which correlates with the QA activities required by the condition of this subpart.

We provide that the laboratory's QA program must have an ongoing

mechanism for monitoring and evaluating the use and appropriateness of the criteria established for specimen rejection.

We clarify that the laboratory must identify and evaluate patient test results that appear inconsistent with relevant criteria, such as diagnosis or pertinent patient data "when provided."

We clarify that a laboratory has flexibility in establishing a system for documenting and correcting breakdowns in communication that is appropriate for the type of information system the laboratory employs, and that it is not necessary to employ sophisticated computer software to assess breakdowns in communication.

We clarify that a laboratory has the flexibility to develop its own mechanism to evaluate staff performance. (This is now addressed under subpart M under Director, Technical Consultant/ Supervisor responsibilities.) We now provide that the laboratory must have an ongoing mechanism to evaluate the effectiveness of policies and procedures instituted for assuring the competency of employees and, if applicable, consultants.

To avoid confusion, we are deleting the statement concerning assuring employee competency and monitoring performance in cytology.

We require the laboratory to evaluate its test reporting, storage and retrieval systems on a continuing basis. This applies to both manual and automated test reporting systems.

Concerning the investigation of complaints and problems reported to the laboratory, we are adding "when appropriate," to allow for the laboratory to decide when and to what extent an investigation will be based on its established policies and procedures.

The terms "data analysis" and "transmittal" are being deleted from proposed § 493.1501(j), now § 493.1703(f). The section is reworded to clarify that the laboratory must monitor and evaluate the accuracy and reliability of test reporting systems, appropriate storage of records and retrieval of test results.

#### *Subpart Q—Inspection*

##### Summary of Proposed Rule

We proposed, as subpart N, to apply the requirements of existing §§ 493.1601, 493.1603, and 493.1605 to all laboratories under the authority of CLIA. For organizational consideration, we are redesignating the subpart as subpart Q. We proposed that HHS may conduct an unannounced inspection of any laboratory at any time during its hours of operation. These inspections may

include interviewing employees, observation of employees performing tests, data analysis and reporting of test results, and review of all records and data required by HHS to determine compliance with the requirements. Further, HHS may deny approval to a laboratory for at least one year for violation of any of the requirements in regulations at part 493. HHS may waive this one-year period if the laboratory submits good cause for the waiver. Failure to permit an inspection would result in revocation of a certificate of waiver, provisional certificate, certificate or certificate of accreditation, as applicable.

#### Comments and Responses

We received approximately 1,080 comments in response to this section. Nearly 60 percent of the comments represented physician office laboratories (POLs). Almost 50 percent of the commenters were opposed to the requirements as written while nearly 40 percent offered alternative suggestions to the proposed standards.

*Comment:* Numerous comments were received from individuals and organizations regarding the proposed requirements for unannounced inspections of waived, certified and accredited laboratories. A large number of commenters suggested that in lieu of conducting routine unannounced inspections, on-site inspections of only a random number of laboratories after their initial on-site inspection is conducted should be performed. These commenters also recommended that unannounced inspections should only be performed on laboratories that have demonstrated a problem. Another group of commenters offered a suggestion that on-site inspection be required only for "substantial reason" and not for "public complaint". Some commenters agreed that both waived and non-waived laboratories should be subject to inspection while others objected to the requirement that certificate of waiver laboratories be subject to inspection. Finally, a commenter from a military facility expressed his views that unannounced inspections would not be feasible in all military facilities because of security reasons.

*Response:* Section 353(g) (1) and (2) of the Public Health Service Act requires that HHS conduct announced or unannounced biennial inspections of laboratories issued a certificate and requires inspections of laboratories issued a certificate of accreditation on such basis as the Secretary determines necessary to assure compliance with the CLIA requirements and standards.

Under the Medicare Survey and Certification Procedures, it is our policy to conduct unannounced inspections during routine operational hours for all health care providers and suppliers, with the exception of hospitals. It is imperative that a laboratory be inspected during its routine operation so that an appropriate evaluation can be made about the services and activities ordinarily performed by the laboratory. Inspections are not necessarily conducted for the convenience of either the laboratory or the survey agency, but serve as a mechanism to assess the quality of services routinely provided by the laboratory for the diagnosis and treatment of patients.

We disagree with the commenters who suggested that on-site inspections be performed only for "substantial reason" and not for "public complaint" and are retaining our policy as written in order to assure the laboratory's compliance with the regulations and to exonerate the laboratory from the alleged accusation, when appropriate. For laboratories issued a certificate of waiver, random inspections will be conducted to determine compliance with § 493.15(d), to verify that only waived tests are performed, to investigate complaints and to collect information for the addition, deletion or continued inclusion of tests on the waiver lists. For military facilities where security clearance is mandated, we would use personnel who already possess clearance or we would seek security clearance as needed, in order that we may treat all laboratories equally.

*Comment:* A number of commenters expressed the view that unannounced on-site inspections of laboratories would be disruptive since individuals would be removed from routine testing in order to be interviewed, to assist in the observation of test performance, and to retrieve records or copies of records requested by the inspectors. One commenter expressed the concern that the observation of employees performing tests, including the testing of proficiency samples, could create an intimidating situation which may result in the employee failing to properly test a patient or proficiency testing sample.

*Response:* It is not our intent to disrupt the laboratory's operations. Inspectors will be instructed to make every effort to accommodate the laboratory's routine testing activities. Observation of testing will be part of examining the overall operation of the laboratory and we will avoid, as much as possible, interrupting the routine work flow. We would expect the technical staff to perform proficiency

testing to the extent that they are performing patient testing and reporting test results. Interviews of workers are intended to be "on the job" rather than in an area removed from the workplace, unless there is cause for privacy.

*Comment:* A few commenters noted that previous inspections had been beneficial to the laboratory and that test quality had been improved.

*Response:* While the inspection process is focused on evaluating the quality of the laboratory services, corrective actions taken by facilities in response to deficiencies noted during an inspection are beneficial to both the patient and the laboratory.

*Comment:* A few commenters suggested different frequencies for on-site inspections, with some recommending a three year cycle, on an "as needed" basis (as determined by proficiency testing performance), or on a random periodic basis.

*Response:* The law requires biennial issuance of certificates and specifies that inspections should be conducted on a biennial basis or with such frequency as the Secretary determines to be necessary to assure compliance with the CLIA requirements. In order to issue CLIA certificates, we must conduct inspections to evaluate whether the laboratory is in compliance with CLIA standards. However, the laboratory may be subject to more frequent inspections due to public complaints, validation surveys, addition of tests to the certificate, and follow-up inspections to assess compliance when serious deficiencies were noted on a prior inspection.

*Comment:* A few commenters noted that the inspection of physician office laboratories would raise the cost of medical care.

*Response:* Under the provisions of the statute, inspections conducted to assess compliance with the CLIA requirements must be financed through the payment of fees by the regulated laboratories. The CLIA requirements are intended to improve the quality of laboratory services provided to all patients. Therefore, the costs associated with CLIA may be somewhat offset by the benefits accrued by more accurate laboratory test results and the decreasing need for repeat testing. A more complete analysis of the costs and benefits of CLIA are discussed in the Regulatory Impact Analysis.

*Comment:* Several commenters asked how inspection of waived laboratories would be conducted when there are no requirements for proficiency testing or quality control.

*Response:* We will inspect a certificate of waiver laboratory to determine compliance with § 493.15(d), which requires the laboratory to follow manufacturer's instructions for the performance of the waived tests, and compliance with applicable State and local laws. In addition, we will collect information to determine the future addition, deletion, or continued inclusion of tests listed in the waiver category and to confirm that the laboratory is only performing tests in the waiver category. This will be accomplished by reviewing records, interviewing employees, and observing test performance, availability and use of test equipment, reagents and reporting mechanisms for test results.

*Comment:* A commenter recommended that any PT sample used for on-site testing must meet the same standards required of approved proficiency testing programs and that a legal chain of possession document to be maintained for every PT sample used for on-site PT such that the sample is traceable to the source of preparation and documents every person handling the sample.

*Response:* We agree with the commenter that specimen integrity of all PT samples must be assured before any grading criteria can be applied. In most instances, the laboratory's proficiency testing event will be conducted using samples that have been mailed to the laboratory from approved PY programs, and the laboratory will be responsible for proper storage and handling of PT samples prior to testing. Currently, we do not require a legal chain of custody to document transport and receipt of PT samples and we would not require such records for on-site PT sample delivery. If HCFA or one of its agents has PT samples delivered to it for transportation to a laboratory for on-site testing during an inspection, the samples will be stored and transported by the inspecting entity in accordance with the PT programs' instructions.

*Comment:* A number of commenters expressed concerns about the qualification of laboratory inspectors. Several commenters suggested specific qualifications to include pathologists, Ph.D.s and certified medical technologists with extensive bench or work experience as a laboratory inspector. One commenter suggested that for inspections of research laboratories, the inspection should be conducted by an individual possessing the relevant scientific background, or if necessary with the aid of an outside expert consultant who may be a biomedical researcher.

*Response:* Inspections are performed by HCFA regional surveyors and State agency personnel. Generally, these individuals have education, qualifications, and experience similar to the General Supervisor requirements of § 493.1429, in addition to mandatory attendance at HCFA sponsored laboratory surveyor training programs. We also provide written guidelines to assist surveyors in evaluating laboratory compliance with Federal regulations. In a research laboratory, only tests performed that meet the definition of the statute " \* \* \* examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings" would be subject to the CLIA regulations. If a research laboratory performs testing that fall under CLIA, we would expect this testing to be conducted in accordance with part 493, therefore, our inspectors would have the proper qualifications and experience to evaluate the testing system for compliance with the CLIA regulations for those test results directly related to and used for the patient.

*Comment:* Some commenters suggested revising the proposed requirements for interviewing laboratory employees to be amended as follows:

Allow HHS or its designee to interview all employees of the laboratory concerning all aspects of the laboratory's compliance with CLIA and the following related sections of the Federal regulations:—405, 416, 440, 482, 483, 488 and 493.

*Response:* We agree with the commenters and have added the phrase " \* \* \* concerning the laboratory's compliance with the applicable regulations at part 493." at § 493.1801(b)(1), § 493.1803(b)(2), and § 493.1805(c)(2).

*Comment:* A few commenters expressed the view that the proposed requirements providing HHS access to all of a laboratory's records are too broad and suggested they should be amended as follows:—"provide copies to HHS or its designee of all records and data relevant to the laboratory's compliance with CLIA \* \* \*".

*Response:* All records pertaining to the operation of the laboratory, including ownership, testing performed, personnel qualifications, etc., are relevant to the laboratory's compliance with CLIA requirements. Therefore, we have retained the requirement as proposed and have moved it to § 493.1775(b)(5), § 493.1777(b)(5), and § 493.1780(c)(5). We have also added a

requirement at §§ 493.1777(b)(4) and 493.1780(c)(4), which permits HHS access to all areas of the testing facility necessary to evaluate the compliance of the laboratory with the regulations at part 493 to meet statutory requirements at section 353(g)(1) of the PHS Act.

*Comment:* One commenter opposed the proposed requirement in § 493.1601(e) that would prevent approval of a laboratory's application for a period of one year following the effective date of a revocation of its certificate of waiver.

*Response:* We agree with the commenter and are deleting the requirement from §§ 493.1775, 493.1777 and 493.1780.

*Comment:* Some commenters noted that proposed § 493.1603(d) and § 493.1605(f) address record retention requirements which were already addressed in the Patient Test management Subpart, but they do not include pathology or cytology. They recommended dropping the requirements from the Inspection Subpart to avoid confusion.

*Response:* We agree with the commenters that there were inconsistencies between the two proposed subparts, therefore we are adding the requirement for a 10 year maintenance period for reports for the specialty of pathology, which would include reports for the subspecialty of cytology, at § 493.1777(d) and § 493.1780(f), to be consistent with the requirements in Subpart J, Patient Test Management.

#### Changes to the Regulation

We are adding a provision that allows HCFA and its designee access to all areas of the facility necessary to determine compliance with part 493 during an inspection.

We are clarifying that failure of a laboratory to permit an inspection will result in suspension of Medicare and Medicaid payments or termination of the laboratory's participation in the Medicare or Medicaid program, and suspension of or action to revoke the laboratory's CLIA certificate to be in accordance with the subpart R, Enforcement, which is being established in a separate rulemaking in this issue of the **Federal Register**.

We are removing the proposed requirement that if a laboratory's CLIA certificate is revoked, HCFA will not approve the laboratory's application for a period of 1 year.

#### *Proposed Subpart P—Computer Systems for Level I and Level II Testing*

##### Summary of Proposed Rule

##### *Section 493.1801 Condition: Computer Systems*

To ensure that laboratories are able to accurately report patient testing by a properly functioning system, we proposed computer system requirements for laboratories using any size computer system to assist in patient test performance and identification of patient specific information for result reporting. Included in these requirements were provisions for the computer system environment, operation of the computer, scheduled and unscheduled computer interruptions, computer programs, computer data entry, patient result reporting, data retrieval, computer security, and capacity.

##### Comments and Responses

A total of 320 comments were received to subpart P, Computer Systems. Nineteen commenters fully supported the proposed requirements for computer systems as written. Of the more than 200 commenters who suggested alternate language, the majority agree with the intent of the requirements and the need for computer systems regulations. The number of commenters requesting deletion of the subpart was 65. Over 60 physicians misread the requirements, believing that they would be required to purchase and use a laboratory information system (LIS) in their office laboratory.

The subpart would have been applicable only to laboratories that chose to use an LIS in their facility. Upon further review, we are removing this subpart from the final regulations.

##### Conforming Changes

We are making technical and conforming changes to parts 405, 410, 416, 417, 418, 440, 482, 483, 484, 485, 488, 491, 493, and 494 to clarify that if any of these entities provides its own lab services, the services must meet the requirements in part 493. These parts concern suppliers of End-Stage Renal Disease (ESRD) services, ambulatory surgical centers, Federally qualified health maintenance organizations, hospitals, long term care facilities, intermediate care facilities for the mentally retarded, home health agencies, comprehensive outpatient rehabilitation facilities, organ procurement organizations, rural health clinics, and screening mammography services. If the entity refers specimens to another laboratory, the referral

laboratory must be certified in the appropriate specialties and subspecialties in accordance with part 493.

We are clarifying that individual patients and private homes are not subject to CLIA requirements. However, we are providing in § 484.14 that when a home health agency engages in testing outside the context of assisting an individual in his or her own home in self-administering a test with an appliance that has been approved for that purpose by FDA, the testing must be in compliance with the requirements in part 493.

**Regulatory Impact Analysis**

Executive Order (E.O.) 12291 requires us to prepare and publish a final regulatory impact analysis for any proposed regulation that meets one of the Executive Order (E.O.) 12291 criteria for a "major rule." A major rule is defined as any rule likely to result in:

- An annual effect on the economy of \$100 million or more;
- A major increase in costs or prices for consumers; individual industries; Federal, State or local government agencies; geographic regions; or
- Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Also, we generally prepare a regulatory flexibility analysis consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), unless the Secretary certifies that a proposed regulation would not have a significant economic impact on a substantial number of small entities. For purposes of RFA, States and individuals are not small entities. We consider all clinical laboratories to be small entities.

In addition, section 1102(b) of the Social Security Act requires the Secretary to prepare a regulatory impact analysis if a proposed rule may have a significant impact on the operations of a substantial number of small rural hospitals. We define a small rural hospital as a hospital which is located outside a Metropolitan Statistical Area and has fewer than 50 beds.

The four HHS regulations implementing CLIA clearly meet E.O. 12291, RFA, and Social Security Act thresholds for preparation of a regulatory impact analysis. This analysis fulfills impact analysis requirements for all four of the implementing regulations: HSQ-176-FC, HSQ-177-F, HSQ-179F, and HSQ-193-P.

**Executive Summary**

There is a general lack of information on the characteristics of the U.S. clinical laboratory industry. Estimates of the number of laboratories subject to CLIA requirements vary widely. For the purposes of this analysis, we constructed independent estimates, using a variety of sources. To address uncertainty, three assumptions concerning the number of laboratories are used throughout the analysis:

- Low Assumption—180,000 laboratories.
- Intermediate Assumption—210,000 laboratories.
- High Assumption—250,000 laboratories.

These estimates are significantly below the 300,000 to 600,000 laboratory estimates previously cited by HHS. We believe that these earlier estimates are inflated due to double counting of laboratories, which remains a concern even in the current 180,000 to 250,000 estimates.

*Costs of the Regulations*

The direct costs of these regulations will fall on the nation's laboratories. Under the final rule, proficiency testing, quality control, and personnel requirements will be phased in over a two-year period, in order to address the significant implementation concerns of both the government and the laboratory industry.

The full implementation costs of the final rule will not occur until Federal fiscal year (FY) 1994 (October 1993–September 1994), when we project that CLIA costs will total \$1.2 billion to \$2.1 billion. While this is our best estimate, it is based on assumptions we are presently unable to verify.

**COSTS OF THE FINAL RULE UNDER INTERMEDIATE ASSUMPTION**

[Dollars in millions]

	FY 1992	FY 1993	FY 1994	FY 1995	FY 1996
Certification .....	\$27	\$28	\$29	\$30	\$31
Proficiency Testing.....	0	0	445	461	477
Patient Test Management.....	22	15	16	16	17
Quality Control.....	600	609	631	653	676
Inspections.....	15	95	137	98	142
Personnel.....	0	286	296	307	317
Other Startup Activities.....	70	0	0	0	0

**COSTS OF THE FINAL RULE UNDER INTERMEDIATE ASSUMPTION—Continued**

[Dollars in millions]

	FY 1992	FY 1993	FY 1994	FY 1995	FY 1996
Total.....	734	1,033	1,554	1,565	1,660

The costs of CLIA regulation will vary widely among clinical laboratories. Hospitals and independent laboratories already subject to Federal regulation may sustain small incremental increases which, due to their large testing volume, may amount to a penny or less per test. On the other hand, many physician offices may see their laboratory costs increase by 10 percent or more—and the cost of an average test rise in excess of a dollar. Under our intermediate assumptions, the average cost of a laboratory test in the United States could increase by 25 cents as a result of CLIA requirements.

The cost increases that will be incurred by individual laboratories will largely depend on their current operations. Those laboratories presently following what is generally referred to as "good lab practice"—including, for instance, following daily quality control protocols, maintaining instruments according to manufacturers' instructions, participating in proficiency testing, using qualified personnel to perform tests, and keeping detailed, organized records—may see only marginal cost increases as a result of CLIA. Those laboratories currently not following such practices may experience significant increases in the costs of their operations.

*Benefits of the Final Rule*

CLIA anticipates that comprehensive Federal regulation will improve the accuracy of clinical laboratory testing, thereby producing national public health benefits. There is no reliable means of quantifying these expectations, especially given the current lack of data on the clinical laboratory industry.

Nonetheless, we offer two quantitative projections of potential CLIA benefits. While the methodologies reflect the scarcity of definitive data required for more elaborate economic models, we believe that these projections may be useful in framing discussions on the prospective impact of CLIA regulations.

*Willingness-to-Pay.* The first projection is based on a "willingness-to-pay" model. This technique is commonly used by economists to project public health benefits by estimating how much

consumers are willing to pay for decreases in medical or health risk. We project that non-poor American households may be willing to pay anywhere from 5 percent to 25 percent more for laboratory services in order to improve their accuracy, and thereby reduce risk. Using this approach, CLIA benefits may be valued from \$570 million to \$2.8 billion per year.

*Cost Avoidance.* An alternative model attempts to estimate the savings in national health expenditures that would result from reductions in laboratory false positive and false negative rates. False positives occur when test results indicate disease in a patient that does not actually have disease; they can result in unnecessary followup testing and medical treatments. False negatives occur when test results show no disease in a patient that actually does have disease; they can result in delayed treatment, increased morbidity, and unnecessary death.

While no data exist for assessing current and future false negative and positive rates, HCFA offers several scenarios for potential economic benefits to accrue through early intervention, and reductions in unwarranted follow-up tests and unnecessary treatments. If CLIA—through reductions in false positive rates—can reduce national expenditures for unnecessary testing and treatments by ½ percent to 1 percent, annual savings of \$300 million to \$2.1 billion could result. If CLIA—through reductions in false negative rates—can lead to earlier intervention and thereby reduce expenditures for necessary care, annual savings of \$200 million to \$2.8 billion could result.

Therefore, under the cost avoidance model, public health benefits resulting from CLIA could total \$500 million to \$4.9 billion per year.

Such models are, of course, highly speculative. This is due in part to a lack of research data. Perhaps more importantly, it can not be assumed that improvements in testing accuracy will directly translate into better treatment and outcomes. Laboratory testing is only one variable in the medical decision-making equation. Test results only seek to provide answers to the clinical questions posed by physicians and other care providers. CLIA has no bearing on the larger public health issue of whether the clinical questions being asked are the appropriate questions—or, given the lack of access to care for many Americans, of whether the questions are being asked at all.

#### *Potential Impact on Access*

The American health care delivery system is quite complex and diverse, and there is no clear, comprehensive understanding of its laboratory testing component. Without that understanding, it is difficult to predict with confidence how CLIA regulations will affect patient access to medical services. Nonetheless, some ramifications of CLIA regulation can be forecast with certainty, and others reasonably conjectured.

The final rule will significantly increase the operating expenses of the nation's laboratory industry—perhaps by as much as 6 percent per year. Most laboratories will successfully pass on these cost increases to patients and other consumers of their services.

These cost increases may reduce the ability of certain already-financially burdened providers to deliver services, and of the poor, uninsured, and underinsured to obtain needed care. Facilities and individuals in under-served areas, primarily rural America and the inner cities, will be most affected. The actual numbers may be quite small, but we are unable to reliably predict this impact.

Among those providers that will be most vulnerable to increased costs are small rural hospitals, student health services, public health clinics, community screening programs, and other types of providers that must function within constrained budgets. For some of these providers, such as some municipal health programs, passing on costs is not a viable option. They will be forced instead to restrict their services. Of those programs that are able to pass on some or all of their operating cost increases, many may find their initiatives less effective, as their patients are unable or unwilling to pay more for health care services.

While the final rule is designed to protect all consumers from substandard quality laboratory work, the CLIA program could in some instances thwart larger public health objectives by hindering the provision of screening services to the poorest Americans.

Ironically, this could be the case in cytological screening, which was the impetus for CLIA legislation. There is already a national shortage of cytotechnologists, and the final rule will increase demand. In the laboratory industry generally, recent surveys indicate that 80 percent of U.S. laboratories have experienced a shortage of technical personnel. Again, the problems are more acute in rural areas, where the ratio of laboratory personnel per 100,000 population is less than half that of metropolitan areas.

For all of the uncertainty about CLIA implementation, it is certain that the final rule will not restrict access to the extent feared and expressed in public comments on the NPRM. Though there remain some valid questions about potential restrictions on access, especially in under-served and low income communities, the final rule will in one overarching respect broaden access. By setting consistent requirements for all laboratories—regardless of setting, location, or populations served—CLIA legislation and the final rule seek to assure for the first time that all U.S. laboratories provide testing services that meet minimum standards of quality.

#### *Regulatory Impact Analysis*

##### *Methodology and Approach*

This analysis addresses a wide range of projected costs and benefits of the final rule. Whenever possible, it employs appropriate methods for expressing impact quantitatively. These projections are supplemented by narrative discussion.

Any effort to prospectively assess the cost-effectiveness of a major public health initiative must be premised, to some degree, upon educated speculation. This analysis in particular must address regulation of a clinical discipline, about which there is scant cost/benefit data or empirical study, in the context of a complex health care marketplace. The analysis is reliant upon many simplifying assumptions, which are made explicit throughout the analysis.

##### *Laboratory Estimates*

Estimates of the number and characteristics of laboratories vary widely in professional and scientific literature, as do estimates included in public comments to the NPRM. Generally, however, these estimates share one common characteristic: They represent best guesses, and are lacking in reliable supporting data.

In many cases, our analysis cannot rely upon tabulated actual counts or statistical inferences drawn from empirical data. It instead uses estimates based on currently available information. We must await compilation of CLIA laboratory registration and certification information for comprehensive, reliable data on the number and characteristics of CLIA laboratories.

Following our review of the existing body of laboratory estimates, it was decided that the usefulness of this analysis would be improved by

compiling new, independent projections. To this end, the following source materials were used:

- Medicare, Medicaid, and CLIA 67 data.
- Accreditation and professional organization data.
- Physician data from the American Medical Association.
- State licensure and regulatory experience.
- Public comments to the NPRM.
- Academic and professional literature.
- Expert opinion.

In order to address the uncertainty surrounding laboratory estimates, we use three sets of assumptions throughout the analysis.

#### ESTIMATES OF THE NUMBER OF LABORATORIES SUBJECT TO CLIA

	Low assumption	Intermediate assumption	High assumption
Hospitals.....	7,000	7,000	7,000
Independent Labs.....	6,000	6,000	6,000
POLs <sup>1</sup> .....	110,000	130,000	140,000
Other.....	57,000	67,000	97,000
Total.....	180,000	210,000	250,000

<sup>1</sup> Physician Office Laboratories.

The four categories of laboratory estimates vary greatly in degree of reliability. As is to be expected, we are far more confident in the numbers and characteristics of laboratories and other health care providers currently under Federal regulation, such as most hospitals, independent laboratories, and nursing facilities. We are most uncertain about the various entities that may fall into the "Other" category.

**Hospital and Independent Laboratories.** The hospital and independent laboratory estimates are based on Medicare, Medicaid, and CLIA 67 survey and certification data. These laboratory counts are supplemented by State survey agency estimates that include projections of hospitals and independent laboratories not currently subject to HCFA requirements. To the extent possible, these estimates were validated through comparison with accreditation and professional organization data.

**Physician Laboratories.** Estimates of the number of U.S. physician office laboratories (POLs) vary widely. The POL estimates in this analysis are drawn from HCFA extrapolation of published AMA data. AMA reports cite the total number of U.S. physicians in office-based practice as approximately 350 thousand, and distribute these

physicians by practice specialty. These distributions were converted into estimates of laboratories by application of AMA research on the proportions of in-office clinical laboratories found in a large sample of physician specialties. These estimates were then grouped, according to practice specialty, into Primary and Non-Primary Care categories.

#### ESTIMATES OF THE NUMBER OF PHYSICIAN OFFICE LABORATORIES

	Office-based physicians	Proportion with clinical labs	No. of POLs
Primary Care.....	160,000	.56	90,000
Non-Primary Care.....	190,000	.21	40,000
Total.....	350,000	.37	130,000

\*Rounded to nearest 1,000.

Several alternative methodologies were explored, but appeared less reliable. These included an effort to apply information about the size and frequency of group practices to AMA databases of individual physicians. The analysis uses an approach that is appropriately conservative, for it does not appear to understate the POL universe. It attempts to avoid double-counting of physicians working in institutional settings. These estimates also compare favorably with State survey agency estimates collected by HCFA regional offices.

**Other.** The "other" category includes nursing facilities, end stage renal disease dialysis clinics, freestanding home health agencies, hospices, rural health centers, ambulatory surgery centers, dental offices, blood and organ banks, mobile and walk-in screening programs, family planning clinics, corporate health facilities, prisons, student health services, WIC programs, sexually-transmitted disease clinics, methadone clinics, State and local health departments, and the host of other facility types that may be subject to CLIA regulations.

There is great uncertainty about the many disparate entities that may fall into this category of laboratories. Under the CLIA statute, the term "laboratory" is very broadly defined to encompass any facility performing testing on human specimens for health care purposes. We obtained estimates of non-hospital, non-independent, non-physician laboratories from a wide selection of sources, including NPRM comments, State health departments, and Medicare and Medicaid data files. However, we lack a comprehensive understanding of the number and types of these other

facilities that may be subject to CLIA. It is this uncertainty that accounts for the 70 percent variance between the high and low assumptions in the "other" category.

**CLIA Study Coalition Estimates.** Our estimates of the number of CLIA laboratories differ widely from those of the CLIA Study Coalition, which is composed of the AMA, the American Hospital Association, the Health Industry Distributors Association, and the Health Industry Manufacturers Association. This coalition projects that less than 90,000 laboratories will be subject to CLIA regulations—an estimate only one-half as large as our low assumption. We believe that the coalition estimates do not account, either in whole or in part, for significant components of the laboratory universe, such as nursing homes, public health laboratories, and student health clinics. Nonetheless, although we believe their estimates are low, it is possible that the coalition's projections may prove more accurate than independent HHS estimates. If the number of CLIA laboratories is indeed below our low assumption of 180,000 laboratories, then our estimates of the cost of CLIA regulation will likely be high. Again, we await the compilation of CLIA registration data for an accurate depiction of the size of the CLIA laboratory universe.

#### The Market for Laboratory Testing Services

Although the category of "other" laboratories appears large in terms of the sheer number of facilities, it is hospitals, independent laboratories and physician offices that perform the vast majority of clinical laboratory testing in the United States.

There is a lack of comprehensive data about the market for clinical laboratory services. One 1980 study estimated that "\$15 billion was spent on laboratory services of all kinds, (and that) the number of laboratory tests performed each year in this country is huge and growing at a compound rate of about 15 percent per year" (Relman, 1980). In the previous year, another prominent study found "evidence that such technologies as the CT scanner account for far less of the growth in medical expenditures than do the collective expenses of thousands of small tests and procedures \* \* \*. The nation's bill for operating only one class of 'little-ticket' technologies—clinical laboratory tests—far exceeded that of capital equipment purchased by hospitals (Moloney and Rogers, 1977)."

Since 1980, the clinical laboratory market has continued its escalation. and

physician office laboratories have been the most rapidly expanding segment of the industry (Kenney and Greenberg, 1986). The physician portion of this market has been estimated to represent 50 percent of all outpatient laboratory testing, with a projected 16 percent annual growth rate through 1990 (Fischer, 1986). However, this estimate is representative of only one of the many opinions on the size of this market segment. A study by Boston Biomedical Consultants projected that by 1990, POLs would perform 2.7 billion tests valued at \$16 million, a four-fold increase since 1986 (Kenney and Greenberg, 1986). Application of American Medical Association assumptions to their office-based physician count results in much lower annual estimates for the size of the physician market: \$2.7 to \$3.7 billion annually as of 1989 (AMA, 1989). A 1987 report in Hospitals estimated that "laboratory testing is a \$20 billion business, with \$5 billion performed in physician offices, \$5 billion in independent and reference labs, and \$10 billion in hospital labs" (Crane, 1987).

To obtain a working assumption of the dollar volume of the U.S. laboratory market, we utilize HHS and HCFA market projections, and estimates that spending on laboratory services comprised 4.5 percent, or approximately \$30 billion, of 1990 national health care expenditures of \$666.2 billion.

Information concerning the national volume of tests is even more sketchy than dollar estimates. There are no available comprehensive studies. Problems emanating from a lack of data are compounded by definitional problems entailed by modern testing systems that perform many different tests at once.

The House Energy and Commerce Committee Report on CLIA estimates that 4 to 6 billion tests are performed each year. The CLIA Study Coalition projects that 8.8 billion analytes are tested annually. For the purposes of this analysis, we assume that the annual national testing volume totals 6 billion tests.

#### The Complexity Model

Following the CLIA statutory mandate, the final rule sets standards and conditions for certification of laboratories according to the complexity of the tests they perform. Laboratory tests are classified according to Public Health Service criteria in one of three categories:

- Waived tests.

- Tests of moderate complexity.
- Tests of high complexity.

Laboratories may perform tests only in categories in which they are certified by HCFA, unless they are accredited by an approved organization, or are State-exempt.

Laboratories performing only tests on the waived list are required to follow accepted laboratory practice and other applicable Federal, State, or local requirements, but are otherwise not subject to the substantive requirements of the final rule. Moderate and high complexity laboratories must comply with the proficiency testing, patient test management, quality control, quality assurance, and personnel standards of the regulation. Standards for high complexity laboratories exceed the requirements for laboratories performing only waived and moderately complex tests. Many requirements are being phased in over a two-year period.

*Distribution Under the Complexity Model.* In order to assess the impact of the final rule, we projected the number of laboratories that will fall into each of the three complexity categories according to the highest level of testing performed. We made no projections of State-exemption or accreditation, for several reasons. First, there is no reliable basis on which to base such speculation. Second, accreditation bodies and State programs that seek HCFA approval under CLIA regulations must provide assurance that their laboratory standards are as stringent or more stringent than those of the final rule. Thus, it can be assumed that, as any State-exempt or accredited laboratory must maintain compliance with State regulations and accreditation standards comparable to those of the final rule, the costs to laboratories of such compliance may also be assumed to be comparable. Finally, we do not wish to understate the impact through speculation about accreditation and State exemption. Nevertheless, it must be noted that approximately 20 States have some sort of program that could qualify for consideration for CLIA exemption, and that the remaining States may also pursue CLIA exempt status. Additionally, a number of non-profit, voluntary organizations are expected to pursue accredited status. State exemption and accreditation could significantly lower the costs of the CLIA program.

We estimate that the projected number of laboratories subject to CLIA

requirements will be distributed across the three complexity model categories according to the percentages on the following table.

DISTRIBUTION OF LABORATORIES BY HIGHEST LEVEL OF TESTING PERFORMED

	Waived labs (percent)	Moderate complexity (percent)	High complexity (percent)	Total labs (percent)
Hospitals.....	0	0	100	100
Independent Labs.....	0	0	100	100
Primary Care POLs.....	3	87	10	100
Non-Primary Care POLs.....	10	80	10	100
Total, POLs.....	5	85	10	100
Other.....	5	85	10	100

This distribution incorporates gross rounding assumptions for the purposes of this analysis, but is not indicative of the actual makeup of the laboratory industry. For instance, we classify all hospital laboratories under the high complexity category, even though there is a small segment of the hospital industry (including some rural short-term inpatient facilities) that does not perform high complexity tests.

This distribution reflects the final rule's concentration of tests in the moderate complexity category. Although we have not projected a distribution of laboratories according to the provisions of the NPRM, it is clear that the NPRM distribution would have had many more laboratories in the waived and high complexity categories, and fewer in the moderate category.

PROJECTION OF THE NUMBER OF LABORATORIES BY COMPLEXITY MODEL CATEGORY

	Low assumption			Total labs
	Waived labs	Moderate complexity	High complexity	
Hospitals.....	0	0	7,000	7,000
Independent Labs.....	0	0	6,000	6,000
Primary Care POLs.....	2,400	69,600	8,000	80,000
Non-Primary Care POLs.....	3,000	24,000	3,000	30,000
Subtotal, POLs.....	5,400	93,600	11,000	110,000
Other.....	2,850	48,450	5,700	57,000
Total.....	8,250	142,050	29,700	180,000

**PROJECTION OF THE NUMBER OF LABORATORIES BY COMPLEXITY MODEL CATEGORY—Continued**

	Intermediate assumption			Total labs
	Waived labs	Moderate complexity	High complexity	
Hospitals.....	0	0	7,000	7,000
Independent Labs.....	0	0	6,000	6,000
Primary Care POLs.....	2,700	78,300	9,000	90,000
Non-Primary POLs.....	4,000	32,000	4,000	40,000
Subtotal, POLs.....	6,700	110,300	13,000	130,000
Other.....	3,350	56,950	6,700	67,000
<b>Total.....</b>	<b>10,050</b>	<b>167,250</b>	<b>32,700</b>	<b>210,000</b>

**High assumption**

	Waived labs	Moderate complexity	High complexity	Total labs
Hospitals.....	0	0	7,000	7,000
Independent Labs.....	0	0	6,000	6,000

**PROJECTION OF THE NUMBER OF LABORATORIES BY COMPLEXITY MODEL CATEGORY—Continued**

	High assumption			Total labs
	Waived labs	Moderate complexity	High complexity	
Primary Care POLs.....	2,850	82,650	9,500	95,000
Non-Primary POLs.....	4,500	36,000	4,500	45,000
Subtotal, POLs.....	7,350	118,650	14,000	140,000
Other.....	4,850	82,450	9,700	97,000
<b>Total.....</b>	<b>12,200</b>	<b>210,100</b>	<b>36,700</b>	<b>250,000</b>

**Certification**

Under the final rule, all clinical laboratories must possess either a certificate of waiver, a registration certificate, a certificate to perform tests of moderate and/or high complexity, a certificate of accreditation, or be State-

exempt. For the purposes of this analysis, we assume that all laboratories will be certified as waived, moderate complexity, or high complexity. We have made no projections of accreditation or State exemption.

According to the provisions of the final user fee rule, a biennial certificate of waiver will cost \$100. Moderate and high complexity laboratories will pay:

- An initial registration certificate fee of \$100, \$350, or \$600, according to a fee schedule based on annual testing volume, and

- A biennial certification fee, based on the same fee schedule, following Federal inspection and determination of compliance with the standards set in the final rule.

For the purposes of calculating the annual costs of the CLIA program, we assume that all laboratories will pay only one fee in a given two-year period, whether they pay for a certificate of waiver, a registration certificate, or a regular certificate. The tables below project the distribution of laboratories by fee category.

**PROJECTED DISTRIBUTION OF LABORATORIES BY CERTIFICATE FEE CATEGORY**

	Waived:	Moderate and high:			Total
	\$100	\$100	\$350	\$600	
<b>Low Assumption</b>					
Hospital.....	0	0	2,800	4,200	7,000
Independent.....	0	0	2,700	3,300	6,000
POL.....	5,400	47,070	43,932	13,598	110,000
Other.....	2,850	33,032	18,410	2,708	57,000
<b>Total.....</b>	<b>8,250</b>	<b>80,102</b>	<b>67,842</b>	<b>23,806</b>	<b>180,000</b>
<b>Intermediate Assumption</b>					
Hospital.....	0	0	2,800	4,200	7,000
Independent.....	0	0	2,700	3,300	6,000
POL.....	6,700	55,485	51,786	16,029	130,000
Other.....	3,350	38,827	21,640	3,183	67,000
<b>Total.....</b>	<b>10,050</b>	<b>94,312</b>	<b>78,926</b>	<b>26,712</b>	<b>210,000</b>
<b>High Assumption</b>					
Hospital.....	0	0	2,800	4,200	7,000
Independent.....	0	0	2,700	3,300	6,000
POL.....	7,350	59,693	55,713	17,244	140,000
Other.....	4,850	56,212	31,331	4,607	97,000
<b>Total.....</b>	<b>12,200</b>	<b>115,905</b>	<b>92,544</b>	<b>29,351</b>	<b>250,000</b>

The table below presents the annualized projections of biennial certificate fee collections.

**PROJECTED ANNUALIZED CERTIFICATE FEE COLLECTIONS**

[Millions of dollars]

	Low assumption	Intermediate assumption	High assumption
Hospitals.....	\$2	\$2	\$2
Independent Labs....	1	1	1
POLs.....	14	17	18
Other.....	6	7	10
<b>Total.....</b>	<b>23</b>	<b>27</b>	<b>31</b>

*Non-Selected Option.* The three-level fee schedule of the final rule marks a major change from the flat \$261 certificate fee of the NPRM. This new approach responds to public concerns that under the proposed rule, small physician office laboratories performing relatively few tests—with correspondingly low laboratory revenue—would be assessed the same certificate fee as large hospital and independent laboratories. The final rule sets the certificate fees of small laboratories (defined as those with annual testing volume below 25,000 tests) at a modest \$100 level, payable every two years.

The switch to the new fee schedule is designed to be a budget neutral change. That is, if all other assumptions are kept constant, collections under the \$100/\$350/\$600 schedule are projected to equal projections using the \$261 flat fee.

**Proficiency Testing**

CLIA mandates that all non-waived clinical laboratories participate successfully in an approved proficiency testing (PT) program. The House Energy and Commerce Committee report states that PT "is arguably the most important measure of laboratory performance since it reviews actual results rather than merely gauging the potential for good results."

PT may be defined as "evaluating the ability to perform laboratory procedures within acceptable limits of accuracy, through the analysis of unknown specimens distributed at periodic intervals by an external source" (DeBoy and Jarboe, 1991). In essence, it is a means of testing the testers.

Under the final rule, laboratories must participate in PT for all tests for which service is offered and for which approved proficiency testing is available. PT samples must be treated in the same way as patient specimens, and cannot be referred to another

laboratory. Laboratories must analyze five challenges for each test they perform, in three PT events per year.

We project that approximately 160,000 to 225,000 laboratories will be subject to Federal PT requirements for the first time.

In order to provide the necessary lead time to permit PT programs to gear up to meet this enormous new demand and to receive HCFA approval, the final rule sets a two-year phase-in period. This period will also allow the laboratories not currently participating in PT to progress up the PT learning curve. In this way, disruption to laboratory testing in presently unregulated laboratories may be minimized or largely avoided. During this period, emphasis can be placed on identification of the source of PT errors, and laboratories can seek appropriate technical assistance and training.

**NUMBER OF LABORATORIES SUBJECT TO PT REQUIREMENTS FOR THE FIRST TIME**

	Low assumption	Intermediate assumption	High assumption
Hospitals.....	0	0	0
Independent Labs....	0	0	0
POLs.....	104,600	123,300	132,650
Other.....	54,150	63,650	92,150
<b>Total.....</b>	<b>158,750</b>	<b>186,950</b>	<b>224,800</b>

*Costs of the Final Rule*

The direct costs of these requirements will be sustained by laboratories. PT costs are analyzed in two components: General PT and Cytology PT.

*General Proficiency Testing*

For General PT requirements, projected costs include:

- Payments to approved PT programs for enrollment fees and purchase of PT materials and kits, and
- Internal expenses for testing materials (such as reagents and pipettes), staff time devoted to the PT process, and associated overhead.

PT costs of hospitals and independent laboratories, most of which are subject to current Federal PT requirements, are assumed to remain stable. It is also assumed that a reasonable projection of incremental CLIA PT costs for all other non-waived laboratories may be obtained through use of an average cost to be applied without consideration of current voluntary or State-required PT participation.

In order to compute an average PT program participation cost, we obtained a random selection of 1990 PT survey or kit purchases by POLs enrolled in the

Medical Laboratory Evaluation (MLE) program of the American Society of Internal Medicine. That sample revealed a mean annual POL purchase of \$341. We then extrapolated a cost increase attributable to the new five specimen per test, three event per year requirement; added the annual \$66 MLE enrollment fee to this average; and converted our results into current dollars. This resulted in a projected average annual laboratory payment to PT providers of \$909.

Though similar sample data were not readily available from other PT providers, comparison of program participation costs do not indicate significant differences in overall costs.

We project that the laboratory material, personnel, and overhead expenses associated with PT will average 125 percent of the costs of payments to PT providers. This factor is assumed to approximate the average laboratory costs and overhead entailed by PT participation, which requires steps similar or identical to those involved in performing a test on a standard patient specimen. These steps include:

- Handling of specimens.
- Performance of tests.
- Recording and reporting results.
- Maintenance, instrument checks, cleaning and repair.
- Supervision, review, and follow-up.

The \$909 projected average PT program payment plus the 125 percent in-house expense factor result in average annual PT costs of \$2,045 for those laboratories not subject to Federal PT requirements prior to the effective date of the final rule. The projected incremental general PT costs attributable to the final rule are outlined in the table below.

**ANNUAL GENERAL PT COSTS: SELECTED OPTION—FIVE CHALLENGES, THREE EVENTS ANNUALLY**

[Millions of dollars]

	Low assumption	Intermediate assumption	High assumption
Hospitals.....	0	0	0
Independent Labs....	0	0	0
POLs.....	\$214	\$253	\$271
Other.....	111	129	189
<b>Total.....</b>	<b>325</b>	<b>382</b>	<b>460</b>

*Non-Selected Options.* We examined three non-selected options:

- The quarterly, five challenge requirements of the NPRM,

- The quarterly, two challenge program used by many PT providers, and by Medicare and CLIA 67 laboratories prior to the promulgation of the March 1990 final rule, and
- A split sample approach.

We constructed cost projections for the first two non-selected options, using the same laboratory assumptions as the final rule projections, and relying upon MLE average cost data to estimate annual laboratory expenses.

**PROJECTED ANNUAL GENERAL PT COSTS:  
NON-SELECTED OPTION—QUARTERLY  
FIVE CHALLENGE**

(Millions of dollars)

	Low assumption	Intermediate assumption	High assumption
Hospitals.....	0	0	0
Independent Labs....	0	0	0
POLs.....	\$227	\$268	\$289
Other.....	118	139	201
<b>Total.....</b>	<b>345</b>	<b>407</b>	<b>490</b>

The costs of this non-selected option exceed the costs of the final rule from \$20 million to \$30 million per year. This option was not chosen because: (1) There is no scientific or technical basis for selecting a program of quarterly frequency over a program of three events per year, and (2) there are more formidable logistical problems inherent in a quarterly program in comparison with a program of three events per year.

**PROJECTED ANNUAL GENERAL PT COSTS:  
NON-SELECTED OPTION—QUARTERLY  
TWO CHALLENGE**

(Millions of dollars)

	Low assumption	Intermediate assumption	High assumption
Hospitals.....	0	0	0
Independent Labs....	0	0	0
POLs.....	\$101	\$119	\$128
Other.....	52	61	88
<b>Total.....</b>	<b>153</b>	<b>180</b>	<b>216</b>

The annual costs of this non-selected option are approximately one-half the costs of the final rule, or from \$72 million to \$244 million less per year. This option was not chosen for scientific and technical reasons, as two challenges are deemed to provide insufficient information for the purposes of a regulatory program with sanctions for repeated PT failures.

*Split Samples.* "Split Samples" have been discussed as a possible option for

proficiency testing in small laboratories. In split sampling, a laboratory selects actual patient test specimens off the line at some given frequency and sends them to another laboratory for independent testing. Thus, laboratories arrange a trading of sample specimens for PT purposes, and compare results. Errors or differences are identified and problem solving resolution is initiated, similar to PT. A possible variation of this approach would be to organize split sampling as part of a formal PT program. At present, split samples are included in the final rule as a possible quality assurance mechanism for evaluating analyte testing for which there is no acceptably stable proficiency test.

Proficiency testing and split sampling (for those analytes for which there is no stable PT) could well serve as partners in laboratory quality improvement. In order to adopt split sampling as a workable approach in a formal PT program, a great deal of developmental work would be required.

Therefore, we do not consider split sampling to be a viable regulatory option at this time.

*Cytology Proficiency Testing*

PT for the specialty of cytology has unique requirements and associated costs. The key elements of cytology PT include:

- Testing of individuals rather than laboratories;
- Two scoring systems: one for those who screen slides, and one for those who review screened slides;
- Annual testing of all individuals, rather than the three events per year per lab required for general PT;
- Retesting of individuals who fail cytology PT;
- Mandatory slide rescreening after the second failure;
- Screening privileges suspended after the third failure.

The final rule provides an eighteen month phase-in period for enrollment in a HCFA-approved proficiency testing program. These requirements are modeled on the Maryland State Cytology Testing Program. Each person examining cytologic preparations is tested on his or her ability to categorize each slide into one of four response categories. After an initial PT failure, an examinee must take a second 10-slide test within 45 days. After a second failure, the laboratory must provide immediate remedial training.

The second failure also triggers a mandatory rescreen of all subsequent slides by another cytologist. Failure of the third, 20-slide test results in immediate suspension of screening

privileges. Remedial training of at least 35 hours must be completed before the participant can be retested. Another 20-slide test must be passed before screening of gynecological slides may resume.

We estimated the national number of cytotechnologists and cytopathologists by extrapolating Maryland data to the national level. This yielded an estimate of 7,950 cytotechnologists and 8,690 cytopathologists. The cytotechnologists estimate compares well to American Society of Cytotechnologists registration data.

To estimate the number and cost of slide sets, we projected Maryland program data to the nation as a whole, with the result that \$3,649,000 will be needed to produce 1,950 slide sets.

We next estimated the cost of administering the proficiency tests, based upon an average laboratory volume of 24,000 cases a year, and employing five cytotechnologists.

We estimate that the first round of tests will cost between \$5 million and \$7.2 million. In developing this estimate, we assumed the loss of 5 hours for each person taking the proficiency test. Hourly wages were computed at low and high assumptions of \$14 and \$20 respectively for cytotechnologists and \$75 and \$110 for cytopathologists. In order to measure possible costs of retesting, we used a 15 percent initial failure rate for both cytotechnologists and cytopathologists.

We project that costs associated with taking the second test, assumed to be conducted offsite, will be between \$1.8 million and \$2.7 million. In addition, we calculate that the cost to laboratories of rescreening slides for the 20 work days between tests will be between \$1.0 and \$1.4 million.

We estimate that 25 percent of those taking the second test will fail that exam, and be required to take the third test. We calculate that approximately 150 cytologists across the country will take the third exam each year. Again, we assume one day of work per examinee will be lost, due to offsite testing. We calculate total test costs for the third exam will be between \$230,000 and \$439,000. If an on-site testing option is offered and selected, costs may be significantly lower.

Each cytologist who fails the third test will be required to take 35 hours of training to bring their skills up to a passing level. It is the Maryland experience that a high proportion of those who failed the test at one point were able to pass the next, often with a 100 percent score.

**PROJECTED ANNUAL COSTS OF CYTOLOGY PROFICIENCY TESTING**

	Low	High
Cytology slide sets.....	\$3,690,000	\$3,690,000
Conduct of first testing...	5,062,000	7,237,000
Conduct of second testing.....	1,831,000	2,675,000
Cost to rescreen for 20 workdays.....	1,000,000	1,430,000
Conduct of third testing.....	230,000	439,000
Loss of 40 days— Cytotech.....	336,000	460,000
Loss of 40 days— Cytotech.....	1,944,000	3,888,000
Costs through third testing.....	14,093,000	19,839,000

**Combined General and Cytology PT Costs**

The following table displays the incremental projected PT costs of the final rule.

**PROJECTED ANNUAL TOTAL PT COSTS: GENERAL AND CYTOLOGY**  
(Millions of dollars)

	Low assumption	Intermediate assumption	High assumption
Cytology PT.....	\$14	\$17	\$20
General PT.....	325	382	460
Total.....	339	399	480

**Proficiency Testing Issues.**

Approximately 5,700 of the almost 60,000 public comments on NPRM addressed proposed PT requirements. Many were concerned about the costs of the requirements, and the sanctions to be levied on laboratories that failed to meet PT requirements. Many who commented on the NPRM were skeptical about the benefits to be derived from the regulations.

PT had its inception in 1945 as a voluntary educational process for laboratorians. Although the laboratory industry, the medical community, and academia have not reached consensus on the role of PT in the modern clinical laboratory, the intent of Congress in this area is clear: Laboratories must participate in PT, and stop performing tests in those areas in which they cannot pass PT.

In contrast to Congressional emphasis on PT as the most important measure of laboratory performance, to be used as such in a national regulatory program with sanction authority, many laboratorians and physicians see PT

primarily as a tool for externally-aided laboratory self-education. The CLIA mandate for national proficiency testing is viewed by many in the medical profession as an intrusion into an area that the Federal government has no business entering, and in which it has little expertise. Other views correspond to the Congressional opinion, and hold that only national regulation, with mandated uniform application and threats of sanction, can assure the improvement and quality assurance necessary to safeguard patients.

Proficiency testing is neither administratively nor scientifically without flaws or complicating factors. There are well over 2,000 instruments and systems for testing analytes listed in the Centers for Disease Control's Catalog of Instruments and Test Systems. Some of these are manual, some are fully-automated, and some are semi-automated. Certain testing procedures considered in some quarters to be antiquated continue to yield results as meaningful to clinical decisionmaking as those produced by far more sophisticated and expensive systems. Finding adequate, reliable means for providing comprehensive PT nationally across the complete spectrum of testing is very problematic.

In each medical specialty, various tests are performed in different contexts, with differing degrees of frequency, by various methodologies and on many types of equipment. Wide ranges in levels of accuracy occur for these reasons, and are sometimes dependent on personnel, training and experience factors as well. Accuracy may also be greatly affected by the site of testing and other factors, such as the "matrix effect" attributable to the characteristics of water used in laboratory applications.

Though the value of PT as an isolated regulatory measure is debatable, an approach that integrates education with regulation has been supported by many laboratorians and regulators. The Commonwealth of Pennsylvania, for example, which sponsors a PT program for physician offices emphasizing education, is recognized as a national leader among regulatory programs for in-office labs.

**Current PT Participation.** Nearly 13,000 laboratories are already operating under Federal PT requirements as hospital and independent laboratories subject to Medicare and CLIA 67 regulations issued on March 14, 1990. These regulations require successful participation in a quarterly, five-challenge program.

Many other laboratories are either voluntarily enrolled in a PT program as part of their own quality assurance efforts, or as a result of State

requirements. While it is unclear how many laboratories fall into these categories, evaluation of data from the American Association of Bioanalysts, College of American Pathologists, and State programs indicate that perhaps 8 to 11 percent of physician office laboratories in the country are currently enrolled in some form of PT program.

**CLIA's Impact on PT Providers.**

Though some of the larger PT providers have indicated they will be ready to handle the increased workload resulting from the final rule, some admit that preparation of enough samples, reagents, test kits and surveys may prove problematic without sufficient lead time. Industry discussions indicate that the time needed to implement a major program change is usually a minimum of 15 to 18 months. Such lead time allows for proper planning, effective use of computer programming staff, appropriate software and hardware purchases, and preparation of new materials and user literature. The shorter the lead time, the higher the costs.

Changes in the composition, packaging and pricing of proficiency test kits are a likely consequence of the final rule. Most PT programs package multiple, like-specialty test materials into PT kits that generally meet the needs of the majority of their customers. A laboratory may, therefore, receive more PT materials than it requires. As a result of CLIA, there will be increased demand for the creation of menu-type order forms, with which laboratories can select specific PT analytes germane to their operations. This would benefit small and specialized laboratories performing only a few tests. PT program representatives note that such a development would increase PT costs.

For those specialties that require a mix of tests due to the extensive testing they perform, different PT requirements apply. Providing such a representative mix three times a year will assure the full range of tests for which proficiency testing is required is actually performed. However, for small laboratories that perform high complexity testing for a limited number of analytes, it is possible that the mix of tests received from the PT manufacturers for any given testing event will skip tests for the few regularly tested analytes. Since the ingredients of PT test materials cannot be annotated, some laboratories may

take tests on unfamiliar analytes before discovering that they have received kits that do not contain samples of the analytes they should be tested for. Such laboratories consequently would not be tested according to mandated frequency. Program testing procedures will have to be able to detect such testing outliers and to make adjustments in order to assure that no laboratory goes untested. This dilemma will not be easily resolved unless the menu or shopping-list PT approach is offered, or special kits are prepared for special testing situations.

The re-tooling effort and costs for established PT manufacturers is affected by their earlier investment in operational changes made to accommodate the quarterly, five challenge requirement of the March 14, 1990 rule. Software was reprogrammed, new computers were purchased, and program materials redesigned and reprinted. We believe that this gearing up leaves PT providers more capable of addressing the new demand to result from the final rule.

Although we expect that there will be some PT expense reductions for currently regulated laboratories, we do not anticipate that the final rule's 25 percent reduction in the number of the testing events will translate into a corresponding 25 percent reduction in the PT costs of currently regulated laboratories.

One of the most frequently voiced complaints about currently approved PT programs is that they have been unable to return test results in a timely fashion. For PT results to be used effectively as both an educational tool and an indicator of problems, laboratory management must receive results well before the next scheduled testing event. The laboratory director must have adequate time to analyze results; to consult with technicians, peers, PT providers, and manufacturer representatives, as necessary, to determine the sources of problems; and to initiate remedial training or other needed corrective actions. Currently, many laboratories report that their test results arrive after they have started the next round of proficiency testing. The lessening of the PT standard to a three-event per year requirement, in conjunction with the phase-in period of the final rule, could help to alleviate this situation.

**Patient Test Management**

The final rule:

- Requires laboratories to have and follow written policies on patient record preparation, specimen collection and handling, and referrals;

- Sets test requisition and specimen records standards;
- Establishes test reporting requirements; and
- Sets test referral standards.

It is assumed that all hospitals, all independent laboratories, and 50 percent of non-waived POLs and other laboratories currently meet the requirements of the final rule. The estimated number of remaining CLIA laboratories that will incur expenses for these requirements is displayed in the table below.

**PROJECTED NUMBER OF LABORATORIES INCURRING FINAL RULE PATIENT TEST MANAGEMENT COSTS**

	Low assumption	Intermediate assumption	High assumption
POLs .....	52,300	65,000	70,000
Other .....	27,500	33,500	48,500
Total .....	79,800	98,500	118,500

*Non-Recurring Costs.* To calculate the costs of developing written policies, we assume that each laboratory will devote an average of four labor hours, at a cost of \$20 per hour, to this activity. Development of these policies is assumed to be a one-time cost.

**DEVELOPMENT OF WRITTEN POLICIES: NON-RECURRING COSTS**

[Dollars in millions]

	Low assumption	Intermediate assumption	High assumption
POLs .....	\$4.2	\$4.9	\$5.3
Other .....	2.2	2.5	3.7
Total .....	6.4	7.4	9.0

*Recurring Costs.* We estimate that "other" laboratories will incur an average of \$400 per year in additional storage costs to meet the final rule requirements for storage of test requisitions, testing records, and test reports. For the average POL, added storage costs are assumed to be negligible, as the existing patient record/folder is the usual storage medium for test reports.

We also project that two hours per year, at \$20 per hour, will be devoted to updating and revising written procedures in both POLs and other laboratories.

**PROJECTED ANNUAL RECORDKEEPING AND PROCEDURE REVISION COSTS**

[Dollars in millions]

	Low assumption	Intermediate assumption	High assumption
POLs .....	\$1.0	\$1.2	\$1.3
Other .....	11.4	13.4	19.4
Total .....	12.4	14.6	20.7

*Non-Selected Option.* In contrast to the widespread agreement on the need for written procedures and manuals in laboratories employing relatively large numbers of workers, there is a lack of consensus on the need for such documents in small laboratories. In particular, there are questions surrounding the necessity of written procedures in physician office laboratories, especially when a physician is the only person involved in the testing process. The costs of CLIA patient test management requirements could be greatly reduced through the exemption of small laboratory providers, defined either in terms of annual test volume or number of laboratory personnel. However, we believe that current operating manuals—tailored in detail and scope to the needs and practice of each individual laboratory—are a necessary component of any laboratory operation, regardless of size.

**Quality Control**

The final rule sets Quality Control (QC) standards for laboratories performing tests of moderate and/or high complexity. In accord with generally accepted definitions, the regulations distinguish quality assurance from quality control. Quality control is defined as "those standards required to monitor and control the quality of the analytical testing process to assure the accuracy and reliability of the patient test result," although the final rule does include equipment and facility standards as part of quality control. Quality assurance embraces a comprehensive view of the test process, including quality control, patient test management, proficiency testing, and personnel standards.

The rule establishes quality control standards in the following areas:

- Test methods and equipment.
- Adequacy of methods, equipment, supplies, and facilities.
- Equipment maintenance and function checks.
- Procedure manual contents.
- Validation of methods.

- Frequency of quality control.
- Remedial action.
- Quality control records.

In addition to these general laboratory requirements, the rule establishes individual quality control requirements for specialized laboratory services, including cytology, hematology, microbiology, and others.

Quality control requirements in the NPRM were based in large part on the regulations for Medicare and CLIA 67 clinical laboratories published on March 14, 1990. The NPRM added additional requirements for ventilation, specimen storage, and power supply, and eased requirements for the quality control of electrophoresis and thin layer chromatography. The NPRM, of course, departed dramatically from the final rule of March 1990 in proposing regulations for all U.S. laboratories performing human testing, not only for Medicare hospitals and independent laboratories, or laboratories engaged in interstate commerce.

We received about 700 comments opposing the quality control conditions of the NPRM. Most of these expressed the opinion that the burden of the proposed requirements would be excessive to small laboratories. The Health Industry Manufacturers Association (HIMA) estimated that compliance with NPRM quality control requirements could cost a solo practitioner from \$40,000 to \$90,000 per year, depending on the type of testing the physician conducts (HIMA, 1990). The American Society of Internal Medicine estimated more conservatively that quality control requirements would cost the average physician office lab about \$500 per year—about \$50 million for the physician office laboratory industry as a whole (ASIM, 1990).

#### Costs of the Selected Option

It is clear from wide differences in the cost estimates developed by HIMA and ASIM that varying opinions exist about how quality control provisions in the NPRM would affect the clinical laboratory industry. Difficulties arise from the dearth of data about the number of laboratories affected—what kinds of laboratories they are, what types of tests they perform, how many tests they do—and from honest differences in interpretation of the rule. Rapid technological and marketplace changes in the clinical laboratory industry only exacerbate the difficulty of estimating the economic costs of the rule.

The final rule greatly modifies the QC requirements of the NPRM, most notably by limiting the required number of controls and calibrations that

laboratories must perform, and allowing laboratories to follow manufacturers' protocols. Consequently, we expect the administrative burden on small laboratories to be vastly reduced.

In order to estimate the costs of these provisions, we assume that all independent and hospital laboratories already meet the standards of the final rule. Although some of these providers might adjust their procedures, particularly documentation protocols, after implementation of the rule, we assume for the purposes of this analysis that the costs of these adjustments will be negligible.

The remainder of the laboratory universe potentially affected by the final rule consists of physician office and other laboratories. We assume that some physician office laboratories already comply with final rule quality control standards, and have estimated the incremental costs attributed to labs who are currently not in compliance. Because we know little about currently non-regulated laboratories not located in physicians' offices, we decided to treat them in the same way.

There is a lack of reliable data with which to construct physician office QC estimates. A widely quoted survey of family physicians in Ohio and North Carolina (Wilderman and Schneider, 1986) reported that about 44 percent of responding physicians a quality control program in place. Our review of physician office laboratory literature and discussions with industry experts lend credence to the data reported in this survey. We assume, conservatively, that 50 percent of all physician office and other laboratories currently have in place a quality control protocol rigorous enough to meet the standards applied by the final rule. We also assume that those office laboratories that do have quality control in place substantially satisfy the requirements of the final rule. Of the remaining 50 percent of physician and other office laboratories that do not have in place a comprehensive quality control system, we assume that a portion of them meet some of the quality control requirements. These assumptions will be discussed more explicitly below.

To estimate the costs of running quality control, we first reviewed professional and technical literature, but were unable to find any recent studies of the cost of running a quality control program. Kenney and Greenberg reviewed several studies estimating that large, commercial laboratories spend from 8 percent to nearly 30 percent of total operating expenses on quality control activities (Kenney and Greenberg, 1986), but we did not feel

these estimates were reliable enough to use in our model. Instead, we constructed two HCFA models of a "typical" physician office laboratory.

Based on staff experience and reviews of surveys conducted by the American Academy of Family Physicians and others, we divided the universe of physician office and other laboratories into two groups. Group A comprises those small physician office labs that perform a very limited number of tests—none requiring sophisticated instrumentation. We estimate that approximately two-thirds of all physician office laboratories subject to CLIA standards will fall into this group. Group B comprises those physicians who may have simple, bench-top instrumentation such as a chemistry analyzer, and who perform slightly more sophisticated tests. These tests may include urine pregnancy tests, hematocrits, and blood chemistries, among others. We assume that test volume is low—less than 25 tests per day, on average.

#### PROJECTED NUMBER OF LABORATORIES SUBJECT TO QC COSTS AS A RESULT OF THE FINAL RULE

	Low assumption	Intermediate assumption	High assumption
Hospitals.....	0	0	0
Independent Labs.....	0	0	0
POLs.....	52,300	65,000	70,000
Other.....	27,500	33,500	48,500
<b>Total.....</b>	<b>79,800</b>	<b>98,500</b>	<b>118,500</b>

We estimate that in the first year of CLIA implementation, the total costs of laboratory compliance with the quality control provisions of the final rule will be \$600 million. Of this total, recurring costs are projected to be \$587 million a year, and non-recurring costs \$13 million.

#### PROJECTED ANNUAL (RECURRING) QC COSTS OF THE FINAL RULE

[Millions of dollars]

	Low assumption	Intermediate assumption	High assumption
Hospitals.....	\$18	\$20	\$23
Independent Labs.....	18	20	23
POLs.....	305	361	389
Other.....	155	186	268
<b>Total.....</b>	<b>496</b>	<b>587</b>	<b>703</b>

The assumptions utilized in these costs projections are outlined below.

*Test Methods and Equipment.* We assume no significant cost associated with complying with this section.

*Procedure Manual.* Because the final rule allows manufacturers' instructions to be used in the procedure manual, we estimate that evaluating written instructions and assembling procedure protocols for the small number of procedures these labs perform would require 4 only hours labor annually, at a cost of \$60 per lab per year. We estimate the cost of updating the documentation each year to be \$30 per lab, assuming two hours per year per lab.

*Method Performance Verification.* We assume that laboratories will have to conduct formal validation procedures, following National Committee on Clinical Laboratory Standards (NCCLS) protocols, only for those tests introduced in the laboratory after the effective date of the final rule. We assume, therefore, that the cost of complying with this section is negligible in the first two years. In subsequent years, the cost of validation studies is difficult to estimate because of the likelihood of significant technological and marketplace changes.

*Equipment Maintenance and Function Checks.* We believe laboratories should already be following manufacturers' maintenance recommendations, and that no additional costs will be incurred in complying with the requirements of this section.

*Calibration, Recalibration, and Calibration Verification.* We assumed that laboratories will recalibrate at least once every six months, the minimum amount prescribed by the regulation, although many manufacturers of test equipment prescribe more frequent calibration. We assume that the cost of recalibration for labs performing simple, non-instrumented tests, is negligible. For other labs, we calculate that the cost will be \$315 per lab per year based on laboratories' performing calibration twice a year on three different tests.

*Control Procedures.* We do not have data indicating the portion of laboratories that run control samples regularly. We assume conservatively that half of all laboratories do not run daily controls. We estimate that labs that conduct simple tests without instrumentation will run a total of 4 quality control samples daily. We assume that the supply cost for these tests is negligible, but that quality control runs will require one-half hour of labor each day. We assume an hourly rate of \$15. With overhead included, total yearly quality control cost per lab is estimated at \$3,000.

We estimate that labs performing more complex tests will spend nearly

\$10,000 each per year to perform control procedures. This estimate assumes that labs will spend one hour each day performing quality control on four different types of tests. The total labor cost per day is about \$22, including overhead; the remainder of the daily cost, about \$18, includes the costs of supplies.

*Remedial Actions.* We estimate that the costs for laboratories performing simple, non-instrumented tests, will be slight. We estimate that some laboratories performing quantified tests using instruments might have to carry out remedial actions, but we have no reliable way of estimating the cost associated with this provision.

*Quality Control Records.* We estimate that the cost of compliance is \$50 per year, per laboratory. We assume that all documentation of quality control efforts may be kept adequately in binders or in one file drawer. This cost estimate reflects the cost of one file drawer purchased each year.

*Manufacturers' Costs.* FDA estimates that manufacturers of clinical laboratory equipment may choose to carry out quality control validation studies for about 5,000 to 9,000 clinical laboratory devices currently on the market. In addition, the FDA expects that about 1,000 new devices will be marketed each year. Manufacturers will need to develop quality control protocols for these.

It is difficult to estimate manufacturers' costs for developing and validating quality control protocols, in large part because manufacturers' costs will be offset by market advantages associated with having validated quality control protocols and by lower costs to laboratories who are able to follow manufacturers' instructions rather than developing their own.

The expenses associated with FDA review of manufacturers' data and protocols will be financed through laboratory user fees discussed previously.

*Cost Estimates for Quality Control by Specialty.* We received about 250 comments on quality control for specialties and subspecialties. The NPRM proposed no changes of substance from the final rule for Medicare and CLIA 67 laboratories published on March 14, 1990. The final rule adopts FDA standards for testing of blood collected for autologous transfusion, and permits laboratories to follow manufacturers' quality control procedures for many types of automated tests.

We have counted increased costs associated with microbiology, routine chemistry, and hematology in the

general quality control costs counted above, because of the small volume of tests that physician office laboratories perform.

We estimate that the costs of cytological laboratory compliance consist of the additional burden of collecting and analyzing workload and case data, and of reviewing slides of pre-malignant and malignant cases. We estimate the burden to be \$5,000 per year per lab. We assume this to be a new cost for all laboratories.

We are estimating that the cost of rescreening 10 percent of all negative slides will be \$20 million. Although this level of rescreening of negative slides appears to be a common quality control practice, there is a strong difference of opinion among pathologists about its merits or cost effectiveness. We therefore cannot assume that implementing this condition is without economic cost. As we are unable to estimate the number of laboratories currently following this practice, we assume this to be a new cost for all laboratories.

#### *Non-Selected Options*

A number of NPRM comments questioned the utility of applying strict quality control procedures in physician offices, arguing that clinical test accuracy must be viewed and understood in the larger context of the clinical question. Precision may be less useful than timeliness in some clinical settings. To this end, an emphasis on the management of quality control in the context of the clinical setting may be clinically more useful than an application of strict, QC process controls.

HCFA and PHS did not pursue any regulatory options that might be drawn from this approach. While such options might be less costly to the laboratory industry, we decided that to achieve CLIA objectives regular, documented QC protocols must be a component of the integrated quality assurance program of the final rule complexity model.

#### *Personnel Standards*

The final rule sets standards for personnel who direct, supervise, perform, and assist clinical laboratory testing and related activities.

There are no personnel requirements for waived laboratories beyond the general final rule requirement that they use appropriately qualified individuals, and adhere to sound laboratory practices and applicable Federal, State, and local laws. Laboratories certified to perform tests of moderate complexity

must meet requirements for the positions of:

- Laboratory Director.
- Technical Consultant.
- Clinical Consultant.
- Testing Personnel.

Laboratories certified to perform tests of high complexity must meet requirements for the positions of:

- Laboratory Director.
- Technical Supervisor.
- Clinical Consultant.
- General Supervisor.
- Cytology General Supervisor.
- Cytotechnologist.
- Testing Personnel.

**Costs of the Selected Option**

We project the personnel costs of CLIA regulation in three components: Consultant expenses, educational expenses of laboratory directors, and the payroll cost inflation attributable to comprehensive Federal personnel standards.

**Consultant Expenses.** In a major change from the NPRM standards, the final regulations set requirements for technical and clinical consultants. Laboratories may fulfill these requirements in two ways: through the assumption of the consultant(s) role(s) by a qualified laboratory director, and/or through the retention of an external consultant(s).

To estimate the costs of consultant requirements, we assume that 25 percent of laboratories performing tests of moderate complexity will retain paid consultants, at an average annual expense of \$1,000 per laboratory per year. We assume that 50 percent of all non-hospital, non-independent laboratories performing tests of high complexity will retain paid consultants, at an average annual cost of \$1,500 per laboratory per year.

**CONSULTANT EXPENSES**

[Dollars in millions]

	Low assumption	Intermediate assumption	High assumption
POLs.....	\$31.6	\$37.3	\$40.2
Independent.....	16.4	19.3	27.9
Total.....	48.0	56.6	68.1

**Director Educational Expenses.** The final regulations permit laboratory directors of moderate complexity laboratories who are not pathologists, or who do not have 1 year laboratory director or supervisory experience, to fulfill director requirements though 20 credit hours of continuing medical education. We assume that 10 percent of

the directors of moderate complexity laboratories will require some formal training in laboratory science to meet the requirements of the final rule. It is assumed that the unit cost of this additional training will be approximately \$1,500 per year. This assumption is based on the average university training cost for 4 semester-hours of instruction. It is also assumed that this cost would be covered by the laboratory.

**DIRECTOR EDUCATIONAL EXPENSES**

[Dollars in millions]

	Low assumption	Intermediate assumption	High assumption
POLs.....	\$14.0	\$16.6	\$17.8
Independent.....	7.3	8.5	12.4
Total.....	21.3	25.1	30.2

**Personnel Cost Inflation.** We assume that the most significant expense resulting from CLIA personnel standards will be the general inflation in employee salaries and related costs attributable to the tighter labor market resulting from comprehensive Federal credentialing and personnel requirements.

In order to assess the potential economic consequences of payroll inflation, we constructed a simplified current laboratory personnel expense baseline, using data collected from:

- The Statistical Abstracts of the United States
- The States of Pennsylvania, Maryland, California, New York, and Ohio,
- The Bureau of Labor Statistics,
- Scientific and professional literature, and
- Interviews with laboratory professionals.

We estimate that the U.S. may currently spend somewhere between \$16.7 billion and \$21.3 billion per year to support clinical laboratory personnel, including expenditures for salaries, benefits, training, continuing education, and related costs.

There is no clear understanding of the inflationary impact of CLIA regulations upon specific components or personnel categories of this labor market. We concluded, therefore, that the most useful approach to estimating this impact is to assess a range of effects across the market as a whole.

The table below projects incremental CLIA inflationary impact according to three assumptions of annual personnel cost increases: one-half percent, one-percent, and two percent.

**PERSONNEL COST INFLATION ATTRIBUTABLE TO CLIA**

[Dollars in millions]

Annual inflation assumptions	Personnel costs baseline assumptions		
	Low: \$16,700	Intermediate: \$18,400	High: \$21,300
Low: ½% increase.....	\$83.5	\$92.0	\$106.5
Intermediate: 1% increase.....	167.0	184.0	368.0
High: 2% increase.....	334.0	368.0	426.0

**Total Personnel Costs.** We estimate total personnel cost increases attributable to CLIA regulations will range from \$153 million to \$524 million per year. The following table displays the combined effects of consultant, education, and personnel expense inflation costs, distributed by type of laboratory.

**TOTAL CLIA PERSONNEL COSTS**

[Dollars in millions]

	Low assumption	Intermediate assumption	High assumption
Hospitals.....	\$16.1	\$35.3	\$81.8
Independent.....	13.7	30.3	70.1
POLs.....	75.4	119.4	209.7
Independent.....	47.6	80.6	162.6
Total.....	152.8	265.6	524.2

**Non-Selected Options**

**The NPRM Standards.** We project that the final rule personnel standards will be far less costly than the NPRM standards, but we have not estimated the costs of the proposed rule.

**No Consultants in Moderate Labs.** One non-selected option would be to not require the position of consultant in laboratories performing only tests of moderate complexity. Such an option could reduce the costs of the final rule personnel costs model by \$35 million to \$50 million per year. However, we believe that consultant requirements of the final rule will do much to address the perceived deficiencies of physician laboratory practice, and to meet Congressional intent, which was clearly concerned with physician office laboratories.

**Personnel Standards in the Clinical Laboratory Market**

Personnel standards are perhaps the most controversial feature of laboratory regulation. CLIA does not specify detailed requirements for laboratory personnel. However, in a hearing before

the Senate Committee on Labor and Human Resources on proposed revisions to CLIA, the Committee was forceful in its statement of the need for detailed standards for the various levels of personnel employed by clinical laboratories (Senate Report 96-130).

Education and academic credentials have been widely used by the laboratory community and regulators as a surrogate predictor of good laboratory performance. The empirical basis for this practice, however, is mixed. There is an economic incentive for laboratory specialists to try to limit the available labor pool of laboratory personnel to individuals with academic degrees. Given the law of supply and demand, a limited labor pool results in higher wages than would be the case if the supply of eligible workers included individuals whose formal laboratory training was not obtained in academic, degree-granting programs. Tight labor markets, however, produce undesirable consequences for clinical laboratory workers and managers in the form of longer hours and higher levels of stress. This may be a particular problem in public health care systems which may not have funds to raise salaries or attract qualified personnel.

The CLIA statute avoids reliance on formal education and academic credentials and requires comprehensive personnel standards based on consideration of competency, experience, job performance, and training, with formal education being but one component. The person in charge of the laboratory must possess knowledge of laboratory science commensurate with the range and sophistication of the testing being performed, and be capable of maintaining quality services. The Secretary is charged with determining what specific qualifications are necessary and sufficient to satisfy these objectives.

CLIA also directs that laboratory standards be developed with consideration of the methodologies used, the judgement needed, the interpretation required, the difficulty of calculations, quality control requirements of the instruments, and "such other factors" as are relevant. These considerations form what is commonly referred to as the "complexity model" of laboratory regulation.

Most respondents to interviews about laboratory regulation support the concept of personnel standards. In general, there is substantial agreement that training of directors, supervisors, and testing personnel is an essential feature of any quality assurance

program. However, there is considerable disagreement concerning specific levels and types of training and certification that should be required for each job category.

There is currently a multiplicity of personnel requirements for clinical laboratories among the various Federal, State, and private sector licensing, accreditation and inspection programs. Common to these programs are three basic classifications of personnel employed in clinical laboratories: (1) Laboratory directors, (2) supervisory personnel, and (3) testing personnel. Supervisory personnel can be further subdivided into general supervisors and technical or medical supervisors.

#### *Laboratory Director Standards*

Governmental and private sector quality assurance programs generally require that the laboratory director hold an earned doctorate in medicine, dentistry, or an appropriate scientific discipline. This is based on the assumption that doctoral level training for directors is the minimum requirement to assure quality performance by a laboratory. This assumption has not been validated through carefully controlled studies.

Under current Medicare rules, services in hospital laboratories not accredited by an agency with deemed status must be under the supervision of a physician with training and experience in clinical laboratory services or a laboratory specialist qualified by a doctoral degree. Director standards issued by the Joint Commission on Accreditation of Health Care Organizations (JCAHO), an accrediting agency, are quite broad. Specificity is added to these standards through "interpretations" which accompany the standards. JCAHO has a provision for nondoctoral directorship of hospital laboratories under certain conditions and allows for a form of dual directorship where a physician is the formal director but actual technical supervision rests with an employee with greater technical knowledge than the nominal director. The College of American Pathologists (CAP) also sets broad director standards and adds specificity with interpretations keyed to the standards. Current State regulations also vary.

Physicians and representatives of physician organizations generally support the requirement that laboratory directors hold a doctorate. However, some pathologists and physicians agree with observations by persons in other segments of the laboratory profession that the primary factor in producing high quality laboratory results has

historically been training and professional dedication of the technologists responsible for actually conducting tests. The doctoral directorship requirement is also challenged by bioanalysts and technologists. The American Association of Bioanalysts (AAB) has maintained a long-standing position that a baccalaureate degree is sufficient for director and technical supervisor qualifications under Medicare, and that alternate routes to formal academic qualifications be incorporated into all levels of requirements for clinical laboratory personnel, from technicians to directors.

Some State regulators also challenge the doctoral director requirement. The State of Ohio, for example, requires a bachelor's degree plus five years of relevant experience to qualify a laboratory director. Kenney and Greenberg quote one director of a State regulatory agency for clinical laboratories as saying that director standards are irrelevant and that the key to quality performance is the supervisor. The doctoral directorship requirement continues to generate controversy, with the primary split tending to be along professional and economic lines of interest.

One view expressed by laboratory managers is that medical training, including the pathology specialty, and laboratory scientist training does not necessarily prepare a person to direct a laboratory, because the roles of laboratory directors are so varied. There does not appear to be any generally agreed upon definition of laboratory direction. However, at least three components of laboratory directorship skills have been identified: (1) Technical knowledge, (2) medical knowledge and training, and (3) management knowledge and skill. Some laboratorians view laboratory directorship as an inseparable part of the practice of medicine, while others see the management function as the key to defining needed laboratory director skills.

An intermediate position is that laboratories in large health organizations should be directed or managed by persons with M.D. or Ph.D. degrees. The rationale for this argument is that the prestige that these doctoral degrees confer is necessary to assure effective planning and coordination, but that direct supervision of operations can be placed in the hands of persons with B.S. or M.S. degrees. There is little disagreement that laboratory directors need a substantial level of technical training as a minimum base for directing

laboratories, but there is no widespread agreement regarding the specific minimum technical training required (Sheinbach, 1977).

#### *Supervisor Standards*

The need for highly trained and professionally dedicated laboratory supervisors and technical personnel below the director level is widely acknowledged in the literature. In general, both certified technologists and doctoral scientists with relevant experience are identified as appropriate persons to supervise clinical laboratories. The traditional importance of trained medical technologists in assuring laboratory quality, either in their roles as formal supervisors or as bench workers are recognized not only by technologists and representatives of technologists' associations but also by pathologists, other physicians, and State and Federal regulators (Carlson, 1982).

There is substantial variation among clinical laboratory regulatory programs in the level of detail of requirements for personnel below the director level. In general, agencies such as JCAHO and CAP have broad, nonspecific standards for supervisory personnel in hospital laboratories, placing responsibility for setting detailed personnel standards within each laboratory with the laboratory director.

Medicare has set personnel standards for independent laboratories and included detailed requirements for technical and general supervisors, provisions for supervision of emergency procedures after normal working hours, and detailed descriptions of the duties and qualification of technologists, cytotechnologists, and technicians. In contrast to Medicare standards, CLIA 67 imposed one set of personnel requirements on all laboratories falling under its jurisdiction whether they are in hospitals or in the independent setting.

The issue of the amount of time a supervisor spends on site raises the general question of the various levels of technical supervision needed to assure acceptable laboratory performance. A study of physician office laboratories conducted by Crawley, et al. in Idaho suggests that supervision of the laboratory was the responsibility of either a nurse, medical technologist, or an individual without formal laboratory training (Crawley, et al., 1986). Similar findings are common in the literature (Grayson, 1984; McKenzie, et al., 1985; Gleich and Rose, 1973).

#### *Testing Personnel Standards*

There also has been substantial variation among regulatory programs in

the level of detail of requirements for personnel below the director and supervisory levels. In general, the voluntary agencies have broad nonspecific standards for technical personnel in hospital laboratories, placing responsibility for setting detailed personnel standards within each laboratory with the laboratory director.

This perspective was reflected in previously detailed standards for Medicare providers for nondirector levels in independent laboratories, including requirements regarding the number of semester hours of university coursework in organic chemistry, biology, and mathematics that a technologist or technician must have completed before qualifying for work in a Medicare laboratory. The option of passing an HHS-approved proficiency examination was another alternate route toward qualification. In contrast to Medicare standards, CLIA 67 did not regulate testing personnel. There have been no distinctions between hospital and independent laboratory personnel standards under CLIA 67.

Among the States, there is considerable variation in personnel standards for supervisors, technologists, technicians, and other laboratory employment categories. Most States do not recognize certification provided by other States. Laboratory personnel certified as technologists or supervisors in one State may be prohibited from working at comparable jobs in other States because they are unable to qualify for equivalent certification. California requires licensure and sets examination requirements for fully licensed clinical laboratory technologists, limited to specific specialties and specific trainees. Its regulations also specify activities in which unlicensed personnel may engage. On the other hand, Pennsylvania sets no specific qualifications for clinical laboratory technologists. Laboratory directors are responsible for determining the qualifications of personnel below the technologist level.

#### *Empirical Data on the Personnel Environment*

Most professional laboratorians can agree with general Statements regarding the roles of technical laboratory personnel. However, there is a growing understanding that the traditional division of labor in clinical laboratories requires some study and adjustment as a result of advances in laboratory medicine and technology.

In an extensive article by Gaumer reviewing the empirical literature on the

topic of regulating health professionals, evidence supports the conclusion that credentialing does not reflect a link between educational experience and subsequent on-the-job performance. According to Gaumer, these credentials simply certify the ability of the entry-level worker to become competent (Gaumer, 1984).

If Donabedian's classic typology of structure, process, and outcome is applied to clinical laboratory quality assurance, one element of "structure" could be defined as the credentialing or licensing of laboratory personnel and the educational and experience levels required for such certification. In addition, a definition of structure must include specifications of certain physical aspects of the laboratory, its equipment, and who can operate it.

In an empirical study designed by Peddecord and Taylor to analyze descriptive relationships between laboratory performance and structural variables (education, training, experience, professional certification, and work patterns of directors in interstate laboratories), few statistically significant relationships were found (Peddecord and Taylor, Undated). Peddecord asserts that clinical laboratories should be viewed as a cluster of unique smaller laboratories unified under one management system and implies that specific regulation for one specialty area may not be appropriate for other specialty areas.

According to Peddecord, "the best empirically supported strategy for improving performance is specialization of both supervisors and technical personnel, by reducing the number of specialty areas in which technical personnel work or supervise." Peddecord also argued that the results of this study reinforce the value of regulation of clinical laboratories (Peddecord, unpublished). Various studies were conducted by Kenney in the State of California, suggesting that a doctorate is not a necessary condition to assure acceptable laboratory performance (Kenney, 1981). In fact, regulated, non-doctoral directed full-service laboratories consistently performed at higher levels than unregulated laboratories in physicians' offices. This offered tentative evidence that regulatory systems are effective in assuring minimum levels of laboratory performance and, therefore, in providing presumptive public health protection. There is a widely held but previously untested belief that the quality of work in laboratories is in part a function of the scope of services offered by the laboratories. This belief holds that

laboratories providing a broader range of services will be forced to hire more highly trained and experienced personnel than laboratories providing limited services and that they will be able to afford (and will therefore use) more sophisticated, reliable testing equipment and methods.

A follow-up study conducted by Kenney and Greenberg found that there was often a statistically significant relationship between the scope of services provided and laboratory performance. This relationship was most visible in unregulated laboratories. Kenney and Greenberg also found that there was no pattern of statistically significant differences in performance between full-service regulated hospital laboratories and full-service regulated non-doctoral directed independent laboratories. Schaeffer has conducted supporting studies (Schaeffer, et. al., 1967).

This limited evidence suggests that it is quite possible that the JCAHO and CAP approach to setting non-specific personnel standards for employees below the director level is appropriate. Results of this study also imply that the non-doctoral directed regulated independent laboratories performed at a somewhat higher level than unregulated physicians' office laboratories when compared to laboratories offering a similar scope of services. Two conclusions may be drawn from this comparison: (1) A doctorate is not necessary to assure laboratory performance, and (2) regulated laboratories perform at higher levels than unregulated laboratories.

#### Credentialing and Economic Effects

Entry level competence, or evidence indicating that workers have the necessary minimum training and/or experience to allow them to begin performing at a specified level, is at the

core of professional, economic, and political controversy regarding personnel standards. Credentialing or certification of laboratory personnel is the method traditionally used to certify entry level competence for various levels of the workforce.

The primary public justification for private and governmental credentialing or certification requirements in clinical laboratories is to assure professional competence and laboratory quality. Social and economic considerations must include the fact that a natural result of personnel regulation is restricted entry into professions. These barriers to entry artificially sustain wage rates at a level higher than the market equilibrium rate. In addition, there are a number of indirect costs associated with personnel regulation. These indirect costs include higher training requirements, more rigid standards, and lower occupational mobility.

While licensure and personnel standards theoretically may benefit the public, their critics note that these laws also strengthen professional control and, by reducing competition, produce extra economic benefits for the occupations involved. The critics also point out that where serious quality problems exist, alternative solutions may exist for dealing with them. Instead of regulating the practitioners, for instance, it may be more efficient to monitor the quality of services they provide.

#### Inspections

CLIA requires the Secretary to conduct inspections of laboratories to determine compliance with applicable requirements. Inspections are to be conducted on a biennial basis, or with such other frequency as the Secretary determines to be necessary.

The final rule includes requirements for inspections of laboratories issued a

certificate of waiver. HCFA will conduct inspections of laboratories issued a certificate of waiver in order to determine that such laboratories are performing only waived tests, to investigate complaints, to determine that laboratory testing is being performed in an acceptable manner, and to collect information for use in on-going evaluations of the listing of waived tests. HCFA plans to annually conduct such inspections on a 5 percent sample of waived laboratories.

We will also conduct inspections of laboratories not issued a certificate of waiver. HCFA will inspect, on a biennial basis, all non-accredited, non-State-exempt laboratories performing tests of moderate and/or high complexity. In addition, HCFA plans to annually inspect a 5 percent sample of laboratories accredited by HCFA-approved accrediting bodies, and a 5 percent sample of State-exempt laboratories.

#### Costs of the Final Rule

The costs of conducting inspections will be paid by fees assessed under the authority of subsection (m) of CLIA. Laboratories performing moderate and/or high complexity tests will pay biennial compliance fees according to an eleven category fee schedule based on laboratory annual test volume and number of specialties. These fees will range from \$300 for a laboratory of very small volume, to fees in excess of \$3,000 for laboratories performing more than one million tests per year.

We assume that the annual costs of conducting inspections will equal the annualized level of projected biennial fee collections. It assumes no accredited or State-exempt status. The following table presents current HCFA projections of compliance determination fee collections.

#### ANNUALIZED PROJECTED COMPLIANCE DETERMINATION FEE COLLECTIONS

[Dollars in millions]

	Low assumption	Intermediate assumption	High assumption
Hospitals.....	\$7	\$7	\$7
Independent.....	5	5	5
POLs.....	73	86	92
Other.....	31	37	53
<b>Total.....</b>	<b>\$116</b>	<b>\$135</b>	<b>\$157</b>

In addition to HCFA costs, it is assumed that inspected laboratories will also incur costs as a result of inspections, including costs attributable to devoting staff time to the inspections,

primarily laboratory director hours spent with HHS surveyors.

*Non-Selected Options.* The compliance fees discussed above reflect HCFA projections of the number of

hours required to perform complete inspections for CLIA requirements, based on a provision-by-provision review of final rule standards by a panel of experienced State and Federal

laboratory surveyors and supervisors. One alternative to this selected approach would be to arbitrarily limit the number of hours to be devoted to each survey, and structure user fees accordingly. Using such a target approach, rather than the zero-based approach of the selected option, we could have set fees at a reduced level—for example, one-half of the current fees. In such a scenario, the costs of CLIA inspections could be one-half of the current projections. This approach, however, would limit our ability to fulfill our statutory mandate to survey each laboratory for compliance with CLIA requirements.

#### Laboratory Review and Analysis of Final Rule Requirements

Entities subject to CLIA will incur significant expense in reading and analyzing pertinent sections of CLIA regulations. To ease this burden, HHS will provide educational and informational materials to laboratories. We estimate that the average laboratory performing only waived tests will devote 2 hours of laboratory director time to reading and analyzing CLIA materials, and that each moderate and high complexity laboratory will expend an average of 8 laboratory director hours. This will result in national non-recurring costs ranging from \$61 million to \$81 million dollars.

#### Benefits of the Final Rule

In attempting to assess the potential benefits of CLIA regulation, it is first necessary to define the expectations of the statute. The House Energy and Commerce Committee report on CLIA presents the logic of the legislation's framers:

- Accurate and reliable testing is vital to the public health of all Americans;
- Current regulatory standards and procedures fail to protect public health and welfare and fail to eliminate burdens on interstate commerce; and
- Federal regulation is reasonable and appropriate to promote public health and welfare and to protect interstate commerce.

The committee report further suggests that "patients expect such tests to be done properly and rely heavily on others to make sure that is the case. Patients assume, quite reasonably, that their interests and the public health are being protected by appropriate governmental agencies."

Projecting the potential public health benefits of CLIA is not a simple task. Kenney and Greenberg, in a 1988 report to HHS on the issues surrounding regulation of clinical laboratories, address one of the key hurdles of this

undertaking, which is definitional. "Statements linking legislation regulating clinical laboratories to the protection of public health are common \* \* \*. However, public health in the clinical laboratory context is an undefined term." Quality, they argue, is measured "operationally" by accuracy and precision through proficiency testing and quality control programs.

There are three broadly-recognized dimensions to health care: quality, access, and cost. In discussing the benefits of laboratory regulation in terms of improvement of testing quality, there is widespread agreement that quality must be balanced with preservation of access to lab services, as brought home by public comments to the NPRM.

Assigning an economic value to CLIA's attempt to protect the public health through laboratory regulation is problematic, at best. We broadly searched available literature for cost-benefit, cost-effectiveness, or other potentially useful studies of laboratory regulatory or health improvement programs. There is little scholarship and research on the subject. In our analysis, we used the relatively few studies available, but these generally are applicable to isolated topics, and not to a comprehensive regulatory program. Moreover, there exists no irrefutable evidence demonstrating that the performance of clinical laboratories, or public health status, will improve tangibly under regulation. Nonetheless, the majority of scholarly opinion and available research suggests benefits will be derived through Federal regulation.

Any attempt to quantify the benefits of an unimplemented, major public health program is inherently highly speculative. This analysis relies upon two, separate quantitative methods to project the potential benefits of the final rule:

- A willingness-to-pay projection, using a technique employed by economists to estimate the benefits of programs with ill-defined impact, and
- A projection of national health care expenditure cost avoidance resulting from early intervention and reductions of unnecessary treatments.

While both of these analytic methods have shortcomings, we concluded that they are the most useful approaches to the problem at hand. The presentation of two, discrete projections is our response to the unreliability of any one approach.

#### Economic Rationale for Federal Intervention

The HHS Handbook on Developing Low Burden and Low Cost Regulatory

Proposals presents a basic guide to the requirements for assessing regulatory impact. Among the issues which merit consideration in analysis is the need for "emphasizing private market forces whenever feasible." Additionally, the Regulatory Program of the United States Government 1990-91 specifies that agencies must evaluate the existence of a "market failure" as a necessary prerequisite for Federal intervention.

There are four basic reasons that a competitive market may fail: incomplete information, market power, externalities, and public goods. The perceived failure of the clinical laboratory market may be attributed, in varying degrees, to all four of these reasons.

*Incomplete Information.* The suppliers of laboratory tests have vastly better information and understanding about the quality of and need for clinical tests than patients do. This type of situation, which economists refer to as asymmetric information, often leads to market failure. More broadly, some degree of market failure is inherent in the entire health care industry, where consumers generally are relatively uninformed, and reliant upon the actions of suppliers of goods and services.

*Market Power.* Market power may be defined as the control a firm has over price and production decisions in a market. Crane raises the specter of market power as a reason for the failure of the clinical laboratory market. The monopolistic positions of physicians as primary test-orderers in this market gives them market power. This market power in turn leads to inefficiencies in quantity (number of tests) and price in the physician segment of the supply side of the market.

*Externalities.* An externality affects individuals or entities beyond those willingly involved in a market transaction. Negative externalities that affect consumers who are not direct participants in the clinical laboratory market predate CLIA. By largely avoiding regulation of the physician segment of suppliers in this market, regulatory agencies contributed to presence of unnecessary quantities of tests and of inflated test prices. All consumers have borne the brunt of the costs of this inefficiency, while physician-suppliers have reaped the benefits. Therefore, these private costs have not been in balance with the social optimum for production.

*Public Goods.* Federal regulation of laboratories is non-exclusive. That is, there is no way to provide this service, as with other services like national defense, to the public without

potentially benefitting everyone. As such, lab regulation may be called a public good.

In theory, "the efficient level of provision of a public good is determined by comparing the marginal benefit of an additional unit to the marginal cost of producing the unit" (Pindyck and Rubinfeld, 1989). While there are Congressional statements and media presentations of recognized need, there is a deficit of studies of consumer demand for laboratory regulation.

*Projected Public Health Benefits: Willingness-To-Pay*

Many different policy analysis tools and techniques have been used by Federal agencies to project and evaluate programmatic impact that is ill-defined or difficult to measure. In the health arena, efforts to measure improvements based on equivalent measurements for the value of life have been used widely. Some health policy analysts have noted the use of the Discounted Future Earnings (DFE) method, which uses life-expectancy and future earnings expectations discounted to present value, by the Department of Health, Education and Welfare in the 1960s. This method, and other comparable approaches, have been employed by many governmental agencies since that time.

The willingness-to-pay (WTP) method holds more promise for evaluating CLIA regulation. In such an analysis, individuals would be asked to make an informed judgment about how much they were willing to pay to avoid risk of illness or death. There are, of course, considerable limits inherent in this approach. With these limitations in mind, this analysis uses a WTP model to project, in dollar terms, a range of potential valuation of CLIA regulation. When considering this model, it is important to note that assuming consumers would value a potential reduction in health risks is not the same as asserting these risks will be measurably reduced by the implementation of CLIA.

For this model, the number of total potential consumers of regulated laboratory tests is assumed to equal the number of U.S. households or families. Families, instead of individuals, are selected since one member of a family usually makes health care decisions for the entire unit. Moreover, the structure of most insurance options encourages consideration of health care consumption according to number of families rather than individuals.

However, families below the poverty line are unlikely to have discretionary

monies to spend on improvement of the quality of their health care. Nonetheless:

One can grant \* \* \* that the poor should be assured a certain minimum standard of safety and medical care, even if their income is so low that they would not willingly use their money to purchase such services \* \* \*. [Some economists believe] that if the general public is upset because the poor are deprived of a minimum level of life-saving expenditures, then government programs that spend more than the poor would be willing to pay are indeed justified—not by any principle beyond welfare economics, but simply because of the external or spillover benefits to the non-poor of life-saving expenditures for the poor (Rhoads, 1986).

Assuming this argument is acceptable, the number of families near the poverty level could be subtracted from the total number of families to obtain a more meaningful WTP model.

According to 1990 Census data, the total number of families in the United States is 65,133,000. Given the current poverty line of \$10,563 for a family of four, families making \$14,999 or less were subtracted from the total number of families. This computation yields a net approximation of 51,601,000 families with the means to contribute to the costs of Federal regulation of laboratory testing. Ideally, a sample of non-poor families would be asked how much they would be willing to pay for a Federal regulatory program that would improve, to some unknown degree, the accuracy of medical testing in America. Such a sample is beyond the scope of this analysis. Instead, HCFA has projected a potential range of willingness-to-pay responses.

To this end, we assume that estimates of consumer responses may be obtained by expressing willingness-to-pay options as incremental percentage increases to current household spending levels for clinical laboratory services. In order to estimate current spending for laboratory testing, HCFA determined the percentage of the U.S. median family income directed to spending on personal health care. To this amount, we applied the proportion of the U.S. health care dollar spent on laboratory services.

**ESTIMATED U.S. SPENDING FOR LABORATORY SERVICES PER HOUSEHOLD**

1988 Median Family Income .....	\$30,859
Spending on Health Care, Percent .....	13.7%
Spending on Health Care, Dollars .....	\$4,227
Spending on Lab Tests, Percent .....	4.5%
Spending on Lab Tests, Dollars .....	\$190
Conversion to Current Dollars .....	\$221

Sources: Bureau of Census and American College of Surgeons

The willingness-to-pay model uses a range of possible responses to the

hypothetical question: "If the average American family currently spends about \$221 per year on medical lab tests, how much more would your family be willing to spend per year for Federal regulations intended to improve the accuracy and accountability of laboratories—and thereby perhaps to reduce your family's medical risk?"

Our model assumes that, in response to this hypothetical question, households may be willing to pay anywhere from 5 percent to 25 percent more for laboratory services. This would result in valuations of the benefits of the potential risk reduction ranging from \$570 million to \$2.8 billion per year.

**WILLINGNESS-TO-PAY PROJECTIONS**

5 percent more	10 percent more	25 percent more
\$570 million.....	\$1.1 billion.....	\$2.8 billion.

This wide range of WTP projections presents one valuation of the CLIA regulatory program. There are many obvious shortcomings to this approach, including the previously-discussed fact that American families are not educated consumers of clinical laboratory tests. Nonetheless, they are directly or indirectly the purchasers of services, and their willingness to pay has utility in assessing the value of a program that will increase their purchasing costs. For all its weakness, WTP is a useful tool, and "when we are dealing with small changes in small risks of death, most economists would support a WTP criterion" (Rhoads, 1986).

*Projected Public Health Benefits: Cost Avoidance*

As an alternative approach to assessing the benefits of CLIA implementation, we explored potential national health care cost avoidance in three areas:

- Malpractice and Defensive Medicine
- False Positives
- False Negatives

*Malpractice Ramifications.* While the threat of malpractice suits is to some degree a deterrent to provision of poor quality care, it also encourages "defensive medicine," which places the burden of an accelerating number of laboratory tests, with their accompanying costs and inconvenience, primarily on consumers. On the other hand, running an office laboratory increases physician risks of incurring malpractice claims. This increased risk may reduce incentives for physicians to conduct tests in their own laboratories.

Physician reaction to perceived malpractice risks increases consumer costs while also having adverse effects on access.

Crane notes that "malpractice is not often considered a quality assurance or regulatory mechanism, but its effect may be equal to or greater than that of other more explicit regulatory systems owing to the potential penalties involved for providers" (Crane, 1987).

Could comprehensive Federal regulation of laboratories lessen the quasi-regulatory pressure of malpractice actions? Some analysts think yes, particularly in unregulated portions of the market. Some argue that external quality assurance could reduce liability risks. One approach to quantification of such benefits is to project the reduction of costs attributable to regulations that increase accuracy in laboratory performance.

While attempting this analysis, no data could be located that document malpractice award dollars precisely attributable to laboratory errors. A 1984 GAO report estimates that 24 percent of claims, and 29 percent of dollar awards, result from general diagnostic error. Although the contribution of laboratory tests to general diagnostic error is unknown, it is estimated to equal between 1 and 10 percent of all general diagnostic errors, or between .2 and 3 percent of all dollar awards (GAO, 1987). Total malpractice awards for all types of errors were estimated to exceed \$5 billion in 1988. If laboratory error accounted for less than 3 percent of all awards that year, awards resulting from laboratory mistakes would be valued at less than \$150 million.

If an improvement in laboratory accuracy from Federal regulation reduced this amount by 1 percent, ensuing savings would have been approximately \$1.5 million or less. Because mean award amounts and annual number of claims per physician have been decreasing since 1985, a 1991 amount comparable to this 1988 estimate would be even lower than \$1.5 million. While these relatively small dollar figures seem consistent with Belsey's assertion that relative few physician office labs are involved in malpractice suits, the involvement of other types of laboratories in malpractice suits is probably more commonplace (Belsey, et al., 1988).

Factors such as a possible reduction in test ordering due to a relaxing of defensive medicine reflexes are not taken into account in these savings estimates. Such reduction would be thought to ensue if regulation of labs led to improved accuracy and a subsequent reduction in malpractice premiums.

However, the balance of scholarship has tended to dispute the association of a reduction in the number of defensive procedures and consumer costs with a reduction in premiums. Additionally, there is no way to demonstrate that regulated status would lead to increases in consumer confidence, decreases in malpractice suits and ensuing reductions in premiums.

The advent of comprehensive Federal regulation may only marginally ameliorate the malpractice crisis by promulgating easily identifiable national standards for laboratory operation. Physicians themselves can be proactive, not just reactive, when it comes to reducing liability in their own labs. Belsey found in a sample of liability cases that careless procedures were the contributing cause and argues that sound protocols will control risk of liability (Belsey, et al., 1986).

*Valuation Relative to False Positives and False Negatives.* In terms of patient health, the final rule assumes benefits may be derived from two basic improvements in laboratory accuracy: Reduction of rates of false positive and of false negative test results. Reductions in false positives are linked to decreases in spending on unnecessary or inappropriate medical procedures. Reductions in false negative rates are tied to savings brought about by earlier medical intervention and limitation of negative health consequences in provision of appropriate care.

Savings derived from these two results are related to two distinct pools of personal health expenditures. One third of all personal health expenditures is used as the upper bound of estimates for potential savings derived from reductions in false positives. Consequently, two thirds of these expenditures form the lower bound of estimates of savings resulting from lowering the number of false negatives.

Since the assumption that the amount of necessary medical care delivered exceeds the amount of unnecessary care is constant, potential savings derived from reductions in false negative rates would seem likely to exceed those achieved by reductions in false positives in all the following examples. However, this is not the case in this analysis.

This analysis uses higher percentages to model potential savings related to unnecessary care, as opposed to those used for necessary care. This choice was made since savings resulting from reductions in unnecessary lab testing are thought to be more likely to result from CLIA implementation than those savings anticipated to result from reductions in false negative rates and concomitant improvements in health

outcomes effected during the delivery of necessary care.

*Benefits of Reducing False Positives.* A false positive result occurs when a test detects disease in a patient that does not actually have disease. False positives can result in unnecessary treatment, as when a falsely positive biopsy leads to unwarranted surgery. In regard to individual tests, the likelihood of getting a true positive when a patient has a disease is referred to as the test's sensitivity.

If the final rule and the CLIA program reduce false positive rates, it is anticipated there would be reductions in unnecessary testing and treatment, and reductions in health care expenditures. HCFA estimates that national expenditures for health care totaled \$666.2 billion in 1990. We project that 1991 spending will total \$720.8 billion. We estimate that 88 percent of this amount, or \$632.9 billion, will fund personal health expenditures.

Using Relman's observation that one-third of all medical treatment is unnecessary, more than \$208.9 billion in 1991 expenditures may be attributed to unnecessary care. A more conservative estimate of 10 percent unnecessary care could mean unnecessary expenditures of \$63.3 billion; a 20 percent estimate would yield \$126.6 billion. These estimates are vulnerable to legitimate skepticism, but they will be satisfactory for calculations of a possible range of regulatory impact. In any case, a more detailed, research-based approach to deriving estimates of unnecessary care is beyond the scope of this analysis.

There is no apparent basis on which to project reductions in false positive rates quantitatively. A review of the available literature yields no supporting research to aid such an undertaking, especially for a comprehensive regulatory program. Rather, in order to estimate a dollar projection of potential savings emanating from a reduction in false positives, this analysis estimates potential percentage reductions in national expenditures for unnecessary care.

Again, there is no established methodology for estimating such savings. It is assumed that a useful, "ballpark" understanding of the potential benefits associated with reductions in the incidence of false positive laboratory tests can be gained by calculating several possible scenarios. The table below presents a range of scenarios for reductions in unnecessary care.

## POTENTIAL NATIONAL HEALTH CARE SAVINGS SCENARIOS: DECREASES ATTRIBUTABLE TO REDUCING FALSE POSITIVES

[Dollars in billions]

	If 10 percent of care is unnecessary	If 20 percent of care is unnecessary	If 30 percent of care is unnecessary
¼% Cost Reduction: .....	\$0.3	\$0.6	\$1.1
1% Cost Reduction: .....	0.6	1.3	2.1

*Benefits of Reducing False Negatives.* CLIA also looks to reduce rates of false negatives. A false negative result occurs when disease is not detected in a patient when the patient has the disease. In the worst case, failure to recognize false negatives contributes to unnecessary deaths. A less extreme but more likely result of erroneously negative tests is delay of medical treatment. Anecdotal evidence of unacceptably high rates of false negatives in Pap smears contributed heavily to the impetus for CLIA. In regard to individual tests, the likelihood of getting a true negative when a patient has a disease is referred to as the test's specificity.

Patients who receive falsely negative test results still need treatment. Therefore, savings derived from comprehensive reductions in false negative rates should come about through earlier intervention in disease processes. Earlier intervention should result in better health outcomes and savings in health care expenditures, as patients will be less sick when they are treated. Consequently, treatment is likely to be less expensive, and society

should benefit through improved public health status.

A hypothetical approach like the one used to value benefits derived from reducing false positive rates can again be used. As stated in that model, 1991 aggregate health care expenditures are estimated to be approximately \$720.8 billion, \$632.9 billion of which is estimated to represent personal health expenditures. Under Relman's assumption, two-thirds of this spending—\$424.0 billion—is assumed to fund necessary care. In addition to this 67 percent scenario, alternative assumptions include an estimation that 90 percent of all care is necessary, resulting in \$569.6 billion in spending, and an 80 percent assumption resulting in \$506.3 billion in spending for the delivery of necessary health care.

The value of earlier intervention brought about by comprehensive regulation of laboratories is highly subjective, and even more controversial than modeling savings resulting from reductions in unnecessary care. Our model of potential savings utilizes the limited available current research. This research consists of one study conducted in association with CDC that

found that the health of an average of 37.5 patients per 100,000 treated in hospital settings was placed at increased risk because of mistakes in the testing process (Rosa and Boone, 1987). Of note, examination of a small sample during this study also found more than 22 percent patients were subjected to unnecessary procedures, although none of these patients were harmed.

We set the rate of 37.5 per 100,000 as a lower bound of possible percentage reductions in health expenditures resulting from lower false negative rates. However, a rate based solely on hospital experience may be misleading. Hospitals are more highly regulated and have more established quality control procedures than the majority of other laboratory service providers. Therefore, a weighted average rate of 45 per 100,000 was used to take into account increased risk of negative health effects among other types of laboratories. The subsequent range of economic estimates in our model represents avoidance of possible undue health expenditures for necessary care resulting from decreases in false negative rates for three possible levels of percentage reductions.

## POTENTIAL NATIONAL HEALTH CARE SAVINGS SCENARIOS: COST AVOIDANCE ATTRIBUTABLE TO REDUCING FALSE NEGATIVES

[Dollars in billions]

	If 90 percent of care is necessary	If 80 percent of care is necessary	If 67 percent of care is necessary
Research-Based Cost Reduction: .....	\$0.3	\$0.2	\$0.2
¼% Cost Reduction: .....	1.4	1.3	1.1
½% Cost Reduction: .....	2.8	2.5	2.1

Despite the shortcomings of these cost avoidance models, we are hopeful that these necessarily simplified projections will help to frame discussions of the potential benefits of the CLIA program.

*Regulation of Previously Exempt Laboratories*

*Profile of the Market.* Hospitals, independent laboratories and physician offices perform the majority of clinical laboratory testing in the United States. While the Federal government has

regulated hospital and independent laboratories for almost 25 years, it has regulated neither laboratories in physician offices nor labs in non-traditional settings. The histories of public health, private practice and the rapid rate of technological advancement in clinical laboratory equipment and procedures have contributed to this site-specific differentiation in laboratory regulation.

At present, as many as 17 States currently regulate labs in physician

offices, and fewer mandate standards for public health settings. In the case of physician office laboratories (POLs), this is surprising if only because POLs are the largest class of laboratory providers in terms of number of sites. POLs also compose a sizable part of total market revenues. Non-traditional providers, such as mobile clinics, may have been overlooked both because they are difficult to identify and because they account for only a very small portion of

the revenues generated by the laboratory industry.

Analysts of the laboratory industry concur that POLs have comprised the fastest growing segment of the market. Ironically, growth among these providers in the last decade was intensified by Federal regulations (Bartola, 1987). For example, enactment of the Medicare prospective payment system for hospital patients has caused the hospital lab to become a cost center instead of the profit center of the past, resulting in more pre-admission and post-discharge testing being transferred to the physicians' office laboratories to reduce hospital costs. Also, passage of the Deficit Reduction Act of 1984 implemented a new Medicare policy regarding laboratory services, preventing physicians from billing for laboratory services performed in a laboratory which is independent of their offices.

In response to the growing POL market demand, laboratory equipment manufacturers accelerated the development of new instrumentation and kit systems that permit physicians to perform a wider range of testing in their offices. The anticipated surplus of physicians has also continued to provide an incentive for physicians to perform in-house testing to stay competitive and to supplement income (Bartola, 1986).

The growth in POLs may have been spurred, in part, by the competitive advantage that lack of regulation bestowed to POLs. CLIA may bring an end to this competitive advantage.

**Potential Health Consequences.** The rapid growth of testing in POL settings raises the question of whether laboratory work in POLs is more or less accurate than in other settings—and whether any such differences in accuracy have an impact on health outcomes.

Most States have not pursued regulation of low-volume physician office laboratories. The small number of tests performed in these labs for physician evaluation of their own patients have not been perceived as constituting any great risk of public harm. Studies cited by Kenney and Greenberg question that assumption. Crawley et al. have linked larger size laboratories with better performance measures. Both Kenney and Gilbert have demonstrated a positive correlation between the scope of services performed in laboratories and outcome measures of performance. These three sets of findings imply that the lack of regulation of low-volume laboratories may increase the risk of laboratory error.

While there is little research on the question of risk of laboratory error in unregulated settings, there is no reported research on the effect such errors may have on health outcomes. In the case of POLs, may physicians argue that outcomes are improved by in-office testing, which offers the rapid results desired by many physicians in the interest of prompt patient treatment. Furthermore, some laboratory errors are identified by physicians when test results appear inconsistent with clinical expectations. In-office laboratories facilitate this sort of error detection.

**Regulatory Challenges, Options and Effects.** In their final report on clinical laboratory regulations, Kenney and Greenberg state: "there is wide-spread professional agreement that mandatory regulations are an important factor in a perceived improvement in clinical laboratory performance in the past two decades." However, there is far from consensus on this issue. There are strong arguments for voluntary, as opposed to mandatory, standards. Many analysts make the basic assumption that providers of health services—be they physicians or entities providing proficiency testing or quality control products to laboratories—are committed to maintaining quality in the services they deliver. If this were universally the case, and if all lab providers were well-trained, voluntary standards would be sufficient.

A premise common in arguments against mandatory regulation of physician labs is that current laboratory technology already allows physicians to produce test results in their offices which are routinely useful to treatment of their patients. The progression of technological innovation and increasing use of automation is likely to continue to improve test quality in the office setting.

However, confidence in the state of automated testing in physician offices today, as with all testing performed in this setting, has yet to become widespread. Though some analysts suggest that higher variability of automated testing in physician offices is due to operator, rather than to equipment error, results are not conclusive. Inability to assure reliability, and to determine the source of errors in testing, potentially has significant consequences for patients.

In reviewing State programs monitoring POLs, Kenney and Greenberg describe two basic gains made during periods of State oversight: improvements in laboratory accuracy and explicit certification of lab providers. Certification signals to consumers, as well as to their third-party payers, that in the eyes of State

regulators these laboratories provide products comparable to other competitors—including hospital and independent labs—and superior to unregulated facilities.

Some State regulatory programs, such as those in Pennsylvania and Idaho, emphasize provider education as part of their quality improvement efforts. Both these programs use proficiency testing (PT) to monitor quality of testing results, and thereby are able to educate lab personnel who are found to be performing imprecise tests. CLIA does not require educational assistance be given to laboratory providers, but educational assistance will occur naturally during laboratory inspections or as part of routine follow-up of unacceptable PT performance.

Do such educational efforts answer an identified need in the laboratory community? Even brief examination of available literature regarding POLs suggests yes. Pennsylvania's experience has been that physicians are not very familiar with laboratory quality control systems. One can infer that many small laboratories can benefit from the opportunity to share information with their peers. CLIA may have an added benefit of encouraging sound laboratory practice among personnel not previously familiar with proper procedures. It is not clear, however, that CLIA will help practitioners to use lab results in a clinically effective way.

#### *Qualitative Discussion of Health Improvements*

Though no lab test is ever 100 percent accurate, as a sampling of available scholarship on various tests conveys, there are many avenues for attaining realistic improvements:

- **Lyme Disease.** A study conducted in New Jersey, where Lyme Disease has been increasing in public health importance and no proficiency testing for labs performing the serological tests for this disease is available, found there were low levels of agreement in test results on both inter- and intra-laboratory bases. Four independent laboratories, performing 90,000 Lyme disease tests at an estimated cost of \$3.5 million in 1988 alone, were reviewed in this study. The authors of the report following the study concluded that Lyme disease serological testing should be standardized (Schwartz, 1989).

- **High Serum Cholesterol.** A study attempting to determine the accuracy of portable cholesterol analyzers used in public settings found that such testing tended to underestimate values from reference laboratories, and tended to produce false negative results. This

variability was partially caused by insufficient laboratory training, but inadequate quality control procedures in field settings and dilution of capillary blood by tissue fluid also contributed to inaccuracies. Since it is estimated that 60 percent of adults in the United States have greater than the desirable levels of blood cholesterol, and testing in mobile settings is increasing, these results are of concern (Naughton, 1990). Health, a publication of the Public Health Service, agrees with the 60 percent estimate, and adds that high serum cholesterol is a known modifiable risk factor for cardiovascular disease. In 1988, diseases of the heart accounted for 35 percent of all deaths in America.

- Another study of the clinical context for cholesterol testing found the accuracy of cholesterol assays will be improved by use of newly available reference material labeled by definitive methodology, and that this aspect of testing is well monitored by proficiency testing. The study also found that long-term, intra-laboratory variability is well monitored by programs like the College of American Pathologists Quality Assurance Service (Oxley, 1988).

This sampling of accuracy for tests relative to selected diseases raises another dimension of laboratory performance: reliability. Reliability, which is also known as reproducibility or precision, is the ability to reproduce results consistently, and can be measured both on intra-laboratory and inter-laboratory bases. This measure encompasses both the reliability of tests themselves and of their operators. What kind of operational mistakes are made in laboratories? Since perceived abuses in cytology were a prominent catalyst for CLIA, the effects of other types of laboratory errors are often discounted. In his discussion of office laboratory liability, Belsey provides a diverse sampling of cases in other laboratory specialties:

- Failure to communicate or act upon a sputum culture that tested positive for tuberculosis;
- Error in a report of mother's blood type led to a child's hemolytic blood disease;
- Mislabeling of father's blood sample led to a child with Tay-Sachs disease;
- Improper collection technique for urethral smear test caused a patient to faint and to injure head seriously;
- Use of outdated reagents resulted in an unreliable test for bilirubin and severe, permanent brain damage for a child;
- Mingling of cysts from both breasts and no separation during dissection led to a bilateral mastectomy even though only one breast had a malignancy;

- Failure to report the results of bacteriology tests revealing meningococcal infection led to brain damage from untreated meningitis (Belsey, et al., 1986).

Though anecdotal, this list portrays the broad effects of laboratory inaccuracies, and how devastating such mistakes can be. Paying for regulatory requirements like quality control protocols will always seem reasonable to victims of clinical laboratory negligence. The question remains whether comprehensive regulation of laboratories is worth the costs for society as a whole. In cases involving communicable diseases like tuberculosis, where negative health effects can rapidly reach beyond any one patient, the answer may well be "yes."

For example, accuracy in testing for AIDS is essential to limiting the spread of this disease. Both false positive and false negative results have serious personal and public consequences. Overall, AIDS is estimated to have infected 145,000 Americans through 1990, and to have caused 89,605 deaths in the same period. A review of the scientific basis for the evaluation, performance and use of the most commonly employed HIV assays suggests current levels of performance are not minimizing public health risks as much as possible and recommends licensure and proficiency testing as a partial solution (Schwartz, et al., 1988).

#### *Cytologic Treatment and Service Delivery*

A series of articles published in *The Wall Street Journal* and *Newsweek* in 1987 and 1988 spurred the interest of the public, the medical profession and Congress in efforts to assure quality in laboratories performing cervical cytology. The Council on Scientific Affairs of the AMA reacted by convening an expert advisory body to review issues in the collection, processing and interpretation of Pap smears. This interest led to a series of Congressional hearings, which culminated in the passage of CLIA.

Although it was anecdotal evidence presented in the popular press that aroused initial interest, the size of the population effected and the ability of medical intervention to limit fatalities sustained the drive to assure accuracy in cytology labs. The American Cancer Society estimates that 13,000 new cases, and 4,500 deaths, will occur nationally this year as the result of cervical cancer. Though primarily an aid in the detection of cervical cancer, Pap smears have also been shown as contributing to the diagnosis of other gynecological

cancers, such as those of the uterus, ovary, vagina and vulva.

Though a large number of women are still afflicted, the rates of incidence and mortality for cervical cancer have dropped dramatically over the past four decades. Over this period, the death rate from uterine cervix cancer has decreased more than 70 percent—mainly due to the Pap test and regular check-ups (Fink, 1991). Additionally, a task force set up by the Canadian government in 1982 found in a province-by-province survey that uterine cancer mortality, including cervical cancers, had dropped from 36 to 67 percent from 1957 to 1979. The task force concluded that: "squamous cell carcinoma of the cervix can be controlled by the means of a cytologic screening program". Literature from the American Cancer Society finds "that cervical cancer is almost 100 percent curable when detected and treated early."

This decrease in incidence led to examination of the cost-effectiveness of different screening programs and revisions in screening guidelines subsequent to 1976. Though all guidelines concur in recommending adult women undergo Pap screening, the majority now differentiate rates of frequency of testing for high- and low-risk patients. "The resulting trend toward less frequent screening for low-risk patients, however, necessitates increased vigilance by the primary care physician and the pathologist to minimize false-negative smears through optimum communication, technical preparation, and quality control" (Zuna, 1984).

Estimates of false negative results from Pap smears vary widely, but most range from 20 to 30 percent. False negative results, as well as false positives, can significantly impact the lives and health of women undergoing screening. "There are few better examples of where the patient is more vulnerable to the consequences of a falsely negative result than the Pap test for cervical cancer. Little, if any, information redundancy is provided by the earlier clinical indications of cervical cancer that enable the physician to compensate for poor laboratory performance" (Zuna, 1984).

On the other hand, false positives can affect the cost-effectiveness of annual screening as well as individual patients. "The term 'battered-womb syndrome' is used to describe the effects of investigating atypical smears (frequently due to minor inflammatory changes) on the emotional, physical and financial well-being of an otherwise healthy woman" (Zuna, 1984).

In her survey article on Pap smears, Zuna points to three basic factors that diminish the accuracy of Pap smears: clinician-related factors, patient-related factors and laboratory factors. Clinician-related errors are largely comprised of inappropriate gathering and labelling of smears. Patient-related factors include lack of cooperation and failure to provide pertinent information about health status. Laboratory factors, like the improvement of accuracy through reduction of false negative and false positive results, would translate into tangible health benefits for individual women receiving Pap tests and for society.

The 1982 Canadian Task Force Report on cytology screening, which updated Canada's landmark 1976 study, provides detailed information on avoidance of false-negative reports on cervicovaginal smears under the following categories: Errors in documentation of smears, inadequate or improper sampling of lesions, presence of interfering substances, technical problems in processing, and errors in screening and reporting. These problems are addressed by the report in several ways, including specific observations and recommendations regarding lab operations.

The report also finds a role for government in assuring quality control requirements are met. According to its final recommendations, "the jurisdiction responsible for screening programs should ensure that appropriate mechanisms for quality control have been established and are functioning satisfactorily."

The approach of CLIA to regulating cytology laboratories reflects a viewpoint similar to the Canadian. However, CLIA and the final rule are also responsive to the particular concerns motivating Congress' passage of the law. The Committee Report accompanying the law describes five "glaring problems" found with cytological testing:

- First, there was evidence of improper collection of specimens by clinicians, compounded by an unwillingness on the part of laboratories receiving such specimens to refuse to report the results and to notify physicians of the deficiencies.

- Second, the Committee received many reports of cytologists screening excessive numbers of slides—numbers so high that the risk of improper diagnosis was extremely high. The Committee heard about cytotechnologists performing work for many different employers, some of whom paid employees on a piece-work basis, and of other cytotechnologists

who worked at home without proper supervision or quality assurance.

- Third, the Committee learned that inspections of cytology laboratories were being performed by personnel unfamiliar with cytology.

- Fourth, despite the importance of the Pap smear and reports of high numbers of false negatives, there has been no Federal proficiency testing requirement for cytology.

- Fifth, some laboratories have dispensed with proper quality control in order to mass market Pap smear screening to physicians at cut rates. Some physicians, attracted by the prices offered or ignorant of the laboratories' operations, have engaged such laboratories.

In sum, the Committee found serious deficiencies in the regulation of cytology and the need for vigorous regulatory standards and oversight. Therefore, CLIA's mandates for cytology are more explicit than those recommended by the 1982 Canadian Task Force Report.

There is no consensus within the laboratory and medical communities that such requirements will improve the accuracy in cytology. Though as many as twenty States have implemented or are in the process of implementing regulations for physician office laboratories, only New York and Maryland actively regulate cytology laboratories. The Maryland program has been in effect for only two years. However, in its comments on the NPRM, the American Society of Cytology stated that it "supports encourages reasonable, feasible, cost-effective quality assurance measures as an essential component of laboratory practice."

It is difficult to see how even educationally and peer-oriented efforts to assure quality for a large number of labs could be done without reference to a standard outcome measure. Proficiency Testing (PT), which identifies laboratory error, is the outcome measure used by the laboratory community. Pennsylvania uses quarterly PT as a key to the education of physician providers in proper laboratory procedures.

Even dubious health providers may want to meet the minimum standards of laboratory operation, if only to avoid the costs of potential malpractice actions. Consequently, it is difficult to support the existence of a dichotomy between provider and patient interests in assuring laboratory quality. Additionally, although it is nearly impossible to fix the true value of a "pass" in a system that is as easily gamed as unblinded PT, it is hard to ignore the significance of repeated failures.

The extension of such regulations equally to all individuals through Federal action should be a significant benefit to all Americans. Even if a particular individual never becomes a patient, he or she stands to gain through reductions in negative health outcomes for others, and the concomitant reduction in direct, indirect and opportunity costs for society.

#### *Market Impact*

Market failure in the laboratory industry and the apparent need for regulation have already been described in this report, with an emphasis on consumer protection. Regulation in the presence of market failure also holds potential benefits for suppliers in an age of limited resources.

Comprehensive regulation will maintain or increase laboratory prices, while providing a new signal of product quality. Many laboratories may see the visibility of CLIA as an opportunity to pass any new costs of regulation directly to consumers and third-party payers, particularly non-governmental payers. Incentives to shift costs to governmental payers, such as the subsidization of discount customer sales by large labs through their Medicare payments documented by the GAO, may be diminished as private-payer prices rise, governmental payers ratchet down their fee schedules and overall information on laboratory operations becomes standardized and more available. However, price increases may not be uniform. Among currently regulated labs, particularly large labs, there may be offsetting price reductions: their test volume may increase if some competing small providers drop out of the market, and if their current regulatory costs are only marginally affected by the final rule. A contraction in the number of lab providers due to the costs of regulation—particularly small providers in rural areas—is possible and is a continuing cause for concern. Yet the identification and potential expulsion of incompetent labs, whether in rural or urban areas, would be an offsetting gain to society.

Uniform Federal regulation may support innovation in the laboratory industry and ancillary businesses. In reviewing changes in the status of labs subject to Federal regulation since 1967, Belsey noted that industry and regulatory efforts to improve quality among conventional, large laboratories has been very successful and has led to the development of important new techniques and technology (Belsey and Baer, 1986).

However, a contrary view was expressed in a report evaluating the proposed rule completed by the Health Industry Manufacturers Association, which suggested "that the regulations could result in a reduced demand for testing products \* \* \* [and] lead in turn to a reduced investment in research and development for alternative site diagnostic technologies." One major manufacturer of testing equipment for the physician market reported a decline in sales of 25 percent following the publication of the NPRM, which it attributed to the uncertain environment fostered by the proposed rules.

The final rule should alleviate these concerns. In fact, CLIA quality control standards may broaden market opportunities for manufacturers offering equipment with FDA-approved quality control protocols, as laboratories will likely view such equipment as offering the least costly approach to satisfying CLIA requirements.

Tangible economic benefits will accrue to businesses providing ancillary services to regulated labs. For example, interviews completed for this report found that proficiency test kit manufacturers are already gearing up for the increased demand for their services brought about by CLIA. New niches will also be created for some service industries, such as consulting, that can assist lab providers and other affected parties to prepare for, to implement and to operate under CLIA requirements.

No data exists that permits any kind of meaningful financial modeling of these business benefits. Therefore, though they are described here, the failure to value these benefits quantitatively contributes to understatement of the aggregate benefits of CLIA.

#### **Benefits by Major Provision**

##### *Personnel Standards*

Laboratories that produce both good quality and poor quality results often use the same analytic systems, tools, and supplies. Different individuals, using the same equipment, procedure, and reagents, can produce markedly different results when performing laboratory tests from a common patient sample. However, an empirically-proven relationship between personnel standards and laboratory performance has not been found by researchers.

While no statistically valid correlation between personnel standards and laboratory proficiency has ever been demonstrated by empirical study, a certain minimal level of benefits can be expected to accrue from the personnel

standards embodied in the final rule. Establishing personnel requirements serves to standardize the laboratory industry by instituting a common personnel classification scheme. Currently, multiple classification schemes exist across public and private regulatory programs. Each of these programs employs its own definitions, terminology, and personnel classifications. The final rule will create standard classifications that will allow laboratorians and regulators to interpret and to apply personnel policies consistently, and to gauge the impact of regulation on the quality of testing more accurately.

As noted earlier in this analysis, most respondents to interviews about laboratory regulation support the concept of minimal personnel standards. There is substantial agreement that training of directors, supervisors, and testing personnel is an essential feature of any quality assurance program. The final rule extends regulation to previously unregulated sectors of the laboratory industry, especially exempt physician office laboratories. New regulation in such sectors will establish minimum standards, i.e., qualifications and responsibilities of individuals performing and supervising laboratory testing, where none existed before.

In addition, the establishment of laboratory personnel standards creates an entry-level threshold for personnel competence. CLIA personnel standards were designed, when combined with proficiency testing and quality assurance/quality control requirements, to improve the accuracy of the nation's laboratory services. The sheer existence of such standards implicitly sets minimum entry-level standards for testing. This is especially true in the areas of cytology and cytotechnology where much of the debate about laboratorian competence originated.

When compared to the NPRM and a number of State and private sector regulatory programs, the less rigid CLIA personnel standards do not unnecessarily limit upward professional mobility. Flexibility is needed by the laboratory industry to effectively take advantage of the personnel resources available to it. The final rule is much closer to achieving a critical balance between quality, cost, and flexibility than the other regulatory programs reviewed during the course of this analysis.

With the exception of physician office laboratories and laboratories engaging in cytological testing, the status quo is likely to be maintained in most clinical laboratories. Despite the increased costs associated with laboratory standards

under the final rule, most personnel currently employed by laboratories will be able to continue conducting tests as they do currently. Those employees who cannot meet these standards should have sufficient time to qualify for the positions they currently occupy.

Since gaps between current experience and qualifications and the personnel requirements set forth in the final rule can be bridged during the window of opportunity offered by phased-in standards, only minimal new demand for support-services, training programs, or other commercial enterprises are expected to result. In addition, no new job categories are created by the regulation, so we can expect no significant increases in laboratory employment opportunities. However, by further clarifying both personnel categorization and complexity of testing being performed in each lab site, the final rule may cause some shifting of personnel and reorganization of staff duties among lab providers.

##### *Proficiency Testing Provisions*

The final rule requires the performance of proficiency testing (PT) three times a year for most analytes. CLIA mandates four events per year, unless the Secretary can justify fewer events on a scientific or technical basis. Review of professional literature on proficiency testing shows expert opinion is divided with regard to the appropriate frequency for testing. Medicare had long accepted the two-a-year frequency standard in the industry, and then adopted the three-a-year survey cycle of the Joint Commission on the Accreditation of Health Care Organizations.

Maintenance of a three-time-a-year cycle should help limit the rise in expenditures for lab providers currently participating in a PT program. For example, some PT subscribers have complained that their PT programs failed to supply tests in a timely fashion. Current systems for mailing out tests often require strict adherence to a rigid schedule in order to avoid backups in the testing cycle. After tests are completed, PT programs must still enter data and score results. These steps must be completed before results can be reported to individual laboratories. All too often, the provider-supplied results have been returned to laboratories too late to help them initiate the corrective actions suggested by their test results. Requiring testing only three times a year may give both testers and the tested a needed respite, may provide more time to do proper analysis of the causes of

test failures, and may increase the educational value of testing efforts.

Although proficiency testing is used as a regulatory enforcement tool, its impetus and primary benefits are educational. Proficiency testing organizations provide advice to clinical laboratories. PT kit manufacturers help in analyzing testing problems and in assuring laboratories run at acceptable performance levels. The requirement that laboratories subscribe to professional PT programs will result in overall improvement in laboratory expertise. The PT requirements of the final rule will also preclude laboratories from testing in areas in which they can not prove competence.

CLIA is expected to increase demand for proficiency testing products roughly by a factor of sixteen, proportional to the expected increase in the number of Federally-regulated laboratories. This demand will result in growth for proficiency testing manufacturers and other industries, such as packaging and shipping, that support the distribution of PT products to laboratories. New manufacturers may also come into the proficiency testing market, but interviews completed for this analysis reveal existing manufacturers have attempted to gauge new demand and to prepare to meet this growth themselves. It is also possible that some standardization of PT products resulting from the specifications of regulation will lower manufacturer's production costs.

#### *Patient Test Management Provisions*

Benefits are expected to accrue for patients from these requirements through the reduction of laboratory errors in the identification, handling and submission of specimens. Overall, laboratories, along with physicians and their patients, will benefit from specification and standardization of the method by which laboratories are linked to the results they produce.

#### *Quality Assurance and Control Provisions*

Quality control is a necessary but not sufficient guarantee of the quality of laboratory results. Quality control regulates the machining and inspection of parts, using Diamond's industrial analogy, but doesn't assure that the right kind of product is manufactured, or that this product is delivered to the right customer on time. Quality assurance, on the other hand, does attempt to make sure that the customer gets what he or she ordered, on time, and that the product is well made. The primary benefit of the regulation of quality control, therefore, is standardization of procedures, the ability to repeat the

same test in different laboratories, at different times, with reasonable assurance of the same result will be derived (Diamond, 1986).

Westgard and many others have documented the need for process specifications that account for biases and sources of variation (Westgard, 1991). Recent work has also argued for the application of traditional quality control procedures to low-volume physician office lab settings. Yet quality control in isolation from careful clerical procedures, proper test management and sensible clinical use of lab testing may be wasted effort.

Several commentators have observed that in labs without well-trained personnel, without careful clerical practice, the incidence of random, unrepeatable, unidentifiable error may be so high that quality control efforts are useless. To that end, quality assurance, which strives to put in place systems for monitoring and standardizing quality control, proficiency testing, personnel training, and the observation of error, is perhaps the greatest benefit of the final rule. Though the benefits of quality assurance are well recognized, regulators are still hard pressed to measure appropriateness of tests or laboratory efficiency.

#### *Inspection Provisions*

The final rule requires biennial inspection of clinical laboratories performing tests of moderate- or higher-level complexity. Such inspections are intended "to provide on-site education regarding accepted laboratory procedures, thus improving laboratory quality; to determine if a laboratory is complying with mandated requirements; and, to aid in the decision to issue initial or renewal licenses or certification."

Kenney and Greenberg found general support for the inspection process among laboratorians and suggest that inspections performed as part of governmental enforcement efforts were more rigorous than those provided through voluntary agencies. Full implementation of the inspection requirement of the final rule should extend such benefits to the entire laboratory community.

#### *Consultations*

The final rule calls for creation of an ongoing technical advisory committee. This provision stands to benefit both the laboratory industry and consumers by formalizing a channel for active consideration of innovations, problems and consumer and provider opinions. The existence of the committee will allow regulators to be more immediately and uniformly responsive than was ever

possible before. The value of increased responsiveness should not be discounted in an industry subject to an accelerating rate of technological change.

#### *Benefits of Codification*

CLIA and its implementing rules mark the first Federal effort to regulate all clinical laboratories. Having a single regulatory authority offers many benefits. The preeminence of Federal regulation, as opposed to reliance on multiple rules developed in different localities, is more easily and equitably enforced.

No quantification of the benefits of codification, nor of specific provisions, could be done. This inability to compute dollar values for largely qualitative requirements further contributes to underestimation of the benefits of CLIA overall.

#### *Potential Impact on Access*

National public health initiatives face the challenge of attempting to effect improvement in societal health status without upsetting the presently precarious balance of cost, quality and access in U.S. medical services. CLIA implementation will significantly increase the operating costs of laboratories. These laboratories will, in turn, pass on cost increases to consumers to the greatest extent possible. A decrease in access to laboratory services would also represent a cost to society at-large, and must be weighed, along with other costs, against the benefits CLIA may offer.

At the same time, a seeming majority of professional opinion in the medical and clinical laboratory communities asserts that implementation of many of the provisions of the final rule—such as mandatory proficiency testing and quality control measures—will improve laboratory quality. The final rule will create and maintain minimum standards for laboratory operations, which should remove any substandard tiers of laboratories currently in existence. CLIA should guarantee access to laboratory services of adequate quality for all Americans receiving laboratory tests, whether underprivileged or not. While there is still great debate as to whether these less tangible gains in quality will offset measurable dollar increases in operating costs, the effect of the final rule on access, in terms of the ability of providers to continue offering medical and laboratory services and of patients to receive them, is difficult to gauge.

A principal reason for this lack of understanding is the still unknown nature of the nation's laboratory testing

industry. Hospital and independent laboratories, which may collect as much as 75 percent of total U.S. laboratory revenues and number about 13,000, have largely been subject to Federal regulation. On the other hand, there has never been comprehensive regulation of physician office laboratories (POLs). This lack of regulatory experience has contributed to the inability to determine the number and characteristics of POLs, even though these facilities are thought to account for as much as 25 percent of all test revenues. There is even less research on laboratory service providers in non-traditional settings, operationally defined as settings other than hospitals, physician offices and independent laboratories, though we assume that these providers comprise only a small portion of total clinical laboratory revenues and number of tests.

#### *Overview of Access Concerns*

In its analysis of laboratory profits relative to the treatment of Medicare patients, the General Accounting Office indicated that, before an access problem would be created, current profit margins would allow some cost absorption to occur within the laboratory industry. However, this estimate, and other attempts to estimate CLIA's impact on access remain largely theoretical. Consequently, concern that CLIA implementation will be detrimental to access is widespread, as embodied in many of the 60,000 public comments to the NPRM.

Many of these comments relayed anecdotal evidence of potential access problems among specific patient populations like the elderly. These problems were anticipated as results of the NPRM on cost, test-result timeliness and patient transportation issues. Though revisions made between the proposed and final rule alleviated these concerns, they did not remove them. Research will be necessary subsequent to full CLIA implementation to assure the public that access to laboratory services has not been adversely affected.

*Hospital-Specific Issues.* In discussions about CLIA, there has been great focus on access in rural areas. Small hospitals are a primary source of basic health care in many rural communities. These hospitals have watched with alarm over the last several years as patient census has continued to drop in the midst of double-digit inflation in health care industry expenses. Many have little financial flexibility, and are greatly inhibited in their ability to shift costs. Therefore, when a product line such as laboratory testing fails to support its own costs, it is

likely to be dropped from the roster of services, or decreased in emphasis.

In spite of the reduced burden of the final rule in comparison with the NPRM, the cost increases that will most certainly result from CLIA implementation may push marginally-profitable laboratory operations of a smaller number of rural hospitals into the red. Some rural hospitals may cease performing some tests in-house. Some may refer certain tests to commercial laboratories, adding specimen transportation and testing turnaround time to the delivery of medical services, with possible negative consequences for patient health status. Other rural hospital may respond by simply reducing the scope of the laboratory services they offer.

Alternatively, many of these marginal providers may also try to maintain laboratory services by raising prices whenever so permitted by payers. This, of course, would reduce the already hindered ability of the poor, uninsured, and underinsured to obtain complete medical care. The trend of rural hospital closures has continued for several years, and it is not known if the possible curtailment of laboratory testing brought about by CLIA will accelerate this closure rate among these institutions.

*Physician Office Laboratory Issues.* Similar pressures are expected to be felt by POLs. Just as the Medicare Prospective Payment System affected hospitals in the 1980s, doctors will be subject to the implementation of Medicare Physician Fee Schedule in 1992, the probable continuance of the ratcheting down of Medicare Part B laboratory fee schedules, and the culmination of other physician-directed regulations. This may lead physician offices to discard unprofitable product lines, particularly if such services are ancillary to their main businesses and can be more efficiently purchased elsewhere.

As the majority of physicians, particularly those outside of rural areas, are not as dependent on government payers as institutional health care providers, they may have the flexibility to shift costs between payers, as well as between services, and to maintain a broader spectrum of products. Studies completed by the Inspector General's Office suggest that physician owners of laboratories may react by increasing the volume of tests they perform in order to offset regulatory costs. However, the results of a recent report commissioned by the State of Florida implied that access to physician-owned joint ventures, including clinical labs and

diagnostic testing centers, is already not widely available to the poor.

Non-metropolitan physician offices are both more likely to have in-office labs and to generate a higher proportion of revenues from this enterprise. Research completed by the American Medical Association found that 54 percent of non-metropolitan physicians had in-office labs, as opposed to 34 percent of physicians in metropolitan areas of 1 million or more and 40 percent of all physicians. Non-metropolitan physicians generated 10.2 percent of their revenues from these labs, while the corresponding figures for physicians in large metropolitan areas and physicians overall were 8.5 and 9.1 percent respectively (AMA, 1989). According to the AMA, non-metropolitan physicians, faced with a scarcity of commercial clinical laboratories, have responded by developing and maintaining their own in-house clinical labs. In the absence of substantial competition from commercial laboratories, these in-house labs are able to generate a higher proportion of practice revenues.

Higher proportional revenues may help to cushion the impact of the final rule on these providers, and to decrease the likelihood that rural physician offices already performing laboratory tests will discontinue these services. However, if the number of such labs is reduced, "forcing patients to go elsewhere for testing could seriously impede access to care, or could cause a health-threatening delay in receiving test results" (AMA, 1989).

Discussions with State regulators suggest that POLs have not been impeded by governmental review. Comments specific to oversight of cytology laboratories by the State of Maryland are given below. Pennsylvania regulators see little or no evidence of physicians opting to drop laboratory services because of State regulation. However, the CLIA program differs from the Pennsylvania program in several ways. It is more costly, more prescriptive, and it emphasizes sanctions over provider education. However, the effects of these differences, particularly under the final rule, are more likely to cause physicians to abandon infrequently performed and high-complexity tests than to move them to cease performing testing altogether.

#### *Alternative Provider and Public Health Concerns*

Several commenters serving rural populations took a broad perspective in their analysis of the proposed rule. The National Rural Health Association, the

United States Conference of Local Health Officers, and the Association of State and Territorial Health Officials (ASTHO) all conveyed serious concerns about access to health services among non-traditional providers of laboratory tests. Specific concerns were voiced about the continued viability of the WIC program, school health programs, and screening services provided to the poor in various community settings. In particular, commenters noted that State and local public health systems must function within restricted budgets, and often do not have fee authorization or the ability to increase revenues, unless approved by their legislative bodies. Thus, they are unable to pass on rising costs to their patients.

While the final rule relaxes several NPRM Level I (now moderate complexity) and Level II (now high complexity) requirements, the concerns of public and rural health providers have not been completely allayed.

Public health laboratories often play uniquely crucial roles in the U.S. health care delivery system. In California, for instance, these laboratories provide services including HIV testing, identification of the tubercule bacillus (TB), rabies detection and screening for sexually transmitted, bacterial and parasitic enteric diseases. In some cases, as with rabies testing, the private sector does not have the facilities to replicate services solely provided by local health laboratories. Additionally, some State laws place restrictions on the provision of public health services by private entities.

Any increase in the costs of delivering public health services stands to marginally decrease the scope or quality of services. Any potential service curtailment by these providers would most dramatically affect low-income individuals, and would not be limited to rural areas. Inner-city hospital and screening programs, such as for cholesterol and sexually transmitted diseases, are also likely to be constrained.

It is impossible to compute the potential public health costs that may result from curtailment of these local health laboratory services. Such costs have the potential to substantially reduce the aggregate benefits afforded by CLIA.

While the final rule is designed to protect all consumers—no matter their income levels—from poor-quality laboratory work, it would violate larger public health objectives if it prevented the delivery of screening services of adequate quality to the poor. We cannot discount the contention that the availability of high-complexity

laboratory tests for disadvantaged populations may be placed in jeopardy by CLIA implementation in some instances. Additional input needs to be solicited from public health advocates on the final rule in order to assure that the proper balance of cost/quality/access has been struck for all segments of the population.

Consumers will ultimately determine whether they receive access to laboratory services or not. Some people will always avoid doctors and health facilities unless (and sometimes in spite of being) deathly ill. Despite numerous public health promotions and guidelines available to primary care physicians, a large study performed in South Carolina found that a minority of people already captured by the health care system received five basic recommended preventative health services. These services included laboratory procedures such as fecal occult blood testing, Pap smears and serum cholesterol measurements, only one of which is a waived test under the final rule. Factors which seemed to be most strongly correlated with access to laboratory services were: Patient's physician practice type, type of medical insurance, physician visit frequency and increasing age. It is impossible to predict how the implementation of CLIA will fit into this complex equation.

#### *Possible Cytology Effects*

Perceived deficiencies in the quality of cytology testing spurred the enactment of CLIA. Ironically, the final rule may adversely affect access to Pap screening for some women because it may exacerbate current personnel shortages and increase costs of service delivery, as it attempts to assure minimum quality standards are met by all cytology laboratories.

The recognized shortage of cytotechnologists and the increased demand for such personnel fostered by the final rule is problematic, as discussed elsewhere in this analysis. There is also concern that the training and rescreening requirements of the regulation may cause backlogs of unread slides, delaying the delivery of valuable diagnostic information to health practitioners and patients. CLIA's impact on access to Pap screening will have to be carefully studied once the law is implemented.

No research exists on the potential effects of federal regulation of the cytology industry on patient access. However, the American Society of Cytology (ASC) raised this issue as one of its three basic concerns relative to implementation of the proposed rule,

which had more burdensome cytology provisions:

The ASC supports and encourages reasonable, feasible, cost-effective quality assurance measures as an essential component of laboratory practice. However, imposition of the regulations as currently outlined will most likely:

- Result in some high-quality laboratories abandoning cytology thus reducing the availability of services.
- Delay reporting of smear results and thereby delay appropriate patient care, and
- Lead to increased costs and ultimately reduce access of women to cervical cancer cytology screening.

All three effects foreseen by the ASC will be reduced by the less stringent cytology requirements of the final regulations, but they will not be completely assuaged. For example, though the demand on cytotechnologists' time has been reduced in the final rule, it will still increase over current levels. This will undoubtedly result in processing delays. Lengthening slide processing time, along with the other operational and personnel-specific requirements of the regulation, will drive provider costs up. Already an industry with small profit margins, most cytology labs will have little choice but to pass on cost increases to consumers. Some women will then skip or delay having Pap tests due to the cost increases.

New York and Maryland are the only States that currently regulate cytology laboratories. A study of the New York State program, which has been in existence for over 20 years, strongly suggested there had been adverse effects on patient access under the auspices of regulation, while no measurable effect on the cervical cancer mortality rate had been achieved. In reference to the cytology requirements of the NPRM, the author of this New York State study also found "many labs in South Carolina and elsewhere plan to discontinue Pap smear services in the face of these costly and intrusive regulations" (Austin, 1991). Concerns about access arising from a possible diminution in the number of cytology labs seem less valid. In reflecting upon Maryland's implementation of its own cytology proficiency testing program, State officials agree that effects on patient access have been minimal. In the first year of comprehensive regulation, only three cytopathologists failed proficiency tests, and consequently opted to relinquish certification. All three were able to refer their cytology work elsewhere.

Overall, DeBay and Jarboe saw no adverse impact on patient access to

adequate Pap testing. Some increase in patient fees was seen, and physicians said that the cost of proficiency testing caused them to raise their prices. However, in drawing comparisons to the potential effects of the final rule, it must be remembered that the Maryland program is less demanding than the final CLIA rule. Additionally, access to Pap screening in rural States with fewer laboratory services and personnel per capita may be affected more negatively than in Maryland.

Regulatory efficiency entails maintaining the balance of cost, quality and access in delivery of health care. The exhaustive work done by the Canadian Task Force on Cervical Cancer Screening in 1982 came to general conclusions about what constituted efficiency in cytology screening programs:

- First, there are diminishing returns with the increasing frequency of screening in a given cohort of women.
- Second, in light of diminishing returns, and from the point of view of public health, it is better to spend money on increasing the number of women being screened initially than on increasing the frequency of screening for women who have already been screened.

- Third, again from the point of view of public health, establishing a policy in which screening is done on the basis of current screening history of the target population is more beneficial than prescribing a lifetime schedule for all women, particularly if screening programs are organized on a community basis.

- Fourth, improving the quality and sensitivity of screening programs will be more effective than increasing the frequency of screening in reducing mortality.

- Finally, although women are primarily responsible for entering and continuing in screening programs themselves, government-sponsored registries are essential if the full potential of cervical smear programs are to be realized. (Canadian Task Force, 1982)

**Personnel Implications.** Beyond the realm of cytology, existing shortages in health manpower already pose access-related concerns that may be intensified following implementation of the final rule. Data from the U.S. Bureau of Labor Statistics (BLS) project a growth in demand for laboratory personnel of approximately 23 percent over the next 10 years, with an annualized growth rate of approximately 2.3 percent per year. This projected growth in demand is expected to occur unevenly across different sectors of the clinical

laboratory industry. In contrast, by the year 2000, BLS projects that labor demand will grow as follows:

Hospitals Laboratories .....	+6.8%
Physician Office Laboratories.....	+53.5%
Independent Laboratories.....	+53.7%
Outpatient Facility Laboratories.....	+145.3%
All Other Laboratories.....	+102.3%

Surveys indicate that more than 80 percent of clinical laboratories have encountered or are currently experiencing a shortage of technical personnel (CAP, 1988). CAP is one of the few organizations studying this topic, and implementation of the final rule is expected to spur new efforts to quantify the effects of potential personnel shortages further. In the meantime, to make matters worse, 40 percent of the accredited medical technology training programs have closed since 1983 (Cepil, 1989). Laws of supply and demand would predict that, as the labor market constricts and demand increases, the current labor shortage will intensify. Upward pressures on laboratory wages will drive the costs of laboratory services higher than current projects suggest. The present analysis of personnel costs under the final rule does not adjust for these economic forces. As a result, costs that appear to be quite high may actually be understated.

The geographic maldistribution of personnel in some health care fields (i.e., physicians and registered nurses) has been well studied. Less research has focused on the distribution of allied health personnel, as laboratory personnel are often classified. Clinical laboratory education, like most allied health care education, takes place primarily in metropolitan areas. According to research by Hamburg, most clinical experience in laboratory science is provided in health care settings with patient volumes sufficient to support state-of-the-art technology. Graduates are subsequently drawn to employment in metropolitan settings for several reasons. Graduates perceive these settings as offering higher quality care, greater personal challenge, broader use of their education, and the greater stimulation of contact with peers and supervisors.

Hamburg indicates that the non-metropolitan ratio of clinical laboratory technicians is 68.9 per 100,000 population. The metropolitan ratio is 120.5 per 100,000 population. As a percent of the metropolitan ratio, the non-metropolitan ratio is only 57 percent, indicating a potential access problem in rural areas (Hamburg, 1985). However, there is also a dearth of

comparable studies supporting this finding, and CLIA implementation is likely to draw attention to the need for further research.

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**List of Subjects**

**42 CFR Part 405**

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

**42 CFR Part 410**

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Rural areas, X-rays.

**42 CFR Part 416**

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

**42 CFR Part 417**

Administrative practice and procedure, Grant programs—health, Health care, Health facilities, Health insurance, Health maintenance organizations (HMO), Loan programs—health, Medicare, Reporting and recordkeeping requirements.

**42 CFR Part 418**

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

**42 CFR Part 440**

Grant programs—health, Medicaid.

**42 CFR Part 482**

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

**42 CFR Part 483**

Grant programs—health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

**42 CFR Part 484**

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

**42 CFR Part 485**

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

**42 CFR Part 488**

Health facilities, Medicare, Reporting and recordkeeping requirements.

**42 CFR Part 491**

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements, Rural areas.

**42 CFR Part 493**

Grant programs—health, Health facilities, Laboratories, Medicaid, Medicare, Reporting and recordkeeping requirements.

**42 CFR Part 494**

Medicare, Reporting and recordkeeping requirements, X-rays.

42 CFR chapter IV is amended as set forth below:

**PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED**

A. Part 405 is amended as follows:

**Subpart U—Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services**

1. The authority citation for part 405, subpart U is revised to read as follows:

Authority: Secs. 1102, 1861, 1862(a), 1871, 1874, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395x, 1395y(a), 1395hh, 1395kk, and 1395rr); and sec. 353 of the Public Health Service Act (42 U.S.C. 263a), unless otherwise noted.

2. In subpart U, § 405.2163 is amended by revising paragraph (b) to read as follows:

**§ 405.2163 Condition: Minimal service requirements for a renal dialysis facility or renal dialysis center.**

\* \* \* \* \*

(b) *Standard: Laboratory services.* The dialysis facility makes available laboratory services (other than the specialty of tissue pathology and histocompatibility testing), to meet the

needs of the ESRD patient. All laboratory services must be performed by an appropriately certified laboratory in accordance with part 493 of this chapter. If the renal dialysis facility furnishes its own laboratory services, it must meet the applicable requirements established for certification of laboratories found in part 493 of this chapter. If the facility does not provide laboratory services, it must make arrangements to obtain these services from a laboratory certified in the appropriate specialties and subspecialties of service in accordance with the requirements of part 493 of this chapter.

\* \* \* \* \*

3. Section 405.2171 is amended by revising paragraph (d) to read as follows:

**§ 405.2171 Condition: Minimal service requirements for a renal transplant center.**

\* \* \* \* \*

(d) *Standard: Laboratory services:* (1) The Renal Transplantation Center makes available, directly or under arrangements, laboratory services to meet the needs of ESRD patients. Laboratory services are performed in a laboratory facility certified in accordance with part 493 of this chapter.

(2) Laboratory services for crossmatching of recipient serum and donor lymphocytes for pre-formed antibodies by an acceptable technique are available on a 24-hour emergency basis.

\* \* \* \* \*

**PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS**

B. Part 410 is amended as follows:

1. The authority citation for part 410 is revised to read as follows:

Authority: Secs. 1102, 1832, 1833, 1835, 1861(r), (s) and (cc), 1871, and 1881 of the Social Security Act (42 U.S.C. 1302, 1395k, 1395l, 1395n, 1395x(r), (s) and (cc), 1395hh, and 1395rr); and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

2. In § 410.5, the introductory text is revised and a new paragraph (d) is added to read as follows:

**§ 410.5 Other applicable rules.**

The following other rules of this chapter set forth additional policies and procedures applicable to four of the kinds of services covered under the SMI program:

\* \* \* \* \*

(d) Part 493: Laboratory Services.

3. In § 410.32, the introductory text of paragraph (b) is republished and

paragraphs (b)(2) and (5) are revised to read as follows:

**§ 410.32 Diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.**

(b) *Diagnostic laboratory tests.* Medicare Part B pays for covered diagnostic laboratory tests that are furnished by any of the following:

(2) A nonparticipating hospital that meets the requirements for emergency outpatient services specified in subpart G of part 424 of this chapter and the laboratory requirements specified in part 493 of this chapter.

(5) A laboratory, if it meets the applicable requirements of part 493 of this chapter, including the laboratory of a nonparticipating hospital that does not meet the requirements for emergency outpatient services in subpart G of part 424 of this chapter.

**PART 416—AMBULATORY SURGICAL SERVICES**

C. Part 416 is amended as follows:

1. The authority citation for part 416 is revised to read as follows:

Authority: Secs. 1102, 1832(a)(2), 1833, 1863 and 1864 of the Social Security Act (42 U.S.C. 1302, 1395k(a)(2), 13951, 1395z, and 1395aa); and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

2. Section 416.49 is revised to read as follows:

**§ 416.49 Condition for coverage—Laboratory and radiologic services.**

If the ASC performs laboratory services, it must meet the requirements of part 493 of this chapter. If the ASC does not provide its own laboratory services, it must have procedures for obtaining routine and emergency laboratory services from a certified laboratory in accordance with part 493 of this chapter. The referral laboratory must be certified in the appropriate specialties and subspecialties of service to perform the referred tests in accordance with the requirements of part 493 of this chapter. The ASC must have procedures for obtaining radiologic services from a Medicare approved facility to meet the needs of patients.

**PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS**

D. Part 417 is amended as follows:

1. The authority citation for part 417 is revised to read as follows:

Authority: Secs. 1102, 1833(a)(1)(A), 1861(s)(2)(H), 1871, 1874, and 1876 of the Social Security Act (42 U.S.C. 1301, 1395(a)(1)(A), 1395x(s)(2)(H), 1395hh, 1395kk, and 1395mm); sec. 114(c) of Pub. L. 97-248 (42 U.S.C. 1395mm note); 31 U.S.C. 9701; and secs. 215, 353 and 1301 through 1318 of the Public Health Service Act (42 U.S.C. 216, 263a, and 300e through 300e-17), unless otherwise noted.

2. Section 417.107 is amended by revising paragraph (i) to read as follows:

**§ 417.107 Organization and operation.**

(i) *Certification of institutional providers.* Each HMO must ensure that institutional providers through which it provides basic and supplemental health services—

(1) Are certified either under title XVIII of the Social Security Act (Medicare) in accordance with part 405 of this chapter or under title XIX of the Social Security Act (Medicaid) in accordance with the regulations governing participation of providers in the Medical Assistance Program; or

(2) In the case of hospitals, are either accredited by the Joint Commission on Accreditation of Healthcare Organizations or the American Osteopathic Association or certified by Medicare; or

(3) In the case of laboratories are certified in the appropriate specialties and subspecialties of services in accordance with the requirements of Part 493 of this chapter.

3. Section 417.800 is amended by revising paragraph (b) to read as follows:

**§ 417.800 Reimbursement of health care prepayment plans; definitions and basic rule.**

(b) *Qualifying conditions.* (1) Except as provided in paragraph (b)(2) of this section, an organization wishing to participate as an HCPP must—

(i) Enter into a written agreement with HCFA as specified in § 417.801;

(ii) Furnish physicians' services through its employees or under a formal arrangement with a medical group, independent practice association or individual physicians; and

(iii) Furnish covered Part B services to its Medicare enrollees through institutions, entities, and persons that have qualified under the applicable requirements of Title XVIII of the Social Security Act and section 353 of the Public Health Service Act.

(2) An organization that, as of January 31, 1983, was being reimbursed on a reasonable cost basis under section 1833(a)(1)(A) of the Act, and that would

not otherwise meet the conditions specified in paragraph (b)(1) of this section, may receive reimbursement on a reasonable cost basis as an HCPP, provided it files an agreement with HCFA as required by § 417.801.

**PART 418—HOSPICE CARE**

E. Part 418 is amended as follows:

1. The authority citation for part 418 is revised to read as follows:

Authority: Secs. 1102, 1812(a)(4), 1812(d), 1813(a)(4), 1814(a)(7), 1814(i), 1816(e)(5), 1861(dd), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395d(a)(4), 1395d(d), 1395e(a)(4), 1395f(a)(7), 1395f(i), 1395h(e)(5), 1395x(dd), and 1395hh); and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

2. Section 418.92 is revised to read as follows:

**§ 418.92 Condition of participation—Physical therapy, occupational therapy, and speech-language pathology.**

(a) Physical therapy services, occupational therapy services, and speech-language pathology services must be available, and when provided, offered in a manner consistent with accepted standards of practice.

(b)(1) If the hospice engages in laboratory testing outside of the context of assisting an individual in self-administering a test with an appliance that has been cleared for that purpose by the FDA, such testing must be in compliance with all applicable requirements of part 493 of this chapter.

(2) If the hospice chooses to refer specimens for laboratory testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of part 493 of this chapter.

**PART 440—SERVICES: GENERAL PROVISIONS**

F. Part 440 is amended as follows:

1. The authority citation for part 440 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. In § 440.30, the introductory text is republished and paragraphs (a) and (c) are revised to read as follows:

**§ 440.30 Other laboratory and X-ray services.**

Other laboratory and X-ray services means professional and technical laboratory and radiological services—

(a) Ordered and provided by or under the direction of a physician or other licensed practitioner of the healing arts

within the scope of his practice as defined by State law or ordered by a physician but provided by referral laboratory;

(c) Furnished by a laboratory that meets the requirements of part 493 of this chapter.

**PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS**

G. Part 482 is amended as follows:  
 1. The authority citation for part 482 is revised to read as follows:

*Authority:* Secs. 1102, 1138, 1814(a)(6), 1861 (e), (f), (k), (r), (v)(1)(C), (z), and (ee), 1864, 1871, 1883, 1886, 1902(a)(30), and 1905(a) of the Social Security Act (42 U.S.C. 1302, 1338, 1395f(a)(6), 1395x (e), (f), (k), (r), (v)(1)(C), (z), and (ee), 1395aa, 1395hh, 1395tt, 1395ww, 1396a(a)(30), and 1396(a)); and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

**Subpart C—Basic Hospital Functions**

2. Section 482.27 is revised as follows:

**§ 482.27 Condition of participation: Laboratory services.**

(a) The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients. The hospital must ensure that all laboratory services provided to its patients are performed in a facility certified in accordance with part 493 of this chapter.

(b) *Standard: Adequacy of laboratory services.* The hospital must have laboratory services available, either directly or through a contractual agreement with a certified laboratory that meets requirements of part 493 of this chapter.

(1) Emergency laboratory services must be available 24 hours a day.

(2) A written description of services provided must be available to the medical staff.

(3) The laboratory must make provision for proper receipt and reporting of tissue specimens.

(4) The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.

**Subpart D—Optional Hospital Services**

3. Section 482.53 is amended by revising paragraph (b)(3) to read as follows:

**§ 482.53 Condition of participation: Nuclear medicine services.**

(b) *Standard: Delivery of service.*

(3) If laboratory tests are performed in the nuclear medicine service, the service must meet the applicable requirement for laboratory services specified in § 482.27.

4. Section 482.57 is amended by revising paragraph (b)(2) to read as follows:

**§ 482.57 Condition of participation: Respiratory care services.**

(b) *Standard: Delivery of Services.*

(2) If blood gases or other laboratory tests are performed in the respiratory care unit, the unit must meet the applicable requirements for laboratory services specified in § 482.27.

**PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES**

H. Part 483 is amended as follows:

1. The authority citation for part 483 is revised to read as follows:

*Authority:* Secs. 1102, 1819 (a)-(d), 1861(j) and (l), 1863, 1871, 1902(a)(28), 1905 (a) and (c), and 1919(a)-(d) of the Social Security Act (42 U.S.C. 1302, 1395(i)(3) (a)-(d), 1395x (j) and (l), 1395hh, 1396a(a)(28), and 1396d(c) and 1396r(a)-(d)) and sec. 353 of the Public Health Service Act (42 U.S.C. 263a), unless otherwise noted.

**Subpart B—Requirements for Long Term Care Facilities**

2. In subpart B, § 483.75 is amended by revising the section heading and paragraph (j) to read as follows:

**§ 483.75 Level A requirement: Administration.**

(j) Level B requirement: Laboratory services. (1) The facility must provide or obtain laboratory services to meet the needs of its residents. The facility is responsible for the quality and timeliness of the services.

(i) If the facility provides its own laboratory services, the services must meet the applicable requirements for laboratories specified in part 493 of this chapter.

(ii) If the facility provides blood bank and transfusion services, it must meet the applicable requirements for laboratories specified in part 493 of this chapter.

(iii) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the requirements of part 493 of this chapter.

(iv) If the facility does not provide laboratory services on site, it must have an agreement to obtain these services from a laboratory that meets the applicable requirements of part 493 of this chapter.

- (2) The facility must—
- (i) Provide or obtain laboratory services only when ordered by the attending physician;
  - (ii) Promptly notify the attending physician of the findings;
  - (iii) Assist the resident in making transportation arrangements to and from the source of service, if the resident needs assistance;
  - (iv) File in the resident's clinical record laboratory reports that are dated and contain the name and address of the testing laboratory.

**Subpart I—Conditions of Participation for Intermediate Care Facilities for the Mentally Retarded**

3. Section 483.460 is amended by revising paragraph (n) to read as follows:

**§ 483.460 Condition of participation: Health care services.**

(n) *Standard: Laboratory services.* (1) If a facility chooses to provide laboratory services, the laboratory must meet the requirements specified in part 493 of this chapter.

(2) If the laboratory chooses to refer specimens for testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of service in accordance with the requirements of part 493 of this chapter.

**PART 484—CONDITIONS OF PARTICIPATION: HOME HEALTH AGENCIES**

I. Part 484 is amended as follows:  
 1. The authority citation for part 484 is revised to read as follows:

*Authority:* Sec. 1102, 1861, 1866(a), 1871 and 1891 of the Social Security Act (42 U.S.C. 1302, 1395x, 1395cc(a), 1395hh, and 1395bbb); and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

2. Section 484.14 is amended by adding a new paragraph (j) to read as follows:

**§ 484.14 Condition of participation: Organization, services, and administration.**

(j) *Standard: Laboratory services.* (1) If the HHA engages in laboratory testing outside of the context of assisting an individual in self-administering a test

with an appliance that has been cleared for that purpose by the FDA, such testing must be in compliance with all applicable requirements of part 493 of this chapter.

(2) If the HHA chooses to refer specimens for laboratory testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of part 493 of this chapter.

**PART 485—CONDITIONS OF PARTICIPATION AND CONDITIONS FOR COVERAGE: SPECIALIZED PROVIDERS**

J. Part 485 is amended as follows:

1. The authority citation for part 485 is revised to read as follows:

Authority: Secs. 1102, 1138, 1861 (aa) and (cc) and 1871 of the Social Security Act (42 U.S.C. 1302, 1320b-8, 1395x and 1395hh); and sec. 353 of the Public Health Service Act (U.S.C. 263a).

2. Section 485.58 is amended by adding a new paragraph (g) to read as follows:

**§ 485.58 Condition of participation: Comprehensive rehabilitation program.**

(g) *Standard: Laboratory services.* (1) If the facility provides its own laboratory services, the services must meet the applicable requirements for laboratories specified in part 493 of this chapter.

(2) If the facility chooses to refer specimens for laboratory testing, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the requirements of part 493 of this chapter.

3. In § 485.304, the introductory text is republished and a new paragraph (q) is added to read as follows:

**§ 485.304 Condition: Qualifications required of an organization for it to be a designated organ procurement organization.**

To be designated by the Secretary as the OPO for its service area in accordance with § 485.303 of this subpart, an organization must at the time of application and throughout the period of its designation—

(q) Assure appropriate tests consistent with OPTN standards and CDC guidelines are performed by a laboratory that is certified in the appropriate specialty or subspecialty of service in accordance with the requirements of part 493 of this chapter, including tests to prevent the acquisition

of organs that are infected with the etiologic agent for acquired immune deficiency syndrome.

**PART 488—SURVEY AND CERTIFICATION PROCEDURES**

K. Part 488 is amended as follows:

1. The authority citation for part 488 is revised to read as follows:

Authority: Secs. 1102, 1814, 1861, 1865, 1866, 1871, 1880, 1881 and 1883 of the Social Security Act (42 U.S.C. 1302, 1395f, 1395x, 1395bb, 1395cc, 1395hh, 1395qq, 1395rr and 1395tt); and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

**§ 488.52 [Removed]**

2. Section 488.52 is removed and reserved.

**PART 491—CERTIFICATION OF CERTAIN HEALTH FACILITIES**

L. Part 491 is amended as follows:

1. The authority citation for part 491 is revised to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302); and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

**Subpart A—Rural Health Clinics: Conditions for Certification**

2. Section 491.9 is amended by revising paragraph (c)(2), republishing paragraph (d)(1) introductory text, and revising paragraph (d)(1)(iii) to read as follows:

**§ 491.9 Provision of services.**

(c) *Direct services*— \* \* \*

(2) *Laboratory.*

(i) The clinic provides basic laboratory services essential to the immediate diagnosis and treatment of the patient, including:

- (A) Chemical examinations of urine by stick or tablet methods or both (including urine ketones);
  - (B) Microscopic examinations of urine sediment;
  - (C) Hemoglobin or hematocrit;
  - (D) Blood sugar;
  - (E) Gram stain;
  - (F) Examination of stool specimens for occult blood;
  - (G) Pregnancy tests;
  - (H) Primary culturing for transmittal to a certified laboratory; and
  - (I) Test for pinworm.
- (ii) All laboratory services provided by the clinic must meet the applicable requirements of part 493 of this chapter.

(d) *Services provided through agreements or arrangements.* (1) The clinic has agreements or arrangements with one or more providers or suppliers

participating under Medicare or Medicaid to furnish other services to its patients, including:

(iii) Additional and specialized diagnostic and laboratory services that are not available at the clinic. If the facility chooses to refer specimens for testing to another laboratory, the referral laboratory must be certified in accordance with the requirements of Part 493 of this chapter.

**PART 493—LABORATORY REQUIREMENTS**

M. Part 493 is amended as follows:

1. The authority citation for part 493 is revised to read as follows:

Authority: Sec. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following 11861(s)(11), 1861(s)(12), 1861(s)(13), 1861(s)(14), 1861(s)(15), and 1861(s)(16) of the Social Security Act (42 U.S.C. 1302, 1395x(e), the sentence following 1395x(s)(11), 1395x(s)(12), 1395x(s)(13), 1395x(s)(14), 1395x(s)(15), and 1395x(s)(16)).

2. The table of contents for part 493 is revised to read as follows:

**PART 493—LABORATORY REQUIREMENTS**

**Subpart A—General Provisions**

- Sec.
- 493.1 Basis and scope.
- 493.2 Definitions.
- 493.3 Applicability.
- 493.10 Categories of tests by complexity.
- 493.15 Laboratories performing waived tests.
- 493.17 Test categorization.
- 493.20 Laboratories performing tests of moderate complexity.
- 493.25 Laboratories performing tests of high complexity.

**Subpart B—Certificate of Waiver**

- 493.35 Application for a certificate of waiver.
- 493.37 Requirements for a certificate of waiver.
- 493.39 Notification requirements for laboratories issued a certificate of waiver.

**Subpart C—Registration Certificate and Certificate**

- 493.43 Application for registration certificate and certificate.
- 493.45 Requirements for a registration certificate.
- 493.49 Requirements for a certificate.
- 493.51 Notification requirements for laboratories issued a certificate.

**Subpart D—Certificate of Accreditation**

- 493.55 Application for registration certificate and certificate of accreditation.

- Sec.  
493.57 Requirements for a registration certificate.  
493.61 Requirements for a certificate of accreditation.  
493.63 Notification requirements for laboratories issued a certificate of accreditation.

**Subpart E—[Reserved]****Subpart F—General Administration**

- 493.602 Scope of subpart. [Reserved]  
493.606 Applicability of subpart. [Reserved]  
493.610 Certificate requirements for laboratories. [Reserved]  
493.614 Application procedures. [Reserved]  
493.618 Additional application requirements. [Reserved]  
493.622 Appeals procedures. [Reserved]  
493.626 Registration certificate. [Reserved]  
493.630 Certificate. [Reserved]  
493.631 Certificate of waiver. [Reserved]  
493.632 Certificate of accreditation. [Reserved]  
493.633 Applicability of certificate, certificate of waiver, and certificate of accreditation. [Reserved]  
493.634 Notification of changes. [Reserved]  
493.638 Registration certificate and certificate fees.  
493.639 Fee for revised certificate.  
493.643 Fee for determination of program compliance.  
493.645 Fee (s) applicable to accredited laboratories/approved State licensure programs.  
493.646 Payment of fees.  
493.649 Methodology for determining fee amount.

**Subpart G—[Reserved]****Subpart H—Participation in Proficiency Testing for Laboratories Performing Tests of Moderate or High Complexity, or Both**

- 493.801 Condition: Enrollment and testing of samples.  
493.803 Condition: Successful participation.  
493.807 Condition: Reinstatement of laboratories performing tests of moderate or high complexity, or both, after failure to participate successfully.

**Proficiency Testing by Specialty and Subspecialty for Laboratories Performing Tests of Moderate or High Complexity, or Both**

- 493.821 Condition: Microbiology.  
493.823 Standard; Bacteriology.  
493.825 Standard; Mycobacteriology.  
493.827 Standard; Mycology.  
493.829 Standard; Parasitology.  
493.831 Standard; Virology.  
493.833 Condition: Diagnostic immunology.  
493.835 Standard; Syphilis serology.  
493.837 Standard; General immunology.  
493.839 Condition: Chemistry.  
493.841 Standard; Routine chemistry.  
493.843 Standard; Endocrinology.  
493.845 Standard; Toxicology.  
493.849 Condition: Hematology.  
493.851 Standard; Hematology.  
493.853 Condition: Pathology.  
493.855 Standard; Cytology; gynecologic examinations.  
493.857 Condition: Immunohematology.  
493.859 Standard; ABO group and D (Rho) typing.

- Sec.  
493.861 Standard; Unexpected antibody detection.  
493.863 Standard; Compatibility testing.  
493.865 Standard; Antibody identification.

**Subpart I—Proficiency Testing Programs for Tests of Moderate or High Complexity, or Both**

- 493.901 Approval of proficiency testing programs.  
493.903 Administrative responsibilities.  
493.905 Nonapproved proficiency testing programs.

**Proficiency Testing Programs by Specialty and Subspecialty**

- 493.909 Microbiology.  
493.911 Bacteriology.  
493.913 Mycobacteriology.  
493.915 Mycology.  
493.917 Parasitology.  
493.919 Virology.  
493.921 Diagnostic immunology.  
493.923 Syphilis serology.  
493.927 General Immunology.  
493.929 Chemistry.  
493.931 Routine chemistry.  
493.933 Endocrinology.  
493.937 Toxicology.  
493.941 Hematology (including routine hematology and coagulation).  
493.945 Cytology; gynecologic examinations.  
493.959 Immunohematology.

**Subpart J—Patient Test Management for Moderate or High Complexity Testing, or Both.**

- 493.1101 Condition: Patient test management; moderate or high complexity testing, or both.  
493.1103 Standard; Procedures for specimen submission and handling.  
493.1105 Standard; Test requisition.  
493.1107 Standard; Test records.  
493.1109 Standard; Test report.  
493.1111 Standard; Referral of specimens.

**Subpart K—Quality Control for Tests of Moderate or High Complexity, or Both**

- 493.1201 Condition: General quality control for tests of moderate or high complexity, or both.  
493.1202 Standard; Moderate or high complexity testing, or both: Effective from September 1, 1992 to September 1, 1994.  
493.1203 Standard; Moderate or high complexity testing, or both: Effective beginning September 1, 1994.  
493.1204 Standard; Facilities.  
493.1205 Standard; Test methods, equipment, instrumentation, reagents, materials, and supplies.  
493.1211 Standard; Procedure manual.  
493.1213 Standard; Establishment and verification of method performance specifications.  
493.1215 Standard; Equipment maintenance and function checks.  
493.1217 Standard; Calibration and calibration verification procedures.  
493.1218 Standard; Control procedures.  
493.1219 Standard; Remedial actions.  
493.1221 Standard; Quality control records.  
493.1223 Condition: Quality control—specialties and subspecialties for tests of moderate or high complexity, or both.

- Sec.  
493.1225 Condition: Microbiology.  
493.1227 Condition: Bacteriology.  
493.1229 Condition: Mycobacteriology.  
493.1231 Condition: Mycology.  
493.1233 Condition: Parasitology.  
493.1235 Condition: Virology.  
493.1237 Condition: Diagnostic immunology.  
493.1239 Condition: Syphilis serology.  
493.1241 Condition: General immunology.  
493.1243 Condition: Chemistry.  
493.1245 Condition: Routine chemistry.  
493.1247 Condition: Endocrinology.  
493.1249 Condition: Toxicology.  
493.1253 Condition: Hematology.  
493.1255 Condition: Pathology.  
493.1257 Condition: Cytology.  
493.1259 Condition: Histopathology.  
493.1261 Condition: Oral pathology.  
493.1263 Condition: Radiobioassay.  
493.1265 Condition: Histocompatibility.  
493.1267 Condition: Clinical cytogenetics.  
493.1269 Condition: Immunohematology.  
493.1271 Condition: Transfusion services and bloodbanking.  
493.1273 Standard; Immunohematological collection, processing, dating periods, labeling and distribution of blood and blood products.  
493.1275 Standard; Blood and blood products storage facilities.  
493.1277 Standard; Arrangement for services.  
493.1279 Standard; Provision of testing.  
493.1283 Standard; Retention of samples of transfused blood.  
493.1285 Standard; Investigation of transfusion reactions.

**Subpart L—[Reserved]****Subpart M—Personnel for Moderate and High Complexity Testing**

- 493.1401 General.

**Laboratories Performing Moderate Complexity Testing**

- 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director.  
493.1405 Standard; Laboratory director qualifications.  
493.1407 Standard; Laboratory director responsibilities.  
493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant.  
493.1411 Standard; Technical consultant qualifications.  
493.1413 Standard; Technical consultant responsibilities.  
493.1415 Condition: Laboratories performing moderate complexity testing; clinical consultant.  
493.1417 Standard; Clinical consultant qualifications.  
493.1419 Standard; Clinical consultant responsibilities.  
493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel.  
493.1423 Standard; Testing personnel qualifications.  
493.1425 Standard; Testing personnel responsibilities.

**Laboratories Performing High Complexity Testing**

Sec.

- 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.
- 493.1443 Standard; Laboratory director qualifications.
- 493.1445 Standard; Laboratory director responsibilities.
- 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor.
- 493.1449 Standard; Technical supervisor qualifications.
- 493.1451 Standard; Technical supervisor responsibilities.
- 493.1453 Condition: Laboratories performing high complexity testing; clinical consultant.
- 493.1455 Standard; Clinical consultant qualifications.
- 493.1457 Standard; Clinical consultant responsibilities.
- 493.1459 Condition: Laboratories performing high complexity testing; general supervisor.
- 493.1461 Standard; General supervisor qualifications.
- 493.1463 Standard; General supervisor responsibilities.
- 493.1467 Condition: Laboratories performing high complexity testing; Cytology general supervisor.
- 493.1469 Standard; Cytology general supervisor qualifications.
- 493.1471 Standard; Cytology general supervisor responsibilities.
- 493.1481 Condition: Laboratories performing high complexity testing; cytotechnologist.
- 493.1483 Standard; Cytotechnologist qualifications.
- 493.1485 Standard; Cytotechnologist responsibilities.
- 493.1487 Condition: Laboratories performing High Complexity testing; testing personnel.
- 493.1489 Standard; Testing personnel qualifications.
- 493.1495 Standard; Testing personnel responsibilities.

**Subparts N-O—[Reserved]****Subpart P—Quality Assurance for Moderate or High Complexity Testing, or Both**

- 493.1701 Condition: Quality assurance for moderate or high complexity testing, or both.
- 493.1703 Standard; Patient test management assessment.
- 493.1705 Standard; Quality control assessment.
- 493.1707 Standard; Proficiency testing assessment.
- 493.1709 Standard; Comparison of test results.
- 493.1711 Standard; Relationship of patient information to patient test results.
- 493.1713 Standard; Personnel assessment.
- 493.1715 Standard; Communications.
- 493.1717 Standard; Complaint investigations.
- 493.1719 Standard; Quality assurance review with staff.

Sec.

- 493.1721 Standard; Quality assurance records.

**Subpart Q—Inspection**

- 493.1775 Condition: Inspection of laboratories issued a certificate of waiver.
- 493.1777 Condition: Inspection of all laboratories not issued a certificate of waiver or a certificate of accreditation.
- 493.1780 Condition: Inspection of accredited and State-exempt laboratories.

**Subparts R-S—[Reserved]****Subpart T—Consultations**

- 493.2001 Establishment and function of the Clinical Laboratory Improvement Advisory Committee.

3. By revising subpart A, adding subparts B through D, reserving subpart E, amending subpart F by removing the text of §§ 493.602 through 493.634 and reserving the section headings, removing and reserving subpart G, and revising subparts H through K to read as follows:

**Subpart A—General Provisions****§ 493.1 Basis and scope.**

This part sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). It implements sections 1861 (e) and (j), the sentence following section 1861(s)(13), and 1902(a)(9) of the Social Security Act, and section 353 of the Public Health Service Act. This part applies to all laboratories as defined under "laboratory" in § 493.2 of this part. This part also applies to laboratories seeking payment under the Medicare and Medicaid programs. The requirements are the same for Medicare approval as for CLIA certification.

**§ 493.2 Definitions.**

As used in this part—

*Accredited institution* means a school or program which—

(a) Admits as regular student only persons having a certificate of graduation from a school providing secondary education, or the recognized equivalent of such certificate;

(b) Is legally authorized within the State to provide a program of education beyond secondary education;

(c) Provides an educational program for which it awards a bachelor's degree or provides not less than a 2-year program which is acceptable for full credit toward such a degree, or provides an educational program for which it awards a master's or doctoral degree;

(d) Is accredited by a nationally recognized accrediting agency or association.

This definition includes any foreign institution of higher education that HHS or its designee determines meets substantially equivalent requirements.

*Analyte* means a substance or constituent for which the laboratory conducts testing.

*Authorized person* means an individual authorized under State law to order tests or receive test results, or both.

*Automated* means an instrument or test system in which all analytical processes, including sample and reagent uptake, sample/reagent interaction, chemical/biological analysis, result calculation and result readout are mechanized.

*Challenge* means, for quantitative tests, an assessment of the amount of substance or analyte present or measured in a sample. For qualitative tests, a challenge means the determination of the presence or the absence of an analyte, organism, or substance in a sample.

*CLIA* means the Clinical Laboratory Improvement Amendments of 1988.

*HHS* means the Department of Health and Human Services, or its designee.

*Kit* means all components of a test that are packaged together.

*Laboratory* means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

*Performance characteristic* means a property of a test that is used to describe its quality, e.g., accuracy, precision, analytical sensitivity, analytical specificity, reportable range, reference range, etc.

*Performance specification* means a value or range of values for a performance characteristic, established or verified by the laboratory, that is used to describe the quality of patient test results.

*Referee laboratory* means a laboratory currently in compliance with applicable CLIA requirements, that has had a record of satisfactory proficiency testing performance for all testing

events for at least one year for a specific test, analyte, subspecialty, or specialty and has been designated by an HHS approved proficiency testing program as a referee laboratory for analyzing proficiency testing specimens for the purpose of determining the correct response for the specimens in a testing event for that specific test, analyte, subspecialty, or specialty.

*Reference range* means the range of test values expected for a designated population of individuals, e.g., 95 percent of individuals that are presumed to be healthy (or normal).

*Reportable range* means the range of test values over which the relationship between the instrument, kit, or system's measurement response is shown to be valid.

*Sample* in proficiency testing means the material contained in a vial, on a slide, or other unit that contains material to be tested by proficiency testing program participants. When possible, samples are of human origin.

*Semi-automated* means an instrument or system in which some of the steps in the analytical process are mechanized but others require operator intervention.

*State-exempt laboratory* means a licensed laboratory in a State whose licensure program is approved by HCFA and is exempt from CLIA requirements (i.e., State-exempt).

*Target value* for quantitative tests means either the mean of all participant responses after removal of outliers (those responses greater than 3 standard deviations from the original mean) or the mean established by definitive or reference methods acceptable for use in the National Reference System for the Clinical Laboratory (NRSCL) by the National Committee for the Clinical Laboratory Standards (NCCLS). In instances where definitive or reference methods are not available or a specific method's results demonstrate bias that is not observed with actual patient specimens, as determined by a defensible scientific protocol, a comparative method or a method group ("peer" group) may be used. If the method group is less than 10 participants, "target value" means the overall mean after outlier removal (as defined above) unless acceptable scientific reasons are available to indicate that such an evaluation is not appropriate.

*Unsatisfactory proficiency testing performance* means failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for a testing event.

*Unsuccessful proficiency testing performance* means a failure to attain the minimum satisfactory score for an

analyte, test, subspecialty, or specialty for two consecutive or two of three consecutive testing events.

#### § 493.3 Applicability.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, a laboratory will be cited as out of compliance with section 353 of the Public Health Service Act unless it—

(1) Has a current, unrevoked or unsuspended certificate of waiver, a registration certificate, a certificate, or a certificate of accreditation issued by HHS applicable to the category of examinations or procedures performed by the laboratory; or

(2) Is State exempt.

(b) *Exception.* These rules do not apply to components or functions of—

(1) Any facility or component of a facility that only performs testing for forensic purposes;

(2) Research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients; or

(3) Laboratories certified by the National Institutes on Drug Abuse (NIDA), in which drug testing is performed which meets NIDA guidelines and regulations. However, all other testing conducted by a NIDA-certified laboratory is subject to this rule.

(c) *Federal laboratories.* Laboratories under the jurisdiction of an agency of the Federal Government are subject to the rules of this part, except that the Secretary may modify the application of such requirements as appropriate.

#### § 493.10 Categories of tests by complexity.

(a) Laboratory tests are categorized as either—

(1) Waived tests;

(2) Tests of moderate complexity; or

(3) Tests of high complexity.

(b) A laboratory may perform only waived tests, only tests of moderate complexity, only tests of high complexity or any combination.

(c) Each laboratory must be either State-exempt or possess one of the following, as defined in this part:

(1) Registration certificate;

(2) Certificate of waiver;

(3) Certificate; or

(4) Certificate of accreditation.

#### § 493.15 Laboratories performing waived tests.

(a) *Requirement.* Tests for certificate of waiver must meet the descriptive criteria specified in paragraph (b) of this section.

(b) *Criteria.* Test systems are simple laboratory examinations and procedures which—

(1) Are cleared by FDA for home use;

(2) Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or

(3) Pose no reasonable risk of harm to the patient if the test is performed incorrectly.

(c) *Certificate of waiver tests.* A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (c) of this section) and no others:

(1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following:

(i) Bilirubin;

(ii) Glucose;

(iii) Hemoglobin;

(iv) Ketone;

(v) Leukocytes;

(vi) Nitrite;

(vii) pH;

(viii) Protein;

(ix) Specific gravity; and

(x) Urobilinogen.

(2) Fecal occult blood;

(3) Ovulation tests—visual color comparison tests for human luteinizing hormone;

(4) Urine pregnancy tests—visual color comparison tests;

(5) Erythrocyte sedimentation rate—non-automated;

(6) Hemoglobin—copper sulfate—non-automated;

(7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; and

(8) Spun microhematocrit.

(d) *Revisions to criteria for test categorization and the list of waived tests.* (1) The Clinical Laboratory Improvement Advisory Committee, as defined in subpart T, will conduct reviews upon request of HHS and recommend to HHS revisions to the criteria for categorization of tests.

(2) HHS will determine whether a laboratory test meets the criteria listed under paragraph (b) of this section for a waived test. Revisions to the list of waived tests approved by HHS will be published in the *Federal Register* in a notice with opportunity for comment.

(e) Laboratories eligible for a certificate of waiver must—

(1) Follow manufacturers' instructions for performing the test; and

(2) Meet the requirements in subpart B, Certificate of Waiver, of this part.

**§ 493.17 Test categorization.**

(a) *Categorization by criteria.* Notices will be published in the **Federal Register** which list each specific test system, assay, and examination categorized by complexity. Using the seven criteria specified in this paragraph for categorizing tests of moderate or high complexity, each specific laboratory test system, assay, and examination will be graded for level of complexity by assigning scores of 1, 2, or 3 within each criteria. The score of "1" indicates the lowest level of complexity, and the score of "3" indicates the highest level. These scores will be totaled. Test systems, assays or examinations receiving scores of 12 or less will be categorized as moderate complexity, while those receiving scores above 12 will be categorized as high complexity.

**Note:** A score of "2" will be assigned to a criteria heading when the characteristics for a particular test are intermediate between the descriptions listed for scores of "1" and "3."

(1) *Knowledge.* (i) *Score 1.* (A) Minimal scientific and technical knowledge is required to perform the test.

(B) Minimal decision-making is required, and knowledge required to perform the test may be obtained through on-the-job instruction.

(ii) *Score 3.* (A) Specialized scientific and technical knowledge is essential to perform the test.

(B) Specialized knowledge is necessary for decision-making relative to the preanalytic, analytic, or postanalytic phases of testing.

(2) *Training and experience.* (i) *Score 1.* (A) Minimal training is required for preanalytic, analytic and postanalytic phases of the testing process; and

(B) Limited experience is required to perform the test.

(ii) *Score 3.* (A) Specialized training is essential to perform the preanalytic, analytic or postanalytic testing process; and

(B) Substantial experience may be necessary for analytic test performance.

(3) *Reagents and materials preparation.* (i) *Score 1.* (A) Reagents and materials are generally stable and reliable; and

(B) Reagents and materials are prepackaged, or premeasured, or require no special handling, precautions or storage conditions.

(ii) *Score 3.* (A) Reagents and materials may be labile and may require special handling to assure reliability; and

(B) Reagents and materials preparation may include manual steps such as gravimetric or volumetric measurements.

(4) *Characteristics of operational steps.* (i) *Score 1.* Operational steps are either automatically executed (such as pipetting, temperature monitoring, or timing of steps), or are easily controlled.

(ii) *Score 3.* Operational steps in the testing process require close monitoring or control, and may require special specimen preparation, precise temperature control or timing of procedural steps, accurate pipetting, or extensive calculations.

(5) *Calibration, quality control, and proficiency testing materials.* (i) *Score 1.* (A) Calibration materials are stable and readily available;

(B) Quality control materials are stable and readily available; and

(C) External proficiency testing materials, when available, are stable.

(ii) *Score 3.* (A) Calibration materials, if available, may be labile;

(B) Quality control materials may be labile, or not available; or

(C) External proficiency testing materials, if available, may be labile.

(6) *Test system troubleshooting and equipment maintenance.* (i) *Score 1.* (A) Test system troubleshooting is automatic or self-correcting, or clearly described or requires minimal judgment; and

(B) Equipment maintenance is provided by the manufacturer, is seldom needed, or can easily be performed.

(ii) *Score 3.* (A) Troubleshooting is not automatic and requires decision-making and direct intervention to resolve most problems; and

(B) Maintenance requires special knowledge, skills, and abilities.

(7) *Interpretation and judgment.* (i) *Score 1.* (A) Minimal interpretation and judgment are required to perform preanalytic, analytic and postanalytic processes; and

(B) Resolution of problems requires limited independent interpretation and judgment; and

(ii) *Score 3.* (A) Extensive independent interpretation and judgment are required to perform the preanalytic, analytic or postanalytic processes; and

(B) Resolution of problems requires extensive interpretation and judgment.

(b) *Revisions to the criteria for categorization.* The Clinical Laboratory Improvement Advisory Committee, as defined in subpart T of this part, will conduct reviews upon request of HHS and recommend to HHS revisions to the criteria for categorization of tests.

(c) *Process for device/test categorization utilizing the scoring system under § 493.17(a).* (1)(i) For new commercial test systems, assays, or examinations, the manufacturer, as part of its 510(k) and PMA application to FDA, will submit supporting data for

device/test categorization. FDA will determine the complexity category, notify the manufacturers directly, and will simultaneously inform both HCFA and CDC of the device/test category. FDA will consult with CDC concerning test categorization in the following three situations:

(A) When categorizing previously uncategorized new technology;

(B) When FDA determines it to be necessary in cases involving a request for a change in categorization; and

(C) If a manufacturer requests review of a categorization decision by FDA in accordance with 21 CFR 10.75.

(ii) Test categorization will be effective as of the notification to the applicant.

(2) For test systems, assays, or examinations not commercially available, a laboratory or professional group may submit a written request for categorization to PHS. These requests will be forwarded to CDC for evaluation; CDC will determine complexity category and notify the applicant, HCFA, and FDA of the categorization decision. In the case of request for a change of category or for previously uncategorized new technology, PHS will receive the request application and forward it to CDC for categorization.

(3) A request for recategorization will be accepted for review if it is based on new information not previously submitted in a request for categorization or recategorization by the same applicant and will not be considered more frequently than once per year.

(4) If a laboratory test system, assay or examination does not appear on the lists of tests in the **Federal Register** notices, it is considered to be a test of high complexity until PHS, upon request, reviews the matter and notifies the applicant of its decision.

(5) PHS will publish revisions periodically to the list of moderate and high complexity tests in the **Federal Register** in a notice with opportunity for comment.

**§ 493.20 Laboratories performing tests of moderate complexity.**

(a) A laboratory may qualify for a certificate to perform tests of moderate complexity provided that it restricts its test performance to certificate of waiver tests or examinations and one or more tests or examinations meeting criteria for tests of moderate complexity.

(b) A laboratory that performs tests or examinations of moderate complexity must meet the applicable requirements in subpart C, registration certificate and certificate, or if applicable, subpart D,

certificate of accreditation; subpart H, participation in proficiency testing; subpart J, patient test management; subpart K, quality control; subpart M, personnel; subpart P, quality assurance; and subpart Q, inspections, of this part.

(c) If the laboratory also performs certificate of waiver tests listed in § 493.15, compliance with subparts H, J, K, M, P, and Q of this part for routine inspections are not required for the waived tests. However, the laboratory must comply with the requirements in §§ 493.15(d) and 493.1775.

#### § 493.25 Laboratories performing tests of high complexity.

(a) A laboratory must obtain a certificate for tests of high complexity if it performs one or more tests that meet the criteria for tests of high complexity as specified in § 493.17(a).

(b) A laboratory performing one or more tests of high complexity must meet the applicable requirements of subpart C, registration certificate and certificate, or if applicable, subpart D, certificate of accreditation; subpart H, participation in proficiency testing; subpart J, patient test management; subpart K, quality control; subpart M, personnel; subpart P, quality assurance; and subpart Q, inspections, of this part.

(c) If the laboratory also performs certificate of waiver tests, the requirements of subparts H, J, K, M, P, and Q of this part for routine inspections are not applicable for the waived tests. However, the laboratory must comply with the requirements in §§ 493.15(d) and 493.1775.

(d) If the laboratory also performs tests of moderate complexity, the personnel requirements of subpart M are applicable for the performance of tests of moderate complexity as well as subparts H, J, K, P, and Q of this part.

#### Subpart B—Certificate of Waiver

##### § 493.35 Application for a certificate of waiver.

(a) *Filing of application.* Except as specified in paragraph (b) of this section, a laboratory performing only one or more waived tests listed in § 435.15(b) of this chapter must file a separate application for each laboratory location.

(b) *Exceptions.* (1) Each laboratory that is not in a fixed location, must file an application using the address of the home base, including—

(i) A laboratory that moves from testing site to testing site or has a temporary testing location, such as a health screening fair; and

(ii) Each mobile van providing lab services.

(2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (e.g., few types of tests) public health testing may file a single application.

(3) Laboratories within a hospital that are located at the same street address and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.

(c) *Application format and contents.* The application must—

(1) Be made to HHS or its designee on a form or forms prescribed by HHS;

(2) Be signed by an owner, or by an authorized representative of the laboratory who attests that the laboratory will be operated in accordance with requirements established by the Secretary under section 353 of the PHS Act; and

(3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including—

(i) The name and the total number of test procedures and examinations performed annually (excluding tests the laboratory may run for quality control, quality assurance or proficiency testing purposes;

(ii) The methodologies for each laboratory test procedure or examination performed, or both; and

(iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures.

(d) *Access requirements.* Laboratories that perform one or more waived tests listed in § 493.15(b) and no other tests must—

(1) Make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section and § 493.15(d);

(2) Agree to permit unannounced inspections by HHS in accordance with subpart Q of this part—

(i) When HHS has substantive reason to believe that the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health;

(ii) To evaluate complaints from the public;

(iii) On a random basis to determine whether the laboratory is performing tests not listed in § 493.15; and

(iv) To collect information for the addition, deletion, or continued inclusion of tests listed in § 493.15.

(e) *Denial of application.* If HHS determines that the application for a

certificate of waiver is to be denied, HHS will—

(1) Provide the laboratory with a written statement of the grounds on which the denial is based and an opportunity for appeal, in accordance with the procedures set forth in subpart R of this part;

(2) Notify a laboratory that has its application for a certificate of waiver denied that it cannot operate as a laboratory under the PHS Act unless the denial is overturned at the conclusion of the administrative appeals process provided by subpart R; and

(3) Notify the laboratory that it is not eligible for payment under the Medicare and Medicaid programs.

##### § 493.37 Requirements for a certificate of waiver.

(a) HHS will issue a certificate of waiver to a laboratory only if the laboratory meets the requirements of § 493.35.

(b) Laboratories issued a certificate of waiver—

(1) Are subject to the requirements of this subpart and § 493.15(d) of subpart A of this part; and

(2) Must permit unannounced inspections by HHS in accordance with subpart Q of this part.

(c) Laboratories must remit the certificate of waiver fee specified in subpart F of this part.

(d) In accordance with subpart R of this part, HHS will suspend or revoke or limit a laboratory's certificate of waiver for failure to comply with the requirements of this subpart. In addition, failure to meet the requirements of this subpart will result in suspension or denial of payments under Medicare and Medicaid in accordance with subpart R of this part.

(e)(1) A certificate of waiver issued under this subpart is valid for no more than 2 years. In the event of a non-compliance determination resulting in HHS action to revoke, suspend, or limit the laboratory's certificate of waiver, HHS will provide the laboratory with a statement of grounds on which the determination of non-compliance is based and offer an opportunity for appeal as provided in subpart R of this part.

(2) If the laboratory requests a hearing within the time specified by HHS, it retains its certificate of waiver or reissued certificate of waiver until a decision is made by an administrative law judge, as specified in subpart R of this part, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.

(3) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of a non-compliance determination even if there has been no appeals decision issued.

(f) A laboratory seeking to renew its certificate of waiver must—

(1) Complete the renewal application prescribed by HHS and return it to HHS not less than 9 months nor more than 1 year before the expiration of the certificate; and

(2) Meet the requirements of §§ 493.35 and 493.37.

(g) A laboratory with a certificate of waiver that wishes to perform examinations of test procedures not listed in the waiver test category must meet the requirements set forth in subparts C or D of this part.

#### § 493.39 Notification requirements for laboratories issued a certificate of waiver.

Laboratories performing one or more tests listed in § 493.15 and no others must notify HHS or its designee—

(a) Before performing and reporting results for any test or examination that is not specified under § 493.15 for which it does not have a registration certificate as required in subparts C or D of this part; and

(b) Within 30 days of any change(s) in—

- (1) Ownership;
- (2) Name;
- (3) Location; or
- (4) Director.

#### Subpart C—Registration Certificate and Certificate

##### § 493.43 Application for registration certificate and certificate.

(a) *Filing of application.* Except as specified in paragraph (b) of this section, all laboratories performing tests of moderate or high complexity, or both, must file a separate application for each laboratory location.

(b) *Exceptions.* (1) Each laboratory that is not in a fixed location, must file a single application using the address of the home base, including—

(i) A laboratory that moves from testing site to testing site or uses a temporary testing location, such as a health screening fair; and

(ii) Each mobile van providing laboratory services.

(2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (e.g., few types of tests) public health testing may file a single application.

(3) Laboratories within a hospital that are located at the same street address

and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.

(c) *Application format and contents.* The application must—

(1) Be made to HHS or its designee on a form or forms prescribed by HHS;

(2) Be signed by an owner, or by an authorized representative of the laboratory who attests that the laboratory will be operated in accordance with requirements established by the Secretary under section 353 of the PHS Act; and

(3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including—

(i) The name and total number of test procedures and examinations performed annually (excluding tests for quality control, quality assurance or proficiency testing purposes);

(ii) The methodologies for each laboratory test procedure or examination performed, or both; and

(iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures.

(d) *Access and reporting requirements.* All laboratories must make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section.

##### § 493.45 Requirements for a registration certificate.

(a) A registration certificate is required—

(1) Initially for all laboratories performing test procedures listed at §§ 493.17 (b) and (c); and

(2) For all certificate of waiver laboratories that intend to perform testing in addition to those tests listed in § 493.15.

(b) HHS will issue a registration certificate if the laboratory—

(1) Complies with the requirements of § 493.43;

(2) Agrees to notify HHS or its designee within 30 days of any changes in ownership, name, location, director or supervisor (laboratories performing high complexity testing only);

(3) Agrees to treat proficiency testing samples in the same manner as it treats patient specimens; and

(4) Remits the fee for the registration certificate, as specified in subpart F of this part.

(c) Prior to the expiration of the registration certificate, a laboratory must—

(1) Remit the certificate fee specified in subpart F of this part;

(2) Be inspected by HHS as specified in subpart Q of this part; and

(3) Demonstrate compliance with the applicable requirements of this subpart and subparts H, J, K, M, P, and Q of this part.

(d) In accordance with subpart R of this part, HHS will initiate suspension or revocation of a laboratory's registration certificate and will deny the laboratory's application for a certificate for failure to comply with the requirements set forth in this subpart. HHS may also impose certain alternative sanctions. In addition, failure to meet the requirements of this subpart will result in suspension of payments under Medicare and Medicaid as specified in subpart R of this part.

(e) A registration certificate is—

(1) Valid for a period of no more than two years or until such time as an inspection to determine program compliance can be conducted, whichever is shorter; and

(2) Not renewable; however, the registration certificate may be reissued if compliance has not been determined by HHS prior to the expiration date of the registration certificate.

(f) In the event of a non-compliance determination resulting in an HHS denial of a laboratory's certificate application, HHS will provide the laboratory with a statement of grounds on which the non-compliance determination is based and offer an opportunity for appeal as provided in subpart R.

(g) If the laboratory requests a hearing within the time specified by HHS, it retains its registration certificate or reissued registration certificate until a decision is made by an administrative law judge as provided in subpart R of this part, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.

(h) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of denial of the certificate application even if there has been no appeals decision issued.

##### § 493.49 Requirements for a certificate.

(a) HHS will issue a certificate to a laboratory only if the laboratory—

(1) Meets the requirements of §§ 493.43 and 493.45;

(2) Remits the certificate fee specified in subpart F of this part; and

(3) Meets the applicable requirements of this subpart and subparts H, J, K, M, P, and Q of this part.

(b) Laboratories issued a certificate—

(1) Are subject to the notification requirements of § 493.51 of this section; and

(2) Must permit unannounced inspections by HHS in accordance with subpart Q of this part—

(i) To determine compliance with the requirements of this part;

(ii) To evaluate complaints from the public;

(iii) When HHS has substantive reason to believe that any tests are being performed, or the laboratory is being operated in a manner that constitutes an imminent and serious risk to human health; and

(iv) To collect information for the addition, deletion, or continued inclusion of tests listed in §§ 493.15 and 493.17 (b) and (c).

(c) Failure to comply with the requirements of this subpart will result in—

(1) Suspension, revocation or limitation of a laboratory's certificate in accordance with subpart R of this part; and

(2) Suspension or denial of payments under Medicare and Medicaid in accordance with subpart R of this part.

(d) A certificate issued under this subpart is valid for no more than 2 years.

(e) In the event of a non-compliance determination resulting in an HHS action to revoke, suspend or limit the laboratory's certificate, HHS will—

(1) Provide the laboratory with a statement of grounds on which the determination of non-compliance is based; and

(2) Offer an opportunity for appeal as provided in subpart R of this part. If the laboratory requests a hearing within the time specified by HHS, it retains its certificate or reissued certificate until a decision is made by an administrative law judge as provided in subpart R of this part, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.

(f) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of a non-compliance determination even if there has been no appeals decision issued.

(g) A laboratory seeking to renew its certificate must—

(1) Complete and return the renewal application to HHS 9 to 12 months prior to the expiration of the certificate; and

(2) Meet the requirements of § 493.43 and paragraphs (a)(2) and (b)(2) of this section.

(h) If HHS determines that the application for the renewal of a certificate is to be denied or limited, HHS will notify the laboratory in writing of the—

(1) Basis for denial of the application; and

(2) Opportunity for appeal as provided in subpart R of this part.

(i) If the laboratory requests a hearing within the time specified by HHS, it retains its certificate or reissued certificate until a decision is made by an ALJ as provided in subpart R, except when HHS finds that conditions at the laboratory pose an imminent and serious risk to human health.

(j) For laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of nonrenewal of the certificate even if there has been no appeals decision issued.

#### § 493.51 Notification requirements for laboratories issued a certificate.

Laboratories issued a certificate must:

(a) Notify HHS or its designee within 30 days of any change in—

(1) Ownership;

(2) Name;

(3) Location;

(4) Director; or

(5) Supervisor (laboratories performing high complexity testing only).

(b) Notify HHS no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory's certificate, so that compliance with requirements can be determined; and

(c) Notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate.

#### Subpart D—Certificate of Accreditation

##### § 493.55 Application for registration certificate and certificate of accreditation.

(a) *Filing of application.* A laboratory performing one or more tests of moderate complexity or high complexity, or both may be issued a certificate of accreditation in lieu of a certificate provided the laboratory—

(1) Meets the standards of a private non-profit accreditation program

approved by HHS in accordance with subpart E; and

(2) Files a separate application for each location, except as specified in paragraph (b) of this section.

(b) *Exceptions.* (1) Each laboratory that is not in a fixed location must file an application using the address of the home base, including—

(i) A laboratory that moves from testing site to testing site or uses a temporary testing location, such as a health screening fair; and

(ii) Each mobile van providing laboratory testing.

(2) Not-for-profit or Federal, State, or local government laboratories that engage in limited (e.g., few types of tests) public health testing may file a single application.

(3) Laboratories within a hospital that are located at the same street address and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address.

(c) *Application format and contents.* The application must—

(1) Be made to HHS on a form or forms prescribed by HHS;

(2) Be signed by an owner, or by an authorized representative of the laboratory who attests that the laboratory will be operated in accordance with requirements established by the Secretary under section 353 of the PHS Act; and

(3) Describe the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory including—

(i) The name and total number of tests and examinations performed annually (excluding tests for quality control, quality assurance or proficiency testing purposes);

(ii) The methodologies for each laboratory test procedure or examination performed, or both; and

(iii) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and test procedures.

(d) *Access and reporting requirements.* All laboratories must make records available and submit reports to HHS as HHS may reasonably require to determine compliance with this section.

##### § 493.57 Requirements for a registration certificate.

A registration certificate is required for all laboratories seeking a certificate

of accreditation, unless the laboratory holds a valid certificate issued by HHS.

(a) HHS will issue a registration certificate if the laboratory—

(1) Complies with the requirements of § 493.55;

(2) Agrees to notify HHS within 30 days of any changes in ownership, name, location, director, or supervisor (laboratories performing high complexity testing only);

(3) Agrees to treat proficiency testing samples in the same manner as it treats patient specimens; and

(4) Remits the fee for the registration certificate specified in subpart F of this part.

(b)(1) The laboratory must provide HHS with proof of accreditation by an approved accreditation program—

(i) Within 11 months of issuance of the registration certificate; or

(ii) Prior to the expiration of the certificate.

(2) If such proof of accreditation is not supplied within this timeframe, the laboratory must meet, or continue to meet, the requirements of Subpart C, § 493.49 of this part.

(c) In accordance with subpart R of this part, HHS will initiate suspension, revocation, or limitation of a laboratory's registration certificate and will deny the laboratory's application for a certificate of accreditation for failure to comply with the requirements set forth in this subpart. In addition, failure to meet the requirements of this subpart will result in suspension or denial of payments under Medicare and Medicaid as specified in subpart R of this part.

(d) A registration certificate is valid for a period of no more than 2 years. However, it may be reissued if the laboratory is subject to subpart C of this part, as specified in § 493.57(b)(2) and compliance has not been determined by HHS before the expiration date of the registration certificate.

(e) In the event that the laboratory does not meet the requirements of this subpart, HHS will—

(1) Deny a laboratory's request for certificate of accreditation;

(2) Notify the laboratory if it must meet the requirements for a certificate as defined in subpart C of this part;

(3) Provide the laboratory with a statement of grounds on which the application denial is based;

(4) Offer an opportunity for appeal on the application denial as provided in subpart R of this part. If the laboratory requests a hearing within the time specified by HHS, the laboratory will retain its registration certificate or reissued registration certificate until a decision is made by an administrative

law judge as provided in subpart R, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health; and

(5) For those laboratories receiving payment from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory of denial of the request even if there has been no appeals decision issued.

#### § 493.61 Requirements for a certificate of accreditation.

(a) HHS will issue a certificate of accreditation to a laboratory if the laboratory—

(1) Meets the requirements of § 493.57 or, if applicable, § 493.49 of subpart C of this part; and

(2) Remits the certificate of accreditation fee specified in subpart F of this part.

(b) Laboratories issued a certificate of accreditation must—

(1) Treat proficiency testing samples in the same manner as patient samples;

(2) Meet the requirements of § 493.63;

(3) Comply with the requirements of the approved accreditation program;

(4) Permit random sample validation and complaint inspections as required in subpart Q of this part;

(5) Permit HHS to monitor the correction of any deficiencies found through the inspections specified in paragraph (b)(4) of this section;

(6) Authorize the accreditation program to release to HHS the laboratory's inspection findings whenever HHS conducts random sample or complaint inspections; and

(7) Authorize its accreditation program to submit to HHS the results of the laboratory's proficiency testing.

(c) A laboratory failing to meet the requirements of this section—

(1) Will no longer meet the requirements of this part by virtue of its accreditation in an approved accreditation program;

(2) Will be subject to full determination of compliance by HHS;

(3) May be subject to suspension revocation or limitation of the laboratory's certificate of accreditation or certain alternative sanctions; and

(4) May be subject to suspension of payments under Medicare and Medicaid as specified in subpart R.

(d) A certificate of accreditation issued under this subpart is valid for no more than 2 years. In the event of a non-compliance determination as a result of a random sample validation or complaint inspection, a laboratory will be subject to a full review by HHS in accordance with § 488.11 of this chapter.

(e) Failure to meet the applicable requirements of part 493, will result in an action by HHS to suspend, revoke or limit the certificate of accreditation. HHS will—

(1) Provide the laboratory with a statement of grounds on which the determination of noncompliance is based;

(2) Notify the laboratory if it is eligible to apply for a certificate as defined in subpart C of this part; and

(3) Offer an opportunity for appeal as provided in subpart R of this part.

(f) If the laboratory requests a hearing within the time frame specified by HHS—

(1) It retains its certificate of accreditation or reissued certificate of accreditation until a decision is made by an administrative law judge as provided in subpart R of this part, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health; and

(2) For those laboratories receiving payments from the Medicare or Medicaid program, such payments will be suspended on the effective date specified in the notice to the laboratory even if there has been no appeals decision issued.

(g) In the event the accreditation organization's approval is removed by HHS, the laboratory will be subject to the applicable requirements of subpart C of this part or § 493.57.

(h) A laboratory seeking to renew its certificate of accreditation must—

(1) Complete and return the renewal application to HHS 9 to 12 months prior to the expiration of the certificate of accreditation;

(2) Meet the requirements of this subpart; and

(3) Submit the certificate of accreditation fee specified in subpart F of this part.

(i) If HHS determines that the renewal application for a certificate of accreditation is to be denied or limited, HHS will notify the laboratory in writing of—

(1) The basis for denial of the application;

(2) Whether the laboratory is eligible for a certificate as defined in subpart C of this part;

(3) The opportunity for appeal on HHS's action to deny the renewal application for certificate of accreditation as provided in subpart R of this part. If the laboratory requests a hearing within the time frame specified by HHS, it retains its certificate of accreditation or reissued certificate of accreditation until a decision is made by an administrative law judge as provided

in subpart R of this part, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health; and

(4) Suspension of payments under Medicare or Medicaid for those laboratories receiving payments under the Medicare or Medicaid programs.

**§ 493.63 Notification requirements for laboratories issued a certificate of accreditation.**

Laboratories issued a certificate of accreditation must:

(a) Notify HHS and the approved accreditation program within 30 days of any changes in—

- (1) Ownership;
- (2) Name;
- (3) Location; or
- (4) Director.

(b) Notify the approved accreditation program no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included in the laboratory's accreditation, so that the accreditation organization can determine compliance and a new certificate of accreditation can be issued.

(c) Notify the accreditation program no later than 6 months after of any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of accreditation.

**Subpart H—Participation in Proficiency Testing for Laboratories Performing Tests of Moderate or High Complexity, or Both**

**§ 493.801 Condition: Enrollment and testing of samples.**

Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.

(a) *Standard; Enrollment.* The laboratory must—

(1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart.

(2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by HCFA; and

(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy and reliability of its testing procedures, in accordance with § 493.1709.

(3) For each specialty, subspecialty and analyte or test, participate in one approved proficiency testing program or programs, for one year before designating a different program and must notify HCFA before any change in designation; and

(4) Authorize the proficiency testing program to release to HHS all data required to—

- (i) Determine the laboratory's compliance with this subpart; and
- (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.

(b) *Standard; Testing of proficiency testing samples.* The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens.

(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

(2) The laboratory must test samples the same number of times that it routinely tests patient samples.

(3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample(s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent.

Laboratories with multiple testing sites or separate locations must not participate in any communications or discussions across sites/locations concerning proficiency testing sample results until after the date by which the laboratory must report proficiency testing results to the program.

(4) The laboratory must not send PT samples or portions of samples to another laboratory for any analysis

which they are certified to perform in their own laboratory. Any laboratory that HCFA determines intentionally referred its proficiency testing samples to another laboratory for analysis and submits the other laboratory's results as their own will have its certification revoked for at least one year. Any laboratory that receives proficiency testing samples from another laboratory for testing must notify HCFA of the receipt of those samples.

(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.

(6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

**§ 493.803 Condition: Successful participation.**

(a) Each laboratory performing tests of moderate and/or high complexity must successfully participate in a proficiency testing program approved by HCFA, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA.

(b) If the laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, sanctions will be taken as defined in subpart R of this part.

**§ 493.807 Condition: Reinstatement of laboratories performing tests of moderate or high complexity, or both, after failure to participate successfully.**

(a) If a laboratory's certificate is suspended and/or Medicare or Medicaid approval is terminated because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then

demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before HCFA will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test.

(b) The termination period for Medicare or Medicaid approval or period for suspension of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of termination or suspension.

(c) If a laboratory's certificate is suspended and/or Medicare or Medicaid approval is terminated in gynecologic cytology, the laboratory must take corrective action and reapply for certification.

**Proficiency Testing by Specialty and Subspecialty for Laboratories Performing Tests of Moderate or High Complexity, or Both**

**§ 493.821 Condition: Microbiology.**

The specialty of microbiology includes, for purposes of proficiency testing, the subspecialties of bacteriology, mycobacteriology, mycology, parasitology and virology.

**§ 493.823 Standard; Bacteriology.**

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems

associated with a proficiency testing failure.

(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

**§ 493.825 Standard; Mycobacteriology.**

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

**§ 493.827 Standard; Mycology.**

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

**§ 493.829 Standard; Parasitology.**

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

**§ 493.831 Standard; Virology.**

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unsatisfactory testing events, remedial action must be taken and documented, and the documentation

must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

**§ 493.833 Condition: Diagnostic immunology.**

The specialty of diagnostic immunology includes for purposes of proficiency testing the subspecialties of syphilis serology and general immunology.

**§ 493.835 Standard; Syphilis serology.**

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

**§ 493.837 Standard; General immunology.**

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

**§ 493.839 Condition: Chemistry.**

The specialty of chemistry includes for the purposes of proficiency testing the subspecialties of routine chemistry, endocrinology, and toxicology.

**§ 493.841 Standard; Routine chemistry.**

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

**§ 493.843 Standard; Endocrinology.**

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

**§ 493.845 Standard; Toxicology.**

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to

those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

**§ 493.849 Condition: Hematology.**

The specialty of hematology, for the purpose of proficiency testing, is not subdivided into subspecialties of testing.

**§ 493.851 Standard; Hematology.**

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to

those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

**§ 493.853 Condition: Pathology.**

The specialty of pathology includes, for purposes of proficiency testing, the subspecialty of cytology limited to gynecologic examinations.

**§ 493.855 Standard; Cytology: gynecologic examinations.**

To participate successfully in a cytology proficiency testing program for gynecologic examinations (Pap smears), the laboratory must meet the requirements of paragraphs (a) through (c) of this section.

(a) The laboratory must ensure that each individual engaged in the examination of gynecologic preparations is enrolled in a proficiency testing program approved by HCFA by January 1, 1994. The laboratory must ensure that

each individual is tested at least once per year and obtains a passing score. To ensure this annual testing of individuals, an announced or unannounced testing event will be conducted on-site in each laboratory at least once each year. Laboratories will be notified of the time of each announced on-site testing event at least 30 days prior to each event. Additional testing events will be conducted as necessary in each State or region for the purpose of testing individuals who miss the on-site testing event and for retesting individuals as described in paragraph (b) of this section.

(b) The laboratory must ensure that each individual participates in an annual testing event that involves the examination of a 10-slide test set as described in § 493.945. Individuals who fail this testing event are retested with another 10-slide test set as described in paragraphs (b)(1) and (b)(2) of this section. Individuals who fail this second test are subsequently retested with a 20-slide test set as described in paragraphs (b)(2) and (b)(3) of this section. Individuals are given not more than 2 hours to complete a 10-slide test and not more than 4 hours to complete a 20-slide test. Unexcused failure to appear by an individual for a retest will result in test failure with resulting remediation and limitations on slide examinations as specified in (b)(1), (b)(2), and (b)(3) of this section.

(1) An individual is determined to have failed the annual testing event if he or she scores less than 90 percent on a 10-slide test set. For an individual who fails an annual proficiency testing event, the laboratory must schedule a retesting event which must take place not more than 45 days after receipt of the notification of failure.

(2) An individual is determined to have failed the second testing event if he or she scores less than 90 percent on a 10-slide test set. For an individual who fails a second testing event, the laboratory must provide him or her with documented, remedial training and education in the area of failure, and must assure that all gynecologic slides evaluated subsequent to the notice of failure are reexamined until the individual is again retested with a 20-slide test set and scores at least 90 percent. Reexamination of slides must be documented.

(3) An individual is determined to have failed the third testing event if he or she scores less than 90 percent on a 20-slide test set. An individual who fails the third testing event must cease examining gynecologic slide preparations immediately upon notification of test failure and may not

resume examining gynecologic slides until the laboratory assures that the individual obtains at least 35 hours of documented, formally structured, continuing education in diagnostic cytopathology that focuses on the examination of gynecologic preparations, and until he or she is retested with a 20-slide test set and scores at least 90 percent.

(c) If a laboratory fails to ensure that individuals are tested or those who fail a testing event are retested, or fails to take required remedial actions as described in paragraphs (b)(1), (b)(2) or (b)(3) of this section, HCFA will initiate intermediate sanctions or revoke the laboratory's certificate for gynecologic cytology testing under CLIA, and, if applicable, terminate the laboratory's Medicare approval for gynecologic cytology testing in accordance with subpart R of this part.

**§ 493.857 Condition: Immunohematology.**

The specialty of immunohematology includes four subspecialties for the purposes of proficiency testing: ABO group and D (Rho) typing; unexpected antibody detection; compatibility testing; and antibody identification.

**§ 493.859 Standard; ABO group and D (Rho) typing.**

(a) Failure to attain a score of at least 100 percent of acceptable responses for each analyte or test in each testing event is unsatisfactory analyte performance for the testing event.

(b) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.

(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(e)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unacceptable analyte or unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(f) Failure to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

(g) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

**§ 493.861 Standard; Unexpected antibody detection.**

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by

the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

**§ 493.863 Standard; Compatibility testing.**

(a) Failure to attain an overall testing event score of at least 100 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

**§ 493.865 Standard; Antibody identification.**

(a) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to

those laboratories failing to participate in a testing event only if—

(1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results;

(2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and

(3) The laboratory participated in the previous two proficiency testing events.

(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure.

(2) For any unsatisfactory testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

(e) Failure to identify the same antibody in two consecutive or two out of three consecutive testing events is unsuccessful performance.

(f) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

**Subpart I—Proficiency Testing Programs for Tests of Moderate or High Complexity, or Both**

**§ 493.901 Approval of proficiency testing programs.**

In order for a proficiency testing program to receive HHS approval, the program must be offered by a private nonprofit organization or a Federal or State agency, or entity acting as a designated agent for the State. An organization, Federal, or State program seeking approval or reapproval for its program for the next calendar year must submit an application providing the required information by July 1 of the current year. The organization, Federal, or State program must provide technical assistance to laboratories seeking to qualify under the program, and must, for each specialty, subspecialty, and

analyte or test for which it provides testing—

(a) Assure the quality of test samples, appropriately evaluate and score the testing results, and identify performance problems in a timely manner;

(b) Demonstrate to HHS that it has—  
 (1) The technical ability required to—  
 (i) Prepare or purchase samples from manufacturers who prepare the samples in conformance with the appropriate good manufacturing practices required in 21 CFR parts 606, 640, and 820; and  
 (ii) Distribute the samples, using rigorous quality control to assure that samples mimic actual patient specimens when possible and that samples are homogeneous, except for specific subspecialties such as cytology, and will be stable within the time frame for analysis by proficiency testing participants;

(2) A scientifically defensible process for determining the correct result for each challenge offered by the program;

(3) A program of sufficient annual challenge and with the frequency specified in §§ 493.90 through 493.959 to establish that a laboratory has met minimum performance requirements;

(4) The resources needed to provide Statewide or nationwide reports to regulatory agencies on individual's performance for gynecologic cytology and on individual laboratory performance on testing events, cumulative reports and scores for each laboratory or individual, and reports of specific laboratory failures using grading criteria acceptable to HHS. These reports must be provided to HHS on a timely basis when requested;

(5) Provisions to include on each proficiency testing program report form used by the laboratory to record testing event results, an attestation statement that proficiency testing samples were tested in the same manner as patient specimens with a signature block to be completed by the individual performing the test as well as by the laboratory director;

(6) A mechanism for notifying participants of the PT shipping schedule and for participants to notify the proficiency testing program within three days of the expected date of receipt of the shipment that samples have not arrived or are unacceptable for testing. The program must have provisions for replacement of samples that are lost in transit or are received in a condition that is unacceptable for testing; and

(7) A process to resolve technical, administrative, and scientific problems about program operations;

(c) Meet the specific criteria for proficiency testing programs listed by specialty, subspecialty, and analyte or

test contained in §§ 493.901 through 493.959 for initial approval and thereafter provide HHS, on an annual basis, with the information necessary to assure that the proficiency testing program meets the criteria required for approval; and

(d) Comply with all applicable packaging, shipment, and notification requirements of 42 CFR part 72.

#### § 493.903 Administrative responsibilities.

The proficiency testing program must—

(a)(1) Provide HHS or its designees and participating laboratories with an electronic or a hard copy, or both, of reports of proficiency testing results and all scores for each laboratory's performance in a format as required by and approved by HCFA for each CLIA-certified specialty, subspecialty, and analyte or test within 60 days after the date by which the laboratory must report proficiency testing results to the proficiency testing program.

(2) Provide HHS with reports of PT results and scores of individual performance in cytology and provide copies of reports to participating individuals, and to all laboratories that employ the individuals, within 15 working days of the testing event;

(b) Furnish to HHS cumulative reports on an individual laboratory's performance and aggregate data on CLIA-certified laboratories for the purpose of establishing a system to make the proficiency testing results available, on a reasonable basis, upon request of any person, and include such explanatory information as may be appropriate to assist in the interpretation of the proficiency testing results;

(c) Provide HHS with additional information and data upon request and submit such information necessary for HHS to conduct an annual evaluation to determine whether the proficiency testing program continues to meet the requirements of §§ 493.901 through 493.959;

(d) Maintain records of laboratories' performance for a period of five years or such time as may be necessary for any legal proceedings; and

(e) Provide HHS with an annual report and, if needed, an interim report which identifies any previously unrecognized sources of variability in kits, instruments, methods, or PT samples, which adversely affect the programs' ability to evaluate laboratory performance.

#### § 493.905 Nonapproved proficiency testing programs.

If a proficiency testing program is determined by HHS to fail to meet any criteria contained in §§ 493.901 through 493.959 for approval of the proficiency testing program, HCFA will notify the program and the program must notify all laboratories enrolled of the nonapproval and the reasons for nonapproval within 30 days of the notification.

#### Proficiency Testing Programs by Specialty and Subspecialty

##### § 493.909 Microbiology.

The subspecialties under the specialty of microbiology for which a program may offer proficiency testing are bacteriology, mycobacteriology, mycology, parasitology and virology. Specific criteria for these subspecialties are found at §§ 493.911 through 493.919.

##### § 493.911 Bacteriology.

(a) *Types of services offered by laboratories.* In bacteriology, for proficiency testing purposes, there are five types of laboratories:

(1) Those that interpret Gram stains or perform primary inoculation, or both; and refer cultures to another laboratory appropriately certified for the subspecialty of bacteriology for identification;

(2) Those that use direct antigen techniques to detect an organism and may also interpret Gram stains or perform primary inoculation, or perform any combination of these;

(3) Those that, in addition to interpreting Gram stains, performing primary inoculations, and using direct antigen tests, also isolate and identify aerobic bacteria from throat, urine, cervical, or urethral discharge specimens to the genus level and may also perform antimicrobial susceptibility tests on selected isolated microorganisms;

(4) Those that perform the services in paragraph (a)(3) of this section and also isolate and identify aerobic bacteria from any source to the species level and may also perform antimicrobial susceptibility tests; and

(5) Those that perform the services in paragraph (a)(4) of this section and also isolate and identify anaerobic bacteria from any source.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for bacteriology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided to the laboratory through

mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing. For the types of laboratories specified in paragraph (a) of this section, an annual program must include samples that contain organisms that are representative of the six major groups of bacteria: anaerobes, Enterobacteriaceae, gram-positive bacilli, gram-positive cocci, gram-negative cocci, and miscellaneous gram-negative bacteria, as appropriate. The specific organisms included in the samples may vary from year to year. The annual program must include samples for bacterial antigen detection, bacterial isolation and identification, Gram stain, and antimicrobial susceptibility testing.

(1) An approved program must furnish HHS with a description of samples that it plans to include in its annual program no later than six months before each calendar year. At least 50 percent of the samples must be mixtures of the principal organism and appropriate normal flora. The program must include other important emerging pathogens (as determined by HHS) and either organisms commonly occurring in patient specimens or opportunistic pathogens. The program must include the following two types of samples; each type of sample must meet the 50 percent mixed culture criterion:

(i) Samples that require laboratories to report only organisms that the testing laboratory considers to be a principal pathogen that is clearly responsible for a described illness (excluding immunocompromised patients). The program determines the reportable isolates, including antimicrobial susceptibility for any designated isolate; and

(ii) Samples that require laboratories to report all organisms present. Samples must contain multiple organisms frequently found in specimens such as urine, blood, abscesses, and aspirates where multiple isolates are clearly significant or where specimens are derived from immuno-compromised patients. The program determines the reportable isolates.

(2) An approved program may vary over time. For example, the types of organisms that might be included in an approved program over time are—

*Anaerobes:*

*Bacteroides fragilis* group  
*Clostridium perfringens*  
*Peptostreptococcus anaerobius*  
 Enterobacteriaceae:  
*Citrobacter freundii*  
*Enterobacter aerogenes*  
*Escherichia coli*  
*Klebsiella pneumoniae*  
*Proteus mirabilis*  
*Salmonella typhimurium*

*Serratia marcescens*  
*Shigella sonnei*  
*Yersinia enterocolitica*  
 Gram-positive bacilli:  
*Listeria monocytogenes*  
*Corynebacterium* species CDC Group JK  
 Gram-positive cocci:  
*Staphylococcus aureus*  
 Streptococcus Group A  
 Streptococcus Group B  
 Streptococcus Group D (*S. bovis* and *enterococcus*)  
*Streptococcus pneumoniae*  
 Gram-negative cocci:  
*Branhamella catarrhalis*  
*Neisseria gonorrhoeae*  
*Neisseria meningitidis*  
 Miscellaneous Gram-negative bacteria:  
*Campylobacter jejuni*  
*Haemophilus influenzae*, Type B  
*Pseudomonas aeruginosa*

(3) For antimicrobial susceptibility testing, the program must provide at least one sample per testing event that includes gram-positive or gram-negative strains that have a predetermined pattern of sensitivity or resistance to the common antimicrobial agents.

(c) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c) (1) through (7) of this section.

(1) The program determines staining characteristics to be interpreted by Gram stain. The program determines the reportable bacteria to be detected by direct antigen techniques or isolation. To determine the accuracy of a laboratory's response for Gram stain interpretation, direct antigen detection, identification, or antimicrobial susceptibility testing, the program must compare the laboratory's response for each sample with the response which reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories.

(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must isolate and identify the organisms to the same extent it performs these procedures on patient specimens. A laboratory's performance will be evaluated on the basis of its final answer, for example, a laboratory specified in paragraph (a)(3) of this section will be evaluated on the basis of the average of its scores for paragraphs (c)(3) through (c)(6) as determined in paragraph (c)(7) of this section.

(3) Since laboratories may incorrectly report the presence of organisms in addition to the correctly identified principal organism(s), the grading

system must provide a means of deducting credit for additional erroneous organisms that are reported. Therefore, the total number of correct responses for organism isolation and identification submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not considered reportable, the sample grade would be  $1/(1+1) \times 100 = 50$  percent.

(4) For antimicrobial susceptibility testing, a laboratory must indicate which drugs are routinely included in its test panel when testing patient samples. A laboratory's performance will be evaluated for only those antibiotics for which service is offered. A correct response for each antibiotic will be determined as described in §§ 493.911(c) (1) using criteria such as the guidelines established by the National Committee for Clinical Laboratory Standards. Grading is based on the number of correct susceptibility responses reported by the laboratory divided by the actual number of correct susceptibility responses determined by the program, multiplied by 100. For example, if a laboratory offers susceptibility testing for Enterobacteriaceae using amikacin, cephalothin, and tobramycin, and the organism in the proficiency testing sample is an Enterobacteriaceae, and the laboratory reports correct responses for two of three antimicrobial agents, the laboratory's grade would be  $2/3 \times 100 = 67$  percent.

(5) The performance criterion for qualitative antigen tests is the presence or absence of the bacterial antigen. The score for antigen tests is the number of correct responses divided by the number of samples to be tested for the antigen, multiplied by 100.

(6) The performance criteria for Gram stain is staining reaction, i.e., gram positive or gram negative. The score for Gram stain is the number of correct responses divided by the number of samples to be tested, multiplied by 100.

(7) The score for a testing event in bacteriology is the average of the scores determined under paragraphs (c)(3) through (c)(6) of this section based on the type of service offered by the laboratory.

§ 493.913 Mycobacteriology.

(a) *Types of services offered by laboratories.* In mycobacteriology, there

are five types of laboratories for proficiency testing purposes:

(1) Those that interpret acid-fast stains and refer specimen to another laboratory appropriately certified in the subspecialty of mycobacteriology;

(2) Those that interpret acid-fast stains, perform primary inoculation, and refer cultures to another laboratory appropriately certified in the subspecialty of mycobacteriology for identification;

(3) Those that interpret acid-fast stains, isolate and perform identification and/or antimycobacterial susceptibility of *Mycobacterium tuberculosis*, but refer other mycobacteria species to another laboratory appropriately certified in the subspecialty of mycobacteriology for identification and/or susceptibility tests;

(4) Those that interpret acid-fast stains, isolate and identify all mycobacteria to the extent required for correct clinical diagnosis, but refer antimycobacterial susceptibility tests to another laboratory appropriately certified in the subspecialty of mycobacteriology; and

(5) Those that interpret acid-fast stains, isolate and identify all mycobacteria to the extent required for correct clinical diagnosis, and perform antimycobacterial susceptibility tests on the organisms isolated.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for mycobacteriology, the annual program must provide a minimum of five samples per testing event. There must be at least two testing events per year. The samples may be provided through mailed shipments or, at HHS' option, provided to HHS or its designee for on-site testing events. For types of laboratories specified in paragraphs (a)(1) and (a) (3) through (5) of this section, an annual program must include samples that contain species that are representative of the 5 major groups (complexes) of mycobacteria encountered in human specimens. The specific mycobacteria included in the samples may vary from year to year.

(1) An approved program must furnish HHS and its agents with a description of samples that it plans to include in its annual program no later than six months before each calendar year. At least 50 percent of the samples must be mixtures of the principal mycobacteria and appropriate normal flora. The program must include mycobacteria commonly occurring in patient specimens and other important emerging mycobacteria (as determined by HHS). The program determines the reportable isolates and

correct responses for antimycobacterial susceptibility for any designated isolate.

(2) An approved program may vary over time. For example, the types of mycobacteria that might be included in an approved program over time are—

TB

*Mycobacterium tuberculosis*

*Mycobacterium bovis*

Group I

*Mycobacterium kansasii*

Group II

*Mycobacterium szulgai*

Group III

*Mycobacterium avium-intracellulare*

*Mycobacterium terrae*

Group IV

*Mycobacterium fortuitum*

(3) For antimycobacterial susceptibility testing, the program must provide at least one sample per testing event that includes mycobacterium tuberculosis that has a predetermined pattern of sensitivity or resistance to the common antimycobacterial agents.

(4) For laboratories specified in paragraphs (a)(1) and (a)(2), the program must provide at least five samples per testing event that includes challenges that are acid-fast and challenges which do not contain acid-fast organisms.

(c) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (c) (1) through (6) of this section.

(1) The program determines the reportable mycobacteria to be detected by acid-fast stain and for isolation and identification. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response for each sample with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories.

(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must interpret acid-fast stains and isolate and identify the organisms to the same extent it performs these procedures on patient specimens. A laboratory's performance will be evaluated on the basis of the average of its scores as determined in paragraph (c)(6) of this section.

(3) Since laboratories may incorrectly report the presence of organisms in addition to the correctly identified principal organism(s), the grading system must provide a means of deducting credit for additional erroneous organisms reported. Therefore, the total number of correct

responses submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not present, the sample grade would be  $1/(1+1) \times 100 = 50$  percent

(4) For antimycobacterial susceptibility testing, a laboratory must indicate which drugs are routinely included in its test panel when testing patient samples. A laboratory's performance will be evaluated for only those antibiotics for which susceptibility testing is routinely performed on patient specimens. A correct response for each antibiotic will be determined as described in § 493.913(c)(1). Grading is based on the number of correct susceptibility responses reported by the laboratory divided by the actual number of correct susceptibility responses as determined by the program, multiplied by 100. For example, if a laboratory offers susceptibility testing using three antimycobacterial agents and the laboratory reports correct response for two of the three antimycobacterial agents, the laboratory's grade would be  $2/3 \times 100 = 67$  percent.

(5) The performance criterion for qualitative tests is the presence or absence of acid-fast organisms. The score for acid-fast organism detection is the number of correct responses divided by the number of samples to be tested, multiplied by 100.

(6) The score for a testing event in mycobacteriology is the average of the scores determined under paragraphs (c)(3) through (c)(5) of this section based on the type of service offered by the laboratory.

#### § 493.915 Mycology.

(a) *Types of services offered by laboratories.* In mycology, there are four types of laboratories for proficiency testing purposes that may perform different levels of service for yeasts, dimorphic fungi, dermatophytes, and aerobic actinomycetes:

(1) Those that isolate and identify only yeasts and/or dermatophytes to the genus level;

(2) Those that isolate and identify yeasts and/or dermatophytes to the species level;

(3) Those that isolate and perform identification of all organisms to the genus level; and

(4) Those that isolate and perform identification of all organisms to the species level.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for mycology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing. An annual program must include samples that contain organisms that are representative of five major groups of fungi: Yeast or yeast-like fungi; dimorphic fungi; dematiaceous fungi; dermatophytes; and saprophytes, including opportunistic fungi. The specific fungi included in the samples may vary from year to year.

(1) An approved program must, before each calendar year, furnish HHS with a description of samples that it plans to include in its annual program no later than six months before each calendar year. At least 50 percent of the samples must be mixtures of the principal organism and appropriate normal background flora. Other important emerging pathogens (as determined by HHS) and organisms commonly occurring in patient specimens must be included periodically in the program.

(2) An approved program may vary over time. As an example, the types of organisms that might be included in an approved program over time are—

*Candida albicans*  
*Candida* (other species)  
*Cryptococcus neoformans*  
*Sporothrix schenckii*  
*Exophiala jeikei*  
*Fonsecaea pedrosoi*  
*Microsporium* sp.  
*Acremonium* sp.  
*Trichophyton* sp.  
*Aspergillus fumigatus*  
*Nocardia* sp.  
*Blastomyces dermatitidis* \*  
*Zygomycetes* sp.

Note: \* Provided as a nonviable sample.

(c) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's response, in accordance with paragraphs (c)(1) through (5) of this section.

(1) The program determines the reportable organisms. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response for each sample with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories.

(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must isolate and identify the organisms to the same extent it performs these procedures on patient specimens.

(3) Since laboratories may incorrectly report the presence of organisms in addition to the correctly identified principal organism(s), the grading system must deduct credit for additional erroneous organisms reported. Therefore, the total number of correct responses submitted by the laboratory divided by the number of organisms present plus the number of incorrect organisms reported by the laboratory must be multiplied by 100 to establish a score for each sample in each shipment or testing event. For example, if a sample contained one principal organism and the laboratory reported it correctly but reported the presence of an additional organism, which was not present, the sample grade would be  $1/(1+1) \times 100 = 50$  percent.

(4) The score for the antigen tests is the number of correct responses divided by the number of samples to be tested for the antigen, multiplied by 100.

(5) The score for a testing event is the average of the sample scores as determined under paragraph (c)(3) or (c)(4) of this section.

#### § 493.917 Parasitology.

(a) *Types of services offered by laboratories.* In parasitology there are two types of laboratories for proficiency testing purposes—

(1) Those that determine the presence or absence of parasites by direct observation (wet mount) and/or pinworm preparations and, if necessary, refer specimens to another laboratory appropriately certified in the subspecialty of parasitology for identification;

(2) Those that identify parasites using concentration preparations and/or permanent stains.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing in parasitology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided through mailed shipments or, at HHS's option, may be provided to HHS or its designee for on-site testing. An annual program must include samples that contain parasites that are commonly encountered in the United States as well as those recently introduced into the United States. Other important emerging

pathogens (as determined by HHS) and parasites commonly occurring in patient specimens must be included periodically in the program.

(1) An approved program must, before each calendar year furnish HHS with a description of samples that it plans to include in its annual program no later than six months before each calendar year. Samples must include both formalinized specimens and PVA (polyvinyl alcohol) fixed specimens as well as blood smears, as appropriate for a particular parasite and stage of the parasite. The majority of samples must contain protozoa or helminths or a combination of parasites. Some samples must be devoid of parasites.

(2) An approved program may vary over time. As an example, the types of parasites that might be included in an approved program over time are—

*Enterobius vermicularis*  
*Entamoeba histolytica*  
*Entamoeba coli*  
*Giardia lamblia*  
*Endolimax nana*  
*Dientamoeba fragilis*  
*Iodamoeba butschli*  
*Chilomastix mesnili*  
Hookworm  
*Ascaris lumbricoides*  
*Strongyloides stercoralis*  
*Trichuris trichiura*  
*Diphyllobothrium latum*  
*Cryptosporidium* sp.  
*Plasmodium falciparum*

(3) For laboratories specified in paragraph (a)(1) of this section, the program must provide at least five samples per testing event that include challenges which contain parasites and challenges that are devoid of parasites.

(c) *Evaluation of a laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c)(1) through (6) of this section.

(1) The program must determine the reportable parasites. It may elect to establish a minimum number of parasites to be identified in samples before they are reported. Parasites found in rare numbers by referee laboratories are not considered in scoring a laboratory's performance; such findings are neutral. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories.

(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with

paragraph (a) of this section. A laboratory must determine the presence or absence of a parasite(s) or concentrate and identify the parasites to the same extent it performs these procedures on patient specimens.

(3) Since laboratories may incorrectly report the presence of parasites in addition to the correctly identified principal parasite(s), the grading system must deduct credit for these additional erroneous parasites reported and not found in rare numbers by the program's referencing process. Therefore, the total number of correct responses submitted by the laboratory divided by the number of parasites present plus the number of incorrect parasites reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal parasite and the laboratory reported it correctly but reported the presence of an additional parasite, which was not present, the sample grade would be  $1/(1+1) \times 100 = 50$  percent.

(4) The criterion for acceptable performance for qualitative parasitology examinations is presence or absence of a parasite(s).

(5) The score for parasitology is the number of correct responses divided by the number of samples to be tested, multiplied by 100.

(6) The score for a testing event is the average of the sample scores as determined under paragraphs (c)(3) through (c)(5) of this section.

#### § 493.919 Virology.

(a) *Types of services offered by laboratories.* In virology, there are two types of laboratories for proficiency testing purposes—

(1) Those that only perform tests that directly detect viral antigens or structures, either in cells derived from infected tissues or free in fluid specimens; and

(2) Those that are able to isolate and identify viruses and use direct antigen techniques.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing in virology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided to the laboratory through mailed shipments or, at HHS's option, may be provided to HHS or its designee for on-site testing. An annual program must include viral species that are the more commonly identified viruses. The specific organisms found in the samples may vary from year to year. The annual

program must include samples for viral antigen detection and viral isolation and identification.

(1) An approved program must furnish HHS with a description of samples that it plans to include in its annual program no later than six months before each calendar year. The program must include other important emerging viruses (as determined by HHS) and viruses commonly occurring in patient specimens.

(2) An approved program may vary over time. For example, the types of viruses that might be included in an approved program over time are the more commonly identified viruses such as Herpes simplex, respiratory syncytial virus, adenoviruses, enteroviruses, and cytomegaloviruses.

(c) *Evaluation of laboratory's performance.* HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (c) (1) through (5) of this section.

(1) The program determines the reportable viruses to be detected by direct antigen techniques or isolated by laboratories that perform viral isolation procedures. To determine the accuracy of a laboratory's response, the program must compare the laboratory's response for each sample with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories.

(2) To evaluate a laboratory's response for a particular sample, the program must determine a laboratory's type of service in accordance with paragraph (a) of this section. A laboratory must isolate and identify the viruses to the same extent it performs these procedures on patient specimens.

(3) Since laboratories may incorrectly report the presence of viruses in addition to the correctly identified principal virus, the grading system must provide a means of deducting credit for additional erroneous viruses reported. Therefore, the total number of correct responses determined by virus culture techniques submitted by the laboratory divided by the number of viruses present plus the number of incorrect viruses reported by the laboratory must be multiplied by 100 to establish a score for each sample in each testing event. For example, if a sample contained one principal virus and the laboratory reported it correctly but reported the presence of an additional virus, which was not present, the sample grade would be  $1/(1+1) \times 100 = 50$  percent.

(4) The performance criterion for qualitative antigen tests is presence or absence of the viral antigen. The score

for the antigen tests is the number of correct responses divided by the number of samples to be tested for the antigen, multiplied by 100.

(5) The score for a testing event is the average of the sample scores as determined under paragraph (c)(3) and (c)(4) of this section.

#### § 493.921 Diagnostic immunology.

The subspecialties under the specialty of immunology for which a program may offer proficiency testing are syphilis serology and general immunology. Specific criteria for these subspecialties are found at §§ 493.923 and 493.927.

#### § 493.923 Syphilis serology.

(a) *Program content and frequency of challenge.* To be approved for proficiency testing in syphilis serology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing. An annual program must include samples that cover the full range of reactivity from highly reactive to non-reactive.

(b) *Evaluation of test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (b) (1) through (4) of this section.

(1) To determine the accuracy of a laboratory's response for qualitative and quantitative syphilis tests, the program must compare the laboratory's response with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories. The proficiency testing program must indicate the minimum concentration, by method, that will be considered as indicating a positive response. The score for a sample in syphilis serology is the average of scores determined under paragraphs (b)(2) and (b)(3) of this section.

(2) For quantitative syphilis tests, the program must determine the correct response for each method by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria or the number of standard deviations the response differs from the target value. The criterion for acceptable performance for quantitative syphilis serology tests is the target value  $\pm$  1 dilution.

(3) The criterion for acceptable performance for qualitative syphilis serology tests is reactive or nonreactive.

(4) To determine the overall testing event score, the number of correct responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

**§ 493.927 General Immunology.**

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for immunology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of reactivity from highly reactive to nonreactive. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(b) *Challenges per testing event.* The minimum number of challenges per testing event the program must provide for each analyte or test procedure is five. Analytes or tests for which laboratory performance is to be evaluated include:

*Analyte or Test Procedure*

- Alpha-1 antitrypsin
- Alpha-fetoprotein (tumor marker)
- Antinuclear antibody
- Antistreptolysin O, quantitative
- Anti-human immunodeficiency virus (HIV)
- Complement C3
- Complement C4
- Hepatitis markers (HBsAg, anti-HBc, HBeAg)
- IgA
- IgG
- IgE
- IgM
- Infectious mononucleosis
- Rheumatoid factor
- Rubella

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c) (1) through (5) of this section.

(1) To determine the accuracy of a laboratory's response for quantitative and qualitative immunology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories. The proficiency testing program must indicate the minimum concentration that will be considered as indicating a positive response. The score for a sample in general immunology is either the score determined under paragraph (c) (2) or (3) of this section.

(2) For quantitative immunology analytes or tests, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria or the number of standard deviations (SDs) the response differs from the target value.

*Criteria for Acceptable Performance*

The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
Alpha-1 antitrypsin.....	Target value ±3 SD.
Alpha-fetoprotein (tumor marker)	Target value ±3 SD.
Antinuclear antibody.....	Target value +/ - 2 dilutions or positive or negative.
Antistreptolysin O.....	Target value +/ - 2 dilution or positive or negative.
Anti-Human Immunodeficiency virus.	Reactive or nonreactive.
Complement C3.....	Target value ±3 SD.
Complement C4.....	Target value ±3 SD.
Hepatitis (HBsAg, anti-HBc, HBeAg).	Reactive (positive) or nonreactive (negative).
IgA.....	Target value ±3 SD.
IgE.....	Target value ±3 SD.
IgG.....	Target value +/ - 25%.
IgM.....	Target value ±3 SD.
Infectious mononucleosis.	Target value +/ - 2 dilutions or positive or negative.
Rheumatoid factor.....	Target value +/ - 2 dilutions or positive or negative.
Rubella.....	Target value +/ - 2 dilutions or immune or nonimmune or positive or negative.

(3) The criterion for acceptable performance for qualitative general immunology tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable

analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

**§ 493.929 Chemistry.**

The subspecialties under the specialty of chemistry for which a proficiency testing program may offer proficiency testing are routine chemistry, endocrinology, and toxicology. Specific criteria for these subspecialties are listed in §§ 493.931 through 493.939.

**§ 493.931 Routine chemistry.**

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for routine chemistry, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the clinically relevant range of values that would be expected in patient specimens. The specimens may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(b) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure listed below is five serum, plasma or blood samples.

*Analyte or Test Procedure*

- Alanine aminotransferase (ALT/SGPT)
- Albumin
- Alkaline phosphatase
- Amylase
- Aspartate aminotransferase (AST/SGOT)
- Bilirubin, total
- Blood gas (pH, pO2, and pCO2)
- Calcium, total
- Chloride
- Cholesterol, total
- Cholesterol, high density lipoprotein
- Creatine kinase

Creatine kinase, isoenzymes  
 Creatinine  
 Glucose (Excluding measurements on devices cleared by FDA for home use)  
 Iron, total  
 Lactate dehydrogenase (LDH)  
 LDH isoenzymes  
 Magnesium  
 Potassium  
 Sodium  
 Total Protein  
 Triglycerides  
 Urea Nitrogen  
 Uric Acid

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c)(1) through (5) of this section.

(1) To determine the accuracy of a laboratory's response for qualitative and quantitative chemistry tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories. The score for a sample in routine chemistry is either the score determined under paragraph (c)(2) or (3) of this section.

(2) For quantitative chemistry tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria based on the percentage difference from the target value or the number of standard deviations (SDs) the response differs from the target value.

*Criteria for Acceptable Performance*

The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
Alanine aminotransferase (ALT/SGPT)	Target value ± 20%.
Albumin	Target value ± 10%.
Alkaline phosphatase	Target value ± 30%.
Amylase	Target value ± 30%.
Aspartate aminotransferase (AST/SGOT)	Target value ± 20%.
Bilirubin, total	Target value ± 0.4 mg/dL or ± 20% (greater).
Blood gas pO <sub>2</sub>	Target value ± 3 SD.
pCO <sub>2</sub>	Target value ± 5 mm Hg or +/− 8% (greater).
pH	Target value ± 0.04.
Calcium, total	Target value ± 1.0 mg/dL.

Analyte or test	Criteria for acceptable performance
Chloride	Target value ± 5%.
Cholesterol, total	Target value ± 10%.
Cholesterol, high density lipoprotein	Target value ± 30%.
Creatine kinase	Target value ± 30%.
Creatine kinase isoenzymes	MB elevated (presence or absence) or Target value ± 3SD.
Creatinine	Target value ± 0.3 mg/dL or ± 15% (greater).
Glucose (excluding glucose performed on monitoring devices cleared by FDA for home use)	Target value ± 6 mg/dL or ± 10% (greater).
Iron, total	Target value ± 20%.
Lactate dehydrogenase (LDH)	Target value ± 20%.
LDH isoenzymes	LDH1/LDH2 (+ or −) or Target value ± 30%.
Magnesium	Target value ± 25%.
Potassium	Target value ± 0.5 mmol/L.
Sodium	Target value ± 4 mmol/L.
Total Protein	Target value ± 10%.
Triglycerides	Target value ± 25%.
Urea nitrogen	Target value ± 2 mg/dL or ± 9% (greater).
Uric acid	Target value ± 17%.

(3) The criterion for acceptable performance for qualitative routine chemistry tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

**§ 493.933 Endocrinology.**

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for endocrinology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the clinically

relevant range of values that would be expected in patient specimens. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(b) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five serum, plasma, blood, or urine samples.

*Analyte or Test*

Cortisol  
 Free Thyroxine  
 Human Chorionic Gonadotropin  
 T3 Uptake  
 Triiodothyronine  
 Thyroid-stimulating hormone  
 Thyroxine

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c) (1) through (5) of this section.

(1) To determine the accuracy of a laboratory's response for qualitative and quantitative endocrinology tests or analytes, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories. The score for a sample in endocrinology is either the score determined under paragraph (c)(2) or (c)(3) of this section.

(2) For quantitative endocrinology tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using either fixed criteria based on the percentage difference from the target value or the number of standard deviations (SDs) the response differs from the target value.

*Criteria for Acceptable Performance*

The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
Cortisol	Target value ± 25%.
Free Thyroxine	Target value ± 3 SD.
Human Chorionic Gonadotropin	Target value ± 3 SD positive or negative.
T3 Uptake	Target value ± 3 SD.
Triiodothyronine	Target value ± 3 SD.
Thyroid-stimulating hormone	Target value ± 3 SD.
Thyroxine	Target value ± 20% or 1.0 mcg/dL (greater).

**§ 493.937 Toxicology.**

(3) The criterion for acceptable performance for qualitative endocrinology tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for toxicology, the annual program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the clinically relevant range of values that would be expected in specimens of patients on drug therapy and that cover the level of clinical significance for the particular drug. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(b) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five serum, plasma, or blood samples.

*Analyte or Test Procedure*

Alcohol (blood)	Phenytion
Blood lead	Primidone
Carbamazepine	Procainamide
Digoxin	(and metabolite)
Ethosuximide	Quinidine
Gentamicin	Theophylline
Lithium	Tobramycin
Phenobarbital	Valproic Acid

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that

assess the accuracy of a laboratory's responses in accordance with paragraphs (c)(1) through (4) of this section.

(1) To determine the accuracy of a laboratory's responses for quantitative toxicology tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories. The score for a sample in toxicology is the score determined under paragraph (c)(2) of this section.

(2) For quantitative chemistry tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response must be determined by using fixed criteria based on the percentage difference from the target value

*Criteria for Acceptable Performance*

The criteria for acceptable performance are:

Analyte or test	Criteria for acceptable performance
Alcohol, blood.....	Target Value ± 25%.
Blood lead.....	Target Value ± 10% or 4 mcg/dL (greater).
Carbamazepine.....	Target Value ± 25%.
Digoxin.....	Target Value ± 20% or ± 0.2 ng/mL (greater).
Ethosuximide.....	Target Value ± 20%.
Gentamicin.....	Target Value ± 25%.
Lithium.....	Target Value ± 0.3 mmol/L or ± 20% (greater).
Phenobarbital.....	Target Value ± 20%
Phenytoin.....	Target Value ± 25%.
Primidone.....	Target Value ± 25%.
Procainamide (and metabolite).	Target Value ± 25%.
Quinidine.....	Target Value ± 25%.
Tobramycin.....	Target Value ± 25%.
Theophylline.....	Target Value ± 25%.
Valproic Acid.....	Target Value ± 25%.

(3) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 = \text{Analyte score for the testing event}$$

(4) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

**§ 493.941 Hematology (including routine hematology and coagulation).**

(a) *Program content and frequency of challenge.* To be approved for proficiency testing for hematology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of values that would be expected in patient specimens. The samples may be provided through mailed shipments or, at HHS' option, may be provided to HHS and or its designee for on-site testing.

(b) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five.

*Analyte or Test Procedure*

- Cell identification or white blood cell differential
- Erythrocyte count
- Hematocrit (excluding spun microhematocrit)
- Hemoglobin
- Leukocyte count
- Platelet count
- Fibrinogen
- Partial thromboplastin time
- Prothrombin time

(1) An approved program for cell identification may vary over time. The types of cells that might be included in an approved program over time are—

- Neutrophilic granulocytes
- Eosinophilic granulocytes
- Basophilic granulocytes
- Lymphocytes
- Monocytes
- Major red and white blood cell abnormalities
- Immature red and white blood cells

(2) White blood cell differentials should be limited to the percentage distribution of cellular elements listed above.

(c) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's responses in accordance with paragraphs (c) (1) through (5) of this section.

(1) To determine the accuracy of a laboratory's responses for qualitative and quantitative hematology tests or analytes, the program must compare the laboratory's response for each analyte

with the response that reflects agreement of either 90 percent of ten or more referee laboratories or 90 percent or more of all participating laboratories. The score for a sample in hematology is either the score determined under paragraph (c) (2) or (3) of this section.

(2) For quantitative hematology tests or analytes, the program must determine the correct response for each analyte by the distance of the response from the target value. After the target value has been established for each response, the appropriateness of the response is determined using either fixed criteria based on the percentage difference from the target value or the number of standard deviations (SDs) the response differs from the target value.

#### Criteria for Acceptable Performance

The criteria for acceptable performance are:

Analyte or test	Criteria for acceptable performance
Cell identification.....	90% or greater consensus on identification.
White blood cell differential.	Target +/- 3SD based on the percentage of different types of white blood cells in the samples.
Erythrocyte count.....	Target +/- 6%.
Hematocrit (Excluding spun hematocrits).	Target +/- 6%.
Hemoglobin.....	Target +/- 7%.
Leukocyte count.....	Target +/- 15%.
Platelet count.....	Target +/- 25%.
Fibrinogen.....	Target +/- 20%.
Partial thromboplastin time.	Target +/- 15%.
Prothrombin time.....	Target +/- 15%.

(3) The criterion for acceptable performance for the qualitative hematology test is correct cell identification.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

#### § 493.945 Cytology; gynecologic examinations.

(a) *Program content and frequency of challenge.* (1) To be approved for proficiency testing for gynecologic examinations (Pap smears) in cytology, a program must provide test sets composed of 10- and 20-glass slides. Proficiency testing programs may obtain slides for test sets from cytology laboratories, provided the slides have been retained by the laboratory for the required period specified in § 493.1257. If slide preparations are still subject to retention by the laboratory, they may be loaned to a proficiency testing program if the program provides the laboratory with documentation of the loan of the slides and ensures that slides loaned to it are retrievable upon request. Each test set must include at least one slide representing each of the response categories described in paragraph (b)(3)(ii)(A) of this section, and test sets should be comparable so that equitable testing is achieved within and between proficiency testing providers.

(2) To be approved for proficiency testing in gynecologic cytology, a program must provide announced and unannounced on-site testing for each individual at least once per year and must provide an initial retesting event for each individual within 45 days after notification of test failure and subsequent retesting events within 45 days after completion of remedial action described in § 493.855.

(b) *Evaluation of an individual's performance.* HHS approves only those programs that assess the accuracy of each individual's responses on both 10- and 20-slide test sets in which the slides have been referenced as specified in paragraph (b)(1) of this section.

(1) To determine the accuracy of an individual's response on a particular challenge (slide), the program must compare the individual's response for each slide preparation with the response that reflects the predetermined consensus agreement or confirmation on the diagnostic category, as described in the table in paragraph (b)(3)(ii)(A) of this section. For all slide preparations, a 100% consensus agreement among a minimum of three physicians certified in anatomic pathology is required. In addition, for premalignant and malignant slide preparations, confirmation by tissue biopsy is

required either by comparison of the reported biopsy results or reevaluation of biopsy slide material by a physician certified in anatomic pathology.

(2) An individual qualified as a technical supervisor under § 493.1449 (b) or (k) who routinely interprets gynecologic slide preparations only after they have been examined by a cytotechnologist can either be tested using a test set that has been screened by a cytotechnologist in the same laboratory or using a test set that has not been screened. A technical supervisor who screens and interprets slide preparations that have not been previously examined must be tested using a test set that has not been previously screened.

(3) The criteria for acceptable performance are determined by using the scoring system in paragraphs (b)(3)(i) and (ii) of this section.

(i) Each slide set must contain 10 or 20 slides with point values established for each slide preparation based on the significance of the relationship of the interpretation of the slide to a clinical condition and whether the participant in the testing event is a cytotechnologist qualified under §§ 493.1469 or 493.1483 or functioning as a technical supervisor in cytology qualified under § 493.1449 (b) or (k) of this part.

(ii) The scoring system rewards or penalizes the participants in proportion to the distance of their answers from the correct response or target diagnosis and the penalty or reward is weighted in proportion to the severity of the lesion.

(A) The four response categories for reporting proficiency testing results and their descriptions are as follows:

Category	Description
A.....	Unsatisfactory for diagnosis due to: (1) Scant cellularity. (2) Air drying. (3) Obscuring material (blood, inflammatory cells, or lubricant).
B.....	Normal or Benign Changes—includes: (1) Normal, negative or within normal limits. (2) Infection other than Human Papillomavirus (HPV) (e.g., <i>Trichomonas vaginalis</i> , changes or morphology consistent with <i>Candida</i> spp., <i>Actinomyces</i> spp. or <i>Herpes simplex virus</i> ). (3) Reactive and reparative changes (e.g., inflammation, effects of chemotherapy or radiation).
C.....	Low Grade Squamous Intraepithelial Lesion—includes: (1) Cellular changes associated with HPV.

Category	Description
D.....	(2) Mild dysplasia/CIN-1. High Grade Lesion and Carcinoma—includes: (1) High grade squamous intraepithelial lesions which include moderate dysplasia/CIN-2 and severe dysplasia/carcinoma in situ/CIN-3. (2) Squamous cell carcinoma. (3) Adenocarcinoma and other malignant neoplasms.

(B) In accordance with the criteria for the scoring system, the charts in paragraphs (b)(3)(ii)(C) and (D) of this section, for technical supervisors and cytotechnologists, respectively, provide a maximum of 10 points for a correct response and a maximum of minus five (–5) points for an incorrect response on a 10-slide test set. For example, if the correct response on a slide is "high grade squamous intraepithelial lesion" (category "D" on the scoring system chart) and an examinee calls it "normal or negative" (category "B" on the scoring system chart), then the examinee's point value on that slide is calculated as minus five (–5). Each slide is scored individually in the same manner. The individual's score for the testing event is determined by adding the point value achieved for each slide preparation, dividing by the total points for the testing event and multiplying by 100.

(C) Criteria for scoring system for a 10-slide test set. (See table at (b)(3)(ii)(A) of this section for a description of the response categories.) For technical supervisors qualified under § 493.1449(b) or (k):

Correct response category:	A	B	C	D
Examinee's response:				
A.....	10	0	0	0
B.....	5	10	0	0
C.....	5	0	10	5
D.....	0	–5	5	10

(D) Criteria for scoring system for a 10-slide test set. (See table at paragraph (b)(3)(ii)(A) of this section for a description of the response categories.) For cytotechnologists qualified under §§ 493.1469 or 493.1483:

Correct response category:	A	B	C	D
Examinee's response:				
A.....	10	0	5	5
B.....	5	10	5	5
C.....	5	0	10	10
D.....	0	–5	10	10

(E) In accordance with the criteria for the scoring system, the charts in paragraphs (b)(3)(ii)(F) and (G) of this section, for technical supervisors and cytotechnologists, respectively, provide maximums of 5 points for a correct response and minus ten (–10) points for an incorrect response on a 20-slide test set.

(F) Criteria for scoring system for a 20-slide test set. (See table at paragraph (b)(3)(ii)(A) of this section for a description of the response categories.) For technical supervisors qualified under § 493.1449(b) or (k):

Correct response category:	A	B	C	D
Examinee's response:				
A.....	5	0	0	0
B.....	2.5	5	0	0
C.....	2.5	0	5	2.5
D.....	0	–10	2.5	5

(G) Criteria for scoring system for a 20-slide test set. (See table at (b)(3)(ii)(A) of this section for a description of the response categories.) For cytotechnologists qualified under § 493.1469 or 493.1483:

Correct response category:	A	B	C	D
Examinee's response:				
A.....	5	0	2.5	2.5
B.....	2.5	5	2.5	2.5
C.....	2.5	0	5	5
D.....	0	–10	5	5

§ 493.959 Immunohematology.

(a) *Types of services offered by laboratories.* In immunohematology, there are four types of laboratories for proficiency testing purposes—

- (1) Those that perform ABO group and/or D (Rho) typing;
- (2) Those that perform ABO group and/or D (Rho) typing, and unexpected antibody detection;
- (3) Those that in addition to paragraph (a)(2) of this section perform compatibility testing; and
- (4) Those that perform in addition to paragraph (a)(3) of this section antibody identification.

(b) *Program content and frequency of challenge.* To be approved for proficiency testing for immunohematology, a program must provide a minimum of five samples per testing event. There must be at least three testing events at approximately equal intervals per year. The annual program must provide samples that cover the full range of interpretation that would be expected in patient specimens. The samples may be provided through

mailed shipments or, at HHS' option, may be provided to HHS or its designee for on-site testing.

(c) *Challenges per testing event.* The minimum number of challenges per testing event a program must provide for each analyte or test procedure is five.

*Analyte or Test Procedure*

- ABO group (excluding subgroups)
- D (Rho) typing
- Unexpected antibody detection
- Compatibility testing
- Antibody identification

(d) *Evaluation of a laboratory's analyte or test performance.* HHS approves only those programs that assess the accuracy of a laboratory's response in accordance with paragraphs (d)(1) through (5) of this section.

(1) To determine the accuracy of a laboratory's response, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 100 percent of ten or more referee laboratories or 95 percent or more of all participating laboratories except for unexpected antibody detection and antibody identification. To determine the accuracy of a laboratory's response for unexpected antibody detection and antibody identification, a program must compare the laboratory's response for each analyte with the response that reflects agreement of either 95 percent of ten or more referee laboratories or 95 percent or more of all participating laboratories. The score for a sample in immunohematology is either the score determined under paragraph (d)(2) or (3) of this section.

(2) *Criteria for acceptable performance.* The criteria for acceptable performance are—

Analyte or test	Criteria for acceptable performance
ABO group.....	100% accuracy.
D (Rho) typing.....	100% accuracy.
Unexpected antibody detection.....	80% accuracy.
Compatibility testing.....	100% accuracy.
Antibody identification.....	80% accuracy.

(3) The criterion for acceptable performance for qualitative immunohematology tests is positive or negative.

(4) To determine the analyte testing event score, the number of acceptable analyte responses must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for the analyte}}{\text{Total number of challenges for the analyte}} \times 100 = \text{Analyte score for the testing event}$$

(5) To determine the overall testing event score, the number of correct responses for all analytes must be averaged using the following formula:

$$\frac{\text{Number of acceptable responses for all challenges}}{\text{Total number of all challenges}} \times 100 = \text{Testing event score}$$

#### Subpart J—Patient Test Management for Moderate or High Complexity Testing, or Both

##### § 493.1101 Condition: Patient test management; moderate or high complexity testing, or both.

Each laboratory performing moderate or high complexity testing, or both, must employ and maintain a system that provides for proper patient preparation; proper specimen collection, identification, preservation, transportation, and processing; and accurate result reporting. This system must assure optimum patient specimen integrity and positive identification throughout the preanalytic (pre-testing), analytic (testing), and postanalytic (post-testing) processes and must meet the standards of this subpart as they apply to the testing performed.

##### § 493.1103 Standard; Procedures for specimen submission and handling.

(a) The laboratory must have available and follow written policies and procedures for each of the following, if applicable: Methods used for the preparation of patients; specimen collection; specimen labeling; specimen preservation; and conditions for specimen transportation. Such policies and procedures must assure positive identification and optimum integrity of the patient specimens from the time the specimen(s) are collected until testing has been completed and the results reported.

(b) If the laboratory accepts referral specimens, written instructions must be available to clients and must include, as appropriate, the information specified in paragraph (a) of this section.

(c) Oral explanation of instructions to patients for specimen collection, including patient preparation, may be used as a supplement to written instructions where applicable.

##### § 493.1105 Standard; Test requisition.

The laboratory must perform tests only at the written or electronic request

of an authorized person. Oral requests for laboratory tests are permitted only if the laboratory subsequently obtains written authorization for testing within 30 days. Records of test requisitions or test authorizations must be retained for a minimum of two years. The patient's chart or medical record, if used as the test requisition, must be retained for a minimum of two years and must be available to the laboratory at the time of testing and available to HHS upon request. The laboratory must assure that the requisition or test authorization includes—

(a) The patient's name or other unique identifier;

(b) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for utilizing the test results or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminent life threatening laboratory results or panic values;

(c) The test(s) to be performed;

(d) The date of specimen collection;

(e) For Pap smears, the patient's last menstrual period, age or date of birth, and indication of whether the patient had a previous abnormal report, treatment or biopsy; and

(f) Any additional information relevant and necessary to a specific test to assure accurate and timely testing and reporting of results.

##### § 493.1107 Standard; Test records.

The laboratory must maintain a record system to ensure reliable identification of patient specimens as they are processed and tested to assure that accurate test results are reported. These records must identify the personnel performing the testing procedure. Records of patient testing, including, if applicable, instrument printouts, must be retained for at least two years. Immunohematology records must be retained for no less than five years in accordance with 21 CFR part 606, subpart I. The record system must provide documentation of information specified in § 493.1105 (a) through (f) and include—

(a) The patient identification number, accession number, or other unique identification of the specimen;

(b) The date and time of specimen receipt into the laboratory;

(c) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability; and

(d) The records and dates of all specimen testing, including the identity of the personnel who performed the

test(s), which are necessary to assure proper identification and accurate reporting of patient test results.

##### § 493.1109 Standard; Test report.

The laboratory report must be sent promptly to the authorized person, the individual responsible for using the test results or laboratory that initially requested the test. The original report or an exact duplicate of each test report, including final and preliminary reports, must be retained by the testing laboratory for a period of at least two years after the date of reporting. Immunohematology reports must be retained by the laboratory for a period of no less than five years in accordance with 21 CFR part 606, subpart I. For pathology, test reports must be retained for a period of at least ten years after the date of reporting. This information may be maintained as part of the patient's chart or medical record which must be readily available to the laboratory and to HHS upon request.

(a) The laboratory must have adequate systems in place to report results in a timely, accurate, reliable and confidential manner, and, ensure patient confidentiality throughout those parts of the total testing process that are under the laboratory's control.

(b) The test report must indicate the name and address of the laboratory location at which the test was performed, the test performed, the test result and, if applicable, the units of measurement.

(c) The laboratory must indicate on the test report any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

(d) Pertinent "reference" or "normal" ranges, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests or the individual responsible for utilizing the test results.

(e) The results or transcripts of laboratory tests or examinations must be released only to authorized persons or the individual responsible for utilizing the test results.

(f) The laboratory must develop and follow written procedures for reporting imminent life-threatening laboratory results or panic values. In addition, the laboratory must immediately alert the individual or entity requesting the test or the individual responsible for utilizing the test results when any test result indicates an imminent life-threatening condition.

(g) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory

and, in accordance with § 493.1213, as applicable, the performance specifications of each method used to test patient specimens. In addition, information that may affect the interpretation of test results, such as test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results.

(h) The original report or exact duplicates of test reports must be maintained by the laboratory in a manner that permits ready identification and timely accessibility.

**§ 493.1111 Standard; Referral of specimens.**

A laboratory must refer specimens for testing only to a laboratory possessing a valid certificate authorizing the performance of testing in the specialty or subspecialty of service for the level of complexity in which the referred test is categorized.

(a) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory.

(b) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test. The referring laboratory must retain or be able to produce an exact duplicate of each testing laboratory's report.

(c) The authorized person who orders a test or procedure must be notified by the referring laboratory of the name and address of each laboratory location at which a test was performed.

**Subpart K—Quality Control for Tests of Moderate or High Complexity, or Both**

**§ 493.1201 Condition: General quality control; Moderate or high complexity testing, or both.**

The laboratory must establish and follow written quality control procedures for monitoring and evaluating the quality of the analytical testing process of each method to assure the accuracy and reliability of patient test results and reports. In addition, the laboratory must meet the applicable standards in §§ 493.1202 through 493.1221 of this subpart, unless an alternative procedure specified in the manufacturer's protocol has been cleared by the Food and Drug Administration (FDA) as meeting the CLIA requirements for general quality control, and the device/test quality control instructions contain the following statement: "Unless this device

is modified by a laboratory, compliance with these quality control instructions satisfies 42 CFR 493.1201 through 493.1221 implementing the Clinical Laboratory Improvement Amendments of 1988," or HCFA approves an equivalent procedure specified in appendix C of the State Operations Manual (HCFA Pub. 7). HCFA Pub. 7 is available from the Technical Information Service, U.S. Department of Commerce, 5825 Port Royal Road, Springfield, VA 22161, telephone number (703) 487-4630.

**§ 493.1202 Standard; Moderate or high complexity testing, or both: Effective from September 1, 1992 to September 1, 1994.**

(a) For each test of high complexity performed, the laboratory must meet all applicable standards of this subpart.

(b) For each test of moderate complexity performed using a method developed in-house or using an instrument, kit or test system cleared by the FDA through the premarket notification (510(k)) or premarket approval (PMA) process for in-vitro diagnostic use but modified by the laboratory, the laboratory must meet all applicable standards of this subpart.

(c) For all other tests of moderate complexity performed using an instrument, kit or test system cleared by the FDA through the premarket notification (510(k)) or premarket approval (PMA) process for in-vitro diagnostic use, the laboratory must—

(1) Follow the manufacturer's instructions for instrument or test system operation and test performance;

(2) Have a procedure manual describing the processes for testing and reporting patient test results;

(3) Perform and document calibration procedures at least once every six months;

(4) Perform and document control procedures using at least two levels of control materials each day of testing;

(5) Perform and document applicable specialty and subspecialty control procedures as specified under § 493.1223; and

(6) Perform and document that remedial action has been taken when problems or errors are identified as specified in § 493.1219.

**§ 493.1203 Standard; Moderate or high complexity testing, or both: Effective beginning September 1, 1994.**

For each moderate or high complexity test performed, the laboratory will be in compliance with this section if it:

(a) Meets all applicable quality control requirements specified in this subpart; or

(b) Follows manufacturer's instructions when using products (instruments, kits, or test systems) cleared by the FDA as meeting the CLIA requirements for general quality control located at §§ 493.1213, 493.1215, 493.1217 and applicable parts of §§ 493.1205, 493.1211 and 493.1218. In addition, the laboratory must comply with requirements within any section of this subpart that are unique to the laboratory facility and cannot be met by manufacturer's instructions.

**§ 493.1204 Standard; Facilities.**

The laboratory must provide the space and environmental conditions necessary for conducting the services offered.

(a) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of testing, including the preanalytic (pre-testing), analytic (testing), and postanalytic (post-testing), as appropriate.

(b) Safety precautions must be established, posted, and observed to ensure protection from physical hazards and biohazardous materials.

**§ 493.1205 Standard; Test methods, equipment, instrumentation, reagents, materials, and supplies.**

The laboratory must utilize test methods, equipment, instrumentation, reagents, materials, and supplies that provide accurate and reliable test results and test reports.

(a) Test methodologies and equipment must be selected and testing performed in a manner that provides test results within the laboratory's stated performance specifications for each test method as determined under § 493.1213.

(b) The laboratory must have appropriate and sufficient equipment and instruments, reagents, materials, and supplies for the type and volume of testing performed and for the maintenance of quality during the preanalytic, analytic, and postanalytic phases of testing.

(c) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, and accurate and reliable test system operation and test result reporting.

(1) These conditions include, if applicable—

(i) Water quality;

(ii) Temperature;

(iii) Humidity; and

(iv) Protection of equipment and instrumentation from fluctuations and interruptions in electrical current that

adversely affect patient test results and test reports.

(2) Remedial actions taken to correct conditions that fail to meet the criteria specified in paragraph (c)(1) of this section must be documented.

(d) Reagents, solutions, culture media, control materials, calibration materials and other supplies, as appropriate, must be labeled to indicate—

(1) Identity and, when significant, titer, strength or concentration;

(2) Recommended storage requirements;

(3) Preparation and expiration date; and

(4) Other pertinent information required for proper use.

(e) Reagents, solutions, culture media, control materials, calibration materials and other supplies must be prepared, stored, and handled in a manner to ensure that—

(1) Reagents, solutions, culture media, controls, calibration materials and other supplies are not used when they have exceeded their expiration date, have deteriorated or are of substandard quality. The laboratory must comply with the FDA product dating requirements of 21 CFR 610.53 for blood products and other biologicals, and labeling requirements, as cited in 21 CFR 809.10 for all other in vitro diagnostics. Any exception to the product dating requirements in 21 CFR 610.53 will be granted by the FDA in the form of an amendment of the product license, in accordance with 21 CFR 610.53(d). All exceptions must be documented by the laboratory; and

(2) Components of reagent kits of different lot numbers are not interchanged unless otherwise specified by the manufacturer.

**§ 493.1211 Standard; Procedure manual.**

(a) A written procedure manual for the performance of all analytical methods used by the laboratory must be readily available and followed by laboratory personnel. Textbooks may be used as supplements to these written descriptions but may not be used in lieu of the laboratory's written procedures for testing or examining specimens.

(b) The procedure manual must include, when applicable to the test procedure:

(1) Requirements for specimen collection and processing, and criteria for specimen rejection;

(2) Procedures for microscopic examinations, including the detection of inadequately prepared slides;

(3) Step-by-step performance of the procedure, including test calculations and interpretation of results;

(4) Preparation of slides, solutions, calibrators, controls, reagents, stains and other materials used in testing;

(5) Calibration and calibration verification procedures;

(6) The reportable range for patient test results as established or verified in § 493.1213;

(7) Control procedures;

(8) Remedial action to be taken when calibration or control results fail to meet the laboratory's criteria for acceptability;

(9) Limitations in methodologies, including interfering substances;

(10) Reference range (normal values);

(11) Imminent life-threatening laboratory results or "panic values";

(12) Pertinent literature references;

(13) Appropriate criteria for specimen storage and preservation to ensure specimen integrity until testing is completed;

(14) The laboratory's system for reporting patient results including, when appropriate, the protocol for reporting panic values;

(15) Description of the course of action to be taken in the event that a test system becomes inoperable; and

(16) Criteria for the referral of specimens including procedures for specimen submission and handling as described in § 493.1103.

(c) Manufacturers' package inserts or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(13) of this section. Any of the items under paragraphs (b)(1) through (b)(13) of this section not provided by the manufacturer must be provided by the laboratory.

(d) Procedures must be approved, signed, and dated by the director.

(e) Procedures must be re-approved, signed and dated if the directorship of the laboratory changes.

(f) Each change in a procedure must be approved, signed, and dated by the current director of the laboratory.

(g) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance. These records must be retained for two years after a procedure has been discontinued.

**§ 493.1213 Standard; Establishment and verification of method performance specifications.**

Prior to reporting patient test results, the laboratory must verify or establish, for each method, the performance specifications for the following performance characteristics: accuracy; precision; analytical sensitivity and specificity, if applicable; the reportable range of patient test results; the reference range(s) (normal values); and

any other applicable performance characteristic.

(a) The provisions of this section are not retroactive. Laboratories are not required to verify or establish performance specifications for any test method of moderate or high complexity in use prior to September 1, 1992.

(b) (1) After September 1, 1992, a laboratory that introduces a new procedure for patient testing using a moderate or high complexity method (instrument, kit, or test system) cleared by the FDA as meeting the CLIA requirements for general quality control, must demonstrate that, prior to reporting patient test results, it can obtain the performance specifications for accuracy, precision, and reportable range of patient test results, comparable to those established by the manufacturer. The laboratory must also verify that the manufacturer's reference range is appropriate for the laboratory's patient population.

(2) After September 1, 1992, a laboratory that introduces a new procedure for patient testing using: a method developed in-house; a modification of the manufacturer's test procedure; or a method (instrument, kit, or test system) that has not been cleared by the FDA as meeting the CLIA requirements for general quality control, must, prior to reporting patient test results—

(i) Verify or establish for each method the performance specifications for the following performance characteristics, as applicable:

(A) Accuracy;

(B) Precision;

(C) Analytical sensitivity;

(D) Analytical specificity to include interfering substances;

(E) Reportable range of patient test results;

(F) Reference range(s); and

(G) Any other performance characteristic required for test performance.

(ii) Based upon the performance specifications verified or established in accordance with paragraph (b)(2)(i) of this section, establish calibration and control procedures for patient testing as required under §§ 493.1217 and 493.1218.

(c) The laboratory must have documentation of the verification or establishment of all applicable test performance specifications.

**§ 493.1215 Standard; Equipment maintenance and function checks.**

The laboratory must perform equipment maintenance and function checks that include electronic, mechanical and operational checks

necessary for the proper test performance and test result reporting of equipment, instruments and test systems, to assure accurate and reliable test results and reports.

(a) *Maintenance of equipment, instruments, and test systems.* (1) For manufacturers' equipment, instruments or test systems cleared by the FDA as meeting the CLIA requirements for general quality control, the laboratory must—

(i) Perform maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer; and

(ii) Document all maintenance performed.

(2) For equipment, instruments, or test systems not cleared by the FDA as meeting the CLIA requirements for general quality control, or equipment, instruments, or test systems that have been modified or developed in-house, the laboratory must—

(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance necessary for accurate and reliable test results and test result reporting;

(ii) Perform maintenance with at least the frequency specified in paragraph (a)(2)(i) of this section; and

(iii) Document all maintenance performed.

(b) *Function checks of equipment, instruments, and test systems.* (1) For manufacturers' equipment, instruments, or test systems cleared by the FDA as meeting the CLIA requirements for general quality control, the laboratory must—

(i) Perform function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer; and

(ii) Document all function checks performed.

(2) For equipment, instruments, or test systems not cleared by FDA as meeting the CLIA requirements for general quality control, or equipment, instruments, or test systems that have been modified or developed in-house, the laboratory must—

(i) Define a function check protocol that ensures equipment, instrument, and test system performance necessary for accurate and reliable test results and test result reporting;

(ii) Perform function checks including background or baseline checks specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted; and

(iii) Document all function checks performed.

**§ 493.1217 Standard; Calibration and calibration verification procedures.**

Calibration and calibration verification procedures are required to substantiate the continued accuracy of the test method throughout the laboratory's reportable range for patient test results. Calibration is the process of testing and adjusting an instrument, kit, or test system to provide a known relationship between the measurement response and the value of the substance that is being measured by the test procedure. Calibration verification is the assaying of calibration materials in the same manner as patient samples to confirm that the calibration of the instrument, kit, or test system has remained stable throughout the laboratory's reportable range for patient test results. The reportable range is the range of test result values over which the relationship between the instrument, kit or test system measurement response is shown to be valid. Calibration and calibration verification must be performed and documented as required in this section unless otherwise specified in §§ 493.1223 through 493.1285 of this subpart.

(a) For laboratory test procedures that are performed using instruments, kits, or test systems that have been cleared by the FDA as meeting CLIA requirements for general quality control, the laboratory must, at a minimum, follow the manufacturer's instructions for calibration and calibration verification procedures using calibration materials specified by the manufacturer.

(b) For each method that is developed in-house, is a modification of the manufacturer's test procedure, or is an instrument, kit, or test system that has not been cleared by the FDA as meeting the CLIA requirements for general quality control, the laboratory must—

(1) Perform calibration procedures—

(i) At a minimum, in accordance with manufacturer's instructions, if provided, using calibration materials provided or specified, as appropriate, and with at least the frequency recommended by the manufacturer;

(ii) In accordance with criteria established by the laboratory—

(A) Including the number, type and concentration of calibration materials, acceptable limits for calibration, and the frequency of calibration if manufacturer's instructions are not provided; and

(B) Using calibration materials appropriate for the methodology and, if possible, traceable to a reference method or reference material of known value; and

(iii) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification; and

(2) Perform calibration verification procedures—

(i) In accordance with the manufacturer's calibration verification instructions when they meet or exceed the requirements specified in paragraph (b)(2)(ii) of this section; or

(ii) In accordance with criteria established by the laboratory—

(A) Including the number, type, and concentration of calibration materials, acceptable limits for calibration verification and frequency of calibration verification; and

(B) Using calibration materials appropriate for—

(1) The methodology and, if possible, traceable to a reference method or reference material of known value; and

(2) Verifying the laboratory's established reportable range of patient test results, which must include at least a minimal (or zero) value, a mid-point value, and a maximum value at the upper limit of that range; and

(C) At least once every six months and whenever any of the following occur:

(1) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes.

**Note:** If reagents are obtained from a manufacturer and all of the reagents for a test are packaged together, the laboratory is not required to perform calibration verification for each package of reagents, provided the packages of reagents are received in the same shipment and contain the same lot number;

(2) There is major preventive maintenance or replacement of critical parts that may influence test performance;

(3) Controls reflect an unusual trend or shift or are outside of the laboratory's acceptable limits and other means of assessing and correcting unacceptable control values have failed to identify and correct the problem; or

(4) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification than specified in paragraphs (b)(2)(ii)(C)(1), (2), or (3) of this section; and

(3) Document all calibration and calibration verification procedures performed.

**§ 493.1218 Standard; Control procedures.**

Control procedures are performed on a routine basis to monitor the stability of the method or test system; control and calibration materials provide a means to indirectly assess the accuracy and precision of patient test results. Control procedures must be performed as defined in this section unless otherwise specified in §§ 493.1223 through 493.1285 of this subpart.

(a) For each method cleared by the FDA as meeting CLIA requirements for general quality control, the laboratory must, at a minimum, follow the manufacturer's instructions for control procedures. In addition, the laboratory must meet the requirements under paragraphs (c) through (e) of this section and, as applicable, paragraph (f) of this section.

(b) For each method that is developed in-house, is a modification of the manufacturer's test procedure, or is a method that has not been cleared by the FDA as meeting the CLIA requirements for general quality control, the laboratory must evaluate instrument and reagent stability and operator variance in determining the number, type, and frequency of testing calibration or control materials and establish criteria for acceptability used to monitor test performance during a run of patient specimen(s). A run is an interval within which the accuracy and precision of a testing system is expected to be stable, but cannot be greater than 24 hours. For each procedure, the laboratory must monitor test performance using calibration materials or control materials or a combination thereof.

(1) For qualitative tests, the laboratory must include a positive and negative control with each run of patient specimens.

(2) For quantitative tests, the laboratory must include at least two samples of different concentrations of either calibration materials, control materials, or a combination thereof with the frequency determined in § 493.1218(b), but not less frequently than once each run of patient specimens.

(3) For electrophoretic determinations—

(i) At least one control sample must be used in each electrophoretic cell; and  
(ii) The control sample must contain fractions representative of those routinely reported in patient specimens.

(4) Each day of use, the laboratory must evaluate the detection phase of direct antigen systems using an appropriate positive and negative control material (organism or antigen extract). When direct antigen systems include an extraction phase, the system

must be checked each day of use using a positive organism.

(5) If calibration materials and control materials are not available, the laboratory must have an alternative mechanism to assure the validity of patient test results.

(c) Control samples must be tested in the same manner as patient specimens.

(d) When calibration or control materials are used, statistical parameters (e.g., mean and standard deviation) for each lot number of calibration material and each lot of control material must be determined through repetitive testing.

(1) The stated values of an assayed control material may be used as the target values provided the stated values correspond to the methodology and instrumentation employed by the laboratory and are verified by the laboratory.

(2) Statistical parameters for unassayed materials must be established over time by the laboratory through concurrent testing with calibration materials or control materials having previously determined statistical parameters.

(e) Control results must meet the laboratory's criteria for acceptability prior to reporting patient test results.

(f) *Reagent and supply checks.* (1) The laboratory must check each batch or shipment of reagents, discs, stains, antisera and identification systems (systems using two or more substrates) when prepared or opened for positive and negative reactivity, as well as graded reactivity if applicable.

(2) Each day of use (unless otherwise specified in this subpart), the laboratory must test staining materials for intended reactivity to ensure predictable staining characteristics.

(3) The laboratory must check fluorescent stains for positive and negative reactivity each time of use (unless otherwise specified in this subpart).

(4) The laboratory must check each batch or shipment of media for sterility, if it is intended to be sterile, and sterility is required for testing. Media must also be checked for its ability to support growth, and as appropriate, selectivity/inhibition and/or biochemical response. The laboratory may use manufacturer's control checks of media provided the manufacturer's product insert specifies that the manufacturer's quality control checks meet the National Committee for Clinical Laboratory Standards (NCCLS) for media quality control. The laboratory must document that the physical characteristics of the media are not compromised and report any deterioration in the media to the

manufacturer. The laboratory must follow the manufacturer's specifications for using the media and be responsible for the test results.

*Note:* A batch of media (solid, semi-solid, or liquid) consists of all tubes, plates, or containers of the same medium prepared at the same time and in the same laboratory; or, if received from an outside source or commercial supplier, consists of all of the plates, tubes or containers of the same medium that have the same lot numbers and are received in a single shipment.

**§ 493.1219 Standard; Remedial actions.**

Remedial action policies and procedures must be established by the laboratory and applied as necessary to maintain the laboratory's operation for testing patient specimens in a manner that assures accurate and reliable patient test results and reports. The laboratory must document all remedial actions taken when—

(a) Test systems do not meet the laboratory's established performance specifications, as determined in § 493.1213 of this section, which include but are not limited to—

(1) Equipment or methodologies that perform outside of established operating parameters or performance specifications;

(2) Patient test values that are outside of the laboratory's reportable range of patient test results; and

(3) The determination that the laboratory's reference range for a test procedure is inappropriate for the laboratory's patient population.

(b) Results of control and calibration materials fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run or since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected and the laboratory must take the remedial action necessary to ensure the reporting of accurate and reliable patient test results;

(c) The laboratory cannot report patient test results within its established time frames. The laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual of the delayed testing; and

(d) Errors in the reported patient test results are detected. The laboratory must—

(1) Promptly notify the authorized person ordering or individual utilizing the test results of reporting errors;

(2) Issue corrected reports promptly to the authorized person ordering the test

or the individual utilizing the test results; and

(3) Maintain exact duplicates of the original report as well as the corrected report for two years.

**§ 493.1221 Standard; Quality control records.**

The laboratory must document and maintain records of all quality control activities specified in §§ 493.1202 through 493.1285 of this subpart and retain records for at least two years. Immunohematology quality control records must be maintained for a period of no less than five years. In addition, quality control records for blood and blood products must be maintained for a period not less than five years after processing records have been completed, or six months after the latest expiration date, whichever is the later date, in accordance with 21 CFR 606.160(d).

**§ 493.1223 Condition: Quality control—specialties and subspecialties for tests of moderate or high complexity, or both.**

The laboratory must establish and follow written policies and procedures for an acceptable quality control program that include verification and assessment of accuracy, measurement of precision and detection of error for all analyses and procedures performed by the laboratory. In addition to the general requirements specified in §§ 493.1201 through 493.1221 of this subpart, the laboratory must meet the applicable requirements of §§ 493.1225 through 493.1285 unless HCFA approves an equivalent procedure specified in appendix C of the State Operations Manual (HCFA Pub. 7). However, effective September 1, 1994, a laboratory that performs tests of moderate or high complexity, or both, as applicable, will be in compliance with this section if it—

(a) Meets quality control requirements specified in this subpart; or

(b) Follows manufacturer's instructions when using products (instruments, kits, or test systems) cleared by FDA as meeting the CLIA requirements for general quality control as well as specialty and subspecialty quality control.

Failure to meet any of the applicable conditions in §§ 493.1225 through 493.1285 will result in intermediate sanctions, loss of Medicare or Medicaid approval, and/or revocation of CLIA certification for the entire specialty or subspecialty to which the condition applies, in accordance with subpart R of this part.

**§ 493.1225 Condition: Microbiology.**

The laboratory must meet the applicable quality control requirements

in §§ 493.1201 through 493.1221 and in §§ 493.1227 through 493.1235 of this subpart for the subspecialties for which it is certified under the specialty of microbiology.

**§ 493.1227 Condition: Bacteriology.**

To meet the quality control requirements for bacteriology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 and with paragraphs (a) through (c) of this section. All quality control activities must be documented.

(a) The laboratory must check positive and negative reactivity with control organisms—

(1) Each day of use for catalase, coagulase, beta-lactamase, and oxidase reagents and DNA probes;

(2) Each week of use for Gram and acid-fast stains, bacitracin, optochin, ONPG, X, and V discs or strips; and

(3) Each month of use for antisera.

(b) Each week of use, the laboratory must check XV discs or strips with a positive control organism.

(c) For antimicrobial susceptibility tests, the laboratory must check each new batch of media and each lot of antimicrobial discs before, or concurrent with, initial use, using approved reference organisms.

(1) The laboratory's zone sizes or minimum inhibitory concentration for reference organisms must be within established limits before reporting patient results.

(2) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure.

**§ 493.1229 Condition: Mycobacteriology.**

To meet the quality control requirements for mycobacteriology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) Each day of use, the laboratory must check the iron uptake test with at least one acid-fast organism that produces a positive reaction and with an organism that produces a negative reaction and check all other reagents or test procedures used for mycobacteria identification with at least one acid-fast organism that produces a positive reaction.

(b) The laboratory must check fluorochrome acid-fast stains for positive and negative reactivity each week of use.

(c) The laboratory must check acid-fast stains each week of use with an

acid-fast organism that produces a positive reaction.

(d) For susceptibility tests performed on *Mycobacterium tuberculosis* isolates, the laboratory must check the procedure each week of use with a strain of *Mycobacterium tuberculosis* susceptible to all antimycobacterial agents tested.

**§ 493.1231 Condition: Mycology.**

To meet the quality control requirements for mycology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) Each day of use, the laboratory using the auxanographic medium for nitrate assimilation must check the nitrate reagent with a peptone control.

(b) Each week of use, the laboratory must check all reagents used with biochemical tests and other test procedures for mycological identification with an organism that produces a positive reaction.

(c) Each week of use, the laboratory must check acid-fast stains for positive and negative reactivity.

(d) For susceptibility tests, the laboratory must test each drug each day of use with at least one control strain that is susceptible to the drug. The laboratory must establish control limits. Criteria for acceptable control results must be met prior to reporting patient results.

**§ 493.1233 Condition: Parasitology.**

To meet the quality control requirements for parasitology, the laboratory must comply with the applicable requirements of §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (c) of this section. All quality control activities must be documented.

(a) The laboratory must have available a reference collection of slides or photographs, and, if available, gross specimens for identification of parasites and use these references in the laboratory for appropriate comparison with diagnostic specimens.

(b) The laboratory must calibrate and use the calibrated ocular micrometer for determining the size of ova and parasites, if size is a critical parameter.

(c) Each month of use, the laboratory must check permanent stains using a fecal sample control that will demonstrate staining characteristics.

**§ 493.1235 Condition: Virology.**

To meet the quality control requirements for virology, the laboratory

must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (c) of this section. All quality control activities must be documented.

(a) The laboratory must have available host systems for the isolation of viruses and test methods for the identification of viruses that cover the entire range of viruses that are etiologically related to clinical diseases for which services are offered.

(b) The laboratory must maintain records that reflect the systems used and the reactions observed.

(c) In tests for the identification of viruses, the laboratory must simultaneously culture uninoculated cells or cell substrate controls as a negative control to detect erroneous identification results.

**§ 493.1237 Condition: Diagnostic immunology.**

The laboratory must meet the applicable quality control requirements in §§ 493.1201 through 493.1221 and §§ 493.1239 through 493.1241 of this subpart for the subspecialties for which it is certified under the specialty of diagnostic immunology.

**§ 493.1239 Condition: Syphilis serology.**

To meet the quality control requirements for syphilis serology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (e) of this section. All quality control activities must be documented.

(a) For laboratories performing syphilis testing, the equipment, glassware, reagents, controls, and techniques for tests for syphilis must conform to manufacturers' specifications.

(b) The laboratory must run serologic tests on patient specimens concurrently with a positive serum control of known titer or controls of graded reactivity plus a negative control.

(c) The laboratory must employ positive and negative controls that evaluate all phases of the test system to ensure reactivity and uniform dosages.

(d) The laboratory may not report test results unless the predetermined reactivity pattern of the controls is observed.

(e) All facilities manufacturing blood and blood products for transfusion or serving as referral laboratories for these facilities must meet the syphilis serology testing requirements of 21 CFR 640.5(a).

**§ 493.1241 Condition: General immunology.**

To meet the quality control requirements for general immunology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) The laboratory must run serologic tests on patient specimens concurrently with a positive serum control of known titer or controls of graded reactivity, if applicable, plus a negative control.

(b) The laboratory must employ controls that evaluate all phases of the test system (antigens, complement, erythrocyte indicator systems, etc.) to ensure reactivity and uniform dosages when positive and negative controls alone are not sufficient.

(c) The laboratory may not report test results unless the predetermined reactivity pattern of the controls is observed.

(d) All facilities manufacturing blood and blood products for transfusion or serving as referral laboratories for these facilities must meet—

(1) The HIV testing requirements of 21 CFR 610.45; and

(2) Hepatitis testing requirements of 21 CFR 610.40.

**§ 493.1243 Condition: Chemistry.**

The laboratory must meet the applicable quality control requirements in §§ 493.1201 through 493.1221 and §§ 493.1245 through 493.1249 of this subpart for the subspecialties for which it is certified under the specialty of chemistry.

**§ 493.1245 Condition: Routine chemistry.**

To meet the quality control requirements for routine chemistry, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221. All quality control activities must be documented. In addition, for blood gas analyses, the laboratory must—

(a) Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer;

(b) Test one sample of control material each eight hours of testing;

(c) Use a combination of calibrators and control materials that include both low and high values on each day of testing; and

(d) Include one sample of calibration material or control material each time patients are tested unless automated instrumentation internally verifies calibration at least every thirty minutes.

**§ 493.1247 Condition: Endocrinology.**

To meet the quality control requirements for endocrinology, the laboratory must comply with the applicable requirements contained in §§ 493.1201 through 493.1221 of this subpart. All quality control activities must be documented.

**§ 493.1249 Condition: Toxicology.**

To meet the quality control requirements for toxicology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart. All quality control activities must be documented. In addition, for drug abuse screening using thin layer chromatography—

(a) Each plate must be spotted with at least one sample of calibration material containing all drug groups identified by thin layer chromatography which the laboratory reports; and

(b) At least one control sample must be included in each chamber, and the control sample must be processed through each step of patient testing, including extraction procedures.

**§ 493.1253 Condition: Hematology.**

To meet the quality control requirements for hematology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) For automated hematology testing systems, excluding coagulation, the laboratory must include two levels of controls each eight hours of operation.

(b) Cell counts performed manually using a hemocytometer must be tested in duplicate. One control is required for each eight hours of operation.

(c) For all automated coagulation testing systems, the laboratory must include two levels of control each eight hours of operation and each time a change in reagents occurs.

(d) For manual coagulation tests—

(1) Each individual performing tests must test two levels of controls before testing patient samples and each time a change in reagents occurs; and

(2) Patient and control specimens must be tested in duplicate.

**§ 493.1255 Condition: Pathology.**

The laboratory must meet the applicable quality control requirements in §§ 493.1201 through 493.1221 and §§ 493.1257 through 493.1261 of this subpart for the subspecialties for which it is certified under the specialty of

pathology. All quality control activities must be documented.

**§ 493.1257 Condition: Cytology.**

To meet the quality control requirements for cytology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and paragraphs (a) through (g) of this section.

(a) The laboratory must assure that—  
 (1) All gynecologic smears are stained using a Papanicolaou or modified Papanicolaou staining method;

(2) Effective measures are taken to prevent cross-contamination between gynecologic and nongynecologic specimens during the staining process;

(3) Nongynecologic specimens that have a high potential for cross-contamination are stained separately from other nongynecologic specimens, and the stains are filtered or changed following staining;

(4) Diagnostic interpretations are not reported on unsatisfactory smears; and

(5) All cytology slide preparations are evaluated on the premises.

(b) The laboratory is responsible for ensuring that—

(1) Each individual engaged in the evaluation of cytology preparations by nonautomated microscopic technique examines no more than 100 slides (gynecologic or nongynecologic, or both) in a 24 hour period, irrespective of the site or laboratory. This limit represents an absolute maximum number of slides and is not to be employed as a performance target for each individual. Previously examined reactive, reparative, atypical, premalignant or malignant gynecologic cases as defined in paragraph (c)(1) of this section, previously examined nongynecologic cytology preparations, and tissue pathology slides examined by a technical supervisor qualified under §§ 493.1449 (b) or (k) are not included in the 100 slide limit. (For this section, all references to technical supervisor refer to individuals qualified under §§ 493.1449 (b) and (k).);

(2) For purposes of workload calculations, each slide preparation (gynecologic or nongynecologic) made using automated, semi-automated, or other liquid-based slide preparatory techniques which result in cell dispersion over one-half or less of the total available slide area and which is examined by nonautomated microscopic technique counts as one-half slide.

(3) Records are maintained of the total number of slides examined by each individual during each 24 hour period, irrespective of the site or laboratory, and the number of hours each individual

spends examining slides in the 24 hour period;

(i) The maximum number of 100 slides described in paragraph (b)(1) of this section is examined in no less than an 8 hour workday;

(ii) For the purposes of establishing workload limits for individuals examining slides by nonautomated microscopic technique on other than an 8 hour workday basis (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours must be used to prorate the number of slides that may be examined. Use the formula—

$$\frac{\text{No. of hours examining slides} \times 100}{8}$$

to determine maximum slide volume to be examined.

(c) The individual qualified under §§ 493.1449 (b) or (k) who provides technical supervision of cytology must ensure that—

(1) All gynecologic smears interpreted to be showing reactive or reparative changes, atypical squamous or glandular cells of undetermined significance, or to be in the premalignant (dysplasia, cervical intraepithelial neoplasia or all squamous intraepithelial lesions including human papillomavirus-associated changes) or malignant category are confirmed by a technical supervisor in cytology. The report must be signed to reflect the review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor in cytology;

(2) All nongynecologic cytologic preparations are reviewed by the technical supervisor in cytology. The report must be signed to reflect technical supervisory review or, if a computer report is generated with signature, it must reflect an electronic signature authorized by the technical supervisor;

(3) The slide examination performance of each cytotechnologist is evaluated and documented, including performance evaluation through the re-examination of normal and negative cases and feedback on the reactive, reparative, atypical, malignant or premalignant cases as defined in paragraph (c)(1) of this section; and

(4) A maximum number of slides, not to exceed the maximum workload limit described in paragraph (b) of this section is established by the technical supervisor for each individual examining slide preparations by nonautomated microscopic technique.

(i) The actual workload limit must be documented for each individual and established in accordance with the individual's capability based on the performance evaluation as described in paragraph (c)(3) of this section.

(ii) Records are available to document that each individual's workload limit is reassessed at least every 6 months and adjusted when necessary.

(d) The laboratory must establish and follow a program designed to detect errors in the performance of cytologic examinations and the reporting of results.

(1) The laboratory must establish a program that includes a review of slides from at least 10 percent of the gynecologic cases interpreted to be negative for reactive, reparative, atypical, premalignant or malignant conditions as defined in paragraph (c)(1) of this section that are examined by each individual not qualified under §§ 493.1449 (b) or (k). This review must be done by a technical supervisor in cytology, a cytology general supervisor qualified under § 493.1469, or a cytotechnologist qualified under § 493.1483 who has the experience specified in § 493.1469(b)(2).

(i) The review must include negative cases selected at random from the total caseload and from patients or groups of patients that are identified as having a high probability of developing cervical cancer, based on available patient information;

(ii) Records of initial examinations and rescreening results must be available; and

(iii) The review must be completed before reporting patient results on those cases selected.

(2) The laboratory must compare clinical information, when available, with cytology reports and must compare all malignant and premalignant (as defined in paragraph (c)(1) of this section) gynecology reports with the histopathology report, if available in the laboratory (either on-site or in storage), and determine the causes of any discrepancies.

(3) For each patient with a current high grade or above intraepithelial lesion (moderate dysplasia or CIN-2 or above), the laboratory must review all normal or negative gynecologic specimens received within the previous five years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that would affect patient care, the laboratory must notify the patient's physician and issue an amended report.

(4) The laboratory must establish and document an annual statistical

evaluation of the number of cytology cases examined, number of specimens processed by specimen type, volume of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation), number of gynecologic cases where cytology and available histology are discrepant, the number of gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as malignant or premalignant, as defined in paragraph (c)(1) of the section, and the number of gynecologic cases for which histology results were unavailable to compare with malignant or premalignant cytology cases as defined in paragraph (c)(1) of this section.

(5) The laboratory must evaluate the case reviews of each individual examining slides against the laboratory's overall statistical values, document any discrepancies, including reasons for the deviation, and document corrective action, if appropriate.

(e) The laboratory report must—

(1) Clearly distinguish specimens or smears, or both, that are unsatisfactory for diagnostic interpretation; and

(2) Contain narrative descriptive nomenclature for all results.

(f) Corrected reports issued by the laboratory must indicate the basis for correction.

(g) The laboratory must retain all slide preparations for five years from the date of examination, or slides may be loaned to proficiency testing programs, in lieu of maintaining them for this time period, provided the laboratory receives written acknowledgment of the receipt of slides by the proficiency testing program and maintains the acknowledgment to document the loan of such slides. Documentation for slides loaned or referred for purposes other than proficiency testing must also be maintained. All slides must be retrievable upon request.

**§ 493.1259 Condition: Histopathology.**

To meet the quality control requirements for histopathology, a laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and paragraphs (a) through (e) of this section. All quality control activities must be documented.

(a) A control slide of known reactivity must be included with each slide or group of slides for differential or special stains. Reaction(s) of the control slide with each special stain must be documented.

(b) The laboratory must retain stained slides at least ten years from the date of examination and retain specimen blocks

at least two years from the date of examination.

(c) The laboratory must retain remnants of tissue specimens in a manner that assures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under § 493.1449(b) or § 493.1449(l)(1) of this part. In addition, an individual who meets the requirements of § 493.1449(b), § 493.1449(l)(1) or § 493.1449(l)(2), may examine and provide reports for specimens for skin pathology; an individual meeting the requirements of § 493.1449(b) or § 493.1449(l)(3) may examine and provide reports for ophthalmic pathology; an individual meeting the requirements of § 493.1449(b) or § 493.1449(m) may examine and provide reports for oral pathology specimens.

(d) All tissue pathology reports must be signed by an individual qualified as specified in paragraph (c) of the section. If a computer report is generated with an electronic signature, it must be authorized by the individual qualified as specified in paragraph (c) of this section.

(e) The laboratory must utilize acceptable terminology of a recognized system of disease nomenclature in reporting results.

**§ 493.1261 Condition: Oral pathology.**

To meet the quality control requirements for oral pathology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 and § 493.1259 of this subpart. All quality control activities must be documented.

**§ 493.1263 Condition: Radiobioassay.**

To meet quality control requirements for radiobioassay, the laboratory must comply with the applicable requirements of §§ 493.1201 through 493.1221 of this subpart. All quality control activities must be documented.

**§ 493.1265 Condition: Histocompatibility.**

In addition to meeting the applicable requirements for general quality control in §§ 493.1201 through 493.1221, for quality control for general immunology in § 493.1241 of this subpart and for immunohematology in § 493.1269 of this subpart, the laboratory must comply with the applicable requirements in paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) For renal allotransplantation, the laboratory must meet the following requirements:

(1) The laboratory must have available and follow criteria for—

(i) Selecting appropriate patient serum samples for crossmatching;

(ii) The technique used in crossmatching;

(iii) Preparation of donor lymphocytes for crossmatching; and

(iv) Reporting crossmatch results;

(2) The laboratory must—

(i) Have available results of final crossmatches before an organ or tissue is transplanted; and

(ii) Make a reasonable attempt and document efforts to have available serum specimens for all potential transplant recipients at initial typing, for periodic screening, for pre-transplantation crossmatch and following sensitizing events, such as transfusion and transplant loss;

(3) The laboratory's storage and maintenance of both recipient sera and reagents must—

(i) Be at an acceptable temperature range for sera and components;

(ii) Use a temperature alarm system and have an emergency plan for alternate storage; and

(iii) Ensure that all specimens are properly identified and easily retrievable;

(4) The laboratory's reagent typing sera inventory (applicable only to locally constructed trays) must indicate source, bleeding date and identification number, and volume remaining;

(5) The laboratory must properly label and store cells, complement, buffer, dyes, etc.;

(6) The laboratory must—

(i) HLA type all potential transplant recipients;

(ii) Type cells from organ donors referred to the laboratory; and

(iii) Have available and follow a policy that establishes when antigen redefinition and retyping are required;

(7) The laboratory must have available and follow criteria for—

(i) The preparation of lymphocytes for HLA-A, B and DR typing;

(ii) Selecting typing reagents, whether locally or commercially prepared;

(iii) The assignment of HLA antigens; and

(iv) Assuring that reagents used for typing recipients and donors are adequate to define all major and International Workshop HLA-A,B and DR specificities for which reagents are readily available;

(8) The laboratory must—

(i) Screen potential transplant recipient sera for preformed HLA-A and B antibodies with a suitable lymphocyte panel on sera collected;

(A) At the time of the recipient's initial HLA typing; and

(B) Thereafter, following sensitizing events and upon request; and

(ii) Use a suitable cell panel for screening patient sera (antibody screen), a screen that contains all the major HLA specificities and common splits—

(A) If the laboratory does not use commercial panels, it must maintain a list of individuals for fresh panel bleeding; and

(B) If the laboratory uses frozen panels, it must have a suitable storage system;

(9) The laboratory must check—

(i) Each typing tray using—

(A) Positive control sera;

(B) Negative control sera; and

(C) Positive controls for specific cell types when applicable (i.e., T cells, B cells, and monocytes); and

(ii) Each compatibility test (i.e. mixed lymphocyte cultures, homozygous typing cells or DNA analysis) and typing for disease-associated antigens using controls to monitor the test components and each phase of the test system to ensure an acceptable performance level;

(10) Compatibility testing for cellularly-defined antigens must utilize techniques such as the mixed lymphocyte culture test, homozygous typing cells or DNA analysis;

(11) If the laboratory reports the recipient's or donor's, or both, ABO blood group and D(Rho) typing, the testing must be performed in accordance with § 493.1269 of this subpart;

(12) If the laboratory utilizes immunologic reagents (such as antibodies or complement) to remove contaminating cells during the isolation of lymphocytes or lymphocyte subsets, the efficacy of the methods must be verified with appropriate quality control procedures;

(13) At least once each month, the laboratory must have each individual performing tests evaluate a previously tested specimen as an unknown to verify his or her ability to reproduce test results. Records of the results for each individual must be maintained; and

(14) The laboratory must participate in at least one national or regional cell exchange program, if available, or develop an exchange system with another laboratory in order to validate inter-laboratory reproducibility.

(b) If the laboratory performs histocompatibility testing for—

(1) Transfusions and other non-renal transplantation, excluding bone marrow and living transplants, all the requirements specified in this section, as applicable, except for the performance of mixed lymphocyte cultures must be met;

(2) Bone marrow transplantation and living transplants, all the requirements specified in this section, including the performance of mixed lymphocyte cultures or other augmented testing to evaluate class II compatibility, must be met; and

(3) Non-renal solid organ transplantation, the results of final crossmatches must be available before transplantation when the recipient has demonstrated presensitization by prior serum screening except for emergency situations. The laboratory must document the circumstances, if known, under which emergency transplants are performed, and records must reflect any information concerning the transplant provided to the laboratory by the patient's physician.

(c) Laboratories performing HLA typing for disease-associated studies or parentage testing must meet all the requirements specified in this section except for the performance of mixed lymphocyte cultures, antibody screening and crossmatching.

(d) For laboratories performing organ donor HIV testing the requirements of § 493.1241 of this subpart for the transfusion of blood and blood products must be met.

**§ 493.1267 Condition: Clinical cytogenetics.**

To meet the quality control requirements for clinical cytogenetics, the laboratory must comply with the applicable requirements of §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) When determination of sex is performed by X and Y chromatin counts, these counts must be based on an examination of an adequate number of cells. Confirmatory testing such as full chromosome analysis must be performed for all atypical results.

(b) The laboratory must have records that reflect the media used and document the reactions observed, number of cells counted, the number of cells karyotyped, the number of chromosomes counted for each metaphase spread, and the quality of the banding; that the resolution is sufficient to support the reported results; and that an adequate number of karyotypes are prepared for each patient.

(c) The laboratory also must have policies and procedures for assuring an accurate and reliable patient sample identification during the process of accessioning, cell preparation, photographing or other image reproduction technique, and

photographic printing, and storage and reporting of results or photographs.

(d) The laboratory report must include the summary and interpretation of the observations and number of cells counted and analyzed and the use of appropriate nomenclature.

**§ 493.1269 Condition: Immunohematology.**

To meet the quality control requirements for immunohematology, the laboratory must comply with the applicable requirements in §§ 493.1201 through 493.1221 of this subpart and with paragraphs (a) through (d) of this section. All quality control activities must be documented.

(a) The laboratory must perform ABO group and D(Rho) typing, unexpected antibody detection, antibody identification and compatibility testing in accordance with manufacturer's instructions, if provided, and as applicable, with 21 CFR part 606 (with the exception of 21 CFR 606.20a, Personnel) and 21 CFR part 640 et seq.

(b) The laboratory must perform ABO group by concurrently testing unknown red cells with anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells.

(c) The laboratory must determine the D(Rho) type by testing unknown red cells with anti-D (anti-Rho) blood grouping reagent.

(d) If required in the manufacturer's package insert for anti-D reagents, the laboratory must employ a control system capable of detecting false positive D(Rho) test results.

**§ 493.1271 Condition: Transfusion services and bloodbanking.**

If a facility provides services for the transfusion of blood and blood products, the facility must be under the adequate control and technical supervision of the pathologist or other doctor of medicine or osteopathy meeting the qualifications in subpart M for technical supervision in immunohematology. The facility must ensure that there are facilities for procurement, safekeeping and transfusion of blood and blood products and that blood products must be available to meet the needs of the physicians responsible for the diagnosis, management, and treatment of patients. The facility meets this condition by complying with the standards in §§ 493.1273 through 493.1285 of this subpart.

**§ 493.1273 Standard; Immunohematological collection, processing, dating periods, labeling and distribution of blood and blood products.**

In addition to the requirements in paragraphs (a) through (d) of this section, the facility must also meet the applicable quality control requirements in §§ 493.1201 through 493.1221 of this part.

(a) Blood and blood product collection, processing and distribution must comply with 21 CFR part 640 and 21 CFR part 606, and the testing laboratory must meet the applicable requirements of part 493.

(b) Dating periods for blood and blood products must conform to 21 CFR 610.53.

(c) Labeling of blood and blood products must conform to 21 CFR part 606, subpart G.

(d) Policies to ensure positive identification of a blood or blood product recipient must be established, documented, and followed.

**§ 493.1275 Standard; Blood and blood products storage facilities.**

(a) The blood and blood products must be stored under appropriate conditions, which include an adequate temperature alarm system that is regularly inspected.

(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period; and

(2) Inspections of the alarm system must be documented.

(b) If blood is stored or maintained for transfusion outside of a monitored refrigerator, the facility must ensure and document that storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.

**§ 493.1277. Standard; Arrangement for services.**

In the case of services provided outside the blood bank, the facility must have an agreement reviewed and approved by the director that governs the procurement, transfer and availability of blood and blood products.

**§ 493.1279 Standard; Provision of testing.**

There must be provision for prompt ABO blood group, D(Rho) type, unexpected antibody detection and compatibility testing in accordance with § 493.1269 of this subpart and for laboratory investigation of transfusion reactions, either through the facility or under arrangement with an approved facility on a continuous basis, under the supervision of a pathologist or other doctor of medicine or osteopathy meeting the qualifications of § 493.1449(b) or § 493.1449(q).

**§ 493.1283 Standard; Retention of samples of transfused blood.**

According to the facility's established procedures, samples of each unit of transfused blood must be retained for further testing in the event of reactions. The facility must promptly dispose of blood not retained for further testing that has passed its expiration date.

**§ 493.1285 Standard; Investigation of transfusion reactions.**

The facility, according to its established procedures, must promptly investigate all transfusion reactions occurring in all facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. The facility must document that all necessary remedial actions are taken to prevent future recurrences of transfusion reactions and that all policies and procedures are reviewed to assure that they are adequate to ensure the safety of individuals being transfused within the facility.

**Subparts M, L and N—[Redesignated as Subparts P, M, and Q]**

4. Subparts M, L and N are redesignated as subparts P, M, and Q, respectively, and revised, subparts L, N, R, and S are reserved, subpart O is removed and reserved, and subpart T is added to read as follows:

**Subpart L—[Reserved]**

**Subpart M—Personnel for Moderate and High Complexity Testing**

**§ 493.1401 General.**

This subpart consists of the personnel requirements that must be met by laboratories performing moderate or high complexity testing, or both.

**Laboratories Performing Moderate Complexity Testing**

**§ 493.1403 Condition: Laboratories performing moderate complexity testing; Laboratory director.**

The laboratory must have a director who meets the qualification requirements of § 493.1405 of this subpart and provides overall management and direction in accordance with § 493.1407 of this subpart.

**§ 493.1405 Standard; Laboratory director qualifications.**

The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an

operator of a laboratory within the requirements of subpart R of this part.

(a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and

(b) The laboratory director must—

(1) (i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2) (i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Have had laboratory training or experience consisting of:

(A) At least one year directing or supervising non-waived laboratory testing; or

(B) Effective (August 2, 1993) have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in § 493.1407; or

(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or

(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and

(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or

(ii) Have had at least one year experience directing or supervising non-waived laboratory testing;

(4) (i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution;

(ii) Have at least one year of laboratory training or experience, or both; and

(iii) In addition, have at least one year of supervisory laboratory experience; or

(5) (i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution;

(ii) Have at least 2 years of laboratory training or experience, or both; and

(iii) In addition, have at least 2 years of supervisory laboratory experience;

(6) Have previously qualified or could have qualified as a laboratory director under 42 CFR 493.1415 published March 14, 1990, (55 FR 9538) on or before February 28, 1992; or

(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located.

**§ 493.1407 Standard; Laboratory director responsibilities.**

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations.

(a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of §§ 493.1409, 493.1415, and 493.1421, respectively.

(b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

(c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.

(d) Each individual may direct no more than five laboratories.

(e) The laboratory director must—

(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards;

(3) Ensure that—

(i) The test methodologies selected have the capability of providing the quality of results required for patient care;

(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that—

(i) The proficiency testing samples are tested as required under subpart H of this part;

(ii) The results are returned within the timeframes established by the proficiency testing program;

(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and

(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory;

(5) Ensure that the quality control and quality assurance programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, and that patient test results are reported only when the system is functioning properly;

(8) Ensure that reports of test results include pertinent information required for interpretation;

(9) Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions;

(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

(12) Ensure that policies and procedures are established for

monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

**§ 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant.**

The laboratory must have a technical consultant who meets the qualification requirements of § 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

**§ 493.1411 Standard; Technical consultant qualifications.**

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

(a) The technical consultant must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

(b) The technical consultant must—

(1) (i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are

equivalent to those required for such certification; or

(2) (i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Have at least one year of laboratory training or experience, or both, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board on Internal Medicine are qualified to serve as the technical consultant in hematology); or

(3) (i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least one year of laboratory training or experience, or both, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or

(4) (i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.

**Note:** The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual, who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

**§ 493.1413 Standard; Technical consultant responsibilities.**

The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section.

(a) The technical consultant must be accessible to the laboratory to provide on-site, telephone, or electronic consultation; and

(b) The technical consultant is responsible for—

(1) Selection of test methodology appropriate for the clinical use of the test results;

(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system;

(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to—

(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;

(ii) Monitoring the recording and reporting of test results;

(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;

(iv) Direct observation of performance of instrument maintenance and function checks;

(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and

(vi) Assessment of problem solving skills; and

(9) Evaluating and documenting the performance of individuals responsible

for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

**§ 493.1415 Condition: Laboratories performing moderate complexity testing; clinical consultant.**

The laboratory must have a clinical consultant who meets the qualification requirements of § 493.1417 of this part and provides clinical consultation in accordance with § 493.1419 of this part.

**§ 493.1417 Standard; Clinical consultant qualifications.**

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must—

(a) Be qualified as a laboratory director under § 493.1405(b) (1), (2), or (3)(i); or

(b) Be a doctor of medicine or doctor of osteopathy and possess a license to practice medicine or osteopathy in the State in which the laboratory is located.

**§ 493.1419 Standard; Clinical consultant responsibilities.**

The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results. The clinical consultant must—

(a) Be available to provide clinical consultation to the laboratory's clients;

(b) Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations;

(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and

(d) Ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.

**§ 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel.**

The laboratory must have a sufficient number of individuals who meet the qualification requirements of § 493.1423, to perform the functions specified in

§ 493.1425 for the volume and complexity of tests performed.

**§ 493.1423 Standard; Testing Personnel qualifications.**

Each individual performing moderate complexity testing must—

(a) Possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

(b) Meet one of the following requirements:

(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or

(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or

(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or

(4)(i) Have earned an academic high school diploma or equivalent; and

(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has—

(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens;

(B) The skills required for implementing all standard laboratory procedures;

(C) The skills required for performing each test method and for proper instrument use;

(D) The skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed;

(E) A working knowledge of reagent stability and storage;

(F) The skills required to implement the quality control policies and procedures of the laboratory;

(G) An awareness of the factors that influence test results; and

(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality control

sample values prior to reporting patient test results.

**§ 493.1425 Standard; Testing personnel responsibilities.**

The testing personnel are responsible for specimen processing, test performance, and for reporting test results.

(a) Each individual performs only those moderate complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

(b) Each individual performing moderate complexity testing must—

(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;

(2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient samples;

(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;

(4) Follow the laboratory's established corrective action policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;

(5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the technical consultant, clinical consultant or director; and

(6) Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications.

**Laboratories Performing High Complexity Testing**

**§ 493.1441 Condition: Laboratories performing high complexity testing; laboratory director.**

The laboratory must have a director who meets the qualification requirements of § 493.1443 of this subpart and provides overall management and direction in accordance with § 493.1445 of this subpart.

**§ 493.1443 Standard; Laboratory director qualifications.**

The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R.

(a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and

(b) The laboratory director must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or

(ii) Have at least 2 years of experience directing or supervising high complexity testing; or

(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and—

(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, the American Board of Medical Laboratory Immunology or other board deemed comparable by HHS; or

(ii) Until September 1, 1994 must have at least—

(A) Two years of laboratory training or experience, or both;

(B) Two years of experience directing or supervising high complexity testing; and

(C) On September 1, 1994, individuals must meet the qualifications specified in paragraph (b)(3)(i) of this section;

(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or

(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located.

**§ 493.1445 Standard; Laboratory director responsibilities.**

The laboratory director is responsible for the overall operation and

administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations.

(a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under §§ 493.1447, 493.1453, 493.1459, and 493.1487, respectively.

(b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

(c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed.

(d) Each individual may direct no more than five laboratories.

(e) The laboratory director must—

(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

(2) Ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed and provide a safe environment in which employees are protected from physical, chemical, and biological hazards;

(3) Ensure that—

(i) The test methodologies selected have the capability of providing the quality of results required for patient care;

(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

(4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that—

(i) The proficiency testing samples are tested as required under subpart H of this part;

(ii) The results are returned within the timeframes established by the proficiency testing program;

(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the

laboratory's performance and to identify any problems that require corrective action; and

(iv) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory;

(5) Ensure that the quality control and quality assurance programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified, and that patient test results are reported only when the system is functioning properly;

(8) Ensure that reports of test results include pertinent information required for interpretation;

(9) Ensure that consultation is available to the laboratory's clients on matters relating to the quality of the test results reported and their interpretation concerning specific patient conditions;

(10) Ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under § 493.1489(b)(4);

(11) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;

(12) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

**§ 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor.**

The laboratory must have a technical supervisor who meets the qualification requirements of § 493.1449 of this subpart and provides technical supervision in accordance with § 493.1451 of this subpart.

**§ 493.1449 Standard; Technical supervisor qualifications.**

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section.

(a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

(b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor—

(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification.

(c) If the requirements of paragraph (b) of this section are not met and the

laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or

(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology.

(d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology.

(e) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice

medicine or osteopathy in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology.

(f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of parasitology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high

complexity testing within the subspecialty of parasitology;

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or

(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or

(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology.

(g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, the individual functioning as the technical supervisor must—

(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or

(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high

complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or

(4) (i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or

(5) (i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology.

(h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must—

(1) (i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2) (i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or

(3) (i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology; or

(4) (i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or

(5) (i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology.

(i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must—

(1) (i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2) (i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or

(3) (i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of chemistry; or

(4) (i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or

(5) (i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry.

(j) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of hematology, the individual functioning as the technical supervisor must—

(1) (i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2) (i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or

(3) (i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of hematology; or

(4) (i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or

(5) (i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology.

(k) (1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must—

(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Meet one of the following requirements—

(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification;

(2) An individual qualified under § 493.1449(b) or paragraph (k)(1) of this section may delegate some of the

cytology technical supervisor responsibilities to an individual who is in the final year of full-time training leading to certification specified in paragraphs (b) or (k)(1)(ii)(A) of this section provided the technical supervisor qualified under § 493.1449(b) or paragraph (k)(1) of this section remains ultimately responsible for ensuring that all of the responsibilities of the cytology technical supervisor are met.

(l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must—

(1) Meet one of the following requirements:

(i) (A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification;

(ii) An individual qualified under § 493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens.

(2) For tests in dermatopathology, meet one of the following requirements:

(i) (A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and—

(B) Meet one of the following requirements:

(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(3) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or

(ii) An individual qualified under § 493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in

paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens.

(3) For tests in ophthalmic pathology, meet one of the following requirements:

(i) (A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and—

(B) Must meet one of the following requirements:

(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2) Be certified in ophthalmic pathology by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification; or

(ii) An individual qualified under § 493.1449(b) or paragraph (1)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or

(m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements:

(1) (i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and—

(ii) Must meet one of the following:

(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(B) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications that are equivalent to those required for such certification; or

(2) An individual qualified under § 493.1449(b) or paragraph (m)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m)(1)(ii) of this section, the responsibility for examination and interpretation of oral pathology specimens.

(n) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of radiobiology, the

individual functioning as the technical supervisor must—

(1) (i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2) (i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or

(3) (i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and

(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or

(4) (i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or

(5) (i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay.

(o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either—

(1) (i) Be a doctor of medicine or osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Have training or experience that meets one of the following requirements:

(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or

(B) (1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and

(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or

(2) (i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and

(ii) Have training or experience that meets one of the following requirements:

(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or

(B) (1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and

(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility.

(p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must—

(1) (i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or

(2) (i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and

(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics.

(q) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must—

(1) (i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(2) (i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and

(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology.

**Note:** The technical supervisor requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology,

and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology.

**§ 493.1451 Standard: Technical supervisor responsibilities.**

The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section.

(a) The technical supervisor must be accessible to the laboratory to provide on-site, telephone, or electronic consultation; and

(b) The technical supervisor is responsible for—

(1) Selection of the test methodology that is appropriate for the clinical use of the test results;

(2) Verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system;

(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered;

(4) Establishing a quality control program appropriate for the testing performed and establishing the parameter for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to—

(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;

(ii) Monitoring the recording and reporting of test results;

(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;

(iv) Direct observation of performance of instrument maintenance and function checks;

(v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and

(vi) Assessment of problem solving skills; and

(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

(c) In cytology, the technical supervisor or the individual qualified under § 493.1449(k)(2)—

(1) May perform the duties of the cytology general supervisor and the cytotechnologist, as specified in §§ 493.1471 and 493.1485, respectively;

(2) Must establish the workload limit for each individual examining slides;

(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary;

(4) Must perform the functions specified in § 493.1257(c);

(5) Must ensure that each individual examining gynecologic preparations participates in an HHS approved cytology proficiency testing program, as specified in § 493.945 and achieves a passing score, as specified in § 493.855; and

(6) If responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides.

**§ 493.1453 Condition: Laboratories performing high complexity testing; clinical consultant.**

The laboratory must have a clinical consultant who meets the requirements

of § 493.1455 of this subpart and provides clinical consultation in accordance with § 493.1457 of this subpart.

**§ 493.1455 Standard: Clinical consultant qualifications.**

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must—

(a) Be qualified as a laboratory director under § 493.1443(b)(1), (2), or (3)(i); or

(b) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located.

**§ 493.1457 Standard: Clinical consultant responsibilities.**

The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results. The clinical consultant must—

(a) Be available to provide consultation to the laboratory's clients;

(b) Be available to assist the laboratory's clients in ensuring that appropriate tests are ordered to meet the clinical expectations;

(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and

(d) Ensure that consultation is available and communicated to the laboratory's clients on matters related to the quality of the test results reported and their interpretation concerning specific patient conditions.

**§ 493.1459 Condition: Laboratories performing high complexity testing; general supervisor.**

The laboratory must have one or more general supervisors who are qualified under § 493.1461 of this subpart to provide general supervision in accordance with § 493.1463 of this subpart.

**§ 493.1461 Standard: General supervisor qualifications.**

The laboratory must have one or more general supervisors who, under the direction of the laboratory director and supervision of the technical supervisor, provides day-to-day supervision of testing personnel and reporting of test results. In the absence of the director and technical supervisor, the general supervisor must be responsible for the proper performance of all laboratory procedures and reporting of test results.

(a) The general supervisor must possess a current license issued by the

State in which the laboratory is located, if such licensing is required; and

(b) The general supervisor must be qualified as a—

(1) Laboratory director under § 493.1443; or

(2) Technical supervisor under § 493.1449.

(c) If the requirements of paragraphs (b)(1) or (b)(2) of this section are not met, the individual functioning as the general supervisor must—

(1) (i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and

(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing; or

(2) (i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution; and

(ii) Have at least two years of laboratory training or experience, or both, in high complexity testing; or

(3) Have previously qualified or could have qualified as a general supervisor under 42 CFR 493.1427 of the Federal regulations published March 14, 1990, (55 FR 9538) on or before February 28, 1992.

(d) For blood gas analysis, the individual providing general supervision must—

(1) Be qualified under § 493.1461(b) (1) or (2), or § 493.1461(c); or

(2) (i) Have earned a bachelor's degree in respiratory therapy from an accredited institution; and

(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or

(3) (i) Have earned an associate degree related to pulmonary function from an accredited institution; and

(ii) Have at least two years of training or experience, or both in blood gas analysis.

(e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed:

(1) In histopathology, by an individual who is qualified as a technical supervisor under §§ 493.1449(b) or 493.1449(l)(1);

(2) In dermatopathology, by an individual who is qualified as a technical supervisor under §§ 493.1449(b) or 493.1449(l) or (2);

(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under §§ 493.1449(b) or 493.1449(1)(3); and

(4) In oral pathology, by an individual who is qualified as a technical supervisor under §§ 493.1449(b) or 493.1449(m).

**§ 493.1463 Standard: General supervisor responsibilities.**

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

(a) The general supervisor—

(1) Must be accessible to testing personnel at all times testing is performed to provide on-site telephone or electronic consultation to resolve technical problems in accordance with policies and procedures established either by the laboratory director or technical supervisor;

(2) Is responsible for providing day-to-day supervision of high complexity test performance by testing personnel qualified under § 493.1489;

(3) Must be onsite to provide direct supervision when high complex testing is performed by any individuals qualified under § 493.1489(b)(4); and

(4) Is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained.

(b) The director or technical supervisor may delegate to the general supervisor the responsibility for—

(1) Assuring that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications;

(2) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning;

(3) Providing orientation to all testing personnel; and

(4) Annually evaluating and documenting the performance of all testing personnel.

**§ 493.1467 Condition: Laboratories performing high complexity testing; cytology general supervisor.**

For the subspecialty of cytology, the laboratory must have a general supervisor who meets the qualification requirements of § 493.1469 of this subpart, and provides supervision in accordance with § 493.1471 of this subpart.

**§ 493.1469 Standard: Cytology general supervisor qualifications.**

The cytology general supervisor must be qualified to supervise cytology services. The general supervisor in

cytology must possess a current license issued by the State in which the laboratory is located, if such licensing is required, and must—

(a) Be qualified as a technical supervisor under § 493.1449 (b) or (k); or

(b) (1) Be qualified as a cytotechnologist under § 493.1483; and  
(2) Have at least 3 years of full-time (2,080 hours per year) experience as a cytotechnologist within the preceding 10 years.

**§ 493.1471 Standard: Cytology general supervisor responsibilities.**

The technical supervisor of cytology may perform the duties of the cytology general supervisor or delegate the responsibilities to an individual qualified under § 493.1469.

(a) The cytology general supervisor is responsible for the day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

(b) The cytology general supervisor must—

(1) Be accessible to provide on-site, telephone, or electronic consultation to resolve technical problems in accordance with policies and procedures established by the technical supervisor of cytology;

(2) Document the slide interpretation results of each gynecologic and nongynecologic cytology case he or she examined or reviewed (as specified under § 493.1257(d));

(3) For each 24-hour period, document the total number of slides he or she examined or reviewed in the laboratory as well as the total number of slides examined or reviewed in any other laboratory or for any other employer; and

(4) Document the number of hours spent examining slides in each 24-hour period.

**§ 493.1481 Condition: Laboratories performing high complexity testing; cytotechnologist.**

For the subspecialty of cytology, the laboratory must have a sufficient number of cytotechnologists who meet the qualifications specified in § 493.1483 to perform the functions specified in § 493.1485.

**§ 493.1483 Standard: Cytotechnologist qualifications.**

Each person examining cytology slide preparations must meet the qualifications of § 493.1449 (b) or (k), or—

(a) Possess a current license as a cytotechnologist issued by the State in which the laboratory is located, if such licensing is required; and

(b) Meet one of the following requirements:

(1) Have graduated from a school of cytotechnology accredited by the Committee on Allied Health Education and Accreditation; or

(2) Be certified in cytotechnology by a certifying agency approved by HHS; or

(3) Before September 1, 1992—

(i) Have successfully completed 2 years in an accredited institution with at least 12 semester hours in science, 8 hours of which are in biology; and

(A) Have had 12 months of training in a school of cytotechnology accredited by an accrediting agency approved by HHS; or

(B) Have received 6 months of formal training in a school of cytotechnology accredited by an accrediting agency approved by HHS and 6 months of full-time experience in cytotechnology in a laboratory acceptable to the pathologist who directed the formal 6 months of training; or

(ii) Have achieved a satisfactory grade to qualify as a cytotechnologist in a proficiency examination approved by HHS and designed to qualify persons as cytotechnologists; or

(4) Before September 1, 1992, have full-time experience of at least 2 years or equivalent within the preceding 5 years examining slide preparations under the supervision of a physician qualified under § 493.1449(b) or (k)(1), and before January 1, 1969, must have—

(i) Graduated from high school;

(ii) Completed 6 months of training in cytotechnology in a laboratory directed by a pathologist or other physician providing cytology services; and

(iii) Completed 2 years of full-time supervised experience in cytotechnology; or

(5) (i) On or before September 1, 1993, have full-time experience of at least 2 years or equivalent examining cytology slide preparations within the preceding 5 years in the United States under the supervision of a physician qualified under § 493.1449(b) or (k)(1); and

(ii) On or before September 1, 1994, have met the requirements in either paragraph (b)(1) or (2) of this section.

**§ 493.1485 Standard: Cytotechnologist responsibilities.**

The cytotechnologist is responsible for documenting—

(a) The slide interpretation results of each gynecologic and nongynecologic cytology case he or she examined or reviewed (as specified in § 493.1257(d));

(b) For each 24-hour period, the total number of slides examined or reviewed in the laboratory as well as the total number of slides examined or reviewed

in any other laboratory or for any other employer; and

(c) The number of hours spent examining slides in each 24-hour period.

**§ 493.1487 Condition: Laboratories performing high complexity testing; testing personnel.**

The laboratory has a sufficient number of individuals who meet the qualification requirements of § 493.1489 of this subpart to perform the functions specified in § 493.1495 of this subpart for the volume and complexity of testing performed.

**§ 493.1489 Standard; Testing personnel qualifications.**

Each individual performing high complexity testing must—

(a) Possess a current license issued by the State in which the laboratory is located, if such licensing is required; and

(b) Meet one of the following requirements:

(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution;

(2) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution;

(3) Have previously qualified or could have qualified as a technologist under 42 CFR 493.1433 published in March 14, 1990 (55 FR 9538), on or before February 28, 1992;

(4) Until September 1, 1997—

(i) Have earned an academic high school diploma or equivalent; and

(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. Such training must ensure that the individual has—

(A) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens;

(B) The skills required for implementing all standard laboratory procedures;

(C) The skills required for performing each test method and for proper instrument use;

(D) The skills required for performing preventive maintenance, troubleshooting and calibration procedures related to each test performed;

(E) A working knowledge of reagent stability and storage;

(F) The skills required to implement the quality control policies and procedures of the laboratory;

(G) An awareness of the factors that influence test results; and

(H) The skills required to assess and verify the validity of patient test results through the evaluation of quality sample values prior to reporting patient test results.

On September 1, 1997, must meet the qualifications of § 493.1489(b) (1) or (2);

(5) For blood gas analysis, the

individual must—

(i) Be qualified under § 493.1489(b) (1), (2), or (3), (4);

(ii) Have earned a bachelor's degree in respiratory therapy from an accredited institution; or

(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or

(6) For histopathology, tissue examinations must be performed by an individual who meets the qualifications of § 493.1449 (b) or (l) of this subpart.

**§ 493.1495 Standard; Testing personnel responsibilities.**

The testing personnel are responsible for specimen processing, test performance and for reporting test results.

(a) Each individual performs only those high complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities.

(b) Each individual performing high complexity testing must—

(1) Follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results;

(2) Maintain records that demonstrate that proficiency testing samples are tested in the same manner as patient specimens;

(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;

(4) Follow the laboratory's established policies and procedures whenever test systems are not within the laboratory's established acceptable levels of performance;

(5) Be capable of identifying problems that may adversely affect test performance or reporting of test results and either must correct the problems or immediately notify the general supervisor, technical supervisor, clinical consultant, or director;

(6) Document all corrective actions taken when test systems deviate from the laboratory's established performance specifications; and

(7) If qualified under § 493.1489(b)(4), must perform high complexity testing only under the onsite, direct supervision of a general supervisor qualified under § 493.1461.

**Subparts N-O [Reserved]**

**Subpart P—Quality Assurance for Moderate or High Complexity Testing, or Both**

**§ 493.1701 Condition: Quality assurance; moderate or high complexity testing, or both.**

Each laboratory performing moderate or high complexity testing, or both, must establish and follow written policies and procedures for a comprehensive quality assurance program which is designed to monitor and evaluate the ongoing and overall quality of the total testing process (preanalytic, analytic, postanalytic). The laboratory's quality assurance program must evaluate the effectiveness of its policies and procedures; identify and correct problems; assure the accurate, reliable and prompt reporting of test results; and assure the adequacy and competency of the staff. As necessary, the laboratory must revise policies and procedures based upon the results of those evaluations. The laboratory must meet the standards of this subpart as they apply to the services offered, complexity of testing performed and reported, and the unique practices of each testing entity. All quality assurance activities must be documented.

**§ 493.1703 Standard; Patient test management assessment.**

The laboratory must have an ongoing mechanism for monitoring and evaluating the systems required under Subpart J, Patient Test Management. The laboratory must monitor, evaluate, and revise, if necessary, based on the results of its evaluations, the following:

(a) The criteria established for patient preparation, specimen collection, labeling, preservation and transportation;

(b) The information solicited and obtained on the laboratory's test requisition for its completeness, relevance, and necessity for the testing of patient specimens;

(c) The use and appropriateness of the criteria established for specimen rejection;

(d) The completeness, usefulness, and accuracy of the test report information

necessary for the interpretation or utilization of test results;

(e) The timely reporting of test results based on testing priorities (STAT, routine, etc.); and

(f) The accuracy and reliability of test reporting systems, appropriate storage of records and retrieval of test results.

**§ 493.1705 Standard; Quality control assessment.**

The laboratory must have an ongoing mechanism to evaluate the corrective actions taken under § 493.1219, Remedial actions. Ineffective policies and procedures must be revised based on the outcome of the evaluation. The mechanism must evaluate and review the effectiveness of corrective actions taken for—

(a) Problems identified during the evaluation of calibration and control data for each test method;

(b) Problems identified during the evaluation of patient test values for the purpose of verifying the reference range of a test method; and

(c) Errors detected in reported results.

**§ 493.1707 Standard; Proficiency testing assessment.**

Under subpart H of this part, Proficiency Testing, the corrective actions taken for any unacceptable, unsatisfactory, or unsuccessful proficiency testing result(s) must be evaluated for effectiveness.

**§ 493.1709 Standard; Comparison of test results.**

If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using different methodologies, instruments, or testing sites. In addition, if a laboratory performs tests that are not included under Subpart I, Proficiency Testing Programs, the laboratory must have a system for verifying the accuracy and reliability of its test results at least twice a year.

**§ 493.1711 Standard; Relationship of patient information to patient test results.**

For internal quality assurance, the laboratory must have a mechanism to identify and evaluate patient test results that appear inconsistent with relevant criteria such as—

(a) Patient age;

(b) Sex;

(c) Diagnosis or pertinent clinical data, when provided;

(d) Distribution of patient test results when available; and

(e) Relationship with other test parameters, when available within the laboratory.

**§ 493.1713 Standard; Personnel assessment.**

The laboratory must have an ongoing mechanism to evaluate the effectiveness of its policies and procedures for assuring employee competence and, if applicable, consultant competence.

**§ 493.1715 Standard; Communications.**

The laboratory must have a system in place to document problems that occur as a result of breakdowns in communication between the laboratory and the authorized individual who orders or receives the results of test procedures or examinations. Corrective actions taken to resolve the problems and minimize communications breakdowns must be documented.

**§ 493.1717 Standard; Complaint investigations.**

The laboratory must have a system in place to assure that all complaints and problems reported to the laboratory are documented. Investigations of complaints must be made, when appropriate, and, as necessary, corrective actions are instituted.

**§ 493.1719 Standard; Quality assurance review with staff.**

The laboratory must have a mechanism for documenting and assessing problems identified during quality assurance reviews and discussing them with the staff. The laboratory must take corrective actions that are necessary to prevent recurrences.

**§ 493.1721 Standard; Quality assurance records.**

The laboratory must maintain documentation of all quality assurance activities including problems identified and corrective actions taken. All quality assurance records must be available to HHS.

**Subpart Q—Inspection**

**§ 493.1775 Condition: Inspection of laboratories issued a certificate of waiver.**

(a) HHS or its designee will conduct unannounced inspections of any laboratory at any time during its hours of operation to assess compliance with the applicable requirements of part 493.

(b) The laboratory may be required, as part of this inspection, to—

(1) Permit HHS or its designee to interview all employees of the laboratory concerning the laboratory's compliance with the applicable requirements of part 493;

(2) Permit HHS or its designee access to all areas of the facility including—

(i) Specimen procurement and processing areas;

(ii) Storage facilities for specimens, reagents, supplies, records, and reports; and

(iii) Testing and reporting areas.

(3) Permit employees to be observed performing tests, data analysis and reporting;

(4) Permit HHS or its designee upon request to review all information and data necessary to—

(i) Determine that testing is being performed or the laboratory is being operated in a manner that does not constitute an imminent and serious risk to public health;

(ii) Evaluate complaints from the public;

(iii) Determine whether the laboratory is performing tests not listed in § 493.15; and

(iv) Collect information to determine the addition, deletion, or continued inclusion of tests listed in § 493.15; and

(5) Provide copies to HHS or its designee of all records and data that the agency requires under these regulations.

(c) The laboratory must provide upon reasonable request all information and data needed by HHS or its designee to make a determination of compliance with the requirements of part 493.

(d) Failure to permit an inspection under this subsection will result in the suspension of Medicare and Medicaid payments to the laboratory or termination of the laboratory's participation in Medicare and Medicaid for payment, and suspension of or action to revoke laboratory's CLIA certificate of waiver in accordance with subpart R of this part.

**§ 493.1777 Condition: Inspection of all laboratories not issued a certificate of waiver or a certificate of accreditation.**

(a) HHS or its designee will conduct unannounced inspections on at least a biennial basis of any laboratory at any time during its hours of operation. To assess compliance with the requirements of part 493, HHS will inspect a laboratory possessing a registration certificate before issuance of a certificate.

(b) The laboratory may be required, as part of this inspection, to—

(1) Test samples (including proficiency testing samples) or perform procedures as HHS or its designee requires;

(2) Allow HHS or its designee to interview all employees of the laboratory concerning the laboratory's compliance with the applicable requirements of part 493;

(3) Permit employees to be observed performing tests (including proficiency testing specimens), data analysis and reporting;

(4) Permit HHS or its designee access to all areas of the facility including—

(i) Specimen procurement and processing areas;

(ii) Storage facilities for specimens, reagents, supplies, records, and reports; and

(iii) Testing and reporting areas; and

(5) Provide copies to HHS or its designee of all records and data it requires.

(c) The laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection.

(d) The laboratory must retain—

(1) Immunohematology records for a period of not less than 5 years, in accordance with 21 CFR part 606, subpart I;

(2) Pathology test reports for at least 10 years after the date of reporting as required in § 493.1109; and

(3) All other laboratory records for at least 2 years.

(e) The laboratory must provide upon request all information and data needed by HHS or its designee to make a determination of the laboratory's compliance with the applicable requirements of part 493.

(f) HHS or its designee may reinspect a laboratory at any time necessary to evaluate the ability of the laboratory to provide accurate and reliable test results.

(g) Failure to permit an inspection under this subsection will result in the suspension of Medicare and Medicaid payments to the laboratory, or termination of the laboratory's participation in Medicare and Medicaid for payment, and suspension of or action to revoke the laboratory's CLIA certificate in accordance with subpart R.

**§ 493.1780 Condition: Inspection of accredited and State-exempt laboratories.**

(a) HHS or its designee will conduct unannounced, random validation inspections of any accredited or State-exempt laboratory at any time during its hours of operation.

(b) HHS or its designee will conduct unannounced complaint inspections of an accredited or State-exempt laboratory at any time during its hours of operation upon receiving a complaint about that laboratory.

(c) The laboratory may be required, as part of either of the above inspections, to—

(1) Test samples (including proficiency testing samples) or perform procedures as required by HHS or its designee;

(2) Allow HHS or its designee to interview all employees of the laboratory concerning the laboratory's compliance with the applicable requirements of part 493;

(3) Permit employees to be observed performing tests (including proficiency testing specimens), and performing data analysis and reporting activities; and

(4) Permit HHS or its designee access to all areas of the facility including—

(i) Specimen procurement and processing areas;

(ii) Storage facilities for specimens, reagents, supplies, records, and reports; and

(iii) Testing and reporting areas; and

(5) Provide copies to HHS of all records and data required under these requirements.

(d) The laboratory must have all records and data accessible and retrievable within a reasonable time during the inspection.

(e) The laboratory must retain—

(1) Immunohematology records for a period of not less than 5 years, in accordance with 21 CFR part 606, subpart I;

(2) Pathology test reports for at least 10 years after the date of reporting, as required in 493.1109; and

(3) All other laboratory records for at least 2 years unless otherwise specified in part 493.

(f) The laboratory must provide, upon request, all information and data needed by HHS to make a determination of compliance or noncompliance with the applicable requirements of part 493.

(g) Failure to permit an inspection under this subsection will result in the suspension of Medicare and Medicaid payments to the laboratory or termination of the laboratory's Medicare and Medicaid approval for payment; and suspension of or action to revoke the laboratory's CLIA certificate of accreditation in accordance with subpart R of this part.

**Subpart T—Consultations**

**§ 493.2001 Establishment and function of the Clinical Laboratory Improvement Advisory Committee.**

(a) HHS will establish a Clinical Laboratory Improvement Advisory Committee to advise and make recommendations on technical and scientific aspects of the provisions of this part 493.

(b) The Clinical Laboratory Improvement Advisory Committee will be comprised of individuals involved in the provision of laboratory services,

utilization of laboratory services, development of laboratory testing or methodology, and others as approved by HHS.

(c) HHS will designate specialized subcommittees as necessary.

(d) The Clinical Laboratory Improvement Advisory Committee or any designated subcommittees will meet as needed, but not less than once each year.

(e) The Clinical Laboratory Improvement Advisory Committee or subcommittee, at the request of HHS will review and make recommendations concerning:

(1) Criteria for categorizing tests and examinations of moderate and high complexity;

(2) Categorization of waived tests;

(3) Personnel standards;

(4) Patient test management, quality control, quality assurance standards;

(5) Proficiency testing standards;

(6) Applicability to the standards of new technology; and

(7) Other issues relevant to part 493, if requested by HHS.

(f) HHS will be responsible for providing the data and information, as necessary, to the members of the Clinical Laboratory Improvement Advisory Committee.

**PART 494—CONDITIONS FOR COVERAGE OF PARTICULAR SERVICES**

N. Part 494 is amended to read as follows:

1. The authority citation for part 494 is revised to read as follows:

**Authority:** Secs. 1833(a)(2)(E), 1834, 1861, 1862(a), 1863, 1864(a), 1865(a), 1902(a)(9)(C), and 1915(a)(1)(B)(ii)(I) of the Social Security Act (42 U.S.C. 13951(a)(2)(E), 1395m, 1395x, 1395y(a), 1395z, 1395aa(a), 1395bb(a), 1396a(a)(9)(C), and 1396n(a)(1)(B)(ii)(I)).

**Subpart B—Conditions for Coverage of Screening Mammography**

2. Section 494.51 is revised to read as follows:

**§ 494.51 Conditions for coverage: Compliance with Federal, State, and local laws and regulations.**

(a) The supplier of screening mammography services must comply with all applicable Federal, State, and local laws and regulations pertaining to radiological services and screening mammography services. This includes—

(1) Licensure or registration of supplier;

(2) Licensure or registration of personnel;

(3) Licensure or registration of equipment; and

(4) Compliance with health and safety requirements.

(b) In addition, if the supplier of screening mammography services also provides laboratory services, these services must be provided in accordance with the applicable requirements of part 493 of this chapter. If the supplier of screening mammography services chooses to refer specimens for testing to another laboratory, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements or part 493 of this chapter.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: December 30, 1991.

**James O. Mason,**  
*Assistant Secretary for Health.*

Dated: December 30, 1991.

**Gail R. Wilensky,**  
*Administrator, Health Care Financing Administration.*

Approved: January 23, 1992.

**Louis W. Sullivan,**  
*Secretary.*

[FR Doc. 92-4053 Filed 2-20-92; 12:26 pm]

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# **Federal Register**

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Friday  
February 28, 1992

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## **Part III**

# **Department of Health and Human Services**

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**Health Care Financing Administration  
Public Health Service**

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**42 CFR Part 493  
Clinical Laboratory Improvement  
Amendments of 1988; Final Rules and  
Notice**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Health Care Financing Administration****42 CFR Part 493**

[HSQ-177-FC]

RIN 0938-AE28

**Clinical Laboratory Improvement Act Program Fee Collection****AGENCY:** Health Care Financing Administration (HCFA), HHS.**ACTION:** Final rule with comment.

**SUMMARY:** This rule implements provisions of section 353 of Public Health Service Act (as amended by the Clinical Laboratory Improvement Amendments of 1988). Those provisions require laboratories to pay fees for issuance of registration certificates, certificates of waiver, certificates of accreditation, or certificates and to fund activities to determine compliance with the requirements established by the Department of Health and Human Services for laboratory testing. It also establishes the policy that laboratories licensed by and located in States with licensure programs approved by HHS may be exempt from the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). This rule also establishes the methodology used to determine the amount of the fees charged for certificates of waiver, registration certificates, certificates of accreditation, or certificates and activities to establish application procedures and determine compliance with applicable certification requirements.

**DATES:** *Effective date:* These regulations are effective March 30, 1992. They are being issued as a final rule with comment for reasons explained under "Supplementary Information," in section VII, "Final Rule with Comment Period."

*Comment period:* We will accept comments on the collection of fees related to State-exempt laboratories from the respective States. Comments on this issue only will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on April 28, 1992.

**ADDRESSES:** *Comments:* Mail written comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HSQ-177-FC, P.O. Box 26676, Baltimore, MD 21207.

If you prefer, you may deliver your comments to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201, or  
Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland 21207.

Due to staffing and resource limitations, we cannot accept audio or video comments or facsimile (FAX) copies of comments. In commenting, please refer to file code HSQ-177-FC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in room 309-G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 245-7890).

**Questionnaires:** While the law places the responsibility to apply for a certificate on the entity that conducts laboratory testing, to facilitate the initial phase of implementation, we have mailed questionnaire materials to all affected entities that we could identify to solicit initial information. If an entity that conducts laboratory testing has not yet received a questionnaire, write to the following address to obtain one: HCFA Laboratory, P.O. Box 26687, Baltimore, MD 21207.

**Copies:** To order copies of the **Federal Register** containing this document, send your request to the Government Printing Office, Attn: New Order, P.O. Box 371954, Pittsburgh, PA 15250-7954. Specify the date of the issue requested and stock number 069-001-00042-4. Enclose a check payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 783-3238 or by faxing to (202) 512-2250. The cost for each copy is \$3.50. In addition, you may view and photocopy the **Federal Register** document at most libraries designated as U.S. Government Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**. Ask the order desk operator for the location of the U.S. Government Depository Library nearest to you.

**FOR FURTHER INFORMATION CONTACT:** Jeffrey A. Clark (410) 966-6802.

**SUPPLEMENTARY INFORMATION:****I. Background****A. Federal Oversight**

Before the establishment of the Health Care Financing Administration (HCFA) in 1977 and the signing of an interagency

agreement, the Public Health Service (PHS) was responsible for the administration of the Clinical Laboratories Improvement Act of 1967 (CLIA '67). Currently, HCFA has inspection and administrative responsibility for both the Medicare and CLIA programs. HCFA and PHS have the joint responsibility for the development of the Federal requirements for laboratories. Within the PHS, the Centers for Disease Control (CDC) and the Food and Drug Administration (FDA) provide technical and scientific expertise in the establishment of regulations.

**B. Legislative History**

Prior to the enactment of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, laboratories engaged in testing specimens in interstate commerce were required, under CLIA '67, to meet the requirements of section 353 of the Public Health Service Act (42 U.S.C. 263a). In October 1988, Public Law 100-578 amended section 353 of the Public Health Service Act (PHSA) to expand the authority for the regulation of laboratories, with some provisions having varying effective dates depending on whether or not the laboratory was subject to CLIA '67 on December 31, 1988. The provisions that are the subject of this rule have the following effective dates: The fee provisions (section 353(m) of PHSA) are effective January 1, 1989 for all laboratories; the application provisions (section 353(d) of PHSA) are effective January 1, 1990 for all laboratories; the provision in section 353(g)(2) relating to inspection and the provision in section 353(f)(1)(C) relating to personnel qualifications are effective January 1, 1990 for laboratories that were subject to CLIA '67 on December 31, 1988, and on July 1, 1991 for all other laboratories.

Prior to the 1988 amendments, only those laboratories performing interstate testing were subject to the provisions of CLIA '67. CLIA '67 included a provision that authorized the Secretary of the Department of Health and Human Services (HHS) to collect fees from approved laboratories for the issuance and renewal of CLIA licenses. The fee was set at \$25 for each test category with a \$125 cap on the amount any laboratory would be required to pay. This fee was eliminated because the administrative costs required for collection exceeded the revenue derived from the fees.

The 1988 CLIA amendments require that any entity performing laboratory testing have a certificate, certificate of

accreditation, or certificate of waiver or be licensed by an approved State licensure program (that is, State-exempt) and comply with the standards for laboratory testing established by HHS. In addition, section 353(m) of the PHSA, as amended by CLIA, requires HHS to impose fees for the issuance and renewal of certificates, certificates of waiver, and accreditation certificates and for determining program compliance. Although the fee required for issuance and renewal of a certificate of waiver is to be only a nominal fee, the overall fees for certificates and certificates of accreditation must be sufficient to cover the general costs of administration incurred by HHS in carrying out the provisions of section 353 of the PHSA, including evaluating and monitoring approved proficiency testing programs and accreditation bodies and implementing and monitoring compliance with the requirements of section 353 of the PHSA. The fee imposed for determining compliance must also be sufficient to cover the costs incurred by HHS in inspecting laboratories that are not accredited. Section 353(m) also requires that the fees imposed vary by group or classification of laboratory, based on such considerations as HHS determines are relevant.

HHS is also required, under section 353(n) of the PHSA, to annually compile and make available to physicians and the general public information that HHS determines is useful in evaluating the performance of a laboratory. This information must include a listing of laboratories whose certificates have been revoked, suspended, or limited and those laboratories that have been subject to intermediate sanctions, exclusion from Medicare or Medicaid, injunctions, or withdrawal of accreditation. Additionally, sections 353(e)(2)(D) and 353(e)(3) of the PHSA require HHS to evaluate annually the performance of each approved accreditation body and submit an annual report to Congress that describes the results of that evaluation.

Section 6141 of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101-239) requires that laboratories participating in the Medicare program comply with CLIA requirements. Only laboratories that have a current unrevoked and unsuspended certificate of waiver, registration certificate, certificate, or certificate of accreditation, or are State-exempt will be eligible for reimbursement in the Medicare or Medicaid programs or both.

On August 3, 1990, we published our proposed rule (55 FR 31758) to

implement the certificate and fee requirements of CLIA.

## II. Implementation of CLIA

The following is a general explanation of our plan to implement CLIA, as well as CLIA's relationship to Medicare and Medicaid.

### A. Activities to Date

In order to implement CLIA, in addition to this final rule, we published three proposed rules. The three proposed rules are:

**HSQ-176-P Medicare, Medicaid and CLIA Programs: Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA)**

This proposed rule was published on May 21, 1990, with the comment period closing on September 21, 1990. It set forth our proposed requirements for laboratories that must be inspected, as well as the criteria for determining if a laboratory qualifies for a certificate of waiver. In addition, this proposed rule outlined how laboratories would be regulated as a function of the complexity of tests and their risk of harm to the patient if mistakes were made in testing. Provisions include requirements dealing with personnel, quality control, quality assurance, proficiency testing, and recordkeeping, among others. These provisions will also be used as the basis of comparison of State or private accreditation program requirements when organizations are seeking deemed status under the law or States are seeking an exemption. This regulation generated 60,000 comments. The final rule is published in this edition of the **Federal Register**.

**HSQ-179-P Medicare and Clinical Laboratory Improvement Amendment Programs: Enforcement Procedures for Laboratories**

This proposed rule, which was published on April 2, 1991, outlines how the Federal Government proposes to implement the provisions of section 1846 of the Social Security Act, as amended by section 4064(d) of the Omnibus Budget Reconciliation Act of 1987 and sections 353(h), (i), (j), (k), and (l) of the PHSA. This rule applies to laboratories that are subject to CLIA or that participate in Medicare/Medicaid. The final version of this proposed rule is published in this edition of the **Federal Register**.

**HSQ-181-P Clinical Laboratories Improvement Amendments Program: Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and State Licensure Agencies**

The CLIA law (at sections 353(e) and (p) of the PHSA) permits States and private, nonprofit accreditation organizations to seek our approval of their programs. A laboratory that is accredited by an approved State or private accreditation program would be "deemed" to meet CLIA requirements. (Note that, as a change from the requirements outlined in HSQ-177-P, a laboratory licensed in a State whose licensure program is approved would be exempt from CLIA requirements). The proposed rule, published on August 20, 1990, with the comment period closing on October 19, 1990, sets forth the criteria we would use to approve and to withdraw approval of State or private accreditation programs.

### B. Sequence of Implementation Events

CLIA requires that all laboratories in the United States subject to its provisions be regulated by the Federal Government. Regulation is mandated regardless of whether or not a laboratory is being reimbursed for services by the Federal or State government. CLIA legislation requires that such regulation focus on the issuance of a certificate, without which a laboratory may not legally test human specimens for the purpose of "providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings." The publication of this final rule concerning application procedures and fee schedules is a first step in the full implementation of CLIA. After considering comments received in response to the proposed rule, we have decided to adopt the following implementation plan.

#### 1. Mailing of Questionnaire

The law requires every laboratory subject to the provisions of CLIA to hold a certificate issued by HCFA. Initially, we sent a questionnaire to entities performing laboratory testing soliciting basic information concerning the name and address of the laboratory, the type of ownership, type of facility, name of director, types of personnel, test volume by specialty and subspecialty, and test methodologies and reagents. All laboratories subject to CLIA must complete the questionnaire so that HCFA is provided with information on laboratories performing testing that can

be used by HCFA to develop a database.

To determine the entities that received the questionnaire, HCFA took a number of actions. These included mailings to professional groups and State licensing components to request their assistance in identifying facilities affected by CLIA, and advertising (through a variety of trade periodicals and special interest journals) our implementation of the CLIA law and instructions for laboratories to follow to obtain the necessary certificate. If a facility performing laboratory testing has not received a questionnaire from HCFA, it is the responsibility of the facility to request a questionnaire from HCFA. This request should be made to the address previously indicated.

## 2. Mailing of Applications and Bills

After receipt of the completed questionnaire and publication of the standards rule, HSQ-176-F, we will send an application and a bill for the certificate fee (based on the volume of testing indicated on the questionnaire) to each laboratory that we believe (based on the information provided in response to the questionnaire) is subject to the requirements of CLIA. Mailing after publication of the final standards rule will allow laboratories sufficient time to review the standards and criteria established by HSQ-176-F and determine whether they want to continue testing based on the standards.

## 3. Issuance of Registration Certificate or Certificate of Waiver

Upon receipt of the completed application and fee, we will issue a registration certificate or certificate of waiver. (In this final rule, we are using the term "registration" certificate(s) in place of "provisional" certificate(s) in order to accurately reflect the fact that this type of certificate represents only the registration of the laboratory and does not indicate a certification of quality. This change is reflected throughout the preamble and regulation.) If upon review of the information provided by a laboratory in the application, we determine the laboratory qualifies for a certificate of waiver, we will issue a certificate of waiver to the laboratory instead of a registration certificate. If we find that the fee amount that the laboratory was billed and paid is greater than the fee for a certificate of waiver, a refund of the difference will be made to the laboratory. No fees will be collected from existing laboratories electing to discontinue laboratory testing before the effective date of the standards rule HSQ-176.

The registration certification indicates that the laboratory has properly registered with the government and is legally entitled to test human specimens and to conduct business and agrees to comply with CLIA requirements. The registration certificate will remain in effect for up to 2 years, although the registration certificate may be re-issued if additional time is necessary for HHS to conduct an inspection; or pending an appeal. This will ensure that the laboratory has a valid certificate authorizing the testing of human specimens. The registration certificates will be effective until we are able to conduct inspections, approve State programs and private accreditation programs (deemed status), and determine which laboratories qualify for certificates.

## 4. Final Implementation Steps

As final implementation steps, we will:

- Approve (or disapprove) private nonprofit accreditation programs for deemed status.
- Approve (or disapprove) State licensing programs for exemption of their laboratories from the requirements of CLIA.
- Communicate with all laboratories that hold registration certificates, instructing them on how to apply for a regular certificate, certificate of waiver, or certificate of accreditation, whichever applies. The laboratory will be billed for the appropriate certificate and compliance fees and, if an inspection to determine compliance is necessary, it will be scheduled and conducted. The laboratory will be required to submit the billed amount to HHS prior to the determination of compliance (including inspection). The inspection, if required, will be performed generally by State surveyors who will determine, with the assistance of guidelines developed by us, if the laboratory successfully meets CLIA's requirements. If the State survey agency determines that the laboratory meets CLIA's requirements, it will recommend that we issue a certificate. This (regular) certificate indicates that the laboratory has demonstrated that it has met all of the conditions and standards outlined in CLIA. A laboratory that meets the requirements for a certificate of waiver and has submitted the appropriate fee will not be subject to routine inspection.
- Implement procedures for the reissuance of certificates upon expiration. A certificate will be valid not more than for 2 years. Prior to the expiration date of the certificate, HHS will send an application to the laboratory and collect the necessary

fee(s), and the compliance determination survey cycle and certificate issuance will be repeated.

- Establish and maintain a computer system to manage the above processes.
- Implement the system of alternative sanctions and enforcement procedures described in the law and the final version of HSQ-179.
- Continue to conduct the mandated studies and make reports to Congress concerning the implementation of CLIA

## C. Implementation of Certificates of Accreditation

If, after HHS has approved accreditation programs, a registered or certified laboratory seeks a certificate of accreditation, the laboratory must show proof of accreditation by an approved private accreditation body or proof that the laboratory has applied for such accreditation. We will allow the laboratory up to 11 months to receive accreditation. If the laboratory is not accredited by then, we will notify the laboratory that it is subject to Federal inspection, and include a bill for the inspection costs. We believe 11 months from the time application for accreditation is made is adequate time for accreditation to take place.

While the approved accreditation body will bill the laboratory separately for its inspection and any other fees applicable, we will send an accredited laboratory a bill for a registration certificate (if necessary) and/or a certificate of accreditation to cover our administrative costs and the costs of monitoring the performance of approved private accreditation bodies as required by CLIA.

## D. State-Exempt Laboratories

If a laboratory is licensed by and located in a State that has had its licensure and inspection program approved by HHS under section 353(p) of the PHSA, the laboratory is exempt from CLIA's requirements and, therefore, need not apply for certification, pay any certificate fee(s), or undergo a routine onsite CLIA compliance determination survey. These "State-exempt" laboratories are subject, however, on a sample basis, to surveys to determine the extent and appropriateness of the State's licensing criteria. For purposes of establishing a user fee amount for this activity, we considered 5 percent of the State-exempt laboratories an appropriate sample size. State-exempt laboratories will not receive certificates or pay fees. Rather, HHS may assess their State licensing programs fees for all validation

surveys conducted and any follow-up visits that may be necessary.

### III. Provisions of the Proposed Rule

We proposed to implement section 353(m) of the PHSA by establishing regulations at 42 CFR part 493, subpart F. We proposed the requirements all laboratories must meet in order to apply for and be issued a certificate under CLIA and proposed the methodology for determining the amount of the fees for issuing provisional certificates, certificates, certificates of waiver, and certificates of accreditation, and for the proposed fee schedules for determining compliance with the standards.

We proposed, in § 493.606, that part 493, subpart F would apply to all entities that perform laboratory testing, except that it would not apply to any component or function of a laboratory that has been certified by the National Institute on Drug Abuse (NIDA) under Executive Order 12564 and section 503 of Public Law 100-71 for the performance of forensic urine drug testing or to laboratories that perform research testing on human specimens but do not report patient specific results for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, an individual patient. If a laboratory conducts both NIDA certified forensic urine drug testing and other laboratory tests, the laboratory would be subject both to NIDA certification for the forensic urine drug testing and these rules for all other tests, including other urine drug testing, performed by the laboratory.

We proposed, in § 493.610, to prohibit solicitation or acceptance of materials derived from the human body for laboratory examination or other procedure unless the laboratory has an effective provisional certificate issued by HHS or a certificate, certificate of waiver, or certificate of accreditation issued by HHS applicable to the specialty or subspecialty of services offered by the laboratory.

In § 493.614, we proposed the procedure a laboratory must follow to obtain a provisional certificate, certificate, certificate of accreditation, or certificate of waiver. We proposed to require that a separate application be made for each laboratory location using a form(s) prescribed by HHS and that the application be signed by the owner, operator, or authorized representative of the laboratory.

Based on section 353(d)(1)(A) of the PHSA, the application would require information that describes the characteristics of the test procedures

and examinations performed by the laboratory including—

(a) The names of the test procedures and examinations performed and the total number of test procedures and examinations performed annually;

(b) The methodologies for the test procedures and examinations performed; and

(c) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the test procedures and examinations.

We specifically requested public comment on ways to minimize the reporting burden for laboratories, both in initial applications and in updating certificates, while meeting the legislative requirements.

We proposed, in § 493.618, to require that, in submitting an application for a provisional certificate, a certificate of waiver, certificate of accreditation, or a certificate, a laboratory must agree to the following:

(a) To make records available and submit reports to HHS as HHS may require.

(b) To permit routine inspections by HHS as specified in subpart N of part 493, except that the effective date of this requirement for laboratories not subject to section 353 of the PHSA as in effect on December 31, 1988, is July 1, 1991. This requirement would not apply to laboratories issued certificates of waiver.

(c) Except for certificate of waiver laboratories, to treat proficiency testing samples in the same manner as it treats materials derived from the human body referred to it for laboratory examinations or other test procedures in the ordinary course of business.

(d) To provide HHS with satisfactory assurances, through an attestation statement signed by the laboratory owner, operator, or authorized representative, that the laboratory will be operated in accordance with the requirements established by the Secretary under section 353 of the PHSA.

We proposed, in § 493.622, that if HHS denies a laboratory's application for a provisional certificate, certificate, certificate of accreditation, or certificate of waiver or limits its applicable certificate, the laboratory would be given a statement of the grounds on which the denial or limitation is based and an opportunity for a hearing in accordance with procedures set forth in part 498.

We also proposed that if a laboratory that is seeking a certificate of any kind for the first time has its application denied or the applicable certificate

limited, it would not be able to conduct business as a laboratory under the PHSA unless the denial or limitation is overturned at the conclusion of the administrative appeals process.

As mentioned in section II.B, we plan to implement interim procedures and policy for the issuance of certificates and collection of fees until we are able to fully implement the requirements of CLIA. In § 493.626 we proposed to issue a provisional certificate to each laboratory that was not licensed under section 353 of the PHSA as in effect on December 31, 1988, provided that the laboratory meets the application requirements and pays the applicable fee. Following the full implementation of CLIA, upon payments of the provisional certificate fee, a provisional certificate would be issued initially to any new laboratory not eligible for a certificate of waiver, including a laboratory that is seeking accreditation, to permit the laboratory to test specimens and to allow time for HHS to determine compliance with the CLIA standards.

We also proposed that a provisional certificate would be valid for a period of not more than 2 years. If necessary, a provisional certificate would be reissued until such time as an inspection to determine program compliance can be conducted or the laboratory demonstrates it qualifies to receive a certificate of waiver or certificate of accreditation. We also proposed that the provisional certificate would not be renewable. However, HHS would reissue a provisional certificate to any laboratory that HHS or its designee has not had an opportunity to evaluate for compliance with the requirements for certification.

We proposed that, prior to expiration of the provisional certificate, HHS would notify the laboratory of the requirements to obtain the appropriate certificate. If a laboratory fails to comply with the applicable requirements as specified in the notification, HHS would suspend or deny Medicare payments, if applicable, and initiate revocation or limitation of a laboratory's provisional certificate and would deny the application for a certificate, certificate of accreditation, or certificate of waiver. In this case, HHS would provide the laboratory with a statement of the grounds on which the revocation and denial is based and with an opportunity for a hearing. If the laboratory requests a hearing, the expiration date of the provisional certificate would be extended until a hearing decision by an Administrative Law Judge (ALJ) is issued. The Medicare payments would be suspended or

denied pending the hearing decision because the Act authorizes termination of payments under Medicare for those laboratories that fail to meet the requirements, with the opportunity for a hearing to occur subsequent to payment suspension or denial. Under CLIA, laboratories that do not meet the requirements would be notified of the basis for noncompliance determination and offered an opportunity for a hearing prior to any adverse action, unless HHS determines that the laboratory's deficiencies are such that they constitute an imminent and serious threat to human health.

In § 493.630, we proposed to issue a certificate to each laboratory that was licensed under CLIA '67 as of December 31, 1988 provided the laboratory meets the application requirements and pays the applicable fees.

In § 493.631, we proposed the requirements for certificates of waiver and, in § 493.632, we proposed the requirements for certificates of accreditation.

We proposed that the certificate, certificate of waiver, or certificate of accreditation issued would be applicable to only those test procedures and examinations performed by the laboratory that were included on the laboratory's application. In accordance with section 353(b) of the PHSA, a laboratory may not perform any test procedure or examination within a specialty or subspecialty that is not included on the laboratory's certificate, certificate of waiver, or certificate of accreditation. Laboratories must notify HHS prior to the performance of any test not included as a waiver test for performance by certificate of waiver laboratories or any test not included on the laboratory's certificate. A laboratory may not perform any "new" test or examination until it has requested and been issued an appropriate revised certificate that covers the examination or procedure. Additionally, we proposed that the laboratory must notify HHS or its designee within 6 months of any deletions and/or changes in methodologies for any test procedure or examination for which the laboratory has been issued a certificate, certificate of waiver, or certificate of accreditation.

We also proposed that HHS will initiate revocation or limitation of a laboratory's certificate, certificate of waiver, or certificate of accreditation for failure to comply with applicable requirements. For those laboratories that were licensed under CLIA '67 or participate in the Medicare or Medicaid programs, the applicable health and safety requirements are contained in part 493. The applicable health and

safety requirements implementing CLIA will be published in a separate rulemaking. If a determination is made that the laboratory is not in compliance with applicable requirements, the laboratory would be given a statement of grounds on which the revocation or limitation action is based and an opportunity for a hearing. The effective date of the revocation or limitation would not be earlier than the date of decision by an ALJ, unless we find that conditions at the laboratory pose an imminent and serious risk to human health. In such cases, we would suspend or limit the laboratory's certificate before the hearing is held. Failure to meet the applicable requirements could also result in loss of Medicare approval or intermediate sanctions to be specified in a separate proposed rule.

In the interest of administrative efficiency, we proposed in § 493.634 that a laboratory must notify HHS or its designee within 30 days if changes occur in the laboratory's ownership, name, location, or director.

In § 493.638, we proposed that a laboratory must pay a fee for the issuance of a provisional certificate, certificate of waiver, certificate of accreditation, or a certificate, as applicable. We proposed that the total fees collected must be sufficient to cover the general cost of administering the laboratory certification program, including evaluating and monitoring proficiency testing programs and accreditation bodies and implementing and monitoring compliance with section 353 of the PHSA. For a certificate of waiver, the fee includes the cost of issuing a certificate of waiver, collection of fees, and analyzing applications to determine if a laboratory should be issued a certificate of waiver. For a certificate of accreditation, the fee includes the cost of issuing a certificate of accreditation, collection of fees, and analyses of standards and administrative policies of programs of accrediting organizations. The fees for the issuance of a provisional certificate, certificate of waiver, certificate of accreditation, or certificate will be assessed biennially. (Our proposed methodology for determining the amounts of the fees is discussed later in this preamble.)

We also proposed that the fee would be set annually on a calendar year basis and would be based on schedules, or ranges, of laboratory test volume and scope of specialties tested, with the amounts of inspection fees in each schedule a function of the average hourly rates for the required activities and the average length of time required for the activity. The amount of the fee

applicable to the issuance of a provisional certificate or to the issuance or renewal of a certificate would be the fee amount in effect at the time the application is received. Upon receipt of an application for a provisional certificate or an application (or renewal request) for a certificate, certificate of waiver, or certificate of accreditation, we would send the laboratory a notice advising it of the amount of the fee. We also stated our intent to inform the public of the fee amounts each year by publishing a notice containing that information in the *Federal Register*.

In § 493.639, we proposed that if after a certificate, certificate of accreditation, or a certificate of waiver is issued a laboratory adds services and requests that its certificate or certificate of accreditation be upgraded, or certificate of waiver be changed or eliminated, the laboratory must pay a fee to cover the cost of issuing an appropriate revised certificate. We proposed to base this fee on the actual cost to issue the revision to the laboratory. (Note that an additional fee is also required under § 493.643(e) if it is necessary to fund activities to determine compliance with additional requirements.)

In § 493.643, we proposed that a laboratory that was licensed under section 353 of the PHSA as of December 31, 1988 must pay a fee to cover the cost of determining program compliance. We also proposed that effective July 1, 1991, the other laboratories would be subject to a fee to determine their compliance with Federal requirements. We would not begin collecting this fee from these laboratories, however, until applicable criteria and standards are established in final regulations. Further, the laboratory would not be assessed this fee if it qualifies for a certificate of waiver or certificate of accreditation. We proposed to include in this fee the cost of: conducting onsite surveys, evaluating qualifications of personnel, monitoring proficiency testing, documenting deficiencies, evaluating laboratories' plans to correct deficiencies, and State and Federal surveyor preparation for and attendance at ALJ hearings. Laboratories will not be required to pay the cost of investigating followup surveys and sanction activities if allegations are not substantiated. Although the amount of the fee will be determined annually, inspections will be conducted biennially. Therefore, the fee covers a 2-year period. The proposed methodology used to determine the amount of the fee is discussed later in this preamble.

For purposes of determining the amount of the fee a laboratory that must

be inspected must pay, we proposed to initially establish ten fee schedules. The schedules have been established based on the experience of Federal laboratory surveyors and other experts in HCFA to estimate appropriate parameters for classifying laboratories. In addition, we analyzed data from the Federal government's national data base that captures facility-specific information on laboratories, in an attempt to establish parity among the ten schedules listed.

We analyzed the various sizes and workloads of laboratories that are currently participating in the Medicare/Medicaid program and concluded that the average costs to inspect laboratories of various sizes are represented by the benchmarks set forth. These are averages based on a relatively limited amount of experience since the universe of the total number of regulated laboratories will eventually be much greater. We proposed that, as we obtain experience in future years, we will analyze the data and develop new estimates.

We proposed to define a test as a test procedure or examination for a single analyte. Each profile (that is, group of tests) would be counted as the number of separate procedures; for example, a chemistry profile consisting of 18 tests would be counted as 18 separate test procedures or examinations. We specifically invited comments on the appropriateness of the number of specialties and tests we plan to use as thresholds. We also invited comments on our definition of a test and its feasibility, particularly in the area of quantitative testing.

We also proposed that, for purposes of determining a laboratory's fee schedule classification, the specialties and subspecialties currently used for Medicare, Medicaid, and CLIA '67 would be used initially to describe a laboratory's services.

We also proposed that, if after a certificate is issued, a laboratory adds services and requests that its certificate be upgraded, the laboratory must pay an additional fee if, in order to determine compliance with additional requirements, it is necessary to conduct an inspection, evaluate personnel, or monitor proficiency testing participation. We proposed to base the additional fee on the actual resources

and time necessary to perform the activities.

In § 493.645, we proposed that, in addition to the certificate fee, a laboratory that is issued a certificate of accreditation would also be assessed a fee to cover the cost of evaluating individual laboratories to determine overall whether an accreditation program's standards and inspection policies are equivalent to the Federal program. An annual random sample of 5 percent of all accredited laboratories would be inspected in order to compare inspection findings of HHS or its agents with the findings of the accreditation organizations. All accredited laboratories would share in the cost of these inspections. These costs are the same as those that would be incurred when inspecting nonaccredited laboratories.

Additionally, we proposed that if, in the case of a laboratory that has been issued a certificate of accreditation, it is necessary to conduct a complaint investigation, impose sanctions or conduct a hearing, the affected laboratory would be assessed a fee to cover the cost of these activities. Sanction activity costs for State surveyors and sanction activity costs for the Federal Government (which include testimony of Federal experts and costs for ALJs and attorney representation) would be in addition to the certificate of accreditation fee. If a complaint investigation results in a complaint being unsubstantiated or if an HHS adverse action is overturned at the conclusion of the appeals process, the cost of the inspection would not be imposed upon the laboratory. The inspection fee for the complaint investigation would not be assessed until after a laboratory concedes the existence of the deficiencies or an ALJ rules in favor of HHS.

In § 493.646, we proposed to notify laboratories by mail of the appropriate fee(s) and instructions for submitting the fee(s), including the due date for payment and the United States Department of Treasury designated commercial bank to which payment must be made. These fees, when finally calculated, would be nonrefundable, and provisional certificates, certificates of waiver, certificates of accreditation, and certificates would not be issued until the applicable fees have been paid.

Three different entities perform activities related to the issuance or renewal of the various types of certificates and determining program compliance. They are: State survey agencies, Federal agencies, and HHS contractors. In § 493.649, we proposed to establish fee amounts fixed to the schedule in which the laboratory falls, which is related to the average hourly rates established for these three entities and to the average number of hours required to perform the activities. We also proposed the costs to be included in establishing the average hourly rate.

We proposed that the number of hours used to determine the overall fee in each of the schedules initially would be HCFA's estimate of the average time needed by each entity to perform the activities for which it is responsible. We asked for comments from all laboratories on the methodology proposed for establishing the fee amounts for determination of compliance because we propose to use the same methodology to determine fees for laboratories that were not subject to CLIA '67 but will be subject to CLIA '88 determinations of compliance. We also proposed that, as we gain experience using the schedules, we would consider appropriate adjustments to the methodology for assessing fees to ensure that each laboratory is charged the fee amount related to the time and resources needed to determine the laboratory's compliance with the requirements.

On the basis of this methodology, we proposed a fee of \$261 for issuing a provisional certificate or a certificate to each laboratory, regardless of its relative size. We also proposed this same fee for issuing a revised certificate. (We are changing this approach in this final rule by stipulating that the fee a laboratory must pay for a registration certificate or a certificate will depend upon the laboratory's scope and volume of testing. A discussion of this change is contained in section IV of this preamble in response to comments under § 493.638, "Registration Certificate and Certificate Fees.")

We proposed that, under the proposed methodology, the average time and cost required to determine compliance during fiscal year 1991 would be as follows:

	Hours	Average <sup>1</sup> hourly rate	Biennial user fee
Schedule A Laboratories:			
Biennial inspection *	24	\$35	\$840
Followup visit or complaint investigation.....	15	35	525

	Hours	Average <sup>1</sup> hourly rate	Biennial user fee
Sanctions/Hearings.....	8	35	280
Schedule B Laboratories:			
Biennial inspection <sup>2</sup> .....	32	35	1,120
Followup visit or complaint investigation.....	17	35	595
Sanctions/Hearings.....	9	35	315
Schedule C Laboratories:			
Biennial inspection <sup>2</sup> .....	40	35	1,400
Followup visit or complaint investigation.....	19	35	665
Sanctions/Hearings.....	10	35	350
Schedule D Laboratories:			
Biennial inspection <sup>2</sup> .....	47	35	1,645
Followup visit or complaint investigation.....	21	35	735
Sanctions/Hearings.....	11	35	385
Schedule E Laboratories:			
Biennial inspection <sup>2</sup> .....	54	35	1,890
Followup visit or complaint investigation.....	24	35	840
Sanctions/Hearings.....	12	35	420
Schedule F Laboratories:			
Biennial inspection <sup>2</sup> .....	61	35	2,135
Followup visit or complaint investigation.....	26	35	910
Sanctions/Hearings.....	13	35	455
Schedule G Laboratories:			
Biennial inspection <sup>2</sup> .....	68	35	2,380
Followup visit or complaint investigation.....	28	35	980
Sanctions/Hearings.....	14	35	490
Schedule H Laboratories:			
Biennial inspection <sup>2</sup> .....	75	35	2,625
Followup visit or complaint investigation.....	30	35	1,050
Sanctions/Hearings.....	15	35	525
Schedule I Laboratories:			
Biennial inspection <sup>2</sup> .....	82	35	2,870
Followup visit or complaint investigation.....	32	35	1,120
Sanctions/Hearings.....	16	35	560
Schedule J Laboratories:			
Biennial inspection <sup>2</sup> .....	The sum of 82 hours plus 7 hours for each additional 500,000 tests or portion thereof multiplied by a \$35 hourly rate.		
Followup visit or complaint investigation.....	The sum of 32 plus 2 hours for each additional 500,000 tests or portion thereof multiplied by a \$35 hourly rate.		
Sanctions/Hearings.....	The sum of 16 hours plus 1 hour for each additional 500,000 tests or portion thereof multiplied by a \$35 hourly rate.		

<sup>1</sup> Average hourly rates and user fees are shown since individual contracts are negotiated with 53 State survey agencies. The actual user fee for determining compliance would depend upon the State in which the laboratory is located. The \$35 hourly rate is based on total surveyor time, which includes the time surveyors are not involved in activities directly related to determinations of compliance. The unit cost budget methodology is based on actual surveyor time to conduct compliance evaluations, which is about \$27 per hour. We add an adjustment of \$8 per hour to cover surveyor costs for holidays, vacation, sick leave, and attendance at training courses. Therefore, the cost of these other work-related activities has been included in the user fee methodology.

<sup>2</sup> Includes evaluating qualifications of personnel; monitoring proficiency testing; conducting onsite surveys; developing deficiency statements; and evaluating laboratories plans to correct deficiencies.

(Note that this final rule contains a change concerning compliance inspections of State-exempt laboratories that is discussed, in section IV of this preamble, in response to comments on § 493.645. Also, note that this final rule adds a new category within Schedule A for those laboratories performing no more than 2,000 laboratory tests per year. The fee associated with determining compliance for this category during FY 1992 is \$300.)

We proposed that, under the proposed methodology, the fee that a laboratory issued a certificate of accreditation would pay<sup>1</sup> in fiscal year 1991 to share

<sup>1</sup> Includes evaluating qualifications of personnel; monitoring proficiency testing; conducting onsite surveys; developing deficiency statements; and evaluating laboratories plans to correct deficiencies.

the cost of the 5 percent random inspections discussed earlier would be:

Schedule A Laboratories.....	\$42
Schedule B Laboratories.....	58
Schedule C Laboratories.....	70
Schedule D Laboratories.....	82
Schedule E Laboratories.....	95
Schedule F Laboratories.....	107
Schedule G Laboratories.....	119
Schedule H Laboratories.....	131
Schedule I Laboratories.....	144
Schedule J Laboratories.....	( <sup>1</sup> )

<sup>1</sup> Schedule I base fee plus \$12 for each additional 500,000 tests or portion thereof.

(Note that this final rule contains a change concerning responsibility for the cost of compliance inspections of State-exempt laboratories that is discussed in section IV of

this preamble in response to comments on § 493.645.

We proposed that, under the proposed methodology, the average fee that a laboratory issued a certificate of accreditation would pay, if it is necessary to perform the following activities in the case of that particular laboratory during fiscal year 1991, would be:

Follow-up visits or complaint investigations:

Schedule A Laboratories.....	\$25
Schedule B Laboratories.....	595
Schedule C Laboratories.....	665
Schedule D Laboratories.....	735
Schedule E Laboratories.....	840

Schedule F Laboratories.....	910
Schedule G Laboratories.....	980
Schedule H Laboratories.....	1,050
Schedule I Laboratories.....	1,120
Schedule J Laboratories.....	( <sup>1</sup> )

<sup>1</sup> Schedule I base fee plus \$70 for each additional 500,000 tests or portion thereof.

**Sanctions/Hearing:**

Schedule A Laboratories.....	\$280
Schedule B Laboratories.....	315
Schedule C Laboratories.....	350
Schedule D Laboratories.....	385
Schedule E Laboratories.....	420
Schedule F Laboratories.....	455
Schedule G Laboratories.....	490
Schedule H Laboratories.....	525
Schedule I Laboratories.....	560
Schedule J Laboratories.....	( <sup>1</sup> )

<sup>1</sup> Schedule I base fee plus \$35 for each additional 500,000 tests or portion thereof.

(Note that this final rule contains a change concerning the application of the above costs to State-exempt laboratories that is discussed in section IV of this preamble in response to comments on § 493.645.)

We proposed that the minimum fee that a laboratory would be required to pay for determination of program compliance would be the amount representing the biennial inspection costs in the aforementioned schedules. If the laboratory requires additional survey time as a result of followup visit(s), certificate revisions, complaint investigation(s) that are substantiated, intermediate sanctions, appeals or hearings, an additional assessment will be made for such activities.

**IV. Analysis of and Responses to Public Comments**

We received 93 comments in response to the proposed rule published August 3, 1990. Commenters included professional organizations, hospitals, home health agencies, medical and professional organizations, and individuals. While many of the commenters raised general concerns about the proposed application procedures and fee schedule, their major concerns pertained to the proposed regulations published in the *Federal Register* on May 21, 1990 (55 FR 20836) that would establish CLIA health and safety requirements based on the complexity of testing performed. The issues raised by commenters concerning tests and procedures that will be eligible for waiver or exclusion are addressed in the final rule and complexity list published elsewhere in this edition of the *Federal Register*. We have based our fees on our best estimates of the costs necessary to implement and administer the CLIA program. Once better data are available on the actual costs necessary to operate the CLIA program, we will adjust the fee schedules, as appropriate.

**General Comments**

*Comment:* A few commenters recommended that HCFA republish or "repropose" the proposed rule for user fees or postpone publication of the final rule until the proposed certification standards published May 21, 1990 (HSQ-176-P) are established. The commenters indicated that without knowledge of the certification standards establishing the regulatory framework applicable to all facilities performing testing, they could not provide meaningful comments on the proposed regulations governing fee schedules.

*Response:* Based upon concerns of the commenters, we have decided to wait until publication of the final CLIA laboratory standards (HSQ-176-F) before we collect fees. We will collect fees based upon the volume and scope of testing that laboratories perform. No fees will be collected from laboratories that elect to discontinue laboratory testing before the effective date of HSQ-176-F.

Also, to minimize the overall impact of this regulation on the laboratory community, we have: (1) Restructured the fee schedule by establishing, in Schedule A, a separate fee (\$300) for compliance inspections of low-volume laboratories that conduct 2,000 or fewer tests per year, and (2) revised the cost of issuing registration certificates and certificates from \$261 across-the-board to \$100, \$350, or \$600 depending on the scope and volume of laboratory testing.

**Section 493.602 Scope and Section 493.608 Applicability**

We received numerous inquiries questioning whether CLIA is applicable to laboratories that conduct testing only for forensic purposes. We have determined that CLIA does not apply to such entities provided that these entities do not conduct testing for "the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health, of human beings." This means that, generally, CLIA would not apply to law enforcement agencies that conduct such testing to determine whether there is a violation of the law. Specifically, the clear thrust of the CLIA legislative history is in seeing that medical diagnosis and treatment are based upon accurate and reliable laboratory test results, not that laboratory testing should be regulated outside the patient care context. However, if the entity conducts testing for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of

the health of, human beings, the entity would be subject to CLIA. The determining factor is not the test itself, but the purpose for which the test is conducted. We have revised proposed § 493.602 to clarify that the requirements of this rule apply to all laboratories "that test human specimens for health purposes."

*Comment:* One commenter suggested that it may be appropriate to conduct inspections of laboratories that are not under any regulatory agency but that hospitals that are accredited by the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) should not be subject to CLIA.

*Response:* CLIA authorizes the recognition of accreditation and State programs that have standards equal to or more stringent than the CLIA requirements. On August 20, 1990, we published in the *Federal Register* (55 FR 33938) proposed criteria for recognition of accreditation and State licensure programs. Once the CLIA requirements are published in final, including the health and safety standards and criteria for recognition of accreditation and State licensure programs, accreditation programs and State licensure programs will be able to apply for recognition under CLIA. Those programs with standards equal to or more stringent than CLIA will be recognized. A laboratory accredited by an approved accreditation program will be deemed to meet the CLIA requirements provided the laboratory submits an application, meets the application requirements, and pays the appropriate fee for a certificate of accreditation. Laboratories with certificates of accreditation will be subject to random inspections to monitor the accreditation organization standards with respect to their equivalency with CLIA requirements.

Further, in response to comments received on the August 20, 1990 proposed rule concerning recognition of accreditation and State programs, we reexamined the statutory provisions regarding State licensing programs. Section 353(p)(2) of PHSA specifies that, if a State enacts laws that provide for requirements equal to or more stringent than the CLIA statutory requirements or requirements of the regulations, the Secretary may exempt clinical laboratories in that State from the CLIA requirements. We have chosen to exercise that authority and will exempt from the requirements of CLIA laboratories located in States whose licensure programs are approved by HHS. Such "State-exempt" laboratories will not require certification by HHS and will not be subject to fees. We have

revised proposed § 493.610, "Registration certificate or certificate required for laboratories," to reflect this change. We have also changed the title of the section to "Certificate requirements for laboratories" to more accurately reflect the content of this section. State-exempt laboratories will be required to permit Federal inspectors to conduct inspections to ensure standards are being enforced in an appropriate manner. We have revised proposed § 493.602 to add that this rule sets forth the methodology for determining the amount of the fees for Federal validation of State-exempt laboratories. Further, we have revised proposed § 493.645, which concerns additional fees, to add that HHS assesses the State the costs of the validation inspections and its proportionate share of the general overhead costs for the development and implementation of CLIA. We have made this revision because we realize that laboratories in these States are exempt from all CLIA requirements, including the statute's fee provisions. At the same time, because the Congress expects us to recover all Federal CLIA expenses through the collection of fees, we realized that the costs of validation inspections for a CLIA-exempt laboratory had to be reflected in our fee structure. Accordingly, we concluded that such costs ought to be recovered through the assessment of fees from those States seeking Federal approval of their licensure programs under section 353(p) of the PHS Act. We view this agreement to pay such fees as a condition of our approval of such licensure programs. Whether States would in turn assess laboratories these fees is a matter that is beyond the scope of CLIA '88.

*Comment:* One commenter suggested that a laboratory that is enrolled in and acceptably participating in an independent or external commercial quality control program should be exempt from inspections and the fees for inspection. The commenter agreed that a fee for issuing certificates should be charged.

*Response:* With the exception of laboratories exempted by § 493.3 (published elsewhere in this issue of the Federal Register), every facility testing human specimens "for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings" is subject to CLIA. There is no provision in CLIA to exempt laboratories because they are enrolled and participate in a quality control program.

*Comment:* One commenter suggested that the fees paid for JCAHO accreditation and the inspection by the State for licensure should be accepted in total and in place of collecting any additional fees or conducting inspections under CLIA.

*Response:* Once CLIA is fully implemented, a laboratory that is accredited by an accreditation program that is approved by HHS will need to apply for a CLIA certificate of accreditation and pay the appropriate fee. All certificate fees include the Federal costs associated with establishing the CLIA requirements, conducting the studies mandated by CLIA, contractor-related costs, and costs for the implementation and operation of the CLIA program. In addition, HHS must recoup all costs associated with the monitoring of the approved private accrediting organization's performance in determining the laboratory's compliance with the CLIA requirements. CLIA requires that all certificate holders, including those which might have a certificate of accreditation, must share in the costs that the government incurs in administering the CLIA program.

A clinical laboratory located within a State that has had its licensing program approved by HHS (that is, a "State-exempt" laboratory) is not required to apply for a certificate. State-exempt laboratories are closely monitored by their State licensing program. However, like an accredited laboratory, a State-exempt laboratory may undergo a random survey to validate that the licensing program's standards and criteria continue to be applied appropriately. Unlike accredited laboratories, which must pay for their share of the costs of these sample validation surveys, State-exempt laboratories do not pay these costs to HHS. Rather, as stated above, HHS will assess the State for all costs associated with these surveys.

*Comment:* A few commenters indicated that, in consideration of costs, we should perform random inspections of laboratories or target inspections of laboratories that have been responsible for providing inaccurate results. The commenters noted that inspecting all the laboratories in the country would increase medical costs.

*Response:* Consistent with section 353(g)(2) of the PHS Act, once CLIA is fully implemented, we intend to conduct an inspection at least every 2 years of all laboratories issued a certificate. Laboratories with a certificate of accreditation or State-exempt laboratories are subject to random

validation inspections. However, no routine inspections are required for certificate of waiver laboratories.

*Comment:* One commenter recommended that, with the expanded level system, there should be a role for self certification by means of the application for the lower laboratory levels. The commenter stated that HHS should retain the right to inspect for cause or as part of a random survey, but the commenter saw no need for HHS to inspect every laboratory location during the initiation phase of the regulation.

*Response:* Because the statute requires that the Secretary undertake inspections, we could not adopt the system of self-certification suggested by the commenter. After an initial certificate is issued, we intend to conduct at least biennial inspections.

*Comment:* Several commenters indicated that home health agencies (HHAs) and hospices should be exempt from the CLIA requirements because HHAs and hospices are not clinical laboratories since these facilities typically perform screening procedures only or provide instructions to patients for performing self-administered tests. The commenters stated that the fees and requirements imposed by these regulations would have devastating effects on the budgets of HHAs. They also stated that the fee requirements, even those for certificates of waiver, combined with threatened cuts in Medicare payments and State budgets for Medicaid, will force HHAs to stop offering these patient services and assisting patients in the performance of self-administered tests in the home.

*Response:* Section 353 of the PHS Act applies to every facility testing human specimens "for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings \* \* \*." If an HHA or hospice performs testing for these purposes, we cannot exempt it from the CLIA requirements. On the other hand, we acknowledge that certain activities that involve testing are not within the range of concerns that the Congress had when it enacted CLIA. Specifically, we do not believe that the Congress had any wish to see us regulate, as laboratories, individuals who may be self-administering a test in their own home with an appliance that has been approved for that over-the-counter purpose by the Food and Drug Administration. Thus, to the extent that an HHA or hospice that is providing care in an individual's home is engaged solely in assisting an individual in performing a test, which if performed by

the individual would be beyond CLIA's reach, we have no intent to impose a CLIA fee on the HHA or hospice by virtue of that activity. If the HHA or hospice engages in testing outside this narrow context, however, section 353 of the PHSA also requires "payment of fees for the issuance and renewal of certificates, except that the Secretary shall only require a nominal fee for the issuance and renewal of certificates of waiver." After publication of the final CLIA standards regulation (HSQ-176-F), laboratories will be required to meet CLIA application requirements and pay the established fee for a certificate of waiver or registration certificate. The bases for the fee amounts are discussed in our responses to comments under § 493.638, "Registration certificate and certificate fees," and § 493.646, "Payment of fees."

*Comment:* One commenter (representing an HHA) questioned whether we expect individual HHA patients to apply for CLIA certification since they own reflectance meters and conduct blood glucose testing on themselves. Initially, HHA staff provides training to the patients to assist them in performing tests on themselves after discharge from the HHA.

*Response:* We will not require individual patients to apply for CLIA certification. CLIA only applies to "facilities" performing laboratory testing on human specimens. Therefore, except for those laboratories listed in § 493.3 (published elsewhere in this issue of the *Federal Register*) that are excluded from CLIA, facilities that test human specimens must apply for a registration certificate. In HSQ-176-F, we will establish regulations that are based on complexity of testing and specify which tests meet the requirements for waiver. In addition, as previously explained, to the extent that an HHA or hospice that is providing care in an individual's home is engaged solely in assisting an individual in performing a test, which if performed by the individual would be beyond CLIA's reach, we have no intent to impose a CLIA fee on the hospice by virtue of that activity.

*Comment:* Another commenter (representing an HHA/hospice) indicated that registered nurses on occasion perform finger sticks and/or venapunctures as a courtesy to a patient, family member, or physician. The commenter questioned whether, since the related examinations are not conducted in the hospice or HHA office, the certification would be issued to the patient's home, the nurse's automobile, or the office. The commenter also asked

whether the HHA/hospice would be identified as a laboratory if staff perform an occasional waived test as a courtesy to the patient or physician.

*Response:* In situations in which a hospice or HHA conducts testing at a temporary location or patients home, the hospice or HHA is subject to the requirements of CLIA. However, the certificate would be issued to the HHA or hospice office or branch location not to the temporary location of the patient's home or the nurse's automobile unless the automobile is a mobile vehicle that patients come to for testing. Since waived tests are encompassed by the CLIA statute, an HHA or hospice staff that performs such a test for the convenience of the patient would automatically subject the HHA or hospice to CLIA's requirements. In addition, as previously explained, to the extent that an HHA or hospice that is providing care in an individual's home is engaged solely in assisting an individual in performing a test, which if performed by the individual would be beyond CLIA's reach, we have no intent to impose a CLIA fee on the HHA or hospice by virtue of that activity.

*Comment:* A commenter, representing a State Home Care Association, recommended that the definition of location not be construed to include home health care clinics held at a variety of sites throughout a county or at individual homes. They advocated the location being defined as the office location of the agency or the area of service for home health agencies.

*Response:* Facilities that provide services at temporary sites such as patients' homes or shopping centers do not have to obtain certificates for these locations, but the home base must apply.

*Comment:* One commenter recommended that the proposed fee schedules be reexamined to consider the burden and cost imposed on rural facilities. The commenter noted that public health departments and small rural hospitals will not be able to effectively accommodate these uncertain costs in their financially strapped budgets.

*Response:* In a change from our proposed rule and in an attempt to fairly distribute the cost of this program, we are reducing the fees for registration certificate purposes. Largely to benefit laboratories such as those found in small rural hospitals, we have established a range of fees that is based on the scope and volume of laboratory testing. We have also reduced the compliance fee for low-volume laboratories that conduct 2,000 or fewer tests per year. As better data become

available on the cost necessary to operate the CLIA program, we will revise the fees.

*Comment:* Several commenters expressed concern about the effect of CLIA certification on the Women, Infants and Children (WIC) program. They stated that the financial burden for obtaining a certificate for the limited number of tests performed (primarily hemoglobin/hematocrit) will increase the administrative cost and limit the ability of these programs to provide patient services.

*Response:* WIC programs are subject to CLIA because they test human specimens for health purposes. We have revised the regulation to permit laboratories that do limited testing and are directed by not-for-profit or Federal, State, or local government organizations to operate under one certificate.

*Comment:* One commenter expressed concern that the fee schedule is unfavorably skewed against his facility because his laboratory performs a very large volume of a limited number of test types.

*Response:* Our fee schedules reflect our best estimates of current cost information associated with completing the inspection process. The greater a laboratory's test volume, the more time it will take (and the higher the cost will be) to properly evaluate whether the laboratory is conducting tests in compliance with Federal requirements. As more definitive data becomes available, we intend to adjust the fee schedules, as appropriate.

*Comment:* One commenter questioned how we will determine the affected entities and adequately enforce the CLIA provisions, since we had stated in the proposed rule that "currently we are unable to determine with any high degree of accuracy, due to lack of data, the universe of laboratories that would be compelled to meet the requirements of these provisions."

*Response:* As we outlined under section II.B. of this preamble, we will use various approaches to identify all entities that test human specimens and are not excluded from CLIA and notify them of the CLIA requirements and necessity of being certified under CLIA. However, the law places the burden on the laboratory to come forward and obtain a certificate if it is to test specimens. Unless the laboratory is State-exempt, operation of a laboratory without a certificate is a violation of the law and will subject the laboratory to the penalties outlined in the law.

*Comment:* Several commenters indicated that physicians who perform laboratory tests for their patients view

these laboratory tests as an integral component of their practice, not as a function of a separate, distinct facility or a "laboratory" in the common meaning, and, therefore, should be exempt from CLIA requirements. One commenter also indicated that we have not defined what constitutes a "laboratory" in either this rule or the proposed rule published May 21, 1990 and that has created problems in estimating the number of entities regulated under CLIA.

*Response:* Congress fully intended that CLIA apply to physician offices that perform testing services for patients, as reflected in the Report from the Committee on Energy and Commerce that accompanied the CLIA legislation (H.R. Rep. No. 5150, 100th Cong., 2nd Sess. pages 27-39 (1988)). For example, when discussing standards, the Report specifically states at section 101(f) that " \* \* \* two laboratories otherwise identical, would be subject to the same standards and requirements, notwithstanding that one is located in a physician's office and the other in a different setting." Additionally in section 102, with respect to effective dates, the Report states that " \* \* \* the number of laboratories subject to Federal certification for the first time on January 1, 1990 may exceed 100,000. Moreover, many of these will be physician office laboratories performing a limited range of testing."

*Section 493.610 Registration Certificate or Certificate Required for Laboratories (Now Titled "Certificate Requirements for Laboratories")*

Comments that affect § 493.610 are reflected in other sections of this preamble.

*Section 493.614 Application Procedures*

*Comment:* Some commenters believed that it is the government's responsibility to inform all laboratories of what actions are necessary to comply with the law (CLIA).

*Response:* We have sent a questionnaire to all laboratories approved for participation in the Medicare or Medicaid program or authorized to test specimens in interstate commerce, as well as any other laboratories we were able to identify that we believe may be subject to the provisions of CLIA. However, the law clearly places the burden on the laboratory to secure the needed certification to operate as a laboratory. Once the standards regulation, HSQ-176-F, is published, we will bill laboratories based on test volume.

*Comment:* Many commenters indicated that the application

requirements for certification are burdensome due to the data required and time involved for the staff to collect the information. Laboratories indicated that the paperwork involved in completing the initial application as well as maintaining the ongoing statistics for renewal application will increase the laboratory's operational expenses.

*Response:* As stated above, we sent a questionnaire to entities we were able to identify as performing laboratory testing. After the standards rule, HSQ-176-F, is published, we will send applications and bills to laboratories subject to CLIA. We will attempt to reduce the burden of these forms as much as possible; however, certain information is required by the statute.

*Comment:* One commenter indicated that the application requirements would be particularly burdensome for hospitals that have multiple laboratory locations (that is, a hospital with a critical care unit, operating rooms, surgery center, dialysis unit, etc.).

*Response:* The application requirements are those required by section 353(d)(1)(A) of the PHS Act. In consideration of the organizational and operational aspects of hospitals, we will allow laboratories within a hospital that are under common direction and located at the same street address to apply for a single certification or multiple certificates. Therefore, a hospital could apply for a single certificate to cover all testing sites at the same address, or, at its option, apply for separate certificates for each department of service; for example, a critical care unit, operating rooms, surgery centers, dialysis units. In addition, an organization that does limited testing (that is, few types of tests) for screening or treatment of individuals that is directed by a not-for-profit or Federal, State, or local government organization can operate (at its option) under one certificate; for example, the WIC program. We have revised proposed § 493.614 to include these options.

*Comment:* One commenter indicated that the proposed application process seems time consuming and costly. The commenter suggested that we carefully consider each laboratory's current operation, particularly those facilities that are already licensed by the State or approved by an accrediting organization.

*Response:* Section 353(b) of the PHS Act requires that "No person may solicit or accept materials derived from the human body for laboratory examination or other procedure unless there is in effect for the laboratory a certificate issued by the Secretary \* \* \*." The statute requires as well that, in order for

a laboratory to receive a certificate, it must comply with the statute's application requirements. This includes laboratories accredited by an accrediting organization. As stated previously, we are exercising the authority contained in section 353(p) of PHS Act to exempt from CLIA requirements laboratories licensed by an approved State licensure program. Those laboratories will not be required to have a certificate.

*Comment:* One commenter expressed concern that CLIA does not take into consideration the impact that the application process would have on home health and community based agencies.

*Response:* CLIA provides no exclusion for HHAs. All facilities testing human specimens "for the purpose of providing information for diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings" are required to conform to CLIA. However, to the extent that an HHA or hospice that is providing care in an individual's home is engaged solely in assisting an individual in performing a test, which if performed by the individual would be beyond CLIA's reach, we have no intent to impose a CLIA fee on the HHA or hospice by virtue of that activity. In addition, since we will not begin the application or billing process until HSQ-176-F is published, an entity will be in a better position at that time to determine whether it wishes to continue laboratory testing.

*Comment:* One commenter stated that methodologies are often instrument-dependent for chemistry and immunochemistry testing and expressed the concern that laboratories would be unable to include the upgrade of equipment until a new application for certification was filed and acted upon. The commenter also questioned whether a laboratory would be in violation of CLIA if it began using a kit or methodology not on its certificate application. Another commenter indicated that if notification to HHS is required before modifications can be made to the test menu, the efficient and effective operation of the laboratory will be severely inhibited. The commenter recommended that laboratories adding tests that would be included in the service levels specified on the certificate should not be charged an additional fee or need to notify HHS before performing the test. Additions to, deletions from, and changes in the list of tests for which the laboratory has been issued a certificate could be communicated to

HHS every 2 years, at the time of biennial inspection.

*Response:* The CLIA statute requires that we collect information on the methodologies for the test procedures performed. Registration certificates will not specify the specialties/subspecialties of services offered, except as indicated in § 493.633. Thus, laboratories will be able to notify us of the revised services offered and are not required to obtain an amended registration certificate. With respect to certificates and certificates of accreditation, we plan to list categories or specialties or subspecialties of testing on the certificate. (Except that certificates of waiver will only reflect testing in the waived category.) We will not routinely list individual test procedures. Therefore, laboratories will not be required to obtain a revised certificate provided the test additions are covered in the specialties or subspecialties of services listed on the certificate. CLIA requires laboratories that are issued a regular certificate or certificate of accreditation to report changes in tests not later than 6 months after the change has been put in effect as indicated in § 493.633. However, if a laboratory with a certificate of waiver expands its services beyond the waived tests, it must notify HHS before performing such testing. In such instances, a registration certificate will be issued to the laboratory so that the additional testing can be performed until we determine compliance with Federal requirements and issue a regular certificate.

*Comment:* One organization supports the intent of CLIA to strengthen quality control and quality assurance activities in the performance of laboratory tests. However, the commenter is concerned that burdensome application processes and excessive fees may cause a significant reduction in laboratory services provided in physician offices. The commenter indicated that this may result in a potentially large gap in access to laboratory services for patients everywhere, but most critically for those in rural areas and other sites where alternative testing sites are scarce.

*Response:* As stated earlier, the application and fee collection requirements are specified in the law. The fee schedules are based on our best estimates of the Federal costs associated with the development and administration of CLIA regulations, reviewing applications and collecting fees, Federally mandated studies, contractor costs, and evaluating laboratories for determination of compliance. As better data become

available on the cost necessary to operate the CLIA program, we intend to seek input from the public and will adjust the fee schedules as appropriate. In addition, we have reduced the compliance fee for small laboratories conducting not more than 2,000 tests per year and have also lowered the certificate fee for small laboratories to \$100 from the proposed \$261 level. These very small laboratories are the type often found in low volume, rural clinics or small doctors' offices.

#### *Section 493.614 Responses to Request for Comments*

In the preamble of the proposed rule we specifically requested suggestions on ways the reporting burden required for certificate application can be minimized, while meeting the legislative intent. We received the following responses to this request.

*Comment:* Many commenters urged that the application include a pre-printed "checklist." One commenter recommended that we develop special forms to update certifications that would require information only on the "changes" that occurred since the initial application. Another commenter suggested that separate applications be developed and utilized for waiver, Level I, and Level II laboratories, with the information requested targeted to the requirements for each type of certificate.

*Response:* We will take into account any measure that is feasible to simplify the application process. When CLIA is fully implemented, we plan to have application forms that are simple, easy to complete, and appropriate for all categories of laboratory testing. Until that time we will use a questionnaire that will collect the basic information necessary to identify laboratories subject to CLIA.

*Comment:* One commenter urged HHS to consider revising the fee schedule to discount multiple certificates issued to a single institution and to reduce reporting burden by allowing hospitals to file a single application that would encompass all the certificates to be issued to its laboratories.

*Response:* A certificate may be issued to a hospital location identified by a specific street address to cover multiple testing sites within the hospital provided the different testing sites are under common directorship. Likewise the hospital may wish to have multiple certificates for different testing sites in the same location. We believe the fee schedule is established appropriately to represent general CLIA implementation and operational costs as well as the costs for determining compliance that correlate with the volume and scope of

services performed. Additionally, organizations that do limited testing (that is, few types of tests) for screening or treatment of individuals that are directed by not-for-profit or Federal, State, or local government organizations can operate (at their option) under one certificate, for example, the WIC program.

*Comment:* One commenter expressed concern that the fee regulations as proposed did not consider the testing situations of public health agencies. These agencies traditionally provide services for underserved populations and for the prevention and control of communicable diseases. Even though the laboratory testing may be simple and the testing volume may be low, in order to be effective, those agencies must provide services that are convenient to the populations served. The application procedures and fee schedules proposed would be a tremendous burden to public health agencies.

*Response:* CLIA is specific that "No person may solicit or accept materials derived from the human body for laboratory examination or other procedure unless there is in effect for the laboratory a certificate issued by the Secretary \* \* \* ." For a laboratory that is not at a fixed location, that is, a "laboratory" that moves from testing site to testing site such as a health screening fair or other temporary testing location, we would issue a certificate to the home base. If the laboratory has a certificate, other than a certificate of waiver, we would conduct routine inspections at selected testing sites or locations.

*Comment:* One commenter noted that the proposed rule states that the certificate application requirements are based on section 353(d)(1)(A) of the PHSA, which requires laboratories to describe "characteristics," "number and types," and "methodologies" of the tests proposed to be performed. Individual test names are not required by the statute. Therefore, the commenter recommended that the application not require specific names, but rather list groups of procedures, such groups being defined by their characteristics, types, and methodologies. Then, as long as a laboratory has included a group of procedures on its application, it may add any additional procedure within that group without notifying HHS or paying an additional fee.

*Response:* Except as exempt by § 493.3 (published elsewhere in this issue of the Federal Register), all laboratories must obtain a registration certificate or certificate of waiver. An

inspection will not be required for issuance of a registration certificate. Once CLIA is fully implemented, we must know the "types" of tests or names of tests that a laboratory performs to determine whether a laboratory may be issued a certificate of waiver. Additionally, test names are needed to correlate with methodologies performed and to categorize the procedures or examinations by specialty or subspecialty of service for issuance of a regular certificate. CLIA requires that each laboratory have a certificate applicable to the specialty or subspecialty of service to cover the categories of examinations or procedures performed by the laboratory unless it is granted an exemption as a laboratory licensed by an approved State licensure program. The certificate will not include test names but instead specialties or subspecialties of services. As long as the laboratory has a valid certificate to cover the specialties or subspecialties of services performed, the laboratory may add or delete tests or examinations without revising the CLIA certificate. (Certificates of waiver will only reflect testing in the waived category.) As indicated in § 493.633, a laboratory with a certificate of waiver must notify HHS before performing tests not listed in the waiver test category, while a laboratory with a certificate must notify HHS or a laboratory with a certificate of accreditation must notify the accrediting organization within 6 months of any change in testing.

*Comment:* In order to minimize the reporting burden, one commenter recommended that laboratories be allowed to indicate on the application form that there are several methodologies that they could potentially use to perform a particular test without regard to the methodology most commonly used. The commenter suggested that a list of the methodologies most commonly performed could be attached to the application. In this regard, another commenter asked whether, if several alternative methods for performing a particular analysis or examination were listed on the application, the laboratory would be required to stock all the reagents and perform proficiency surveys using all methodologies listed. One commenter indicated that the use of pre-printed forms listing methodologies and tests could be restrictive and would rapidly become outdated.

*Response:* CLIA legislation and application procedures require laboratories to include as part of the application "the methodologies for laboratory examinations and other

procedures employed." Therefore, the laboratory must include only those methodologies actually used for testing. Test reagents should be available to perform the methodologies listed. Laboratories will be required to perform proficiency testing surveys as required under CLIA standards regulation HSQ-176-F, which is published as a separate rule in this edition of the Federal Register. We recognize that pre-printed forms could rapidly become outdated, and we will consider this factor in designing the forms.

*Comment:* A number of commenters indicated support of the use of pre-printed application forms. One commenter suggested that pre-printed application forms be used to collect information on the education, training, and experience of each employee rather than requiring employee résumés. One commenter recommended that the form not require a detailed description of the qualifications of each laboratory employee but rather a printed statement that all personnel comply with CLIA requirements. The commenter said this statement could be signed and attested to by the individual representing the facility who signs the application form. Another commenter pointed out, however, that the use of pre-printed forms for the certification of technical personnel would be restrictive and would not allow for the continual updating of educational status.

*Response:* As stated above, we recognize that pre-printed forms could rapidly become outdated and will consider this factor in designing the forms. However, CLIA requires that we obtain information concerning "the qualifications (educational background, training and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and other procedures \* \* \*." We all strive to develop application forms that require the least burden possible to complete.

*Comment:* Several commenters expressed concern with respect to the requirement that a separate application be filed for each laboratory location. One commenter recommended that the institution be allowed to determine the number of applications for that institution based on who has control or jurisdiction over the testing site within the institution. The institution could elect to be "certified as a whole" (that is, one certificate) or have multiple sites with separate certificates. Another commenter recommended that there should only be one application and fee required if the same supervising

personnel are working in multiple test sites within one corporation.

*Response:* As stated earlier, we will provide flexibility to a hospital located at one street address and under common direction to allow it to determine the number of certificates required. However, if the hospital conducts testing at separate locations, (that is, different street addresses) each location must be evaluated for determination of compliance with CLIA. Laboratories that do limited testing (that is, few types of tests) for screening or treatment of individuals that are directed by not-for-profit or Federal, State, or local government organizations can operate (at their option) under one certificate; for example, the WIC program.

*Comment:* One commenter requested clarification on whether separate waiver certificates would be required for one-time sites, such as health fairs.

*Response:* A separate certificate will be required for each permanent testing location, as discussed in § 493.614(b); however, health fairs that move to temporary sites to provide services will not be required to have a certificate or certificate of waiver at each temporary location. Once CLIA is fully implemented, if the temporary sites perform only waived tests, we will issue a certificate of waiver to the home base location. For laboratories not qualifying for a certificate of waiver, we will issue the certificate to the home base and evaluate compliance, on occasion, at one or more temporary locations.

*Comment:* One commenter indicated that there would be an increase in administrative costs for an agency to complete each application. In the event that the WIC program is covered by final CLIA regulations, the commenter recommended that special, simpler application forms be developed for use by WIC programs to reduce the time and costs involved and eliminate irrelevant paperwork.

*Response:* We will make every effort to simplify application forms for all laboratories, including WIC program laboratories, to ensure that only minimum effort consistent with statutory requirements is necessary to complete the forms.

*Comment:* One commenter indicated that the requirement for collecting annual test volumes as part of the application for certification was not relevant to proficiency testing since it should be the same whether one or multiple tests are performed. The commenter also recommended that the updating of a certificate should be as simple as possible.

*Response:* As stated earlier, CLIA application requirements specify that HHS collect information on "the number and types of laboratory examinations and other procedures performed." This information collection requirement is not related to proficiency testing. As previously indicated, we will make every effort to simplify the application forms, which will include the procedures for updating information.

*Comment:* One commenter recommended that the application be correlated with test complexity as proposed in a separate CLIA rule. The commenter suggested that we permit applicants to determine the level of testing based on testing performed and that, in all cases, the forms should be generic enough to not impede the use of new technology. The commenter also indicated that the term laboratory "location" should be changed to laboratory "practice" since this change would allow a reduction in paperwork and preserve the ability of mobile "screeners" to conduct their services.

*Response:* We will allow mobile laboratories to obtain a single certificate for each mobile testing facility (or van) that will reflect the home base address for each testing entity that furnishes services. A mobile laboratory is a permanent unit that is comprised of all equipment and supplies necessary to provide or perform services in the van or conveyance that travels to the patient(s) to furnish services. Laboratories that transport equipment and supplies to a patient's home, a shopping center, or between temporary locations in which the testing is performed at the temporary location will be issued a single certificate for the home base to cover testing at each temporary location. We have revised proposed § 493.614 to clarify that laboratories within a hospital can be covered by a single certificate to allow testing at a number of temporary locations.

*Comment:* One commenter indicated that since tests on the waived list are not subject to personnel requirements, entities applying for a certificate of waiver should not be required to report this information. Similarly, the applicants should not be required to disclose the methodologies used for waived tests, as these methodologies have already been waived as well. The commenter also stated that, since certificate of waiver laboratories are not subject to proficiency testing, they should not be required to furnish data on the total number of tests performed annually.

*Response:* The application requirements specified are required by law regardless of whether the laboratory

is issued a regular certificate, certificate of waiver, or certificate of accreditation. Note that certificate of waiver laboratories are not required to report changes in supervisor.

*Comment:* One commenter recommended that HHS send, if time permits, application forms to a sample of laboratories to ensure that the forms solicit the necessary information in the most appropriate manner.

*Response:* The application forms will be based on the application requirements of the statute. We will use the experience gained from the questionnaire issued as part of the implementation process of this rule to develop the application forms to be used after CLIA is fully implemented.

#### *Section 493.618 Additional Application Requirements*

*Comment:* One commenter (a State Health Department) indicated that the proposed rule was unclear as to when onsite visits are required and what they will cost. The commenter indicated that § 493.618 does not state which laboratories will require onsite visits.

*Response:* Section 493.618 sets forth application requirements and is not the appropriate place to include the detailed requirements related to inspections. Inspection requirements were specified in the proposed rule HSQ-176-P published on May 21, 1990. However, as we explained in this preamble, all laboratories will be issued registration certificates or certificates of waiver initially. Laboratories will not be subject to routine inspections for compliance with health and safety standards under CLIA until those standards are established. However, laboratories that are currently approved to participate in the Medicare or Medicaid program or authorized to test specimens in interstate commerce remain subject to the current Federal standards for laboratories at 42 CFR part 493. In addition, all laboratories (including those issued registration certificates) are subject to inspections as the result of complaints or other problems related to noncompliance with CLIA statutory requirements.

Once the CLIA health and safety standards contained in HSQ-176-F are effective, all laboratories not issued a certificate of waiver will be subject to onsite inspections on a biennial basis. A laboratory issued a certificate of waiver will not be subject to these "routine" inspections; however, the Secretary has the authority to evaluate complaints and verify the tests being performed by the laboratory. Laboratories that qualify for a certificate of accreditation will be subject to routine inspections by the

accreditation programs, as well as validation surveys on a random basis to verify accreditation program equivalency, and surveys to investigate complaints that allege regulatory noncompliance. Licensed laboratories located in a State whose licensure program is approved by HHS are exempt from CLIA (that is, State-exempt) but would be subject to Federal inspections on a random basis to verify that standards are being enforced in a manner comparable to those applied under CLIA.

*Comment:* One commenter indicated that the proposed rule requires all laboratories, except those issued a certificate of waiver, to agree to routine inspections and this contradicted the proposed rule published May 21, 1990 (HSQ-176-P). The commenter indicated that in HSQ-176-P, at 55 FR 20903, we proposed unannounced inspections of certificate of waiver laboratories even though these laboratories are exempt from routine inspections under 42 U.S.C. 263a(d)(2)(C) of CLIA. The commenter suggested that HHS take the position that certificate of waiver laboratories would not be subject to routine inspections, since this is consistent with the statute, and that we address the discrepancy between the two proposed rules.

*Response:* The language in both rules is correct. While certificate of waiver laboratories will not be subject to "routine" scheduled inspections (that is, every 2 years), the Secretary reserves the right to inspect a laboratory's operations if there is cause to question whether the laboratory is operating in a lawful and safe manner. In the preamble to the May 21, 1990 rule, we explained that "certificate of waiver laboratories, while exempted from routine inspections under section 353(d)(2)(C) of the PHS Act, are nevertheless subject to extraordinary inspections in certain instances through our enforcement authority contained in section 353(i) of the PHS Act." This section reserves the Secretary's right to make reasonable requests to conduct an unannounced inspection of a laboratory's operation if there is cause to question whether the laboratory is operating in a lawful and safe manner. While subsection (i) speaks to certificates, it is clear from sections 353 (b) and (c) of the PHSA that this term encompasses certificates of waiver as well. Such inspections would not be "routine." Since there is no conflict, no change has been made to the regulation.

*Section 493.622 Appeals Procedures*  
 ["Opportunity for hearing" in proposed rule]

*Comment:* Several commenters expressed concern that the proposed rule would prohibit laboratories seeking initial certification from conducting business if their certification is denied or limited, unless the denial is overturned on appeal. They indicated that this could create a substantial hardship and that laboratories should not be penalized for a possible HHS error or the need to supply additional information. One commenter indicated that we should include provision for a reconsidered determination while another suggested that a "show cause" hearing be held before such action so that the laboratory can either correct problems before such a hearing or contest the denial of the initial certification. This commenter also suggested that a cost-benefit analysis be developed to determine whether some type of hearing should be afforded a person or entity denied an initial certificate.

*Response:* Registration certificates or certificates of waiver will be issued to all laboratories that meet application procedures prescribed by law and regulations and that pay the appropriate fee. Any laboratory that fails to comply with the application procedures will be notified of the requirements not met and be given an opportunity to achieve compliance. For example, if a laboratory failed to supply information concerning test methodologies, we would contact the laboratory and provide an opportunity for the submission of this information. In addition to providing laboratories an opportunity for an appeal in part 493, the proposed rule concerning enforcement procedures for laboratories (HSQ-179-P) published in the *Federal Register* on April 2, 1991 provides reconsideration of actions that are initial determinations. Any laboratory dissatisfied with HHS's denial of its application for a CLIA certificate or denial of approval to receive Medicare payment for its services or with HHS's refusal to convert the laboratory's registration certificate to a CLIA certificate may request a reconsideration in accordance with § 493.622. Section 493.622, as proposed in HSQ-177-P, specified that, in the above circumstances, the laboratory is provided an opportunity for "a hearing" in accordance with procedures set forth in part 498. We are revising proposed § 493.622 by changing the section heading to "Appeals procedures" and, in paragraph (a), substituting the words "an appeal" for

the words "a hearing." These changes clarify that the laboratory has access to the full appeals process provided to it by part 498.

Since reconsideration of initial determinations are authorized, we do not believe that a cost-benefit analysis is necessary.

*Comment:* One commenter indicated that, in order to avoid financial hardships, either Medicare payments should continue until a hearing decision is issued or the hearing should be scheduled within 2 weeks of the finding of noncompliance.

*Response:* We disagree with the comment. Laboratories that are not in compliance with Federal requirements cannot be approved or maintain their approval for participation in Medicare unless they correct deficiencies within prescribed timeframes. Payments under Medicare may not be made to laboratories that are not approved for participation. Historically, it has always been the case that providers and suppliers in the Medicare program have no entitlement to a prior hearing once the agency has determined that deficiencies exist that prompt termination or approval cancellation—a position long upheld by the courts. Moreover, continuation of Medicare payments until a hearing decision would be contrary to the directive of the statute (section 6141 of Pub. L. 101-239) which requires all laboratories that participate in Medicare to meet the CLIA requirements. The purpose of this provision is to encourage compliance with the CLIA requirements.

With respect to requiring specific timeframes for scheduling hearings, we are unable to establish such timeframes due to unpredictability of the workload that may be generated by CLIA as well as other hearing obligations that the Department routinely incurs. The proposed rule on enforcement procedures for laboratories (HSQ-179-P) published in the *Federal Register* on April 2, 1991 elaborates on the effect on noncompliance with the CLIA requirements with respect to Medicare payment.

*Comment:* Another commenter indicated that we should elaborate on the appeals method, addressing time parameters, basis of cases, and who will rule on the denials.

*Response:* These issues are addressed in detail in the proposed rule on enforcement procedures for laboratories (HSQ-179-P) published in the *Federal Register* on April 2, 1991 and the final rule published elsewhere in this edition of the *Federal Register*. HSQ-179-F sets forth the rules for sanctions that HHS

may impose on laboratories that are found not to meet Federal requirements.

*Section 493.626 Registration Certificate*

*Note:* As stated earlier, we have substituted, in this final rule, the term "registration certificate(s)" for the term "provisional certificate(s)." We have made this substitution even when discussing a comment.

*Comment:* One commenter indicated that the proposed rule was unclear as to whether laboratories would have to apply and pay twice; once for the registration certificate and again for the certificate. Another commenter sought clarification concerning the requirement for registration certificates and whether all new laboratories would be issued a registration certificate. They also questioned whether fees would be prorated if, for example, a full certificate was issued before the expiration of the registration certificate.

*Response:* Separate payments are required for the issuance of a registration certificate or certificate of waiver and, unless a laboratory is State-exempt, for any subsequent issuance of a "regular" certificate, certificate of waiver, or certificate of accreditation. The issuance of the registration certificate will allow time for HHS or its designee to determine compliance with the CLIA standards or for the laboratory to become accredited by an approved accreditation program or for approval of the State licensure program to exempt the laboratory from CLIA requirements.

Laboratories will not be expected to apply for their certificates. Rather, laboratories will be billed for certificates after successful completion of their on site compliance determination inspections.

In addition, as indicated in § 493.633(a)(2), a registration certificate will be issued to a laboratory that has a certificate of waiver and wishes to perform any examination or procedure not listed in the waived test category. To clarify this issue, we have revised proposed § 493.626 by adding that, except for a registration certificate issued to cover initial testing areas after a certificate has been issued as indicated in § 493.633(a)(2), the registration certificate will not include specialties/subspecialties of service, but will authorize the entity to conduct laboratory testing until a determination of the appropriate level of compliance can be made. Before expiration of the registration certificate, HHS will notify the laboratory of the fee amount for issuing the certificate and, if applicable, the amount of the fee for determination of compliance. The fees will not be

prorated since they are based on the Federal and State costs associated with the implementation and administration of CLIA and the cost involved in processing the applications and issuing certificates.

*Comment:* One commenter questioned the requirements in § 493.805 of the proposed rule to implement the CLIA health and safety requirements (HSQ-176-P) published May 21, 1990 that would require laboratories performing Level I or Level II tests to demonstrate satisfactory performance in one proficiency testing event of an approved proficiency testing program before issuance of a registration certificate. The commenter was concerned that there might not be any "approved" proficiency testing programs before the issuance of registration certificates.

*Response:* Laboratories are not required to achieve satisfactory performance in any proficiency testing event before issuance of a registration certificate. We proposed this requirement in HSQ-176-P as a mechanism to evaluate laboratory performance before authorizing "provisional" certification. HSQ-176 will have effective dates that ensure approval of proficiency testing programs before any laboratory would be penalized for non-participation. Moreover, the proposed requirements for HSQ-176 are being modified in the final rule published elsewhere in this edition of the Federal Register. However, Medicare, Medicaid, and interstate laboratories currently subject to the provisions of part 493 are subject to proficiency testing requirements at § 493.805.

*Comment:* One commenter expressed concern that proficiency testing might not be available to all laboratories for many reasons, including volume of customers to be serviced. The commenter indicated that HHS should provide for such situations by offering alternatives such as "in the event that the proficiency testing program is not able to administer the initial proficiency testing event required for provisional certification, the laboratory may be allowed to provide alternative evidence of satisfactory performance such as a manufacturer's proficiency testing program, or split sample testing."

*Response:* As indicated in the previous response, laboratories will not be required to participate in proficiency testing before issuance of a registration certificate. We understand proficiency testing program providers may have difficulty in accommodating the large number of applicant laboratories seeking enrollment. We will establish

policies and procedures in HSQ-176-F to respond to this problem.

#### *Section 493.631 Certificate of Waiver*

*Comment:* Many commenters indicated that there should be no fee assessed for issuing a certificate of waiver, or that this fee should include only processing costs. One commenter also indicated that surveys for compliance would not be calculated into the waiver fees.

*Response:* Under CLIA, all certificate fees collected must be sufficient to cover the general costs of establishing the requirements to implement CLIA, including determining tests eligible for waiver. In addition to these general costs, the certificate of waiver fee includes the cost of issuing the certificate of waiver, the collection of the fees, and analysis of applications to determine if a laboratory should be issued a certificate of waiver. It also includes a share of the cost of random inspections to gather information for PHS evaluation of waiver test performance. In fact, the statute requires that we assess a "nominal fee" for the certificate of waiver. The fee we have set for a certificate of waiver is the lowest of any CLIA fees, and it is nominal.

#### *Section 493.632 Certificate of Accreditation*

*Comment:* One commenter noted that regulations concerning the programs acceptable for accreditation were not published, while other commenters recommended utilizing knowledge and experience of other inspecting agencies and focusing the HHS inspections on unlicensed unaccredited laboratories.

*Response:* As we indicated in the preamble of the proposed rule, a separate proposed rule contains the criteria for approving accreditation and State programs. That proposed rule (HSQ-181-P) was published August 20, 1990 (55 FR 33936) and sets forth the criteria we would use to evaluate and approve State programs and private non-profit organizations as accreditation programs. We are in the process of evaluating the comments received on that rule, and we will respond to them in the preamble of the final rule. However, based upon comments received on HSQ-181-P and upon further review of the statute, we are exempting from CLIA requirements laboratories licensed by and located in a State whose licensure program is approved by HHS. These State-exempt laboratories will not be required to have a certificate or pay fees. However, such laboratories are subject to random Federal inspections to validate that the State licensing program

is applying standards at least equal to the CLIA standards. HHS will assess the State the costs of these inspections. We have revised proposed §§ 493.610, which concerns additional fees, and 493.645, which requires laboratory certification, to reflect this change.

#### *Section 493.633 Applicability of the Certificate, Certificate of Waiver, and Certificate of Accreditation*

*Comment:* Several commenters expressed concern about the proposed requirement that would prohibit a facility from performing a new test not included on the laboratory's certificate. Commenters indicated that requiring a laboratory to apply for and obtain a revised certificate before adding a test not listed on the certificate would have a negative impact on the laboratory's ability to furnish new test services in a timely manner. Commenters recommended that laboratories be permitted to notify us of the change and be permitted to perform the new test(s) on a provisional basis if the test(s) are within a previously certified specialty.

*Response:* Under this rule, registration certificates generally will not specify categories of testing performed. With respect to regular certificates, the certificate will not include test names but rather the specialties/subspecialties of services offered. Laboratories will not be required to obtain a revised certificate provided the test additions are covered in the categories of testing or specialties or subspecialties of service listed on the certificate. Changes in certificates will be necessary if there is a change in the categories of tests or specialties or subspecialties. A laboratory with a certificate must notify HHS within 6 months of any changes in tests or examinations performed. If the added testing is not in a specialty or subspecialty on its certificate, HHS may conduct (depending on the type and timing of the changes) a survey to determine compliance. A laboratory will be charged for survey costs only the cost incurred in evaluating the additional test. If compliance is determined, and upon payment of the revised certificate fee, a revised certificate will be issued that includes the additional specialties or subspecialties. A laboratory with a certificate of accreditation must notify the accreditation organization within 6 months of changes in its testing, and, when compliance is verified, a revised certificate of accreditation will be issued. We have revised proposed § 493.633, by adding a new paragraph (4), to include this requirement. A laboratory with a certificate of waiver must notify HHS before performing tests

that are not included in the waiver test list. We will issue a registration certificate for the new services (that is, a restricted registration certificate) authorizing the laboratory to initiate the new testing until we can determine compliance with Federal requirements. The laboratory will be able to continue all other testing specified on its certificate of waiver. Proposed § 493.633 has been revised to reflect that a registration certificate will be issued to allow a laboratory with a certificate of waiver to initiate testing in an area not listed on its certificate.

*Comment:* One commenter indicated that the proposed rule does not specify a time period for reporting the addition of new test procedures and recommended that laboratories be allowed at least 6 months to report such additions. This would permit laboratories time to introduce new testing services while gathering data to determine whether the laboratory can conduct the testing in a cost-effective quality manner.

*Response:* Section 493.633 has been revised to reflect the statutory requirements of section 353(d) of the PHSA. As indicated previously, a laboratory with a certificate or certificate of accreditation must notify HHS or the accreditation organization (as applicable) within 6 months of any changes in its scope of practice as indicated in section 353(d)(1)(A). However, as required by section 353(d)(2)(B), a laboratory with a certificate of waiver must obtain prior approval if it wishes to add testing not listed in the waiver test category.

*Comment:* One commenter stated that §§ 493.633(a)(1) and (2) were incompatible unless the word "changes" in paragraph (2) means "deletion" and excluded "additions." The commenter indicated that § 493.633(a)(1), which discusses performing tests not on the certificate, appears to be based on section 353(d)(2)(B) of the PHSA, which is limited to laboratories holding certificates of waiver. Therefore, this part of the regulation should be limited to certificate of waiver laboratories.

*Response:* The commenter is correct. As previously discussed, the regulation at § 493.633 has been revised accordingly.

*Comment:* One commenter expressed concern that there is no provision in the proposed regulation for assigning newly developed tests to a specialty or subspecialty of service, making it impossible for laboratories to know which personnel, quality control, etc. standards are applicable.

*Response:* Once CLIA is fully implemented, we will resolve any questions concerning the categorization

of tests into the appropriate specialty or subspecialty of services. HHS will evaluate new technologies and methodologies for test categorization and inform laboratories of the Federal requirements that are applicable to the testing or examinations performed.

#### *Section 493.634 Notification of Changes*

*Comment:* One commenter indicated that the 30-day requirement for notification of changes in location would be burdensome. This commenter's clinic sites are located within community centers, schools, etc., and often must relocate on short notice. The commenter further indicated that 30 days would not allow the clinic sites sufficient time to notify HHS of the change.

*Response:* The regulation did not require that the laboratory notify HHS or its designee "prior" to a change in site, only that notification occur within 30 days of the actual relocation. Therefore, we do not believe that this requirement imposes an unreasonable burden, and we have retained the proposed language in the final rule. We have, however, determined that the notification requirements for changes in laboratory director should apply to laboratories issued a registration certificate to ensure that we have accurate information for program administration. We have revised the regulation to reflect this change. We have also added language to this section to reflect the same consequences of failure to notify HHS of changes as noted in § 493.633(b) for noncompliance with any of the requirements of part 493, and to reference § 493.639, the regulation section concerning the fees imposed for revising certificates as a result of changes in laboratory status.

#### *Section 493.638 Registration Certificate and Certificate Fees*

*Comment:* Two commenters specifically addressed the \$261 proposed certificate fee and argued that the amount is too high. Another indicated that these fees will ultimately get passed on to the consumer and that it is entirely possible that access to laboratory testing will be reduced when small laboratories reduce their test menus to avoid certain CLIA fees or close down completely.

*Response:* In response to commenters' concerns, we have developed new fee schedules for certificates (\$100, \$350, and \$600). The amount of the fee will be based on whether a laboratory is considered small, medium, or large (based on the volume and scope of testing performed by the laboratory.) These individual fee amounts do not

reflect the actual resources needed to issue a registration certificate or certificate to each size group. However, the estimated total amount of fees generated under this graduated fee approach, along with the fees for compliance determination, is the amount we estimate is needed to cover the costs of the CLIA program. The graduated fee amounts have been adopted in order to avoid any undue burden on small laboratories, and it is our best attempt to structure the fee amounts in a way that maintains parity among the laboratories.

*Comment:* Two commenters encouraged us to publish an annual statement of income and expenses applicable to the CLIA program in the *Federal Register*.

*Response:* As with other HHS programs, the CLIA certification program will be audited periodically by the General Accounting Office and the Department's Office of the Inspector General. The results of these audits, designed specifically to determine HHS's accuracy in applying the mandates and guidelines of the programs, will be available to the public.

*Comment:* Section 493.638 addresses fees for waivers, indicating that, for a certificate of waiver, the fee "includes the cost of issuing the certificate of waiver, collection of fees and the administrative costs associated with evaluating tests to determine if a certificate of waiver should be issued." A commenter suggested that the language be changed to read: "\* \* \* and the administrative costs associated with the evaluation of applications to determine if a certificate of waiver should be issued."

*Response:* We are not adopting the suggestion. The costs associated with evaluating the application for issuance of a certificate of waiver are included in the costs of issuing the certificate of waiver. Additional costs associated with the evaluation of tests for inclusion on the list of waiver tests are also included in the fee for issuance of certificates of waiver, as are other administrative costs associated with the operation of the program (for example, the cost of the billing system). In addition, we have revised proposed § 493.643(e) (now redesignated as § 493.643(d)) by adding a new subparagraph (2) to address the costs associated with complaint investigations. We specify that, if it is necessary to conduct a complaint investigation, impose sanctions, or conduct a hearing, HHS assesses the involved laboratory a fee to cover the

cost of these activities if the complaint is substantiated or the adverse action upheld. In the proposed rule, through an oversight, this was discussed only in § 493.645(h) with respect to laboratories issued a certificate of accreditation.

*Section 493.639 Fee for Revised Certificate*

*Comment:* One commenter believed that the administrative costs for the various regulatory services necessary to issue revised certificates, based on the actual cost of the resources and time involved, are too open-ended. The commenter suggested that an estimated fee for such services should be established and published.

*Response:* Costs for revising a certificate will be based on the administrative cost of processing the request for revision and issuing the revised certificate. A laboratory must inform us of any changes in the information on which the registration or other certificate is based.

Revisions in the registration certificate are required if changes occur in the laboratory's name or location. Revisions in regular certificates, certificates of accreditation, or certificates of waiver are necessary if the laboratory changes its name, location, or director, or if a laboratory with a "regular" certificate or certificate of accreditation adds services not included in the specialties or subspecialties listed on the certificate or deletes services that are included on its certificate. If a laboratory with a certificate of waiver adds tests that require issuance of a regular certificate, a registration certificate to cover the new testing will be required to enable the laboratory to conduct testing in the added services until a compliance determination can be made. Following a determination of compliance, a certificate will be issued and a fee for issuance of a certificate will be assessed.

We have reexamined our estimate of the time that would be necessary to issue a revised certificate and have determined that our original estimate was too long. We now estimate ½ hour (at \$50 per hour) for Federal administration and ½ hour (at \$50 per hour) for contractor administration. This results in a fee of \$50 for a revised certificate.

We adjusted our time requirements downward to account for the fact that a nominal amount of time would be required to analyze and enter the revised application into the system and to issue a revised certificate. We believe that the analysis burden and direct data entry for a revised application is much

less than for a regular application. In addition, the required contractor burden and the burden to the HHS data base to issue a revised certificate is much less than for a certificate. The initial certificate of registration cost of \$100 to \$600 includes significant costs incurred by HHS to administratively establish CLIA through development of regulations and required revisions; development of requests for contracts; development and maintenance of a complex data system; and development and updating of comprehensive manual and instructional guides. We have eliminated these large overhead administrative costs from the cost of issuing revised certificates.

If, for any of the certificates, a survey to determine compliance is necessary because of any of the changes, a laboratory must pay, in addition to the fee for issuing the revised certificate, the costs incurred to evaluate the changes.

*Section § 493.643 Fee for Determination of Program Compliance*

*Comment:* A commenter encouraged us to simplify the entire process by making random spot checks of physicians' offices without warning, with no fees, guidelines, or periodic evaluations.

*Response:* Section 353(g) of the PHSA requires compliance inspections, and section 353(c)(2) specifies that a certificate is valid for no more than 2 years. Therefore, we intend that each laboratory subject to the provisions of CLIA (other than those waived or State-exempt) receive at least a biennial inspection. We have an agreement with States to utilize and pay their survey agency staff to conduct these inspections on our behalf. CLIA legislation states that the costs incurred in implementing the laboratory certification program be borne by the laboratories themselves through user fees. This is true for all laboratories subject to CLIA regardless of type (and this includes physician office labs). Only if a laboratory is operating pursuant to a certificate of waiver will it not be subject to routine inspections.

*Comment:* A commenter contended that the system as proposed seems to focus more on the opportunity to assess and collect charges than to assure the laboratories' quality and cites that additional charges are to be imposed for follow-up visits, sanctions, and appeals. The commenter believed that charging for each sanction would appear to encourage the inspectors to find problems, while fees for appealing these findings could discourage the laboratories from using the appeals process.

*Response:* We disagree with the comment. The commenter's argument might be valid if State agencies were paid on the basis of numbers of problems cited or separate instances of sanctions to be applied to a deficient laboratory. However, the fees for determining compliance were developed in such a way that States are paid regardless of their findings of compliance or noncompliance, or instances of sanction actions. If upon reconsideration or appeal, the findings are not upheld, the laboratory is not responsible for these costs.

*Comment:* A commenter suggested that, because the CLIA implementation schedule is slipping, the effective dates for the fee collections will need to be revised.

*Response:* We decided to postpone collection of the fees until the CLIA standards regulation (HSQ-176-F) was published and, therefore, we are publishing both the fee and the standards regulations at the same time.

*Comment:* A State Health Department expressed concern that a State might have to absorb the costs associated with a hearing if a State takes a laboratory through a hearings process and the Administrative Law Judge (ALJ) rules in favor of the laboratory.

*Response:* We have taken into consideration the State agency's costs and time associated with participation in the hearings process. A laboratory that receives a favorable hearing decision will not pay any hearings costs. States will be fully paid for all reasonable costs associated with the enforcement of CLIA requirements.

*Comment:* A commenter expressed concern that laboratories should not have to face unwarranted fees which result from unnecessary inspections and investigations. The commenter suggested that the rule be clarified to ensure that laboratories are charged only for follow-up inspections when necessitated by the laboratory and not due to the failure of the inspector to allow adequate time and/or have adequate resources to complete the inspection on the initial visit; are charged for complaint investigations only when the complaint is shown to be valid; and charged for sanctions or hearings only when the laboratory is shown, after appeals, to have violated the requirements of CLIA.

*Response:* We agree that laboratories should not be burdened with inappropriate or unjustified fees. The fees are designed to determine a laboratory's compliance with program requirements. Follow-up inspections will occur only to determine whether a

laboratory found to be in non-compliance has corrected the cited deficiencies. State surveyors who determine laboratory compliance with CLIA requirements are not paid by the numbers of problems cited nor the numbers of sanctions applied. We believe that we have clearly stated in this rule that the fees to be assessed for complaint investigations or sanction activities will be for those that are substantiated.

*Comment:* Several commenters stated that the costs proposed for certification and inspection appear exorbitant. Another added that the costs are detrimental to small laboratories and hospitals that are barely solvent. Administration of the proposed fee schedule, the commenter continued, would discourage laboratories from offering a broader spectrum of tests since they would be monetarily at risk for expanding their services.

*Response:* We disagree that the fees are exorbitant. We recognize that some laboratories may experience more financial difficulty than others in meeting the requirements of CLIA. However, CLIA legislation requires that all laboratories subject to its provisions be assessed fees for certification and laboratories not issued a certificate of waiver be charged a fee for inspection and that these fees must be sufficient to cover all costs involved. In developing the fees for certification and compliance determination, we considered average time estimated and average surveyor pay scales across the country. These estimates also consider laboratory size based on types of specialties and volume of tests. In addition, we have established a lower fee within Schedule A for low-volume laboratories conducting less than 2,000 tests per year. As we gain experience from administering the CLIA program, we intend to revise the fee schedules as necessary.

*Comment:* A commenter said that the classifications in the proposed rule appear incomplete and unclear and make it difficult for pediatricians to determine the scope of the testing procedures and their corresponding fee responsibilities. HHS is obligated, the commenter continued, to make these explicit and understandable to prevent needless errors in filing applications, delays in issuing certificates, and excessive denials. A question which followed asked, if strep tests are performed using immunochemistry procedures, would the testing be classified an immunology, chemistry, or microbiology?

*Response:* The specialties/subspecialties listed in the preamble

correlate with current terminology used to classify tests performed in Medicare and interstate licensed laboratories. We do not classify methodologies, technologies, or instrumentation; rather, classification is based on the constituent analyzed, measured, or identified. Direct strep antigen detection procedures are categorized in the subspecialty of bacteriology because the *Streptococcus* organism is detected and identified.

*Section 493.643 Fee for Determination of Program Compliance*

*Comment:* In the preamble of the proposed rule, we specifically invited comments on the type of methodology, process, and schedule to be used in updating the estimated fees for compliance determination surveys. We received 11 comments concerning the grouping of the 10 schedules and the number of specialties within each schedule. A summary of the comments follows:

- Six commenters argued against the number of specialties and/or volume of tests per schedule. Two of these suggested that schedules A and B be combined, as well as schedules C and D.
- Two more suggest that the schedules, as proposed, will unfairly affect smaller laboratories.
- Two Women, Infants, and Children (WIC) program clinics said that the schedules, as proposed, will seriously jeopardize their budgets, especially in light of the simple screening procedures they offer.
- Another commenter suggested that the large majority of laboratories conduct fewer than 10,000 tests per year.

*Response:* The schedules that were listed in the proposed rule were compiled using the currently available data from State survey agencies and HHS regarding estimated time and costs to determine program compliance with CLIA requirements. We had originally planned to propose a very limited number of schedules to encompass small, medium, and large laboratories. However, we believe that a larger number of schedules, such as 10, results in lower increments in fee amounts from one schedule to the next than would be so with fewer schedules and will allow the smaller laboratories to pay the least amount necessary to cover the costs of implementing CLIA's requirements. In this final rule, we will recognize within Schedule A, those low-volume laboratories that conduct 2,000 or fewer tests per year. We have established a separate, reduced compliance determination fee for these entities. As we gain experience with the timeframes

and costs involved in determining laboratory compliance with CLIA requirements, we will reanalyze the fee-setting methodologies and intend to seek input from the public and make adjustments as necessary in size and volume ratios.

*Comment:* In the preamble of the proposed rule, we specifically invited comments on the definition of a test and on the feasibility of collecting test information, particularly in the area of quantitative testing. Several commenters responded to this request and indicated that assessing a facility's work volume by counting each analyte tested would be burdensome. One commenter indicated that this definition inflates the actual workload of the laboratory since from a laboratory perspective a test panel or profile (which includes multiple analytes) is really a selection of tests that are generally performed in a group or in combination. Commenters suggested the following alternatives to the proposed definition of a test:

- Define a test as a current procedural terminology (CPT) codeable charge with the codes (range of codes) identified and routinely updated by HHS.
- Define a test as a single reportable patient result, thus excluding tests on quality control samples from the annual test volume.
- Use the number of specimens analyzed rather than the number of tests to determine laboratory volume.
- Determine laboratory volume based on the type of laboratory factored by the number of employees, rather than tests.

*Response:* We appreciate the suggestions offered by the commenters. However we cannot define a test as a CPT codeable charge because profiles are included on the CPT codes and this would not reflect the actual laboratory testing activity involved in conducting the testing and determining the test results. The same holds true for the suggestion of using the number of specimens; each specimen could have multiple tests and would not be reflective of the actual laboratory performance. We do not believe that the suggestion for using a factor of the number of employees is feasible since this would encourage laboratories to employ fewer personnel and could have adverse implications on the quality of the laboratory services provided.

We do agree that tests run on quality control samples should not be included when calculating the annual volume of laboratory tests and have modified proposed § 493.638, "Registration

certificate and certificate fees," and § 493.643(d) (1) and (2) (now redesignated as § 493.643(c) (1) and (2)) to indicate that, when determining annual volume, tests performed for quality control, quality assurance and proficiency testing are to be excluded.

*Section 493.645 Additional fee(s) for Accredited Laboratories (and State-exempt Laboratories)*

*Comment:* A commenter, in discussing fees to be paid for complaint investigations, sanctions, or hearings, said that if we will assess fees and costs where the investigated laboratory is unsuccessful, the investigated laboratory should also be entitled to some of its costs should proposed adverse actions be found to be without foundation.

*Response:* We cannot accept this comment. The law provides no authority to pay costs of laboratories that are either successful or unsuccessful at an ALJ hearing.

*Comment:* Another commenter said that our assessment of fees against laboratories certified by other agencies is not appropriate since the laboratories have already incurred substantial costs in complying with accreditation programs standards. If HHS has concerns about the certification process of accreditation programs, it should collect fees from the accreditation programs. As an alternative, the commenter continues, HHS should not reinspect laboratories but acknowledge that inspections conducted by private nonprofit organizations if it appears that their standards are higher than HHS's.

*Response:* We are adopting this suggestion in part. CLIA does not provide authority for billing accreditation programs for the costs of monitoring their programs. CLIA mandates the assessment of fees from the individual laboratories. We are required by section 353(e)(2) of the PHSa to monitor the survey process of accrediting bodies and routinely scrutinize the standards and accreditation procedures of these entities to ensure that the standards applied are at least equal to the standards established by HHS. To accomplish this, a sample of accredited laboratories will be surveyed, with the costs shared by all accredited laboratories. The fee for a certificate of accreditation will include a proportionate share (based on our best estimate of the number of accredited laboratories) of the administrative costs associated with CLIA (including the cost of issuing the certificate) and a proportionate share of the cost of the monitoring surveys.

However, section 353(p) of PHSa indicates that if the Secretary determines equivalency of a State's licensure standards, the Secretary may exempt laboratories licensed in that State from the CLIA requirements, including the payment of fees. As previously discussed, we are exercising that authority and have revised the proposed regulation to reflect this change. While State-exempt laboratories are exempt from CLIA requirements, Federal inspections may be conducted at random to ensure that standards are being enforced in an appropriate manner. States will be billed for the random Federal inspections of their State-exempt laboratories and for their proportionate share of the general overhead costs for the development and implementation of CLIA.

*Comment:* Referring to the additional fee an accredited laboratory will pay to cover the cost of evaluating individual laboratories in accreditation programs, a commenter said that these additional costs will be unnecessarily burdensome because they will also have to pay their own biennial inspection fees. Further, the commenter suggests that we should consider the possibility that many different accreditation programs may be approved and that we should conduct random sampling of each accreditation program, as opposed to a 5 percent sample of all accredited laboratories as proposed.

*Response:* As we have stated, CLIA legislation requires that the fees imposed on laboratories be sufficient to cover the costs of evaluating and monitoring accrediting bodies. The legislation also requires ongoing evaluation of accreditation programs and requires the assessment of fees to cover the costs of evaluating and monitoring accreditation programs. Regarding the sampling approach for evaluating accreditation programs, we agree that a 5 percent sample of laboratories accredited by each accrediting program that we have approved will provide more assurance of quality and accuracy than selecting 5 percent from the "total universe" of accredited laboratories. However, we have deleted the 5 percent provision that appeared in proposed § 493.645 since that provision reflects only an administrative goal, not a fixed obligation of the Department. We will administratively implement the commenter's suggestion to attain the 5 percent sample goal. In addition, although State-exempt laboratories have been exempted from CLIA requirements, such laboratories will be subject to Federal inspections. We intend to

conduct inspections of a 5 percent sample of State-exempt laboratories to ensure that standards are being enforced in an appropriate manner. Costs of such inspections will be paid by the State licensure program. Section 493.645 has been revised to include State-exempt laboratories.

*Comment:* A commenter referred to apparent discrepancies between preamble and regulatory language involving the financial obligation of an accredited laboratory subject to a complaint investigation. The commenter would like to have us clarify that all costs (that is, for the complaint investigation, any sanctions, or hearings) would be dismissed if the complaint is found to be unsubstantiated.

*Response:* As stated earlier, through an oversight, the regulatory language only addressed the costs associated with complaint investigations in regard to laboratories issued a certificate of accreditation (§ 493.645(b)). We have corrected this by adding a new § 493.643(d)(2), which specifies that costs for unsubstantiated complaint investigations or sanctions/hearings activities would not be imposed on the laboratory. We have also revised proposed § 463.645 to specify that the State licensure program may be assessed the costs incurred for complaint investigations of State-exempt laboratories if the complaint is substantiated.

*Section 493.646 Payment of Fees*

As indicated earlier, in response to comments received on the proposed regulation, we have made revisions to the proposed fee amounts. Charts showing the bases for the revised fee amounts are included at the end of the comment and response section.

*Comment:* A commenter representing multiple clinics within a State indicated that costs to purchase equipment for hematocrit testing in order to be eligible for a certificate of waiver would be prohibitive.

*Response:* CLIA anticipates that the regulations will be enforced at each location where tests are performed. Section 353(b) of the PHSa specifically states that a laboratory must have in effect an HHS-issued certificate (that is, a certificate, registration certificate, certificate of accreditation, or certificate of waiver) that is applicable to the specialty or subspecialties of services being offered. We will require that a separate application be filed for each laboratory location. Consequently, we will not allow laboratories located at different street addresses to apply for a

single certificate to cover all locations. However, we are providing some flexibility to a hospital that has multiple laboratory components that are at the same address and under common directorship to apply for a single certificate. In addition, laboratories that do limited testing (that is, few types of tests) for screening or treatment of individuals that are directed by not-for-profit or Federal, State, or local government organizations (for example, the WIC program) can operate (at their option) under one certificate.

*Comment:* In discussing fees for waivers, two commenters said that they could support a waiver fee of \$100 (one of the two added that glucose, cholesterol, and hematocrits should be included as waived tests).

*Response:* We agree with the comment that the proposed waiver fee of \$156 is too high. We have, in this final rule, therefore, revised the cost of issuing a certificate of waiver to \$100. This reduction is based primarily on recalculations of the administrative effort required to issue a certificate of waiver and on estimates of the number of laboratories that may be able to qualify for waiver.

As previously mentioned, the classification of tests is addressed in the final CLIA rule, HSQ-176-F, appearing elsewhere in this Federal Register.

*Comment:* A commenter stated that the fees as proposed will hinder cost-effective testing in smaller sites and that they should be re-analyzed based on comments and subsequent analysis of an earlier rule dealing with the variety of laboratory levels and personnel requirements.

*Response:* We disagree that the fees will hinder cost-effective testing. The fees are designed to cover the costs we will incur to evaluate compliance of large and small testing operations and the cost associated with establishing standards under CLIA, as well as all contractor-related costs. The commenter's suggestion that the fees be re-analyzed is valid. We will review the fee schedules once the Federal health and safety requirements are established based on test complexity. We will also, on an actual basis, review the fee schedules in light of actual experience.

*Comment:* The above commenter also suggested that laboratories be allowed to submit a deposit of \$25 with each initial application, with the balance due during the second year of the 2-year fee cycle. This would afford us quicker access to funding in order to begin implementing CLIA.

*Response:* We are not adopting this suggestion. Although the commenter is certainly correct about the gross amount

such a proposal could provide, we believe that the accounting and reporting costs associated with tracking the remittances of all laboratories subject to CLIA would be extremely high. As stated earlier, we have postponed assessing fees until the final CLIA standards rule (HSQ-176-F) was published. Now that HSQ-176-F is published elsewhere in this Federal Register, we will begin to send out applications and bills to laboratories. The amount of the bill will be based on the information provided by the laboratory in response to the questionnaire mailed earlier and will be for the full amount (that is, \$100, \$350, or \$600). This should provide sufficient funding in order to begin implementing CLIA.

*Comment:* One commenter suggested that we incorrectly assumed that most of physician office laboratories would fall within the waiver category and consequently require a minimum of Federal and State resources and time. The commenter continued that, if we based the fee schedules and other estimates of administrative costs on this, probably faulty assumption, insufficient funds will be collected to cover CLIA costs. Fees, then, will have to be substantially increased during the second year of CLIA implementation.

*Response:* We disagree with the comment. We estimated the resources and time necessary to conduct compliance determinations based on the volume and scope of laboratories services. Although these are only estimates, they are not arbitrary. They were developed after collaboration with State Health Departments and other Federal agencies. If we find that our estimates are, in fact, incorrect, we will revise the fee schedules accordingly and will publish them for public review in the Federal Register.

*Comment:* Regarding the assessment of fees for the issuance and renewal of certificates of waiver, a commenter suggested that, should these fees be assessed to nursing facilities and intermediate care facilities for the mentally retarded, they should be considered allowable costs under Medicare and Medicaid for payment rate purposes.

*Response:* We agree with the intent of the comment. User fees for laboratories within either a participating nursing facility or intermediate care facility for the mentally retarded are allowable costs that states should take into account as part of their facility payment rates.

*Comment:* A commenter indicated that there are currently regional differences considered in the Medicare

program's payments to physicians, depending on where in the country they practice medicine. The commenter continued that CLIA should take into consideration the concept of regional fees to be based on the laboratory's size and payment potential.

*Response:* We are not adopting regional fees. The fees for compliance determination contained in this rule take into consideration individual State variances such as geographic locations, travel costs, and State civil service pay scales. Therefore, State differences have been considered with regard to high and low cost areas.

*Comment:* A commenter, in discussing the fees for certification and determining compliance, suggested that the application and the fees for certification could be considered on the sliding scale of criteria according to hospital size and laboratory services.

*Response:* We have adopted this approach in part. A laboratory should be considered a separate entity and not necessarily linked to the size or operation of a hospital (in which many laboratories may be located). In the preamble of the proposed rule, we have outlined CLIA's scope by listing those "entities that perform laboratory testing" in the various types of facilities. But throughout the preamble and, more importantly, throughout the legislation itself, laboratories are treated as separate entities to which CLIA's unique provisions apply. We have, however, considered individual laboratory "size" based on number of specialties or scope of services performed and test volume in order to establish an appropriate range of fees.

*Comment:* A commenter indicated that some of the fees as currently proposed seem to affect smaller laboratories unfairly, resulting ultimately in inequitably high per test costs. Further, the commenter contended that such high per test fees for small laboratories could adversely affect patient access and that some small laboratories might even be forced to close.

*Response:* We disagree with this comment. We have considered small laboratories by establishing varying rates depending on volume and laboratory size. The ten proposed schedules, including a new low-volume category within Schedule A, attempt to minimize the negative impact on smaller laboratories. We intend to seek input from the public and will adjust the fee schedules as better data becomes available.

*Comment:* Responding to our solicitation for comments on existing

inspection experience with numbers and groupings of laboratories, a commenter offered that our proposed ten schedules could easily be reduced to five.

*Response:* We placed laboratories within the ten-schedule structure after conducting detailed analyses of information available on the amount of time necessary and the number of people required to determine laboratory compliance. We also believe that a ten-schedule structure is more beneficial since, by having the larger number of schedules, laboratories will more likely find themselves grouped more homogeneously. In addition, we have included another fee within Schedule A for low-volume laboratories that conduct 2,000 or fewer tests per year. As experience is gained in applying these fee schedules on all testing sites, we intend to seek input from the public and will revise them as appropriate.

*Comment:* Another commenter, responding to our request for comments on existing inspection experience and how it may relate to CLIA, objected strongly to the proposed fees and cites his State's \$300 annual laboratory regulation program as being more realistic.

*Response:* We acknowledge that there may be significant differences in the amounts charged by an individual State's laboratory regulation program and the fee schedules proposed in this rule. These differences may be the result of a number of factors, including the extensive requirements contained in CLIA and the mandate that all costs incurred, including contractual and administrative costs, are to be borne by the laboratories. We have developed fees to cover all Federal, State, and contractor costs, as well as the costs for certificate issuance and for compliance determination, based on projections of costs to administer CLIA. These fees are subject to revision based on actual experience.

*Section 493.649 Methodology for Determining Fee Amount*

*Comment:* A commenter disagreed with our methodology for determining fee amounts, arguing that basing the fees on estimates of time needed to complete the survey and assessment of individual tests is cumbersome and subject to varied interpretation. Further, the commenter continued, time estimates will not allow a laboratory requesting certification to accurately project its costs.

*Response:* We disagree with the comment. We believe that basing survey costs on time estimates is an accurate approach to fee development. CLIA legislation includes the mandate that the

costs for certification activities be borne by the laboratories. Since 1966, we have had in place an agreement through which we pay State agencies to determine program compliance through monitoring proficiency testing, evaluating personnel qualifications, and onsite surveys. Payment for these survey activities are negotiated with the States based on the number of people and the time estimated for the survey workload; in this case, on the time estimated to determine a laboratory's compliance with the various proficiency testing, personnel, recordkeeping, quality control, and quality assurance requirements of CLIA.

*Comment:* Another commenter addressing the methodology used to determine the fee amount expressed concern that we intend to use some of the CLIA revenues to fund studies and research not statutorily mandated by the legislation. The commenter believed that only mandated studies should be so funded.

*Response:* CLIA provides that fees assessed are to be sufficient to meet the costs incurred in administering the program. If studies and research are required to improve specific approaches to the development of laboratory regulations and survey and certification activities, regardless of whether they are specifically mentioned in CLIA, the costs of those studies become integral to the proper and efficient administration of CLIA and, as such, are to be borne by the laboratory community.

**Basis for Fee Amounts**

The fee schedules listed herein are designed to generate sufficient revenues to fully cover Federal costs for the development, administration, and implementation of CLIA, as required by law. They are based on the Department's best estimates regarding the number and testing volume of laboratories to be regulated, as well as estimates of associated Federal costs. As more definitive information becomes available as a result of the registration process, the fees for certificates of accreditation, inspection, and compliance will be reviewed and may require adjustment upward or downward.

The fees laboratories must pay for the issuance of a registration certificate or a certificate are as follows:

Small laboratory, that is, a laboratory categorized in this rule as Schedule A (including Low-Volume), Schedule B, or Schedule C..... \$100

Medium laboratory, that is, a laboratory categorized in this rule as Schedule D, Schedule E, Schedule F, or Schedule G..... 350  
 Large laboratory, that is, a laboratory categorized in this rule as Schedule H, Schedule I, or Schedule J..... 600

**Note:** The fee amount for a revised certificate of any type is \$50.

A certificate of waiver or certificate of accreditation fee would be assessed as follows:

Functions or tasks for all laboratories	Hours needed	Hourly rate	User fee
Federal Administration... Contractor Administration.....	1	\$50	\$50
Administration.....	1	50	50
<b>TOTAL</b> .....			<b>100</b>

(The hourly rate of \$50 for Federal Administration includes approximately \$30 for salaries and fringe benefits, and approximately \$20 for overhead costs, including the support of a nationwide satellite training network.)

The hours required for biennial inspections are a fixed national number by category; however, since the hourly rate varies by State, there will, in effect, be 53 separate fee schedules for biennial inspections. The average time and cost required to determine compliance during calendar year 1992 would be as follows:

	Hours	Average <sup>1</sup> hourly rate	Biennial user fee
Schedule A Low-volume Laboratories.....			\$300
Schedule A Laboratories:			
<sup>2</sup> Biennial inspection.....	24	\$35	\$840
Followup visit or complaint investigation.....	15	35	525
Sanctions/Hearings.....	8	35	280
Schedule B Laboratories:			
<sup>2</sup> Biennial inspection.....	32	35	1,120
Followup visit or complaint investigation.....	17	35	595
Sanctions/Hearings.....	9	35	315
Schedule C Laboratories:			
<sup>2</sup> Biennial inspection.....	40	35	1,400
Followup visit or complaint investigation.....	19	35	665
Sanctions/Hearings.....	10	35	350
Schedule D Laboratories:			
<sup>2</sup> Biennial inspection.....	47	35	1,645
Followup visit or complaint investigation.....	21	35	735

	Hours	Average <sup>1</sup> hourly rate	Biennial user fee
Sanctions/Hearings.....	11	35	385
Schedule E Laboratories:			
<sup>2</sup> Biennial inspection.....	54	35	1,890
Followup visit or complaint investigation.....	24	35	840
Sanctions/Hearings.....	12	35	420
Schedule F Laboratories:			
<sup>2</sup> Biennial inspection.....	61	35	2,135
Followup visit or complaint investigation.....	26	35	910
Sanctions/Hearings.....	13	35	455
Schedule G Laboratories:			
<sup>2</sup> Biennial inspection.....	68	35	2,380
Followup visit or complaint investigation.....	28	35	980
Sanctions/Hearings.....	14	35	490
Schedule H Laboratories:			
<sup>2</sup> Biennial inspection.....	75	35	2,625
Followup visit or complaint investigation.....	30	35	1,050
Sanctions/Hearings.....	15	35	525
Schedule I Laboratories:			
<sup>2</sup> Biennial inspection.....	82	35	2,870
Followup visit or complaint investigation.....	32	35	1,120
Sanctions/Hearings.....	16	35	560
Schedule J Laboratories:			
<sup>2</sup> Biennial inspection—The sum of 82 hours plus 7 hours for each additional 500,000 tests or portion thereof multiplied by a \$35 hourly rate.			
Followup visit or complaint investigation—The sum of 32 plus 2 hours for each additional 500,000 tests or portion thereof multiplied by a \$35 hourly rate.			
Sanctions/Hearings—The sum of 16 hours plus 1 hour for each additional 500,000 tests or portion thereof multiplied by a \$35 hourly rate.			

<sup>1</sup> Average hourly rates and user fees are shown since individual contracts are negotiated with 53 State survey agencies. The actual user fee for determining compliance would depend upon the State in which the laboratory is located. For the purpose of the unit cost budget methodology, the \$35 is broken out by two components: actual surveyor time to conduct compliance evaluations, which is about \$27 per hour, which includes but is not necessarily limited to preparation, travel, and report writing time; and an adjustment of \$8 per hour to cover surveyor costs for holidays, vacation, sick leave, and attendance at training courses. Therefore, the cost of these other work-related activities has been included in the user fee methodology.

<sup>2</sup> While the hours for the biennial surveys are fixed, the hours necessary for followup visits, complaint investigations and sanction/hearings activities will be the actual number of hours involved. (We show averages in the chart above for illustrative purposes.) The fee to be assessed, therefore, will vary depending on the actual time spent and the State's hourly rate.

The \$300 biennial inspection fee for Low-Volume laboratories is a fixed fee, regardless of the State's hourly rate. We anticipate relatively little followup, complaint investigations, etc., for this grouping of laboratories and do not intend to charge them sepa-

rately for these activities. The costs for these activities will be subsumed as part of the \$300 fee. Includes evaluating qualifications of personnel; monitoring proficiency testing; conducting onsite surveys; developing deficiency statements; and evaluating laboratories' plans to correct deficiencies.

In addition to the certificate of accreditation fee, the fee that a laboratory issued a certificate of accreditation would pay<sup>1</sup> in calendar year 1992 to share the cost of the 5 percent random inspections discussed earlier would be:

Schedule A Laboratories.....	\$42
Schedule B Laboratories.....	56
Schedule C Laboratories.....	70
Schedule D Laboratories.....	82
Schedule E Laboratories.....	95
Schedule F Laboratories.....	107
Schedule G Laboratories.....	119
Schedule H Laboratories.....	131
Schedule I Laboratories.....	144
Schedule J Laboratories.....	( <sup>1</sup> )

<sup>1</sup> Schedule I base fee plus \$12 for each additional 500,000 tests or portion thereof.

Note: The above schedules and corresponding fees also apply to the 5 percent annual random inspection of State-exempt laboratories. State-exempt laboratories will not be billed for these amounts. Rather, their State must pay these fees.

The fee that a laboratory issued a certificate of accreditation would pay, if it is necessary to perform the following activities in the case of that particular laboratory during 1992, would be as follows. (In this final rule, we are likewise associating the following costs for State-exempt laboratories. These laboratories will not be billed the following amounts; rather, their respective State must pay all costs associated with these activities.)

**Follow-up Visits or Complaint Investigations**

Schedule A Laboratories.....	\$525
Schedule B Laboratories.....	595
Schedule C Laboratories.....	665
Schedule D Laboratories.....	735
Schedule E Laboratories.....	840
Schedule F Laboratories.....	910
Schedule G Laboratories.....	980
Schedule H Laboratories.....	1,050
Schedule I Laboratories.....	1,120
Schedule J Laboratories.....	( <sup>1</sup> )

<sup>1</sup> Schedule I base fee plus \$70 for each additional 500,000 tests or portion thereof.

<sup>1</sup> Includes evaluating qualifications of personnel; monitoring proficiency testing; conducting onsite surveys; developing deficiency statements; and evaluating laboratories' plans to correct deficiencies.

A laboratory will be billed the above amounts for its certificate of accreditation when its accreditation organization has been approved by HHS.

**Sanctions/Hearing**

Schedule A Laboratories.....	\$280
Schedule B Laboratories.....	315
Schedule C Laboratories.....	350
Schedule D Laboratories.....	385
Schedule E Laboratories.....	420
Schedule F Laboratories.....	455
Schedule G Laboratories.....	490
Schedule H Laboratories.....	525
Schedule I Laboratories.....	560
Schedule J Laboratories.....	( <sup>1</sup> )

<sup>1</sup> Schedule I base fee plus \$35 for each additional 500,000 tests or portion thereof.

All laboratories subject to inspection are required to pay the amount representing the biennial inspection costs in the aforementioned schedules. If the laboratory requires additional survey time as a result of followup visit(s), certificate revisions, complaint investigation(s) that are substantiated, intermediate sanctions, appeals or hearings, an additional assessment, based on actual costs, will be made for such activities.

**V. Summary of Changes in the Final Regulations**

As stated in our response to comments, we have made changes to the proposed regulations published August 3, 1990. With the exception of the changes identified below, the final regulations reflect the proposals made in the August 3, 1990 proposed rule.

- We have retitled the "provisional" certificate as a "registration" certificate. We have made this change throughout the rule.

- We have revised proposed § 493.602, "Scope of subpart," to clarify that part 493, subpart F, applies to all laboratories "that test human specimens for health purposes." We have also added that it sets forth requirements related to State-exempt laboratories.

- We have changed "waiver test" or "certificate of waiver test" to "waived test" throughout this rule.

- We have revised proposed § 493.606, which concerns applicability, by replacing the proposed text with a cross reference to the applicability provisions of § 493.3, which is established in the standards regulation (HSQ-176-F) published elsewhere in this issue of the Federal Register.

- We have revised proposed § 493.610, which requires that laboratories have an appropriate certificate, to indicate that certificates of waiver will not be applicable to specialties or subspecialties of services. We are also revising this section to specify that a laboratory licensed by and located in a State whose licensure program is approved by HHS is exempt

from CLIA requirements and does not require a certificate issued by HHS.

- We have revised proposed § 493.614, which covers application procedures, to remove the distinction between (1) laboratories not licensed under CLIA '67 and laboratories not Medicare/Medicaid approved and (2) all other laboratories. The process for obtaining applications will be the same for both groups. We have further revised § 493.614 to specify that laboratories in a hospital that are located at the same address and under common directorship have the option of applying for a single certificate or multiple certificates. We also clarify that a laboratory that is not at a fixed location must file a single application using the address of its designated primary site. However a separate certificate is required for each unit that serves as a mobile laboratory. The certificate(s) would reflect the address of the primary site.

Additionally, not-for-profit or Federal, State, or local government laboratories that engage in limited public health testing (few types of tests) at different street addresses may operate, at their option, under one certificate. We also have made a change in the punctuation in proposed paragraph (c) to indicate that the certificate of waiver will not apply to specialties or subspecialties of services.

- We have further revised proposed paragraph (c), which specified that an application for a certificate of any type must be signed by the owner, operator, or authorized representative of the laboratory, by deleting reference to the operator. In reviewing this provision, we have concluded that if the laboratory owner wishes to authorize the laboratory operator to submit the various forms, he or she may do so, but it would be inappropriate for this regulation to independently empower the operator regardless of the laboratory owner's wishes. We have revised proposed paragraph (d) to clarify that tests for quality control, quality assurance, and proficiency testing purposes are not included when counting the number of tests performed annually. We further revised proposed § 493.614 to refer to licensing under CLIA '67 in the past tense, rather than the present, since CLIA '67 has been superseded by the Clinical Laboratory Improvement Amendments of 1988.

- We have revised proposed § 493.618, "Additional application requirements," to remove, from paragraph (b), the reference to the July 1, 1991 effective date, since this date has now occurred. We have also specified that the laboratory must agree to permit

inspections by HHS's designee, as well as by HHS. In paragraph (d), we have removed the word "operator", for the same reason we removed it from § 493.614(c).

- We have revised proposed § 493.622, "Opportunity for a hearing," and retitled it "Appeals procedures," to clarify that any laboratory that has its certification denied or limited cannot operate as a laboratory under the PHSA in the areas covered by the limitation or denial unless the denial or limitation is overturned. We have also revised this section to more accurately reflect the appeals process for laboratories.

- We have revised proposed § 493.626, "Provisional certificate," by retitling it as "Registration certificate" and adding, in paragraph (a), that the registration certificate generally will not include specialties/subspecialties of service, but will authorize the entity to conduct laboratory testing until a determination of the appropriate level of compliance can be made. We have also revised paragraph (a) to indicate that laboratories that were licensed under CLIA '67 will also initially receive registration certificates. We have also made a change (not discussed elsewhere) to proposed paragraph (b). Proposed paragraph (b) specified that, prior to expiration of the provisional (now "registration") certificate, HHS would notify the laboratory of the applicable requirements to obtain the appropriate certificate. It also stated that HHS would initiate revocation or limitation of a laboratory's provisional (now "registration") certificate "for failure to comply with the applicable requirements as set forth in the notification by HHS \* \* \*." We have revised this section to more accurately reflect the appeals process applicable under CLIA.

- As a change not discussed elsewhere in this preamble, we have revised proposed §§ 493.630, 493.631, and 493.632, which concern the requirements for a certificate, certificate of waiver, and certificate of accreditation, respectively, to add that each type of certificate is valid for not more than 2 years. This addition is consistent with the term specified in section 353(c)(2) of the PHSA.

- We have revised proposed § 493.630, "Certificate," by removing paragraph (a) and redesignating paragraph (b) as § 493.630. We then revised it to remove the distinction between laboratories that were licensed under CLIA '67 and those that were not.

- We have revised proposed § 493.632, "Certificate of accreditation," to be changing "accreditation program" to

"accreditation organization" in order to be consistent with the terminology used in other rules.

- We have revised proposed § 493.633, which addresses the applicability of the certificate, certificate of waiver, and certificate of accreditation to specify that a certificate of waiver is applicable to tests listed in the waiver test category. We have added that, if a laboratory with a certificate of waiver wishes to add services not included in the waived test category, it must notify HHS or its designee before performing the testing and that HHS will issue a registration certificate to authorize the laboratory to initiate testing. We specify that the limited registration certificate for the new testing is valid for 2 years or until a compliance determination can be conducted, whichever is shorter. We have also revised § 493.633 to reflect the statutory requirement that laboratories possessing a certificate or certificate of accreditation must agree to notify HHS or its designee or the accreditation organization (as appropriate) within 6 months of any changes in testing or methodologies.

Paragraph (b) of § 493.633 has been revised to indicate that various sanctions may be imposed upon a laboratory for failure to comply with the notification requirements of § 493.633 and to more accurately reflect the appeals process available with regard to such sanctions.

- We have redesignated the text of proposed § 493.634, "Notification of changes," as paragraph (a) and revised it to require that all laboratories, including those with registration certificates, must give notice of a change in director and to add that only laboratories performing Level II (retitled high complexity) testing are required to give notice of a change in supervisor. We have added new paragraphs (b) and (c). Paragraph (b) specifies that various sanctions may be imposed upon a laboratory for failure to comply with the notification requirements of § 493.634 and sets forth the appeals process available in such cases. We also specify that, for laboratories participating in Medicare and Medicaid, payments are suspended for failure to comply with the notification requirements. Paragraph (c) specifies that the laboratory must pay a fee for a revised certificate.

- We have revised §§ 493.638(b), 493.643(c) (1) and (2), which concern fees, to specify that tests performed for quality control, quality assurance, and proficiency testing purposes are excluded from the laboratory's annual volume. We have also revised

§ 493.638(b) to clarify, through the use of cross-references, the costs that are included in a fee schedule amount. Further, in recognition of the fact that those laboratories surveyed first may have to pay a certificate fee sooner than 2 years after paying the fee for a registration certificate, we have revised the reference to fee assessment and payment on an biennial basis to specify that the fee is assessed and payable at least biennially. We have also added that the fee for the issuance of the appropriate certificate is based on whether the laboratory is considered small, medium, or large.

- We have revised proposed § 493.639, "Fee for revised certificate," by redesignating it as paragraph (b) and adding a new paragraph (a) to specify that, if after a laboratory is issued a registration certificate, it changes its name or location, it must pay for a revised certificate. We have revised the paragraph redesignated as paragraph (b) to add that, if a laboratory with a certificate, certificate of accreditation, or certificate of waiver changes its name, location or its director or deletes services specified on its certificate, it must pay for a revised certificate. We also add that, if a laboratory with a certificate of waiver wishes to perform tests not included in the waiver test category, it also must pay for a registration certificate to allow the new testing.

Additionally (and not discussed elsewhere), we have deleted the word "actual" from the sentence "The fee for issuing an appropriate revised certificate is based on the actual cost to issue the revised certificate to the laboratory." We believe "actual cost" may be misread to imply that an adjustment of some sort would be made in each instance to reconcile estimated costs with incurred costs. In this preamble, we have established a fee of \$50 (reducing it from the proposed estimated cost of \$261). This represents our estimate of the average actual cost to issue a revised certificate. We do not believe that the small amount of any adjustment would justify the administrative burden (and cost) of adjusting the fee for individual laboratories.

- We have revised the proposed § 493.643, "Fee for determination of program compliance," by incorporating paragraph (b) into paragraph (a) and redesignating proposed paragraph (c) as paragraph (b). In redesignated paragraph (b), we have clarified that the fee for determining program compliance includes necessary administrative costs. Also, for clarification, we have moved

the sentence regarding additional expenses in the proposed rule to the end of the paragraph and added a sentence at the end that specifies that the additional fee is based on actual resources and time necessary to perform the various activities.

In the redesignated paragraph (c), "Classification of laboratories that require inspection for purpose of determining amount of fee," in order to accommodate the concerns of small testing entities, we have established a new category within Schedule A for those laboratories performing no more than 2,000 laboratory tests per year.

We have revised proposed § 493.643(e) (now redesignated as § 493.643(d)), which addresses additional fees that a laboratory must pay, to add that, if an additional fee is assessed in connection with upgrading a certificate, failure to pay the fee will result in revocation of the certificate. We have also removed reference to a certificate of accreditation from this paragraph. Because compliance determinations of accredited laboratories are made by the accreditation organization, a HHS fee for compliance determination does not apply to these laboratories. We are also adding that, if it is necessary to conduct a complaint investigation, impose sanctions, or conduct a hearing, HHS assesses the involved laboratory (other than a State-exempt laboratory) a fee to cover the cost of these activities and that failure to pay this fee will result in the revocation of the certificate. We specify that, if a complaint investigation results in a complaint being unsubstantiated or if an HHS adverse action is overturned, the laboratory is not assessed the fees that would have covered the cost of these activities.

- We have revised proposed § 493.645, "Additional fee(s) for accredited laboratories," by changing its title to "Fee(s) applicable to accredited laboratories/approved State licensure programs." We have also deleted the provision that would have set a 5 percent inspection sample of all accredited laboratories since that number reflects only an administrative goal and not the kind of fixed obligation that the proposed rule might have suggested. We have also made revisions to specify that the State is assessed for the costs incurred for the inspection of State-exempt laboratories and for investigations of complaints against the State's State-exempt laboratories if the complaint is substantiated, and the State's prorata share of general overhead to develop and implement CLIA.

- We have revised proposed § 493.646, "Payment of fees," by redesignating the text as paragraph (a) and adding that State-exempt laboratories are not notified of fee amounts. We have also revised paragraph (a) to specify that HHS will advise the laboratory where to send payment. We removed the reference to commercial banks because it is possible that not all laboratories subject to CLIA will make payment to commercial banks. We have added a new paragraph (b), which specifies that, in the case of a State with an HHS-approved licensure program, the State is billed for the costs of validation surveys and the costs of complaint investigation of a State-exempt laboratory if the complaint is substantiated.

- We have revised proposed § 493.649, "Methodology for determining fee amount," to clarify that the hourly rate includes both the costs to perform the required activities and necessary administration costs. We also have added that the fee for issuance of the registration certificate or certificate is based on the laboratory's scope and volume of testing.

In addition to the above changes that have been made in the regulation, as a change from the preamble of our proposed rule, we are establishing \$50 (and not \$261) as the fee for issuing a revised certificate of any type. Additionally, we are establishing, within Schedule A, a separate fee (\$300) for low-volume laboratories that conduct 2,000 or fewer tests per year. We are also revising the cost of issuing certificates and registration certificates from \$261 across-the-board to \$100, \$350, or \$600, depending on whether the laboratory is, respectively, a small, medium, or large facility (as defined in this preamble).

## VI. Regulatory Impact Statement

Executive Order (E.O.) 12291 requires us to prepare and publish a final regulatory impact analysis for any proposed regulation that meets one of the E.O. 12291 criteria for a "major rule"; that is, that will be likely to result in—

- An annual effect on the economy of \$100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

In addition, we generally prepare a final regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), unless the Secretary certifies that a final regulation will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we consider all laboratories as small entities. Individuals and States are not included in the definition of small entity.

In addition, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a final rule will have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 102(b) of the Act, we define a small rural hospital as a hospital that has fewer than 50 beds and is located outside a Metropolitan Statistical Area.

At the time we published the proposed rule (55 FR 31758, August 3, 1990), we indicated that these provisions constituted a major rule, and we provided a limited analysis. Since our analysis was not conclusive, we encouraged comments and submission of any applicable data concerning these provisions, particularly if there was a perception that they may result in significant increased costs. Although the overwhelming majority of the comments we received expressed concern over costs, specifically user fees, we received only general statements and no hard data. Further analysis of the requirements contained in this rule and of their impact on the public is incorporated in the Regulatory Impact Analysis for HSQ-176, the CLIA standards rule.

For the most part CLIA law requires that all laboratories be assessed fees for certification and inspection and that these fees should be sufficient to cover all costs involved. We fully expect to gain experience from administering the CLIA program and will reconsider our approach to establishing fee schedules, and we will revise schedules as necessary. We believe the majority of the costs alluded to by commenters are the result of a misunderstanding of the regulations or a result of the statute. Most of the costs mentioned by commenters are addressed in the comment and response section (section IV) of this final rule.

#### VII. Final Rule With Comment Period

In the proposed rule published on August 3, 1990, we proposed, in § 493.631, to issue a certificate of accreditation to laboratories licensed by a State whose licensure program had

been approved by HHS. This final rule exempts such laboratories from the requirements of CLIA (§ 493.610) and requires the State to pay a fee for inspection of a sample number of these laboratories to ensure that standards are being enforced in an appropriate manner (§ 493.645(b)(1)). This final rule also requires the State to pay the cost of a complaint investigation of a State-exempt laboratory if the complaint is substantiated (§ 493.645(b)(2)). Further, this final rule also requires the State to pay its prorata share of general overhead to develop and implement CLIA (§ 493.645(b)(3)). As stated under "Comment period" in the DATES section of this preamble, we will accept comments on only the State fee provision that are received timely.

#### VIII. Collection of Information Requirements

Regulations at §§ 493.614, 493.618, 493.633(a), and 493.634 contain information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). A notice will be published in the *Federal Register* after approval is obtained. The information collection requirements concern information that must be provided on a laboratory's application for a registration certificate, certificate of waiver, certificate of accreditation, or certificate and subsequent notification of any changes in the information provided on the application. All laboratories would be required to provide the information.

Public reporting burden for this collection of information is estimated to be approximately 3 hours per application. Organizations and individuals desiring to submit comments on the information collection and recordkeeping requirements should direct them to the Office of Management and Budget, Office of Information and Regulatory Affairs, room 3002, New Executive Office Building, Washington, DC 20503, Attention: Allison Herron Eydt, HCFA Desk Officer.

#### List of Subjects in 42 CFR Part 493

Health facilities, Laboratories, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR part 493 is amended as follows:

#### PART 493—LABORATORY REQUIREMENTS

1. The authority citation for part 493 continues to read as follows:

**Authority:** Sec. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following 11861(s)(11), 1861(s)(12), 1861(s)(13), 1861(s)(14), 1861(s)(15), and 1861(s)(16) of the Social Security Act (42 U.S.C. 1302, 1395x(e), the sentence following 1395x(s)(11), 1395x(s)(12), 1395x(s)(13), 1395x(s)(14), 1395x(s)(15), and 1395x(s)(16)).

2. A new subpart F is added to part 493 to read as follows:

#### Subpart F—General Administration

Sec.	
493.602	Scope of subpart.
493.606	Applicability of subpart.
493.610	Certificate requirements for laboratories.
493.614	Application procedures.
493.618	Additional application requirements.
493.622	Appeals procedures.
493.626	Registration certificate.
493.630	Certificate.
493.631	Certificate of waiver.
493.632	Certificate of accreditation.
493.633	Applicability of certificate, certificate of waiver, and certificate of accreditation.
493.634	Notification of changes.
493.638	Registration certificate and certificate fees.
493.639	Fee for revised certificate.
493.643	Fee for determination of program compliance.
493.645	Fee(s) applicable to accredited laboratories/approved State licensure programs.
493.646	Payment of fees.
493.649	Methodology for determining fee amount.

#### Subpart F—General Administration

##### § 493.602 Scope of subpart.

This subpart sets forth requirements all laboratories that test human specimens for health purposes must meet in order to apply for and be issued a registration certificate, certificate of waiver, certificate of accreditation, or certificate under section 353 of the Public Health Service Act (42 U.S.C. 263a). It also sets forth the methodology for determining the amount of the fees for issuing registration certificates, certificates of waiver, certificates of accreditation, or certificates and for determining compliance with the applicable standards of the Public Health Service Act (the PHS Act) and the Federal validation of State-exempt laboratories.

##### § 493.606 Applicability of subpart.

The rules of this subpart are applicable to those laboratories specified in § 493.3.

##### § 493.610 Certificate requirements for laboratories.

(a) Except as specified in paragraph (b), no person may solicit or accept

materials derived from the human body for laboratory examination or other procedure unless there is in effect for the laboratory a registration certificate or a certificate of waiver issued by HHS, or a certificate or a certificate of accreditation issued by HHS that is applicable to the specialty or subspecialties of services offered by the laboratory.

(b) A laboratory licensed by a State whose licensure program is approved by HHS is exempt from CLIA requirements (that is, State-exempt) and does not require a certificate issued by HHS.

#### § 493.614 Application procedures.

(a) HHS or its designee will send an application to those laboratories it has identified as potentially being subject to the requirements of CLIA. Those laboratories that do not receive an application must contact HHS or its designee to receive application forms.

(b) A separate application must be filed for each laboratory location. However, laboratories within a hospital that are located at the same street address and under common direction have the option of applying for a single certificate or multiple certificates for the laboratory sites within the same physical location or street address. In addition, not-for-profit or Federal, State, or local government laboratories that engage in limited public health testing (that is, few types of tests) may operate under one certificate. A laboratory that is not at a fixed location, that is, a laboratory that moves from testing site to testing site (such as health screening fairs) or other temporary testing location must file a single application using the address of its designated primary site. A separate certificate, which reflects the address of the designated primary site, is required for each mobile unit providing laboratory testing.

(c) An application for the issuance of a registration certificate, a certificate of waiver, or a certificate or certificate of accreditation applicable to one or more laboratory test procedures or examinations included in the specialties or subspecialties listed in § 493.643(d)(3) must be made to HHS or its designee on a form or forms prescribed by HHS and must be signed by the owner or authorized representative of the laboratory.

(d) The application must include information that describes the characteristics of the laboratory operation and the examinations and other test procedures performed by the laboratory, including—

(1) The names of the test procedures and examinations performed and the total number of test procedures and

examinations performed annually, excluding tests for quality control, quality assurance, and proficiency testing purposes;

(2) The methodologies for test procedures and examinations performed; and

(3) The qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory test procedures and examinations.

#### § 493.618 Additional application requirements.

In submitting an application for a registration certificate, a certificate of waiver, certificate of accreditation, or a certificate, a laboratory must agree to the following:

(a) To make records available and submit reports to HHS as HHS may require.

(b) To permit inspections by HHS or its designee as specified in subpart Q of this part. (Certificate of waiver laboratories are not subject to routine inspections.)

(c) To treat proficiency testing samples in the same manner as it treats materials derived from the human body referred to it for laboratory examinations or other procedures in the ordinary course of business. (Certificate of waiver laboratories are not subject to proficiency testing requirements.)

(d) To provide HHS with satisfactory assurances, through an attestation statement, signed by the laboratory owner or authorized representative, that the laboratory will be operated in accordance with the requirements established by the Secretary under section 353 of the PHS Act.

#### § 493.622 Appeals procedures.

(a) If HHS denies a laboratory's application for a registration certificate, certificate of waiver, certificate of accreditation, or certificate or limits the laboratory's certificate, HHS gives the laboratory a statement of the grounds on which the denial or limitation is based and an opportunity for an appeal, in accordance with the procedures set forth in part 498 of this chapter.

(b) If a laboratory that is seeking a registration certificate, certificate of waiver, certificate of accreditation, or certificate has its application denied or its certificate limited, it cannot operate as a laboratory under the PHS Act (or, in the case of a limitation, in the areas covered by the limitation) unless the denial or limitation is overturned at the conclusion of the administrative appeals process provided by part 498 of this chapter. (In addition, the laboratory is

not eligible for payment under the Medicare or Medicaid programs or, in the case of a limitation, cannot receive Medicare or Medicaid payment for services in the limited areas.)

(c) Additional provisions relating to appeal rights are set forth in §§ 493.626(b), 493.633(b), and 493.634(b).

#### § 493.626 Registration certificate.

(a) HHS or its designee initially issues a registration certificate or, if the laboratory meets the requirements, a certificate of waiver to each laboratory, provided that the laboratory meets the application requirements of §§ 493.614 and 493.618 and pays the applicable fee as specified in § 493.638. A registration certificate does not include specialties/subspecialties of service, except as noted in § 493.633, but authorizes the entity to conduct laboratory testing until a determination of the appropriate level of compliance can be made and the appropriate certificate issued. The registration certificate issued in accordance with § 493.633(a)(2) to a laboratory that has a certificate of waiver to allow the laboratory to add a service(s) not listed in the waived test category reflects only the added service(s) noted on the laboratory's application. A registration certificate issued under this section is valid for a period of not more than 2 years or until such time as an inspection to determine program compliance can be conducted or the laboratory demonstrates that it qualifies to receive a certificate of waiver or a certificate of accreditation, whichever is shorter. HHS reissues a registration certificate to any laboratory for which HHS or its designee has not had an opportunity to determine compliance.

(b) Prior to expiration of the registration certificate, HHS notifies the laboratory of the applicable requirements to obtain a certificate of accreditation or a certificate and the amounts of the fees for issuing these certificates and, if applicable, the amount of the fee for determination of compliance. HHS may suspend, revoke, or limit a laboratory's registration certificate for failure to comply with the applicable requirements and may deny the laboratory's application for the applicable certificate. HHS may also impose certain alternative sanctions. HHS provides the laboratory with a statement of the grounds on which the sanctions and denial are based, an opportunity to respond to the imposition of the sanctions, and an opportunity for appeal, in accordance with the procedures set forth in part 498 of this chapter. If the laboratory requests an

appeal of a suspension or revocation, it may keep its registration certificate until a decision is made by an Administrative Law Judge (ALJ), unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health. In cases where the registration certificate would expire, a registration certificate is reissued to authorize testing until a decision is made by an ALJ, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health. HHS may impose certain alternative sanctions prior to a hearing. (In addition, for laboratories receiving payment from the Medicare or Medicaid programs, such payments are suspended on the effective date specified in the notice to the laboratory of the denial of the application for the applicable certificate, even if there has been no appeal decision issued.)

(c) In the event of a non-compliance determination resulting in denial of a laboratory's application for a certificate of accreditation or certificate, HHS may suspend, revoke, or limit a laboratory's registration certificate. HHS may also impose certain alternative sanctions. HHS provides the laboratory with a statement of the grounds on which the sanctions and application denial are based and with an opportunity for an appeal, in accordance with the procedures set forth in part 498 of this chapter. If the laboratory requests an appeal of a suspension, revocation, or limitation, it may keep its registration certificate until a decision is made by an ALJ, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health. In cases where the registration certificate would expire, a registration certificate is reissued to authorize testing until a decision is made by an ALJ, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health. HHS may impose certain alternative sanctions prior to a hearing. (In addition, for laboratories receiving payment from the Medicare or Medicaid programs, such payments are suspended on the effective date specified in the notice to the laboratory of the denial of the application for the applicable certificate, even if there has been no appeals decision issued.)

#### § 493.630 Certificate.

HHS or its designee issues a certificate to each laboratory, provided the laboratory has a registration certificate and meets the application requirements of §§ 493.614 and 493.618, pays the applicable fee as specified in § 493.638, and meets all other applicable

requirements of this part. A certificate is valid for not more than 2 years.

#### § 493.631 Certificate of waiver.

HHS or its designee issues a certificate of waiver to a laboratory if it performs only waived tests, provided the laboratory meets the application requirements of §§ 493.614 and 493.618, pays the applicable fee as specified in § 493.638, and meets all other applicable requirements of this part. A certificate of waiver is valid for not more than 2 years.

#### § 493.632 Certificate of accreditation.

HHS or its designee issues a certificate to a laboratory accredited by an HHS-approved accreditation organization, provided the laboratory has a registration certificate and meets the application requirements of §§ 493.614 and 493.618, pays the applicable fee as specified in § 493.638, and meets all other applicable requirements of this part. A certificate of accreditation is valid for not more than 2 years.

#### § 493.633 Applicability of certificate, certificate of waiver, and certificate of accreditation.

(a) The certificate of waiver issued is applicable to tests listed in the waived test category. The certificate or certificate of accreditation issued is applicable to those specialties and subspecialties of service offered by the laboratory in accordance with this part.

(1) A laboratory performing only waived tests may not perform any examination or procedure not listed in the waived test category until it has requested and HHS has issued to it a registration certificate that covers the additional examinations or procedures requested by the laboratory. The laboratory may continue to perform waived tests that are covered by the certificate of waiver already issued to the laboratory. The registration certificate is valid for 2 years or until a compliance determination can be conducted, whichever is shorter. After HHS or its designee determines compliance, HHS issues a certificate that includes the additional specialties or subspecialties for which compliance has been determined.

(2) A laboratory possessing a certificate must notify HHS or its designee within 6 months of any changes in methodologies for any test procedure or examination it performs and any additions or deletions of tests or examinations performed. If the laboratory adds testing in a specialty or subspecialty not listed on its certificate, HHS or its designee will determine

compliance. After HHS or its designee determines compliance, a revised certificate is issued that includes the additional specialties or subspecialties for which compliance has been determined.

(3) A laboratory possessing a certificate of accreditation must notify its approved accreditation organization within 6 months of any changes in methodologies for any test procedure or examination it performs or any additions or deletions of tests or examinations performed so that appropriate actions can be taken by the accreditation organization and a revised certificate can be issued when appropriate.

(b) HHS may suspend, revoke, or limit a laboratory's registration certificate and may impose certain alternative sanctions for failure to comply with the notice requirements of this section. HHS provides the laboratory with a statement of grounds on which the sanctions are based, an opportunity to respond to the imposition of the sanctions, and an opportunity for an appeal, in accordance with the procedures set forth in part 498 of this chapter. If the laboratory requests an appeal of a suspension, revocation, or limitation, it retains its certificate or a reissued certificate until a decision is made by an ALJ, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health. HHS may impose certain alternative sanctions prior to a hearing. In addition, for laboratories receiving payment from the Medicare or Medicaid programs, such payments are suspended during the pendency of any hearing for failure to comply with the requirements of this part.

#### § 493.634 Notification of changes.

(a) A laboratory must notify HHS or its designee within 30 days if changes occur in—

- (1) Ownership;
- (2) Name;
- (3) Location;
- (4) Director; or
- (5) Supervisor (only applicable for a high complexity laboratory).

(b) HHS may suspend, revoke, or limit a laboratory's registration certificate, certificate of waiver, or certificate of accreditation or may impose certain alternative sanctions for failure to comply with the notice requirements of this section. In such an event, HHS provides the laboratory with a statement of grounds on which the sanction is based and an opportunity for an appeal, in accordance with the procedures set forth in part 498 of this

chapter. If the laboratory requests an appeal of a suspension, revocation, or limitation, it retains its certificate or a reissued certificate until a decision is made by an ALJ, unless HHS finds that conditions at the laboratory pose an imminent and serious risk to human health. (In addition, for laboratories participating in Medicare or Medicaid, payments are suspended during the pendency of any hearing for failure to comply with the notice requirements.)

(c) If a revised certificate is necessary because of the changes identified in paragraph (a) of this section, the laboratory must pay the fee for a revised certificate as required in § 493.639

**§ 493.638 Registration certificate and certificate fees.**

(a) *Basic rule.* Laboratories must pay a fee for the issuance of a registration certificate, certificate of waiver, certificate of accreditation, or a certificate, as applicable. Laboratories must also pay a fee to reapply for a certificate of waiver, certificate of accreditation, or a certificate. The total of fees collected by HHS under the laboratory program must be sufficient to cover the general costs of administering the laboratory certification program under section 353 of the PHS Act. For registration certificates and certificates, this includes evaluating and monitoring proficiency testing programs and accreditation bodies and implementing, monitoring, and enforcing compliance with section 353 of the PHS Act and collection of fees and issuing registration certificates and certificates. For a certificate of waiver, this includes the cost of issuing the certificate of waiver, collection of fees and the administrative costs associated with evaluating tests to determine if a certificate of waiver should be issued. For a certificate of accreditation this includes the cost of issuing the certificate of accreditation, collection of fees and the administrative costs associated with evaluating programs of accrediting bodies and the costs to conduct sample validation surveys of accredited laboratories.

(b) *Fee amount.* The fee amount is set annually by HHS on a calendar year basis and is based on schedules, or ranges, of laboratory test volume (excluding tests performed for quality control, quality assurance, and proficiency testing purposes) and scope of specialties tested, with the amounts of the fees in each schedule a function of the costs for all aspects of general administration of CLIA as set forth in §§ 493.649 (b) and (c). This fee is assessed and payable at least biennially. The methodology used to

determine the amount of the fee is found in § 493.649. The amount of the fee applicable to the issuance of the registration certificate or the issuance or renewal of the certificate of waiver, certificate of accreditation, or certificate is the amount in effect at the time the application is received. Upon receipt of an application for a registration certificate, certificate of waiver, certificate of accreditation, or certificate, HHS or its designee notifies the laboratory of the amount of the required fee. The amount of the fee is based on whether the laboratory is considered small, medium, or large (based on the volume and scope of testing performed by the laboratory).

**§ 493.639 Fee for revised certificate.**

(a) If, after a laboratory is issued a registration certificate, it changes its name or location, the laboratory must pay a fee to cover the cost of issuing a revised registration certificate. The fee for the revised registration certificate is based on the cost to issue the revised certificate to the laboratory.

(b) A laboratory must pay a fee to cover the cost of issuing a revised certificate in any of the circumstances specified in paragraphs (b) (1) and (2). The fee for issuing an appropriate revised certificate is based on the cost to issue the revised certificate to the laboratory. (An additional fee is also required under § 493.643(e) if it is necessary to determine compliance with additional requirements and, if a laboratory with a certificate of waiver wishes to perform tests not listed in the waived test category, it must, as set forth in § 493.626, pay an additional fee for a registration certificate to cover the new testing.)

(1) If after a certificate, certificate of accreditation, or certificate of waiver is issued, a laboratory changes its name, location, or its director;

(2) If after a certificate or certificate of waiver is issued, a laboratory deletes services or wishes to add services and requests that its certificate be upgraded or that its certificate of waiver be changed or eliminated.

**§ 493.643 Fee for determination of program compliance.**

(a) *Fee requirement.* In addition to the fee required under § 493.638, laboratories regulated subject to the requirements of this part must pay a fee to cover the cost of determining program compliance, unless it is issued a certificate of waiver or a certificate of accreditation.

(b) *Costs included in the fee.* Included in the fee for determining program compliance is the cost of evaluating

qualifications of personnel; monitoring proficiency testing; conducting onsite inspections; documenting deficiencies; evaluating laboratories' plans to correct deficiencies; and necessary administrative costs. HHS sets the fee amounts annually on a calendar year basis. Laboratories are inspected biennially; therefore, fees are assessed and payable biennially. If additional expenses are incurred to conduct follow up visits to verify correction of deficiencies, to impose sanctions, and/or for surveyor preparation for and attendance at ALJ hearings, HHS assesses an additional fee to include these costs. The additional fee is based on the actual resources and time necessary to perform the activities.

(c) *Classification of laboratories that require inspection for purpose of determining amount of fee.* (1) There are ten classifications (schedules) of laboratories for the purpose of determining the fee amount a laboratory is assessed. Each laboratory is placed into one of the ten following schedules based on the laboratory's scope and volume of testing (excluding tests performed for quality control, quality assurance, and proficiency testing purposes).

(i) (A) *Schedule A Low Volume.* The laboratory performs not more than 2,000 laboratory tests annually.

(B) *Schedule A.* The laboratory performs tests in no more than 3 specialties of service with a total annual volume of more than 2,000 but not more than 10,000 laboratory tests.

(ii) *Schedule B.* The laboratory performs tests in at least 4 specialties of service with a total annual volume of not more than 10,000 laboratory tests.

(iii) *Schedule C.* The laboratory performs tests in no more 3 specialties of service with a total annual volume of more than 10,000 but not more than 25,000 laboratory tests.

(iv) *Schedule D.* The laboratory performs tests in at least 4 specialties with a total annual volume of more than 10,000 but not more than 25,000 laboratory tests.

(v) *Schedule E.* The laboratory performs more than 25,000 but not more than 50,000 laboratory tests annually.

(vi) *Schedule F.* The laboratory performs more than 50,000 but not more than 75,000 laboratory tests annually.

(vii) *Schedule G.* The laboratory performs more than 75,000 but not more than 100,000 laboratory tests annually.

(viii) *Schedule H.* The laboratory performs more than 100,000 but not more than 500,000 laboratory tests annually.

(ix) *Schedule I.* The laboratory performs more than 500,000 but not more than 1,000,000 laboratory tests annually.

(x) *Schedule J.* The laboratory performs more than 1,000,000 laboratory tests annually.

(2) For purposes of determining a laboratory's classification under this section, a test is a procedure or examination for a single analyte. (Tests performed for quality control, quality assurance, and proficiency testing are excluded from the laboratory's total annual volume). Each profile (that is, group of tests) is counted as the number of separate procedures or examinations; for example, a chemistry profile consisting of 18 tests is counted as 18 separate procedures or tests.

(3) For purposes of determining a laboratory's classification under this section, the specialties and subspecialties of service for inclusion are:

(i) The specialty of Microbiology, which includes one or more of the following subspecialties:

- (A) Bacteriology.
- (B) Mycobacteriology.
- (C) Mycology.
- (D) Parasitology.
- (E) Virology.

(ii) The specialty of Serology, which includes one or more of the following subspecialties:

- (A) Syphilis Serology.
- (B) General immunology

(iii) The specialty of Chemistry, which includes one or more of the following subspecialties:

- (A) Routine chemistry.
- (B) Endocrinology.
- (C) Toxicology.
- (D) Urinalysis.

(iv) The specialty of Hematology.

(v) The specialty of

Immunohematology, which includes one or more of the following subspecialties:

- (A) ABO grouping and Rh typing.
- (B) Unexpected antibody detection.
- (C) Compatibility testing.
- (D) Unexpected antibody

identification.

(vi) The specialty of Pathology, which includes the following subspecialties:

- (A) Cytology.
- (B) Histopathology.
- (C) Oral pathology.

(vii) The specialty of Radiobioassay.

(viii) The specialty of

Histocompatibility.

(ix) The specialty of Cytogenetics.

(d) *Additional fees.* (1) If after a certificate or certificate of waiver is issued a laboratory adds services and requests that its certificate be upgraded, the laboratory must pay an additional fee if, in order to determine compliance with additional requirements, it is

necessary to conduct an inspection, evaluate personnel, or monitor proficiency testing performance. The additional fee is based on the actual resources and time necessary to perform the activities. HHS revokes the laboratory's certificate for failure to pay the compliance determination fee.

(2) If it is necessary to conduct a complaint investigation, impose sanctions or conduct a hearing, HHS assesses the laboratory, other than a State-exempt laboratory, a fee to cover the cost of these activities. If a complaint investigation results in a complaint being unsubstantiated, or if an HHS adverse action is overturned at the conclusion of the administrative appeals process, the government's costs of these activities are not imposed upon the laboratory. Costs for these activities are based on the actual resources and time necessary to perform the activities and are not assessed until after the laboratory concedes the existence of deficiencies or an ALJ rules in favor of HHS. HHS revokes the laboratory's certificate for failure to pay the assessed costs.

**§ 493.645 Fee(s) applicable to accredited laboratories/approved State licensure programs.**

(a) *Accredited laboratories.* (1) In addition to the certificate fee, a laboratory that is issued a certificate of accreditation is also assessed a fee to cover the cost of evaluating individual laboratories to determine overall whether an accreditation organization's standards and inspection policies are equivalent to the Federal program. All accredited laboratories share in the cost of these inspections. These costs are the same as those that are incurred when inspecting nonaccredited laboratories.

(2) If, in the case of a laboratory that has been issued a certificate of accreditation, it is necessary to conduct a complaint investigation, impose sanctions, or conduct a hearing, HHS assesses that laboratory a fee to cover the cost of these activities. If a complaint investigation results in a complaint being unsubstantiated, or if an HHS adverse action is overturned at the conclusion of the administrative appeals process, the cost of these activities are not imposed upon the laboratory. Costs are based on the actual resources and time necessary to perform the activities and are not assessed until after the laboratory concedes the existence of deficiencies or an ALJ rules in favor of HHS. HHS revokes the laboratory's certificate for failure to pay the assessed costs.

(3) If, in the case of a laboratory subject to an inspection under

paragraph (a), followup visits are necessary because of identified deficiencies, HHS assesses the laboratory a fee to cover the cost of these visits. The fee is based on the actual resources and time necessary to perform the followup visits. HHS revokes the laboratory's certificate of accreditation for failure to pay the assessed fee.

(b) *Approved State licensure programs.* State licensure programs approved by HHS are assessed a fee for the following:

(1) Costs of Federal inspections of laboratories in that State (that is, State-exempt laboratories) to verify that standards are being enforced in an appropriate manner.

(2) Costs incurred for investigations of complaints against the State's State-exempt laboratories if the complaint is substantiated.

(3) Costs of the State's prorata share of general overhead to develop and implement CLIA.

**§ 493.646 Payment of fees.**

(a) Except for State-exempt laboratories, all laboratories are notified in writing by HHS or its designee of the appropriate fee(s) and instructions for submitting the fee(s), including the due date for payment and where to make payment. Registration certificates, certificates of waiver, certificates of accreditation, or certificates are not issued until the applicable fees have been paid.

(b) For State-exempt laboratories, HHS estimates the cost of conducting validation surveys within the State for a 2-year period. HHS or its designee notifies the State by mail of the appropriate fees, including the due date for payment and the address of the United States Department of Treasury designated commercial bank to which payment must be made. In addition, if complaint investigations are conducted in laboratories within these States and are substantiated, HHS bills the State(s) the costs of the complaint investigations.

**§ 493.649 Methodology for determining fee amount.**

(a) *General rule.* The amount of the fee in each schedule for compliance determination surveys is based on the average hourly rate (which includes the costs to perform the required activities and necessary administration costs) multiplied by the average number of hours required, or if activities are performed by more than one of the entities listed in paragraph (b) of this section, the sum of the products of the applicable hourly rates multiplied by the

average number of hours required by the entity to perform the activity. The fee for issuance of the registration certificate or certificate is based on the laboratory's scope and volume of testing.

(b) *Determining average hourly rates used in fee schedules.* Three different entities perform activities related to the issuance or reissuance of certificates of waiver, certificates of accreditation, or certificates and determining program compliance. HHS determines the average hourly rates for the activities of each of these entities.

(1) *State survey agencies.* The following costs are included in determining an average hourly rate for the activities performed by State survey agencies:

(i) The costs incurred by the State survey agencies in evaluating personnel qualifications and monitoring each laboratory's participation in an approved proficiency testing program. The cost of onsite inspections and monitoring activities is the hourly rate derived as a result of an annual budget negotiation process with each State. The hourly rate encompasses salary costs (as determined by each State's civil service pay scale) and fringe benefit costs to support the required number of State inspectors, management and direct support staff.

(ii) Travel costs necessary to comply with each State's administrative requirements and other direct costs such as equipment, printing, and supplies. These costs are established based on historical State requirements.

(iii) Indirect costs as negotiated by HHS.

(2) *Federal agencies.* The hourly rate for activities performed by Federal agencies is the most recent average hourly cost to HHS to staff and support a full time equivalent employee. Included in this cost are salary and fringe benefit costs, necessary administrative costs, such as printing, training, postage, express mail, supplies, equipment, computer system and building service charges associated with support services provided by organizational components such as a computer center, and any other oversight activities necessary to support the program.

(3) *HHS contractors.* The hourly rate for activities performed by HHS contractors is the average hourly rate established for contractor assistance based on an independent government cost estimate for the required workload. This rate includes the cost of contractor support to provide proficiency testing programs to laboratories that do not participate in an approved proficiency testing program, provide specialized

assistance in the evaluation of laboratory performance in an approved proficiency testing program, perform assessments of cytology testing laboratories, conduct special studies, bill and collect fees, issue certificates, establish accounting, monitoring and reporting systems, and assist with necessary surveyor training.

(c) *Determining number of hours.* The average number of hours used to determine the overall fee in each schedule is HHS's estimate, based on historical experience, of the average time needed by each entity to perform the activities for which it is responsible.

(Catalog of Federal Domestic Assistance Program No. 13.714, Medical Assistance Program; No. 13.773, Medicare—Hospital Insurance; and No. 113.774, Medicare—Supplementary Medical Insurance)

Dated: December 1, 1991.

Gail R. Wilensky,  
Administrator, Health Care Financing  
Administration.

Approved: January 23, 1992.

Louis W. Sullivan,  
Secretary.  
[FR Doc. 92-4052 Filed 2-20-92; 12:27 pm]  
BILLING CODE 4120-03-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration 42 CFR Part 493

[HSQ-179-F]

RIN 0938-AE60

#### Medicare Program; Medicare and Laboratory Certification Program; Enforcement Procedures for Laboratories

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Final rule.

**SUMMARY:** These regulations set forth the rules for sanctions that HCFA may impose on laboratories that are found not to meet Federal requirements. These include the principal sanctions of suspending, limiting, or revoking the laboratory's certificate issued under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), and cancelling the laboratory's approval to receive Medicare payment for its services, and the alternative sanctions that may be imposed instead of or before the principal sanctions.

These amendments are necessary to conform HCFA regulations to changes made in the law by the Omnibus Budget Reconciliation Act of 1987 (OBRA '87) and the 1988 amendments to section 353

of the Public Health Service Act (PHS Act). The latter are commonly referred to as "CLIA 88".

The purpose of the amendments is to ensure that functioning laboratories are capable of providing accurate and reliable test results and that the health of individuals served by the laboratory and that of the general public is not adversely affected by laboratory operations and by testing procedures that do not meet the standards set forth in other subparts of part 493 of the HCFA regulations.

**DATES:** *Effective date:* These regulations are effective September 1, 1992.

**ADDRESSES:** *Copies:* To order copies of the **Federal Register** containing this document, send your request to the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325. Specify the date of the issue requested and stock number 069-001-00042-4. Enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 783-3238 or by faxing to (202) 275-6802. The cost for each copy (in paper or microfiche form) is \$1.50. In addition, you may view and photocopy the **Federal Register** document at most libraries designated as U.S. Government Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**. The order desk operator will be able to tell you the location of the U.S. Government Depository Library nearest to you.

**FOR FURTHER INFORMATION CONTACT:** Irene Gibson (410) 966-6768.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

###### A. Changes in the Laws

Before enactment of the laws cited above under "Summary", there were two sets of regulations and two survey and enforcement systems applicable to laboratories. HCFA was responsible for the determination of whether a laboratory met the requirements to be approved to receive Medicare payment for its services. The Public Health Service was responsible for the Federal licensure of laboratories that engaged in interstate commerce.

The only sanctions available under these two systems, for a laboratory that did not meet the Federal requirements, was the denial or cancellation of the approval to receive Medicare payment, and the suspension, revocation or

limitation of the license to engage in interstate commerce.

Section 4064(d) of OBRA '87 added to the Act a new section 1846 which directs the Secretary to develop and implement a range of intermediate sanctions to apply to laboratories that receive Medicare payments. These sanctions must include—

(1) Directed plans of correction;  
 (2) Civil money penalties;  
 (3) Payment for the costs of onsite monitoring by the agency responsible for conducting certification inspections; and

(4) Suspension of all or part of the payments to which the laboratory would otherwise be entitled for services furnished after the effective date of sanction. The Secretary is also required to develop and implement specific procedures with respect to how and when each of the sanctions is to be imposed, and the amount of any penalties. The procedures must be designed to minimize the time lapse between identification of the violations and imposition of the sanctions, and provide for incremental more severe penalties for repeated or uncorrected deficiencies.

The primary purpose of the "CLIA 88" amendments is to strengthen the Federal oversight of laboratories in order to ensure that test results are accurate and reliable.

The new law creates a national, unified enforcement mechanism that affects virtually every laboratory in the country, not just those that are involved in interstate commerce. Every laboratory subject to the statute's broad definition will not be subject to CLIA 88 requirements and, because enforcement comes under the jurisdiction of the Secretary, every laboratory will be subject to regulations promulgated by the Secretary, regardless of whether it participates in Medicare. Under CLIA 88 it is no longer necessary to have separate sets of Federal rules to implement the two statutes. Moreover, section 6141 of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101-239) revoked the exemption of low-volume physician office laboratories from the CLIA certification requirements, and requires all laboratories that participate in Medicare to meet the CLIA 88 requirements. Since it is now possible to have one consolidated set of Federal requirements under a single enforcement system, it will no longer be possible for a laboratory to be sanctioned under one law, while escaping sanction under the other. In order to continue to operate under CLIA 88 all laboratories subject to the law must be inspected under CLIA

88 to obtain a CLIA certificate, with the exception of laboratories that request and receive a certificate of waiver. These laboratories are not inspected unless: a complaint that warrants an inspection is received; HCFA has reason to believe the laboratory is being operated in a manner that constitutes a risk to human health; on a random sample basis; to determine whether the laboratory is performing tests not listed in § 493.15; or to collect information for the addition, deletion or continued inclusion of specific waived tests.

CLIA 88 grants the Secretary new and more flexible enforcement authority, including the use of intermediate sanctions and civil action to enjoin a laboratory from continuing an activity that constitutes a significant hazard to the public health. The amended law also—

- Provides for incarceration and fines for any person convicted for intentionally violating any CLIA requirements;

- Provides for administrative and judicial review procedures available to a laboratory when an intermediate sanction is imposed or its CLIA certificate is suspended, revoked, or limited; and

- Requires the Secretary to publish annually a list of all the laboratories against which a sanction has been imposed or legal action has been taken.

To safeguard against errors in the names of laboratories or individuals cited in the annual laboratory registry publication, we will send to each HCFA regional office its portion of the laboratory registry for verification of information before publication. This procedure will prevent the serious injury to a provider's or individual's professional reputation and problems that could result from inaccurate reporting.

Under previous CLIA rules, licenses were issued annually to laboratories based on the specialties and subspecialties of tests for which the laboratory could demonstrate compliance with Federal quality standards. Under CLIA 88, CLIA certificates will be issued for a two-year period but may be suspended or limited prior to a hearing in cases of noncompliance which pose immediate jeopardy to patients or the general public. In such cases, CLIA certificates can be revoked following a hearing. In cases that do not pose immediate jeopardy, in lieu of suspension, limitation, or revocation of the CLIA certificate, HCFA may impose alternative sanctions after providing the laboratory an opportunity to respond to the sanction and request a hearing.

## B. Consolidation of Previous Rules

On March 14, 1990, we published (at 55 FR 29538) a final rule with comment period to consolidate the previous Medicare and CLIA regulations discussed above and designate them under a new part 493—Laboratory Requirements. The requirements of part 493 were effective as of September 10, 1990 except for subpart H—Participation in Proficiency Testing, which was effective as of January 1, 1991. The requirements of part 493 will apply to virtually all laboratories and will be used to determine whether a laboratory may continue to operate and whether its services qualify for Medicare payment.

These rules amend the new Part 493 to add a Subpart R—Enforcement Procedures. The impact of these changes on the programs is discussed below.

## II. Program Impact

### A. Medicare and Medicaid

Under section 1846 of the Act, Medicare payment for laboratory services may continue for up to 1 year after condition level deficiencies (noncompliance with any of the conditions that a laboratory must meet in order to obtain a CLIA certificate) have been identified as long as one or more intermediate sanctions are being imposed. Because section 1846 permits HCFA to develop and implement alternative sanctions of graduated severity according to levels of severity of deficiencies, we have established three levels of noncompliance:

- Condition level deficiencies with immediate jeopardy.
- Condition level deficiencies without immediate jeopardy.
- Deficiencies below the condition level without immediate jeopardy.

Condition level deficiencies that pose immediate jeopardy to the health and safety of individuals served by the laboratory or that of the general public will result in very swift cancellation of Medicare approval if the jeopardy is not removed immediately.

On the other hand, condition level deficiencies that do not pose immediate jeopardy no longer need trigger immediate cancellation of Medicare approval. While cancellation of approval would always remain an option, other measures may be employed first, while corrections are being made, in an effort to encourage laboratories to achieve compliance in a timely manner. However, condition level deficiencies that remain uncorrected after a reasonable period of time will still lead to cancellation of approval of

Medicare payment for the laboratory's services.

Section 1902(a)(9)(C) of the Act provides that payment for laboratory services may be made under the Medicaid State plan only if the services are furnished by a laboratory that meets CLIA requirements.

#### B. CLIA 88

The major program impacts of the CLIA 88 amendments—the extension of CLIA requirements to all laboratories that test human specimens for health purposes, and the opportunity to integrate the previously separate inspection and enforcement systems—have been discussed above under Background. Since the CLIA inspection and enforcement provisions are essentially the same as those set forth in the Medicare statute or in section 1846 of the Social Security Act, we believe that we should impose sanctions under CLIA based on the same levels of noncompliance as under the Medicare statute.

#### C. Unsuccessful Participation in Proficiency Testing

The CLIA 88 amendments require that laboratories issued a CLIA certificate must participate in an approved proficiency testing program. Laboratories which had been previously regulated under Medicare or CLIA are required to continue to participate in proficiency testing under CLIA 88. Previously unregulated laboratories will be required to begin proficiency testing in 1994. Subpart H of 42 CFR Part 493, included as part of another final CLIA regulation with comment period published elsewhere in this issue of the *Federal Register*, specifies that any laboratory which performs tests of moderate or high complexity, or both, must enroll in a proficiency testing program for each of the specialties, subspecialties, and analytes authorized by its CLIA certificate. Subpart H sets forth successful participation in proficiency testing as a condition level requirement. As stated in this regulation at § 493.1804(b)(2), HCFA may impose alternative or principal sanctions against any laboratory with condition level deficiencies. Therefore, laboratories which do not participate successfully in proficiency testing will be subject to the same sanctions that are applicable for noncompliance with any other CLIA condition. Additionally, if any laboratory fails to participate successfully in proficiency testing, HCFA may impose the training and technical assistance provisions set forth at § 493.1838 of the regulation.

#### D. Phased-in Imposition of Alternative Sanctions for Unsuccessful Participation in Proficiency Testing

In order to provide adequate opportunity for all laboratories to fully understand the PT system under CLIA prior to being sanctioned for unsuccessful participation in PT, we will phase in the enforcement of PT requirements. The authority for this phase-in is based on sections 1846 of the Social Security Act and 353(h) of the Public Health Service Act. These statutory sections provide the Secretary with the opportunity to develop and implement procedures with respect to when and how intermediate sanctions are to be imposed against laboratories. Under CLIA, previously regulated laboratories are subject to PT requirements as of the effective date of all CLIA requirements, published elsewhere in this issue of the *Federal Register*. Previously unregulated laboratories will not be required to meet PT requirements until January 1, 1994. In both cases, however, the first citation of unsuccessful PT participation will not result in the imposition of a sanction. Unsuccessful participation in subsequent PT events will result in the imposition of a sanction. This policy will afford the laboratory a longer period of time to correct its deficiencies than will otherwise be the case for subsequent PT events. We developed this approach in order to provide all laboratories additional time to understand the PT requirements with which they may be unfamiliar and with which they may be initially found to be noncompliant, as well as to enable laboratories to grasp fully the sanctions which may be imposed for unsuccessful PT participation. As always, however, the Secretary will take any action that may be necessary in cases of immediate jeopardy. This could include the imposition of sanctions for the first time occurrence of unsuccessful PT participation in those instances where the Secretary determines that such unsuccessful PT participation itself poses an immediate jeopardy situation or demonstrates the existence of an immediate jeopardy situation. Without such a policy, we would be required to enforce immediately the revised PT requirements published elsewhere in this issue of the *Federal Register* (and designated as HSQ-176-FC). We would also be required to impose sanctions for noncompliance with PT requirements with which the laboratory industry is unfamiliar.

#### E. Phased-in Imposition of Alternative Sanctions for Noncompliance With Other Conditions

For laboratories which were not previously regulated under CLIA or Medicare, HCFA will also phase in the imposition of intermediate sanctions for noncompliance with CLIA conditions other than PT. Under this system, which is intended to be separate from the phase-in of intermediate sanctions for the unsuccessful participation in PT as described above, intermediate sanctions will not be imposed during a laboratory's first inspection cycle against applicable CLIA requirements, if the laboratory's deficiencies do not pose immediate jeopardy. However, the laboratory will be required to correct its deficiencies in the areas specified by HCFA over a longer period of time than will otherwise be the case for noncompliance identified in all subsequent CLIA inspections. We developed this phase-in of alternative sanctions for newly regulated laboratories to provide additional time for them to understand the CLIA conditions with which they are found to be noncompliant upon their initial inspection.

The use of this phased-in system for the imposition of sanctions should mitigate the full impact of the misunderstanding that may be unavoidable—even with our planned educational activity, when dealing with a large number of small laboratory operations that have never previously been subject to any governmental onsite inspections. This will protect against disruption of services in laboratories that are attempting in good faith to comply with the new CLIA requirements. At the same time, it will provide for use of the statutory sanctions where an immediate jeopardy situation is identified.

For those laboratories that have been subject to regulation by the Federal government through CLIA '67, Medicare or Medicaid, we intend to have all CLIA and Medicare sanctions available after the effective date of these regulations. First, these laboratories have been accustomed to the inspection process and, notwithstanding the change in substantive Federal requirements that CLIA represents, the inspection process itself will remain largely unchanged. Thus, there is no need here, as there is for newly regulated laboratories, to allow time for currently regulated laboratories to familiarize themselves with the interplay of inspections, the need for the correction of deficiencies, and the possibility of sanctions should

compliance not be achieved. Second, the Congress was clearly interested in having the enforcement provisions of CLIA become effective at the earliest possible date after CLIA was enacted. To enable laboratories that have been consistently subject to sanctions for noncompliant practices to evade enforcement, would not be consistent with this Congressional intent and would needlessly increase the potential for a reduction in reliable and accurate laboratory testing.

### III. Notice of Proposed Rulemaking

On April 2, 1991, at 56 FR 13430, we published a proposed rule (identified as HSQ-179-P) setting forth the enforcement procedures for laboratories, and provided 60 days for public comment.

In this section of the preamble, we discuss the comments received in response to the April 2 proposed rule, our responses to those comments, and changes made in the proposed policies.

#### A. Definitions (section 493.1801)

Section 493.1801 defined the following terms: "CLIA certificate", "provisional certificate", "condition level requirement" and "condition level deficiency", "HCFA agent", "Immediate jeopardy", and "Lower level deficiency".

1. *Comment:* Several commenters recommended that the final regulation include definitions of "owner" and "operator" as referred to in § 493.1840 because without a definition accountability cannot be placed. In addition, one commenter wanted to know if owner or operator was limited to a person because that party believes "person" also means corporations, partnerships, etc. Other commenters wanted to know if stockholders of publicly held laboratories would be considered owners.

*Response:* We have added definitions of those two terms in § 493.2 of the final rule. In summary, we have stated that an operator means the individual or group of individuals who oversee the operation of a laboratory and who bear primary responsibility for the safety and reliability of laboratory testing, while an owner means an individual who owns an interest in the laboratory.

2. *Comment:* Several commenters want condition level deficiency and lower level deficiency to be more clearly delineated. They were also unclear about the relationship between "elements", "standards" and "conditions".

*Response:* A condition level deficiency is a deficiency with respect to any of the conditions that a laboratory must meet in order to obtain a CLIA

certificate. A deficiency not at the condition level is a deficiency with respect to one or more of the standard level requirements that are below the condition level, and, therefore, are not identified as conditions. These requirements may appear in this part under the heading "standard" or under no heading, and are what is meant by "lower level" requirements. There is no official requirement category designated "element" in this part. We have expanded the definition of "condition-level deficiency" in the final rule.

3. *Comment:* Several commenters questioned what entities (other than State survey agencies) HCFA might use as agents.

*Response:* We have listed other entities which HCFA might use as its agents in the definition of HCFA agent at § 493.2.

4. We received single requests for definitions of each of the following terms:

a. "*Significant hazard to the public health*". This means a deficiency that may cause harm to members of the community who are not necessarily patients served directly by the laboratory (for example, incorrect reporting of accurate test results with respect to communicable diseases). It is equivalent to "immediate jeopardy" for patients served by the laboratory and has been incorporated in the definition of the latter term.

b. "*Repeat deficiencies*". (To explain the number of occurrences necessary for it to be considered a "repeat" deficiency.) We have revised the statements in § 493.1804(d)(1)(iii), § 493.1828(a)(2)(i)(B) and § 493.1834(d)(1)(ii) to make clear that reference is to the "same" deficiency found in three consecutive inspections.

c. "*Intentional violation*". We have added a definition of this term in the final rule, which states that an intentional violation means knowing and willful noncompliance with any CLIA condition.

d. "*Cancellation of Medicare approval*." Cancellation of a laboratory's Medicare approval means that Medicare payment for the laboratory's services will not be made after the effective date of cancellation and the laboratory's Medicare participation has, therefore, been canceled.

e. "*Directed plan of correction*". This is explained in § 493.1832.

f. "*Laboratory*". This term is defined in § 493.2, which contains definitions applicable to all of part 493.

#### B. Imposition of Sanctions (Sections 493.1806—493.1842)

Commenters were concerned both with the effect of sanctions on laboratories, and with the procedures for imposing the sanctions.

1. *Comment:* 32 commenters were concerned that sanctions could lead to closure or to limitations of voluntary testing in many small laboratories such as those in physicians' offices.

*Response:* It is true that sanctions imposed upon small laboratories, including those in physicians' offices, may lead to closure or to limitations on the types of tests done. However, our objective under CLIA is to develop regulations that provide an appropriate balance between the concern for access to care and the need to protect the public from inaccurate and potentially dangerous test results.

2. *Comment:* 25 commenters indicated their concern that these regulations could limit access to or delay laboratory testing for patients.

*Response:* It is true that if a laboratory is unable to perform certain tests because it was found to be out of compliance with CLIA requirements, this could possibly limit access. Individuals who require those tests may have to wait longer for the results since those tests would have to be done elsewhere. It is generally in the patient's better interest to wait a little longer for test results which are accurate and reliable. Once the noncomplying laboratory has come into compliance and the alternative sanction or limitation of certificate is lifted, access to that laboratory will be restored.

3. *Comment:* Ten commenters were concerned that these regulations would create a great hardship on the elderly who, if their physicians' labs are sanctioned, would have to travel farther to have tests done and wait longer for results. The recommendation was that physicians' office laboratories (POLs) be exempted from CLIA requirements as a way to avoid this problem.

*Response:* We have no authority to exempt physicians' office laboratories from CLIA requirements. However, the plan for implementation of CLIA requirements includes a gradual phase-in both as to dates when certain conditions must be met, and the date when we will begin to impose sanctions for failure to comply with those conditions, if the failure to comply with those conditions does not pose immediate jeopardy.

4. *Comment:* Several commenters indicated their concern that sanctions would raise the cost of laboratory

testing and medical care in general, and would create significant paperwork burdens.

*Response:* In the preamble to the proposed rule, under "V. Regulatory Impact Analysis," we explained that this rule could have some potential to have significant impact on some laboratories. However, we have since determined that this rule will not have a significant impact in the form of increased costs of laboratory testing and medical care. In fact, any substantial impact that results from the implementation of CLIA requirements will be due to the CLIA conditions set forth in the regulations published elsewhere in this edition of the *Federal Register* and designated as HSQ-176-FC. Any significant impact would be reflected in the form of the increased costs of upgrading laboratories to meet CLIA requirements, and not the costs associated with being sanctioned. Moreover, both the requirements a laboratory must meet to obtain any type of CLIA certificate, and the Secretary's obligation to impose enforcement sanctions are mandated by the law and must be implemented, regardless of the possibility that costs will rise. This rule does not impose a significant paperwork burden. It does contain some information collection requirements, and we have requested approval of these requirements.

5. *Comment:* Four commenters had concern regarding the impact of CLIA on the States. One commenter indicated that because of the additional work involved (monitoring, imposing sanctions, follow-up visits, notifying clients when laboratories are sanctioned and when the sanctions are rescinded), a "tremendous burden" will be added to the States' workload. This commenter would prefer to publish notices of sanctions and rescission of sanctions in the local newspapers. Another commenter disagrees with the section on "Federalism" within the Regulatory Impact Analysis, which states that there will be "little of the former role for States in laboratory regulation remaining under CLIA 88". The same commenter feels the States will develop, in time, programs more stringent than those required by CLIA. The same commenter would prefer that States continue to have a substantial role in laboratory regulation, rather than defer to the proposed Federal program and diminish their roles in protecting the public health and the safety of their citizens. The third commenter would like a clearer understanding of States' roles in the enforcement process. The last commenter also stated that there

will be little of the former role for States remaining under CLIA 88. He suggested that the Federal government has not been effective in preventing deaths in its own Health and Human Services/Public Health Services/IHS system and indicated that the States should not lightly allow HCFA to usurp their authority in this area.

*Response:* It is true that the role of the States will significantly change as a result of section 1846 of the Social Security Act, section 353 of the Public Health Service Act, and implementing regulations. We explained this in the Preamble to the proposed regulations under the section headed B. Executive Order 12612. In response to the recommendation that the States not defer to the proposed Federal program and diminish their roles, we will acknowledge in a separate regulation the States' right to apply for HCFA approval of their licensure programs so that laboratories licensed in those States would be exempt from CLIA requirements. The term "State-exempt" in the final rule refers to laboratories in States with licensure programs that have requirements equal to or more stringent than the Federal requirements and that have been approved by HCFA. As for its role in the enforcement process, the State will still be responsible for inspecting laboratories for compliance with CLIA requirements even if that State's licensure program is not approved by HCFA as a basis for exemption from CLIA requirements. The State will recommend enforcement action to HCFA and may notify laboratories of the types of adverse actions that HCFA may impose. There are many more specific functions in addition to these general ones.

6. *Comment:* Four commenters were of the opinion that the imposition of sanctions would be tantamount to interference with medical practice. One stated that CLIA 88 is a further Federal government encroachment into the field of medicine that will not improve care but will severely decrease access to care for patients. One physician wrote that the promise that the health of patients is being threatened by laboratories in physicians' offices is nonsense and that closing such laboratories will have a negative impact on overall health care. For example: if tests are sent to bigger laboratories, another step will be added to the diagnostic process which will delay obtaining of test result by both rural and urban physicians who frequently need laboratory results immediately. This commenter feels that automation and technology have advanced to the extent

that smaller laboratories can perform many simple tests just as easily and more reasonably and efficiently than "big" laboratories. Another commenter stated that the intrusion of HCFA into physicians' office laboratories deteriorates the doctor/patient relationship and creates interference when quick results are necessary.

*Response:* We disagree with these commenters, although we understand that the new CLIA regulations may to some extent, interfere in the autonomy of physicians if their laboratories are not in compliance with Federal requirements. However, Congress has mandated that we regulate laboratory practices no matter how small the laboratory, and directed us to use various enforcement remedies when deficiencies are identified. If cancellation of Medicare approval and revocation of CLIA certificates become necessary, then disadvantages of delays caused by submission of specimens to other laboratories are offset by the advantages of accurate testing. Despite the technological advances that have enabled physician's office laboratories to perform tests easily, the possibility of errors still exists, and the consequences of errors could be dangerous, despite the simplicity of the tests.

7. *Comment:* Five commenters were of the opinion that the additional recordkeeping requirements mandated by CLIA would be burdensome and might not be provided in a timely manner, thereby distorting the integrity of the information. They all seem to agree that in order to meet the paperwork requirements, they will require additional funds from HCFA.

*Response:* The response to this comment is located in the Regulatory Impact Analysis of HSQ-176-FC, published elsewhere in this issue of the *Federal Register*.

8. *Comment:* 14 commenters expressed the opinion that CLIA in general should either be repealed or further reviewed by Congress.

*Response:* This comment is outside the purview of these regulations.

9. *Comment:* Five commenters were of the opinion that HCFA should conduct a study to determine whether the added costs of CLIA to laboratories will justify the promulgation of the regulations.

*Response:* We disagree with the commenters' suggestions that further studies should be conducted to determine whether the added costs of CLIA are justified. Many provisions of section 1846 of the Social Security Act and section 353 of the Public Health Service Act can only be implemented after regulations are promulgated.

Unless the laws are repealed, we have no choice but to issue regulations. Congress has not given the Secretary the authority or the responsibility to conduct a study to determine if the laws should remain in effect. However, the Centers for Disease Control will be conducting CLIA-mandated studies in 5 other areas, such as quality assurance and personnel standards.

10. *Comment:* Three commenters were of the opinion that the only way rural health clinics (RHCs) could comply with the CLIA provisions would be if the requirements were modified for RHCs. Otherwise, RHCs should be exempted from CLIA.

*Response:* The law provides no authority for us to exempt laboratories in RHCs from CLIA requirements.

11. *Comment:* Two commenters were concerned that sanctions would put small laboratories out of business. The first suggested that HCFA impose a single sanction for all condition level deficiencies that are interrelated rather than a separate sanction for each condition level deficiency. This commenter feels that multiple actions could force a laboratory to close without having the opportunity to come into compliance. The second commenter feels that sanctions should be eliminated.

*Response:* Under the law, HCFA is required to impose those sanctions that are most likely to bring laboratories into compliance in the shortest possible time. However, HCFA will not necessarily be imposing separate sanctions for separate deficiencies, unless the nature of the deficiencies is so different that a different enforcement remedy is warranted for each. Also, when civil money penalties are imposed, a fine can be imposed for each violation. This is specified at section 353(h) of the PHSA.

12. *Comment:* Some commenters were of the opinion that dental laboratories and laboratories in Women's, Infants and Children's Clinics should be exempted from CLIA requirements.

*Response:* Any laboratory that fits the definition set forth at section 353(a) of the Public Health Service Act is subject to CLIA requirements.

13. *Comment:* Four commenters were of the opinion that suspending Medicare payments might result in discrimination against Medicare beneficiaries by denying them access to specific laboratory services.

*Response:* There is nothing to preclude HCFA from using Medicare sanctions in conjunction with CLIA sanctions in any situation of noncompliance. In fact, in the case of immediate jeopardy deficiencies, alternative sanctions will be paired with

a principal sanction. For example, with immediate jeopardy deficiencies, HCFA would suspend the CLIA certificate immediately, and simultaneously suspend all Medicare payments. This insures protection of all patients using the services of the laboratory not just Medicare patients.

14. *Comment:* 15 commenters expressed concern regarding the potential costs of onsite monitoring. Several felt they might be able to defray costs if they had some input into scheduling and prior notice of on-site monitoring in order to avoid creating costly scheduling situations in their laboratories. Others disagreed with the method of determining costs for on-site monitoring and felt a specific fee schedule based on an average figure instead of number of hours would be less costly to them. One commenter suggested that laboratories holding certificates of waiver should be exempt from paying for on-site monitoring because of limited resources, low-volume of tests performed, and minimal risk to the public. Others want detailed information regarding costs, including hourly rates, frequency, duration and timing of monitoring. Several felt that because HCFA was requiring the monitoring, HCFA should pay for it.

*Response:* There will be at least 15 days notice before the effective date of the sanction of on-site monitoring in situations that do not pose immediate jeopardy and 5 days notice when there is immediate jeopardy. A fee schedule based on average fees rather than actual hours would benefit only those laboratories that require an above average number of hours of monitoring. The fairest approach will be to charge each laboratory for the actual number of hours used. Laboratories holding certificates of waiver will not be required to pay monitoring fees, because we do not intend to subject them to alternative sanctions as provided at § 493.1806(c) of this final rule. Our response to the request for detailed information about hourly rates, frequency, timing and duration of monitoring, is, as stated above, that we believe the fairest approach to be determination on a case-by-case basis.

15. *Comment:* Two commenters questioned the process by which HCFA decides to impose onsite monitoring.

*Response:* The decision to impose onsite monitoring is one which, as in the case of other sanctions, will be made on a case-by-case basis. It will take into account the specifics of each situation which will dictate the type of sanction most likely to motivate correction of deficiencies.

16. *Comment:* Two commenters were of the opinion that a suspension of Medicare payments would not encourage compliance or would not be a significant penalty for laboratories having a low volume of Medicare patients.

*Response:* We realize that not every available sanction will be appropriate for every laboratory. For this reason, in § 493.1804(d)(2) we specify that in selecting a particular sanction, HCFA's primary aim is to ensure that a laboratory corrects its deficiencies. It is up to HCFA to decide if the sanction would be sufficient in any given case to motivate the laboratory to correct deficiencies. Since neither the Medicare nor CLIA statute dictates that any particular remedy be used in any case of noncompliance, we believe that we have complete discretion to make enforcement choices.

17. *Comment:* One commenter expressed support for this regulation indicating that closing poor or marginal laboratories would be a desired effect of this legislation.

*Response:* We appreciate the commenter's overall support for this rule and are fully committed to the development of regulations that will implement CLIA effectively. However, the closing of poor or marginal laboratories is a goal of last resort. Our objective is first to take whatever enforcement action is likely to motivate the laboratory to correct the deficiencies.

18. *Comment:* Five commenters indicated their support for the imposition of alternative sanctions.

*Response:* We appreciate the support we have received for this rule and are committed to the development of regulations that reflect the enforcement-related aspects of the CLIA provisions.

19. *Comment:* Four commenters were of the opinion that punitive measures do not encourage compliance, and one stated that an educational approach would be more productive over the long run.

*Response:* Section 1846 of the Social Security Act and section 353 of the Public Health Service Act contemplate that adverse actions be taken against laboratories that have failed to quickly come into compliance. However, it should be noted that alternative sanctions do offer laboratories the opportunity to come into compliance within a specified period of time instead of immediately having their CLIA certificates suspended, limited, or revoked, or their Medicare approval cancelled. In addition, in cases of adverse action taken in response to

unsuccessful participation in proficiency testing, educational activities such as training and technical assistance may be used.

20. *Comment:* Eight commenters stated that HCFA cannot legally impose sanctions in the absence of published CLIA requirements.

*Response:* Another rule, identified as HSQ-176-FC and published elsewhere in this issue of the *Federal Register*, specifies the requirements for a CLIA certificate, and that rule is effective on the same day as these regulations. As noted in some of our other responses, the phase-in policy for effective dates of CLIA requirements will have a corresponding phase-in policy for enforcement procedures.

21. *Comment:* Six commenters disagreed with being sanctioned for noncompliance in proficiency testing.

*Response:* The law contemplates that we invoke sanctions for noncompliance in proficiency testing because successful performance of this testing is a requirement for obtaining a CLIA certificate. However, the law also provides that we may require additional training of personnel, technical assistance, or both in lieu of or in addition to sanctions or civil action for unsuccessful PT participation. In addition, during the phase-in of proficiency testing, as discussed in section D of program impact, some prior to the effective date of the applicable PT requirements.

22. *Comment:* Two commenters were concerned that available sanctions are subject to broad interpretation and may be applied inequitably.

*Response:* The regulations are rather specific as to appropriate sanctions in specific situations as a function of whether deficiencies are at the condition level, and if they are, whether the deficiencies pose an immediate jeopardy to the laboratory's patients or to the general public. HCFA has the discretionary authority to impose one or more principal or alternative sanctions, based on the severity and nature of deficiencies found during inspections of laboratories. If the deficiencies are determined to pose immediate jeopardy to the health and safety of individuals served by the laboratory or that of the general public, the sanctions imposed will, of necessity, be more severe than those used in situations which are less threatening, and will consist of at least one principal sanction. When there is not immediate jeopardy, alternative sanctions rather than principal sanctions would be imposed first, thus allowing the laboratory a longer period of time to come into compliance. If the laboratory fails to correct all condition

level deficiencies within the specified timeframe, HCFA would impose principal sanctions.

The choice of alternative sanctions is based on the nature of the deficiencies. Therefore, regulatory guidelines that would cover every possible situation would be virtually impossible to develop. There would be no way to include in such guidelines every possible combination of deficiencies and therefore no way to develop policies on which alternative sanction(s) to impose in each case.

23. *Comment:* Thirteen commenters states that HCFA should develop a system for classifying the severity of deficiencies, and should delineate this system in these regulations. There were also requests from eight commenters for a formal link between deficiency type and sanction imposed, with many commenters expressing a lack of confidence in HCFA's "sole reliance" on the judgment of State surveyors when making a determination of compliance or noncompliance in a laboratory.

*Response:* In the future, HCFA may develop a system to classify the scope and severity of deficiencies with regard to CLIA requirements. However, one must remain cognizant of the fact that even if a scope and severity scale for deficiencies is developed, it would not lessen reliance on surveyor judgment in determining the existence of deficiencies or whether those deficiencies pose an immediate jeopardy. With regard to linking specific sanctions with certain deficiency types, we oppose the development of a formal link between each type of deficiency and the sanction imposed. Such a system would predetermine which sanction we must impose if a certain deficiency exists, and would be so rigid as to serve neither HCFA's nor a laboratory's best interests. Our position on the imposition of alternative sanctions is that we must maintain flexibility. We rely on the surveyor to assess the severity of each deficiency and to recommend to us whether each deficiency poses immediate jeopardy, to recommend whether an alternative sanction would be appropriate, and, if so, which one. Based on those recommendations, we will impose the alternative sanction that, in our judgment, would best encourage the laboratory to quickly correct its deficiencies.

The surveyors whom we employ to inspect laboratories are laboratory professionals. They are trained extensively by both HCFA and their respective States in proper inspection techniques under CLIA. They use their professional judgment and expertise in making recommendations. We expect

that each surveyor will demonstrate sound judgment and make good decisions. However, there are "checks and balance" inherent in this system. The surveyors' recommendations are reviewed by the supervisory staff of the State agency or other HCFA agents, and are further reviewed by the HCFA regional office (RO). The RO makes the final determination of compliance or noncompliance and imposes the sanction(s) that would, in the opinion of the RO, most likely precipitate correction.

We reiterate, however, that State surveyors or other agents designated by HCFA to inspect laboratories are highly trained professionals. We do not believe that the differences in each surveyor's professional judgment would negatively affect a laboratory to the degree predicted by commenters, because one of the major objectives in the training of State health department personnel, State surveyors, and other HCFA agents is consistency in the application of all sanctions.

24. *Comment:* A large group of commenters expressed concern about the timeframe for responding to HCFA's written notice of sanction. They stated that the 15-day period of time between the notice of sanction and the actual imposition of the sanction is too short for a laboratory to obtain sufficient documentation in order to prepare a response. For this reason, they requested that the 15-day period be expanded to 30 days.

A few commenters stated that 5 days are insufficient to respond to the notice of, and/or correct, an immediate jeopardy situation.

A number of other commenters felt that HCFA should issue a statement to the laboratory, within a specified number of days after the receipt of the laboratory's response to the HCFA notice of sanction, in order to formally acknowledge the laboratory's response. One commenter stated that HCFA should include in its response a more "uniform" interpretation of the regulations to explain to the laboratory (i.e., a response in greater detail than what the State agency could provide) why the laboratory is out of compliance. A few other commenters requested that the notice contain additional sanction-specific information.

*Response:* We will not increase the 5-day and 15-day periods between notice of sanction and the actual imposition of sanction (or, in the case of civil money penalties, the effective date of accrual), because, regardless of whether there is immediate jeopardy or no immediate jeopardy, further delay in the imposition

of sanctions would mean further risk to the health and safety of the patients the laboratory serves and, in some instances, risk to the health of the general public. Moreover, the laboratory is actually aware of the deficiencies that need to be corrected for more than 5 or 15 days. Specifically, the laboratory is notified of deficiencies at the exit conference and written notification of deficiencies is provided within 10 days of the inspection.

Some commenters were concerned that we should send a formal acknowledgement upon receipt of a laboratory's response to the HCFA notice of sanction. We will acknowledge receipt of the laboratory's evidence of compliance or a credible allegation of compliance in the written decision at the end of the correction period. We have made it clear at § 493.1810(c) that at the end of this period, we will either confirm the imposition of sanction on the proposed effective date, or discontinue the imposition of the sanction. In either case, we believe it is unnecessary for HCFA to provide a "more uniform" interpretation of the regulations, since the States have been trained in our interpretation and use in carrying out their survey and certification duties on behalf of the Secretary.

25. *Comment:* A few commenters requested that we not "duplicate" existing inspection and enforcement mechanisms currently used in provider (such as nursing facilities) which perform laboratory testing.

*Response:* We acknowledge the commenters' concern that these regulations might cause a possible "overlap" of inspection and enforcement activities in providers such as nursing facilities, which are surveyed under the authority of the Nursing Home Reform provisions of OBRA '87. However, the inspection and enforcement mechanisms under CLIA will remain separate from those used for other areas of patient care in such facilities. Section 353(b) of the Public Health Service Act (as amended by CLIA 88) does require that every laboratory soliciting or accepting materials for examination or diagnostic procedures have a certificate issued by the Secretary which permits the laboratory to perform that type of testing. This CLIA certificate indicates that the laboratory has met the requirements imposed under CLIA. These CLIA requirements apply to every laboratory that does testing that meets the CLIA definition, whether the laboratory is a freestanding facility or a component of a provider or other supplier. In fact, the nursing home requirements at 42 CFR 483.75(j)(1)(i)

specify that if the facility provides its own laboratory services, the services must meet the applicable laboratory requirements in part 493 of the regulations. Therefore, the nursing home survey process requires that inspection of the facility against the laboratory conditions at part 493 to determine if the nursing home meets the requirements at § 483.75(j).

The new CLIA conditions will supersede the pre-existing conditions for coverage for independent laboratories as well as the laboratory requirements previously contained in the conditions of participation or conditions for coverage for laboratory services in other suppliers and in providers such as nursing facilities. The implementation of these requirements has been promulgated under a separate rule, published elsewhere in this edition of the Federal Register and identified as HSQ-176-FC.

26. *Comment:* A large number of commenters requested that HCFA consider factors such as the size and test volume of a laboratory when determining which sanctions to impose, particularly when the sanctions being considered involve a monetary penalty.

*Response:* These regulations set forth laboratory sanctions that directly or indirectly involve the expenditure of money by, or the loss of payment to, the laboratory. We are aware that such sanctions might be more easily borne by a large laboratory than a small laboratory. We also know that a sanctioned laboratory in a provider or supplier such as a hospital or physician's office might have access to greater financial resources and thus remain operational for a longer period of time than a similarly-sized free-standing laboratory (provided that HCFA does not suspend, limit, or revoke its CLIA certificate). We realize too that any laboratory which performs a low volume of tests has fewer specialties and subspecialties of testing to offset sanctioned categories.

As stated previously, our approach to imposing sanctions is one of flexibility, and our choice of the sanction(s) which we impose is guided not only by the severity of the deficiencies, but by the nature of the deficiencies and the corrections that must be made. HCFA decides which sanctions to impose on the basis of the surveying agency's recommendations. The size and test volume of a laboratory are among the factors considered in the process of reaching a decision. For example, if we impose a sanction against a small laboratory, we would try not to impose a sanction for which the monetary

component would be large enough to force that laboratory to close rather than correct its deficiencies. In fact, with civil money penalties, the process involves the flexibility for HCFA to set the monetary amounts at lower levels for less severe deficiencies. However, for other sanctions in which expenditures of money are involved, such as a directed plan of correction, a deficiency that is relatively less serious in terms of negative patient outcomes is a deficiency, nonetheless, and may require a significant amount of money to correct, regardless of the size of the laboratory. The choice of sanction(s) could, therefore, precipitate closure of the facility if the laboratory's financial resources were depleted during the correction period.

27. *Comment:* Several commenters requested that HCFA implement a gradual phase-in of sanctions in order to afford laboratories (especially those that were not previously regulated under CLIA) additional time to educate their staff on the CLIA 88 conditions prior to being subject to sanctioning.

*Response:* Both this regulation and HSQ-176-FC (the rule delineating the conditions that laboratories must meet to operate under CLIA), published today, are effective six months from today. This delay in effective dates will afford the laboratory community ample time to become familiar with these requirements prior to the commencement of inspections under CLIA. Additionally, prior to the inspection of any laboratory under these requirements, laboratories that have followed appropriate application procedures, including the payment of required fees, will have been issued an initial registration certification that permits the laboratory to operate. The certificate to be issued after the inspection can be withheld and the registration certificate revoked for noncompliance with conditions of participation. The timing of the first inspection, however, is dependent on workload and other administrative factors and may not occur until quite some time following the issuance of the registration certificate. The period of time that a laboratory is permitted to operate under its registration certificate represents additional time that a laboratory will have to become familiar with the CLIA requirements and ensure that it is operating in compliance with those requirements prior to any inspection.

We have described two separate systems which we developed for the phase-in (delay in the imposition of) alternative sanctions. Both are

described under the Program Impact section (sections II D and E, respectively) of this preamble. The first specifies that for any laboratory with unsuccessful participation in proficiency testing, alternative sanctions will not be imposed at the time of the first citing of such unsuccessful participation in proficiency testing. At section II E, we have described a separate system for the phase-in of alternative sanctions against laboratories not previously regulated under CLIA or Medicare which have condition level deficiencies in areas other than PT. Our rationale for this policy is delineated below.

The requirements established under CLIA and published today will likely result in some changes in the operations of approved PT organizations and their testing procedures. We do not believe it would be equitable to hold previously regulated laboratories, that have routinely participated in PT programs, immediately accountable for changes made in the PT process. We do not believe that these laboratories should be penalized while proficiency testing providers are fine tuning their program to eliminate any operational problems that may exist since changes were implemented as a result of CLIA '88. With respect to previously unregulated laboratories, we estimate that as many as one half of these laboratories have never participated in PT testing programs. These laboratories will also need a phase-in period to become familiar with both the technical and operational aspects of initiating relationships with PT organizations and participating in their programs. With regard to laboratories which were not previously regulated under CLIA or Medicare, we believe that a phased-in system of enforcement for conditions other than PT is an equitable alternative to the immediate sanctioning of such laboratories when their noncompliance with CLIA condition level requirements does not constitute immediate jeopardy. Since many of the newly regulated laboratories have never before been subject to any onsite Federal inspections, we believe that our emphasis on working with laboratories to advise them in correcting deficiencies during the first inspection will be more effective in achieving our goal of laboratory quality than using punitive sanctions. These laboratories which have never been regulated at the Federal level require additional time to become familiar with CLIA and to understand the inspection process and the requirements of the regulations.

**28. Comment:** Two commenters stated that a single sanction should be imposed for all condition level deficiencies.

**Response:** We disagree. Both section 1846(b)(3) of the Social Security Act and section 353(h)(3) of the PHS Act give the Secretary the authority to develop procedures with respect to when and how the alternative sanctions are to be used. Therefore, whether single or multiple sanctions are imposed will depend upon the specific situation within a laboratory as determined by HCFA.

**29. Comment:** Two commenters thought that the activities of the State monitor should be more clearly delineated in the regulation.

**Response:** We accept this comment and have added clarifying language at § 493.1836(a)(1), which explains that the State monitor does not have managerial authority over the laboratory's personnel, and that its sole responsibility is to oversee whether corrections are made.

**30. Comment:** Ten commenters were of the opinion that suspension of Medicare payment is too harsh a remedy, may not be appropriate for situations that do not pose immediate jeopardy and should not be implemented until laboratories receive additional opportunities to correct the deficiencies.

**Response:** With regard to the perceived harshness of the sanction, we can state that all of the alternative sanctions are intended to constitute a means by which laboratories with deficiencies that do not pose immediate jeopardy can avoid immediate cancellation of Medicare approval or revocation of any type of CLIA certificate. The sanction is intended to be harsh enough to motivate correction, but less harsh than Medicare cancellation or CLIA certificate revocation.

**31. Comment:** Five commenters expressed the opinion that the regulations should contain assurances that a suspension of Medicare payments for laboratory services by a provider could not result in the suspension of payments for any non-laboratory services as well. Another two commenters expressed concern that in terms of hospital-based laboratories, it is unclear how payment can be suspended for specific services when diagnostic related group (DRG) payment is an all-inclusive fee.

**Response:** In the case of providers that are not subject to the prospective payment system (PPS), we will use an identifier code to distinguish laboratory services from other services and thus

ensure continuation of Medicare payment for those other services. However, we could not suspend Medicare payments in exact amounts under the PPS system. We can, by approximation, suspend Medicare payment for laboratory services rendered to inpatients of hospitals operating under PPS. We can do this by reducing the total Medicare payment to the hospital by an amount equal to the most current average percent of diagnostic related group (DRG) payments that reflects the laboratory component of each DRG.

**32. Comment:** Five commenters offered the opinion that laboratories may have totally valid reasons for withholding information from HCFA and because of these reasons should not be penalized as specified at § 493.1840.

**Response:** The statute authorizes the Secretary to suspend, revoke, or limit a laboratory's certificate if the laboratory has failed to comply with reasonable requests of the Secretary for any information that the Secretary concludes is necessary to determine the laboratory's continued compliance with requirements and continued eligibility for a CLIA certificate. The statute explicitly authorizes the limitation or suspension of the certificate prior to hearing, as provided in § 493.1844(e)(2)(ii)(B) of this final rule, when a laboratory fails to provide information that we believe is necessary to enable us to undertake our statutory responsibilities. The laboratory could attempt to justify the withholding of information at the time of that hearing.

**33. Comment:** Four commenters voiced the opinion that if a laboratory's CLIA certificate has been revoked within the preceding two-year period, HCFA should initiate adverse action, not only against its owner or operator, but also against those directors involved in the operation of the laboratory.

**Response:** We have added a definition of "operator" which clarifies that directors of laboratories who are involved in their overall operation, are knowledgeable about the workings of the entire facility, and who bear primary responsibility for the safety and reliability of laboratory testing, are considered operators for the purpose of this regulation. It is our belief, consistent with the direction given by Congress in section 353(i)(3) of the PHS Act, that any laboratory director who meets the criteria as an operator should not be permitted to operate or own any laboratory within 2 years of operating a laboratory which has had its CLIA certificate revoked, as set forth at § 493.1840(a)(8) of these regulations.

34. *Comment:* Four commenters questioned that rationale of HCFA notifying the Office of the Inspector General (OIG) whenever HCFA initiates an adverse action to suspend, limit, or revoke a laboratory's CLIA certificate based on noncompliance with CLIA requirements by an owner or operator of a laboratory.

*Response:* We plan to inform the OIG of any adverse actions we impose against laboratories if we determine there has been a violation of any of the laws enforced by the OIG. For example, the violations listed at § 493.1840(a)(1), (a)(2), (a)(6), or (b) involve misrepresentation, fraud against the Medicare and Medicaid programs, or some other type of intentional violation of requirements for the Medicare, Medicaid, or CLIA program that may warrant action by the OIG.

35. *Comment:* Some commenters were opposed to the provision at § 493.1840(a)(8), specifying the use of principal sanctions against owners and operators of groups of legally related laboratories merely because one or some of these laboratories were out of compliance. This commenter stated that mere ownership of a laboratory which has been sanctioned in the past should not jeopardize the operations of some other distantly related laboratory and further requested that we clarify the definition of "owned and operated". Another commenter suggested that laboratories which were sanctioned by having their certificate revoked within the last two years should be allowed to have the sanction removed after only one year.

*Response:* It is the law itself which establishes the prohibition. It provides specifically that the owner or operator of a laboratory that has had its certificate revoked may not own or operate a laboratory for two years after the revocation of the CLIA certificate of the initially sanctioned laboratory. HCFA has no choice but to implement this provision, found at section 353(i)(3) of the Public Health Service Act. We therefore did not accept this comment. The final rule also defines the terms "owner" and "operator", and specifies the types of ownership relationships and operator positions that would prohibit ownership or operation of a laboratory for two years.

36. *Comment:* A few commenters had questions regarding the application of principal sanctions. One questioned whether there is a conflict between § 493.1816(b) and § 493.1820 because of the lack of specified timeframes for implementing and keeping alternative sanctions in effect. The same commenter also wants to know when § 493.1820 is

used exclusively. Another commenter wants us to clarify that the cancellation and suspension sanctions referred to in the existing regulations are the same as those in the proposed rule which guarantee each laboratory the right to due process.

*Response:* The distinction between § 493.1816(b) and 493.1820 is that the latter deals with all deficiencies and the former applies to deficiencies not at the condition level. The maximum timeframes for the duration of alternative sanctions is specified as 12 months at § 493.1820(c) and the timeframe for implementation is specified at § 493.1810. The laboratories' right to due process is specified at § 493.1844.

37. *Comment:* Three commenters were of the opinion that suspension of payment or cancellation of Medicaid approval should be limited to condition-level noncompliance.

*Response:* The suggestion made by these commenters reflects what the policy is. Both alternative sanctions and principal sanctions are imposed only for condition-level deficiencies.

38. *Comment:* Two commenters requested that we add to the menu of available sanctions some less severe penalties such as probation, reprimand and supervision.

*Response:* The phased-in enforcement plan described in the response to comment 27, should serve the same purpose as the type of sanctions suggested by the commenters.

39. *Comment:* One commenter stated that if payments were suspended due to a specific condition-level deficiency, the rule would prohibit payment if that deficiency were corrected but other unrelated condition level deficiencies still exist. The commenter wants the language changed so that suspension of payment will end once the laboratory corrects the sanctioned deficiency even if unsanctioned deficiencies still exist. Another commenter cited § 493.1807(b)(2) which states that it appears that HCFA may impose one or more of several sanctions when condition-level deficiencies are found without necessarily using a suspension of payment sanction.

*Response:* With the exception of the suspension of Medicare payment for specific specialties or subspecialties, alternative sanctions are not deficiency-specific. Therefore, if a laboratory were to correct the noncompliance in the specialties or subspecialties for which a suspension of Medicare payment has been imposed, the suspension of payment would be lifted upon verification of correction of those specific deficiencies. However, if any

condition-level noncompliance remains uncorrected, we will continue to impose some form of alternative sanctions, and will lift only those sanctions which we deem appropriate as we verify correction of each of a laboratory's condition-level deficiencies. For example, if a suspension of payment for all specialties and subspecialties had been imposed, it would continue in effect until all deficiencies are corrected.

40. *Comment:* One commenter questioned whether the corrective action specified in a directed plan of correction are administrative or technical in nature.

*Response:* It is difficult for us to know exactly what this commenter means by the terms "administrative" and "technical". However, these definitions are immaterial in the sense that under a directed plan of correction, every deficiency must be corrected, whatever its form.

41. *Comment:* One commenter suggested that a directed plan of correction should be the preferred sanction used when the deficiency does not pose immediate jeopardy.

*Response:* As stated above, the decision as to which sanction to impose will be made on a case-by-case basis. It will be based on the specifics of each situation which, in HCFA's judgement, will dictate the type of sanction most likely to motivate correction of deficiencies.

42. *Comment:* One commenter stated that any rule linking Medicare status with CLIA must be promulgated pursuant to notice and comment procedures under the Medicare law rather than under CLIA.

*Response:* Section 6141 of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101-239) requires all laboratories that participate in Medicare to meet the CLIA 88 requirements. Therefore, we believe we are justified in consolidating regulatory provisions implementing the Medicare laboratory provisions of the Social Security Act and the CLIA provisions of the PHS Act.

43. *Comment:* One commenter asked if the wording in the rules might be made clearer regarding the criteria for selecting a particular sanction.

*Response:* We believe it is inadvisable to have a rigid system of specific sanctions for each deficiency. HCFA has flexible enforcement capabilities in order to treat each noncompliance situation on a case-by-case basis.

44. *Comment:* One commenter stated that failing to charge Medicare beneficiaries for services for which Medicare payment has been suspended is an inappropriate sanction and would

accomplish nothing because laboratories would then attempt to be reimbursed by beneficiaries' supplementary insurance plans, if applicable.

*Response:* We consider charging the Medicare beneficiary's private insurance carrier tantamount to charging the beneficiary, because that action would, in essence, be predicated on the assumption that the beneficiary is responsible for payment, although indirectly. We have clarified in the regulations at § 493.1826 and § 493.1828 that the laboratory must agree not to charge the beneficiary's private insurance carrier, in order to avoid immediate cancellation of Medicare approval.

### C. Civil Money Penalties (Section 493.1834)

1. *Comment:* Many commenters believed that the civil monetary penalty range of \$3,050–\$10,000 for immediate jeopardy situations is too high.

*Response:* In immediate jeopardy situations, HCFA may impose from \$3,050–\$10,000 for each day of noncompliance, or for each violation. \$10,000 is the maximum amount specified by section 1846 of the Act and section 353(h) of the PHS Act. \$3,050 is the lowest amount judged by HCFA, based on a review of a variety of state civil money penalty systems available under various State licensure laws, to be effective in encouraging compliance in an immediate jeopardy situation. HCFA will assess each laboratory's noncompliance on an individual basis in order to determine the amount of the penalty. We believe that we are establishing a very flexible system by designating the highest 2/3 of the civil money penalty range for immediate jeopardy situations only. Since deficiencies that pose immediate jeopardy occur much less frequently than those that do not, relatively few laboratories will be subject to the higher fines. Moreover, the range of civil money penalties available for immediate jeopardy deficiencies is so broad that a laboratory with such deficiencies may not be fined at the maximum level. If some laboratories are fined at the maximum level, the amounts of the fines are justified by fact that their deficiencies could cause life-threatening situations.

HCFA's long-standing policy is to afford providers and suppliers an opportunity to correct deficiencies before taking adverse action. Before a civil money penalty is imposed, HCFA will give the laboratory written notice of its intent to impose the penalty. The penalty does not begin accruing until the

laboratory is officially informed of its deficiencies and the 5-day or 15-day notice period ends. Moreover, the civil money penalty is not collectible until after the 60-day period for requesting a hearing (if the laboratory does not request a hearing) or, if the laboratory requests a hearing within the prescribed timeframe, until after the hearing decision that upholds the imposition of the penalty.

2. *Comment:* Many commenters were concerned that civil money penalties could financially decimate a laboratory.

*Response:* We recognize that some laboratories may experience more hardships and financial burdens associated with civil money penalties than others. However, HCFA is charged with carrying out the law by promulgating regulations that reflect what we believe to be the most effective means of implementing the statute. If deficiencies in a laboratory remain uncorrected for so long, for example, that the civil money penalties decimate that laboratory, we can only conclude that the protection of the safety of the patients had to supersede continued operation with such serious deficiencies.

3. *Comment:* Several commenters had questions regarding the factors HCFA considers in determining the civil money penalty amount. Many suggested that volume of laboratory tests should be considered in determining the amount of the civil money penalty.

*Response:* As specified at § 493.1834(d), in determining the amount of the penalty, HCFA takes into account the following factors:

a. The nature, scope, severity, and duration of the noncompliance.

b. Whether the same condition level deficiencies have been identified during three consecutive inspections.

c. The laboratory's overall compliance history including, but not limited to, any period of noncompliance that occurred between certifications of compliance.

d. The laboratory's intent or reason for noncompliance.

e. The accuracy and extent of laboratory records and their availability to HCFA, the State survey agency, or other HCFA agent.

We do not believe that we should take into consideration the volume of laboratory tests performed. The correlation between deficiencies and amounts of civil money penalties should be based on severity of noncompliance and the speed with which corrections need to be made, not the laboratory's workload. A relatively small laboratory may exhibit extremely serious deficiencies that require immediate correction for the sake of the patients serviced. We believe that a relatively

high civil money penalty would be the best incentive for prompt correction.

4. *Comment:* Several commenters were concerned about the accrual of a civil money penalty until the laboratory's condition level compliance is verified and believe this provision places the laboratory at the mercy of the surveyor's schedule. The following is a summary of their comments and recommendations.

- Require verification of compliance within a specified time period such as 30 days, or within 2 days of the laboratory's request for reinspection.

- Provide that the accrual of the penalty amount ends on the date that the laboratory achieves compliance, or on the date it requests reinspection.

- Accept as establishing compliance a laboratory's good faith representation, or the submission of suitable documentation, or establish it through an inspection visit.

*Response:* We believe that timeframes for revisits by the survey agency constitute a subject for operating guidelines and should not be included in regulations. We also believe it is the survey agency's responsibility to verify a laboratory's compliance in a timely manner. However, the timeframes for resurveys could vary from State to State and within a State because of various factors, such as variations in geography and available personnel. Therefore, we have concluded that if the laboratory can produce credible evidence at the time of the resurvey, that compliance was achieved before the resurvey, the civil money penalty will stop accruing as of the date that the compliance was achieved. We have revised § 493.1834(f)(2) to so provide.

5. *Comment:* Several commenters were concerned about the start dates and due dates of civil money penalties and about HCFA's computation of the civil money penalty before a fair hearing. With regard to the latter point, one commenter stated that such a policy contradicts the statutory requirement that civil money penalties not be assessed before a hearing.

*Response:* The civil money penalty begins to accrue 5 days after notice of intent to impose the penalty (in immediate jeopardy situations) and 15 days after notice when there is no immediate jeopardy, because we believe that prompt sanctioning is necessary to ensure prompt correction of deficiencies. However, as specified in § 493.1834(g), HCFA does not actually impose the civil money penalty until the later of the following:

• The end of the 60-day period for requesting a hearing, if the laboratory does not request a hearing, or

• If the laboratory does request a hearing within the prescribed timeframe, after a hearing decision that upholds imposition of the penalty is issued.

6. *Comment:* Several commenters objected to the 35% reduction in civil money penalties if no hearing is requested.

*Response:* We did not accept this comment. The 35% reduction of the civil money penalty if a laboratory does not request a hearing was proposed to reflect a savings of costs that would otherwise be incurred by the Federal government if a hearing were conducted. It is at the sole discretion of the laboratory not to request a hearing and accept the 35% reduction. Such a policy does not restrict the laboratory's legal right to due process because the decision to waive the right to a hearing is strictly voluntary.

7. *Comment:* Two commenters are concerned about the provision that would permit HCFA to increase the civil money penalty if a laboratory, which alleges compliance, is found after a revisit to still be out of compliance. They believe HCFA should increase the civil money penalty only if the laboratory willfully or intentionally misrepresents that it has achieved compliance.

*Response:* The task of determining whether a laboratory intentionally or willfully misrepresented compliance would be a responsibility too burdensome for HCFA to undertake. The regulation provides that the amount of any civil money penalty, including any proposed increase or decrease to the initial amount, will be based on any change in the seriousness of the deficiencies.

8. *Comment:* One commenter believes the laboratory should be entitled to a hearing with respect to any increase in the civil money penalty amount.

*Response:* As we explained in a previous response, if a hearing is requested by the laboratory, the notice of the total penalty amount is not sent until the administrative law judge issues a decision adverse to the laboratory following the hearing. The administrative law judge will base his or her calculation of total penalty amount on the per day or per violation rate times the number of days of noncompliance or number of violations. The hearing will, therefore, be held after the revisit, if a revisit was conducted. Any increase in the per day or per violation rate will be proposed by HCFA between the revisit and the hearing. We have clarified this policy at § 493.1834(d)(4). However, as specified

at § 493.1844(d)(4), the amount of a civil money penalty to impose per day or per violation is not an initial determination and therefore is not subject to appeal; rather, the imposition of an alternative sanction, (in this case a civil money penalty) is the action that is subject to appeal.

9. *Comment:* Three commenters expressed overall concern about the implementation of civil money penalties. One commenter recommended a cap be placed on the amount of daily fines assessed while an appeal is pending, to ensure that the total penalty is not disproportionately large. The second commenter believed the regulations should contain standards to be applied by HCFA in determining whether to impose a civil money penalty to assure fair and even imposition of a civil money penalty and such standards would be helpful in avoiding allegations of arbitrary and capricious actions. The third commenter suggested the regulation should be revised to make it clear that civil money penalties will be used only when a laboratory fails to take corrective action to eliminate condition-level deficiencies within a reasonable amount of time and urged HCFA to use civil money penalties sparingly.

*Response:* We appreciate the concerns of the commenters. There is already a statutory cap of \$10,000 per day or per violation. However, the sooner the laboratory corrects its condition-level noncompliance, the sooner such civil money penalties will cease accruing while the hearing is pending. Thus, to a significant degree, the laboratory can control whatever liability it might have for a civil money penalty. In response to the suggestion that the regulation contain standards to determine whether or not to impose a civil money penalty, this decision is made on a case-by-case basis. HCFA will select the sanction(s) that are most likely to encourage the laboratory to meet CLIA requirements promptly. In response to the suggestion that civil money penalties be used only when a laboratory fails to take timely corrective action to eliminate condition-level deficiencies, such is the case with all alternative actions as specified at § 493.1810.

10. *Comment:* One commenter recommended that § 493.1834(1) provide for a specific rate of interest, such as 1 percent above the U.S. Treasury Bill rate.

*Response:* We have revised § 493.1834(i) to specify that the interest rate applicable to civil money penalties is the rate set forth in § 405.376(d) of the HCFA regulations, which states that the

interest rate on such payments will be the prevailing rate(s) specified in bulletins issued under § 8020.20 of the Treasury Fiscal Requirements Manual.

#### *D. Refund of Medicare Payments (Section 493.1830)*

We proposed to establish an alternative sanction that would require a laboratory with deficiencies, in lieu of having its Medicare approval canceled, to promise to refund Medicare payments made during the time allowed for correction of deficiencies if the deficiencies were not corrected during that time period, and to not charge the beneficiary for any services for which the laboratory refunded the Medicare payment.

*Comment:* We received 17 comments regarding this provision. Eleven commenters felt that the sanction would be unduly harsh, since the laboratories would have performed the tests "in good faith." Five commenters suggested that payments only be refunded for areas of noncompliance, while five also questioned the necessity of including this sanction in this regulation at all, since the threat of suspension, limitation, or revocation of the CLIA certificate would presumably be sufficient incentive to a laboratory to correct its deficiencies. Four commenters were of the opinion that if a laboratory refunded Medicare payments to HCFA, HCFA should refund the money to that laboratory once compliance is achieved. Two commenters stated that there should be a limit to the total amount of Medicare payment that must be refunded. Other comments included concerns that this sanction would serve to effectively penalize laboratories that participate in Medicare. Some commenters stated simply that it would be undesirable from a fiduciary standpoint to not privately charge Medicare beneficiaries for tests if they are indeed performed.

*Response:* After further consideration of this proposed sanction, we decided to withdraw it. We considered, for instance, that access to laboratory testing might be reduced if many laboratories chose cancellation of their Medicare approval rather than refund Medicare payments. Accordingly, we have removed this sanction from the final rule.

#### *E. Notification of Clients of Sanctioned Laboratories (Section 493.1832)*

1. *Comment:* Many commenters were generally opposed to client notification. Eleven commenters felt that laboratory clients should only be notified of a

laboratory's sanctioning in cases of immediate jeopardy.

*Response:* The notification of clients of sanctioned laboratories may be necessary to provide these clients with the information required to make an informed decision regarding the retesting of specimens. HCFA will decide whether laboratory clients should be notified of any condition-level noncompliance in a laboratory, not only that which poses immediate jeopardy. Physicians, other providers and suppliers, and other clients who depend on a laboratory for accurate testing of specimens should be informed at HCFA's discretion when a specialty or subspecialty of testing at that laboratory is not being properly performed.

Informing laboratory clients of condition-level noncompliance would facilitate an informed decision regarding the need for retesting of patients. Further, section 353(n) of the PHS Act requires the Secretary to issue an annual report that identifies all laboratories that have been given a principal or intermediate sanction, convicted of a criminal violation, subject to a court injunction, or excluded from participation in Medicare or Medicaid.

2. *Comment:* A few commenters stated that laboratory clients should be notified only if a laboratory has had its CLIA certificate suspended and its Medicare approval cancelled.

*Response:* Waiting until a principal sanction is imposed could create an unnecessary risk. If the noncompliance identified in a laboratory does not pose immediate jeopardy to health and safety, Medicare approval may continue for up to 90 days, and its CLIA certificate may not be revoked until after a hearing (even though the laboratory may have alternative sanctions imposed during that time). If we were, in all cases of noncompliance, to notify laboratory clients only after these principal sanctions have been imposed, we would be waiting until all other attempts at corrective action had failed. Clients, therefore, would not have the opportunity to make timely informed decisions about retesting or the need to send specimens to other laboratories during a period of time in which the danger to the patients remained unchanged or even worsened.

3. *Comment:* Many commenters felt that the notification of a sanctioned laboratory's clients would be too burdensome for the laboratory, physicians and other clients, and the States.

*Response:* We recognize that the process of notification of a laboratory's clients means more work for the laboratory, which would have to provide

the list of clients, if requested; the State, which will have the responsibility of notifying these clients, and clients who may find it necessary to notify patients about being retested. However, the risk to patients is significant if clients are not notified in cases where HCFA makes the decision that such notification should take place. Moreover, although we recognize an increased workload, we do question the extent of the work burden on laboratories since the names and addressees of their patients and other clients would already be compiled for billing purposes.

4. *Comment:* A few commenters voiced concern over the difficulty of notifying past patients of laboratory clients.

*Response:* We would expect that most providers and suppliers keep, for their own information and protection, historical records of patients for a specified number of years. However, we have not issued regulations regarding the notification of individuals who are patients of the laboratory's direct clients, and therefore indirect clients of the laboratory. We consider it beyond the purview of this regulation to regulate the actions of the physicians, providers and other suppliers who are users of a particular laboratory's services. Moreover, requirements for notifying such an extensive network of patients would be virtually impossible for HCFA to enforce. We, instead, leave such notification decisions to the health care facilities and professionals who referred their patients to a particular laboratory. In addition, as discussed previously under client notification issues, HCFA will publish a laboratory registry annually that will be accessible to the general public and will contain information that is useful in evaluating the performance of laboratories.

5. *Comment:* Several commenters were concerned that HCFA has no statutory authority to require the notification of clients of sanctioned laboratories.

*Response:* Section 1846(b)(1) of the Act requires the Secretary to develop "a range of intermediate sanctions" and section 1846(b)(3) of the Act and section 353(h)(3) of the PHS Act specify that the Secretary shall establish procedures with respect to when and how to carry out the imposition of those sanctions. We are using this discretionary statutory authority to notify clients of sanctioned laboratories as necessary to protect the health and safety of a laboratory's clients or the public health.

6. *Comment:* Five commenters expressed concern that the information contained in the client notification letter would be insufficient for a client to

make an "informed decision" regarding how to notify and retest patients.

*Response:* A client will receive notice that a laboratory it uses for specimen testing has been sanctioned by HCFA. The client will be advised of the nature of the laboratory's noncompliance and, if the client requires additional information or clarification in order to make an informed decision regarding patient notification and retesting, or the use of another laboratory's services, it is the responsibility of that client to contact the State agency or the HCFA regional office to obtain this information or clarification.

7. *Comment:* Thirteen commenters were concerned that the notification of physician clients of sanctioned laboratories may increase physician's malpractice liability, and may irrevocably harm the reputations of both the laboratory and the physician.

*Response:* Physicians are responsible for the diagnostic procedures they order for their patients. It is therefore the responsibility of the physician to remain informed of diagnostic services that are substandard. Referring patient specimens, out of lack of information, to any diagnostic service (e.g., a laboratory) that does not comply with congressionally mandated Federal requirements for health and safety could create a much greater risk to a physician's malpractice liability and reputation than would the retesting or redirecting of patient specimens to another laboratory, based on the knowledge of noncompliance in the laboratory ordinarily used. Moreover, we cannot develop policies based on a concern for the reputation of the laboratories. If sanctioned laboratories correct their deficiencies, clients (if they were notified of the sanction) will be notified that the adverse actions have been rescinded. Any remaining negative impact on the reputation of a laboratory is the result of that facility's noncompliance, and not the result of HCFA's enforcement of health and safety requirements that are specified in the Federal law.

8. *Comment:* Several commenters were concerned that the 10 calendar days afforded to a sanctioned laboratory to submit its list of names of all of its clients to HCFA, the State, or other HCFA agent is too short.

*Response:* The 10 day timeframe is necessary to minimize the period between the identification of a laboratory's noncompliance and the notification of its clients of the sanctioning in order for the clients to make informed decisions regarding the

health of their patients and the need for retesting.

**9. Comment:** Seven commenters expressed concern that the notification of patients by clients would unduly alarm the patients.

**Response:** The notification of patients by their physicians, providers, or other suppliers that the retesting of their specimens is necessary due to laboratory noncompliance may initially be unsettling to some patients. However, the client can phrase this notice in such a manner as to minimize patient fear. In the cases of specimens which require retesting, the client can explain that the retesting is in the best interest of the patients' health and safety.

**10. Comment:** Several commenters suggested that it would be easier and more cost-effective for HCFA to place a notice of laboratory sanctioning in a local newspaper than to individually notify each client.

**Response:** HCFA routinely places notices in local newspapers of the termination of provider agreements and supplier participation in the Medicare program.

The problem with relying solely on this method of notification for laboratory clients is that not every client of a particular laboratory will necessarily read the appropriate paper on the particular day a notice is published. Since many laboratories routinely test specimens outside of their locale, a notice placed in a local paper might not be useful. To make certain that every laboratory client is aware that a laboratory is sanctioned, we must, in cases deemed appropriate by HCFA, notify each client individually in addition to publishing a notice in the local newspaper.

**11. Comment:** One commenter questioned whether the client notification would include specific information, such as areas of specific failure in proficiency testing.

**Response:** We will include in the client notification the nature of the noncompliance which led to the sanction. We have clarified this at § 493.1832(b).

**12. Comment:** One commenter stated that the notification of laboratory clients should be transmitted through the Department of Health and Human Services or the appropriate HCFA regional office instead of through the State agency, since the Department of HCFA letterhead "carries more weight" than that of the State, and State agencies would not have sufficient resources to handle such a task.

**Response:** State agencies are agents of both the Department and HCFA, and

therefore can appropriately be given full regulatory authority to notify clients of sanctioned laboratories. As part of the implementation of the CLIA inspection and certification program, States will receive from HCFA sufficient resources to handle their additional responsibilities under CLIA.

#### *F. Correction of Deficiencies (Sections 493.1810-493.1838)*

**1. Comment:** Fifteen commenters voiced concern with the procedures for revisits. Of these fifteen, seven had questions regarding the duration of alternative sanctions, stating that §§ 493.1810 through 493.1816 are confusing, and that it is unclear whether sanctions are lifted on the date correction has been made, or on the date of a revisit which serves to verify correction. Four commenters requested that we develop a mechanism by which to ensure that revisits are conducted within a minimum specified amount of time after a credible allegation of compliance is given by the laboratory to the State, so that sanctions may be removed as soon as possible if the survey agency agrees that compliance has been achieved. One commenter suggested that we schedule the revisit in the notice of sanction. Another commenter, concerned that a request for a revisit may be denied, stated that a laboratory should be able to "self-certify" correction of its deficiencies. Two commenters felt that sanctions should not continue to be imposed if the laboratory makes a credible allegation of compliance, but the revisit has not yet been conducted. Two commenters requested that the term "credible allegation of compliance" be defined, and that the requirement that the allegation be submitted before a revisit can be scheduled be included in the regulation, as well as the preamble.

**Response:** Upon receiving a credible allegation of compliance from a laboratory, the State survey agency or other HCFA agent will determine whether compliance can be certified on the strength of the evidence presented by the laboratory in the verbal or written credible allegation. If this is the case, the appropriate sanctions will be lifted according to the procedures outlined at § 493.1810(e) of these regulations. However, it is frequently necessary for the survey agency to schedule a revisit to the laboratory in order to verify that compliance has been achieved. Revisits are always scheduled upon the receipt of a credible allegation of compliance and are scheduled to take place as soon as possible, but the length of time between the credible allegation and the visit can vary. For this reason,

we will inform the laboratory that if, during the revisit, it can be determined that compliance was achieved prior to the revisit, the sanctions will be lifted as of that earlier date. (We have clarified this policy at § 493.1820(b).) We would, however, not categorize this process as a laboratory's "self-certification" of compliance, because certifications of compliance can only be made by HCFA or HCFA agents. Because it is impossible to predict the date on which a laboratory will be capable of making a credible allegation of compliance, we cannot accept the suggestion that the date of the revisit be contained in the notice of sanction. Moreover, such a policy of including a prospective revisit date in the notice of sanction would imply that the revisit is automatic although it is not. It must follow a credible allegation of compliance submitted by the laboratory. We have added a definition of "Credible allegation of compliance" in § 493.2, and clarified the above described policy in § 493.1810. Specifically, a "credible allegation of compliance" means a statement or documentation by a representative of a laboratory with a positive history of correction of noncompliance or a history of compliance. The allegation must be realistic in terms of the likelihood that the laboratory has been able to accomplish the corrective action within the specified timeframe, and indicate that the noncompliance has been resolved.

**2. Comment:** Several commenters had concerns regarding the formulation and use of the plan of correction, stating that guidelines for the formulation of a plan of correction should be published in these regulations as an aid to small laboratories, and that HCFA instead of the survey agency should be the one to monitor correction of deficiencies.

**Response:** The State agency or other HCFA agent which has inspected the laboratory has the necessary background knowledge to assist the laboratory in the formulation of the plan of correction, and to monitor the corrections, as specified on that plan of correction.

**3. Comment:** Many commenters had various questions regarding the timeframe for correction of deficiencies. Some of these commenters requested more time to correct deficiencies than that set forth in this proposed rule. Others requested additional time in which to fully pay a civil money penalty.

**Response:** In order to minimize the period of time in which a laboratory continues to operate with deficiencies, albeit under sanction, § 1846 of the Act

prohibits such laboratories from receiving Medicare payments for longer than one year from the date the noncompliance was initially identified. If one or more revisits confirm that a laboratory still has deficiencies one year from the date the noncompliance was initially identified, HCFA also notifies the laboratory no less than 15 days prior to taking such action, of its intent to suspend, limit, or revoke the laboratory's CLIA certificate, and of a laboratory's right to a hearing.

In response to the request for additional time to fully pay a civil money penalty, we have provided in the regulation at § 493.1834(h) for an extended payment schedule for laboratories that cannot pay the total amount of their civil money penalties by the due date. In no instance will the extended payment schedule exceed 12 months from the original due date. The details of this extended payment plan will be included in HCFA's operating guidelines.

**4. Comment:** One commenter questioned the absence of OMB approval of the plan of correction provision in these regulations under the Paperwork Reduction Act of 1980. Another commenter stated that our initial estimate of 5 hours needed to formulate a correction plan is unrealistic.

**Response:** The timeframe of 5 hours to complete a plan of correction is simply our initial estimate. When the Office of Management and Budget reviews the plan of correction requirements in order to refine the assessment of the time which would be needed to complete this document, and approves it along with other documents to implement the CLIA program, we will publish a notice in the Federal Register.

**5. Comment:** Two commenters think the contents of a plan or correction should be more explicitly explained, particularly when the plan concerns staffing requirements. For example, in a rural area, where recruitment of qualified people is difficult, is a plan of correction calling for simply an advertisement in the paper sufficient?

**Response:** This level of specificity is inappropriate for regulations. Moreover, broad policies relating to the appropriateness or inappropriateness of plan of correction items would be inconsistent with the approach of evaluating each laboratory's deficiency(ies) on a case-by-case basis.

#### *G. Limitation of Certificates Based on the Test Level Rather Than the Specialty or Subspecialty Level*

**Comments:** In response to our request for comments on the above noted

alternative, we received numerous comments all in favor of applying the sanction at the test level.

**Response:** We appreciate the response to our request. As soon as we have the systems capability to impose limitations at the test level, we will initiate the policy and procedural changes necessary to do so. In the meantime, any laboratory found to be noncompliant in the testing of an individual analyte may, without sanction, voluntarily agree to cease testing of the analyte, according to the procedures at § 493.1832(b)(2). If the laboratory refuses to stop testing the analyte, HCFA may consider the continued testing an immediate jeopardy and impose a principal sanction as described at § 493.1812.

#### *H. Appeal Rights (§ 493.1644)*

**1. Comment:** Numerous commenters requested that the HCFA not impose any sanction until after a hearing.

**Response:** Consistent with both the Medicare and CLIA statutes, we believe that it is important to establish an enforcement process that minimizes the time between the identification of deficiencies and the taking of remedial action. The surest way we know to accomplish this objective is to provide prior notice of an impending sanction with the opportunity for a hearing after the sanction has been imposed. To provide hearings prior to the imposition of sanctions would enable deficient laboratory practices to remain in place for extended periods of time which we believe to be an unacceptable price for the public to pay.

Section 1846 of the Medicare statute specifically directs the Secretary to minimize the time between the identification of deficiencies and the imposition of sanctions, and CLIA clearly suggests the same course. Section 353(i), for example, is notably different from section 353(h). The former requires prior hearings in the case of most principal sanctions whereas the latter only speaks to an obligation to provide notice and a reasonable opportunity to respond. Only with respect to civil money penalties (under Section 1846 of the Act) and principal sanctions (under CLIA) in cases that do not pose immediate jeopardy, do the statutes require prior hearings, and these regulations reflect that mandate.

**2. Comment:** Many commenters requested that the list of initial determinations (§ 493.1844(c)) that are appealable be broadened.

**Response:** We have developed the regulatory list of initial determinations to be consistent with our treatment of other providers and suppliers under Medicare. We have provided for appeals

wherever such opportunity is afforded other providers and suppliers. We have not granted appeal rights that would give laboratories rights broader or more numerous than are available to other Medicare providers and suppliers.

**3. Comment:** Several commenters requested that we develop an expedited hearing process for laboratories, stating that patient access to laboratory testing would be compromised if laboratories had to wait for more than 30 days for a hearing. One commenter stated that hearings should be expedited when a laboratory is determined to have an immediate and serious threat deficiency, in order to reclassify this determination to avoid closure of the laboratory.

**Response:** Hearings on HCFA determinations that affect a laboratory's status under CLIA or in the Medicare program are conducted by the Departmental Appeals Board. The burdens on the Board may be vastly increased by the CLIA enforcement provided for in this regulation. Moreover, many other factors, including the number of cases for other parties awaiting a hearing at any given time, determine how quickly each case is heard. The inclusion in these regulations of a provision for an expedited hearing process would therefore be impossible.

We realize that a laboratory's failure to make corrections very quickly in immediate jeopardy situations will trigger the suspension or limitation of the laboratory's CLIA certificate, thus causing full or partial closure of the facility. However, as noted above, the imposition of these sanctions before a hearing in immediate jeopardy situations is clearly authorized by section 353(i)(2) of the PHS Act. If laboratories are concerned with maintaining access to testing, they should focus all efforts on the expedited correction of their deficiencies, and not the receipt of an "expedited" hearing, by which we assume the commenters mean a hearing before the adverse action is taken. But conducting hearings within the 5 days before principal sanctions become effective in immediate jeopardy situations would be virtually impossible. When there are life-threatening deficiencies, action must be taken no later than this.

**4. Comment:** A few commenters expressed support for sanctioning a noncomplying laboratory before a hearing.

**Response:** We appreciate the support we have received for this rule and are committed to the development of regulations that reflect the enforcement-related aspects of the CLIA provisions

and that will effectively implement the law.

5. *Comment:* Ten commenters requested that a pre-hearing/pre-sanction mechanism be implemented for the laboratory to informally review and respond to inspection findings and/or certifications of noncompliance. Several of these commenters also stated that HCFA needs to clarify what is meant by the "opportunity to respond" at § 493.1810(b).

*Response:* Under Medicare, laboratories have always had numerous opportunities to challenge surveyors' findings throughout the inspection process, including during the actual inspection, at the exit conference, after receipt of the official statement of deficiencies and notice of sanction, and through a dialogue with survey agency staff and HCFA regional office personnel. This informal review mechanism, which constitutes the "opportunity to respond" is now available to all laboratories under CLIA. However, the use of this process will not delay the implementation of any sanction unless the laboratory either corrects the deficiencies within the 5-day or 15-day notice period or presents credible evidence to convince HCFA that a deficiency did not exist and should not have been cited. We have delineated the steps which a laboratory must take in responding to the proposed imposition of sanctions (the opportunity to respond) at § 493.1810(b).

6. *Comment:* Two commenters requested that judicial review be available for prospective and sanctioned laboratories. One of these commenters requested that HCFA delay the imposition of any alternative sanction until after completion of civil action.

*Response:* The right to judicial review, as specified in § 493.1844(g)(3), reflects the provision of both the Social Security Act and the PHS Act. Neither statute grants the right to judicial review to prospective laboratories. Neither law grants the right to judicial review of the imposition of any alternative sanction except civil money penalty. In those cases in which judicial review is authorized by law, it is available only after an ALJ hearing. It cannot and should not delay imposition of sanctions. To permit a noncomplying laboratory to continue to operate until all appeals were exhausted would be dangerous to the health and safety of the individuals served by the laboratory. It would also be inconsistent with the requirement of section 1846(b) of the Act, which requires the Secretary to minimize the time between the identification of violations and the imposition of sanctions.

### I. Laboratory Registry (§ 493.1850)

1. *Comment:* The comments summarized below were received from 8 commenters in response to our request for suggestions of additional information that could be included in the Registry to help physicians and the public evaluate the performance of laboratories.

- Explain the meaning of the various actions taken by HCFA and identify the timeframe and type of deficiency for which a laboratory was cited.
- Include the outcome of all appealed decisions.
- Describe the methodology used to collect and prepare information for the Registry, as well as its uses and limitations.
- Include the same level of detail as is provided in the directed plan or correction.
- Publish the Registry in a form that physicians and clients can purchase if they wish.
- Consult with the industry in drafting explanations.
- Make clear when violations are relatively minor and identify situations in which the patient's health was not at risk.

• Allow laboratories to include their own explanatory information in a format established by HCFA.

The commenters also expressed concern and raised questions as follows:

- How will the information be "made available"? Will physicians and the public be informed when the Registry is available, or will copies be sent to physicians and other individuals?
- Will the information remain in the Registry for more than one year or will each edition list only the information from the preceding year?
- One commenter was concerned that the proposed rule did not require that a laboratory be given notice that it will be included in the registry and an opportunity to correct any error there might be as to whether the laboratory should be included or as to what sanctions were imposed.
- One commenter was of the opinion that the Registry was a good idea and would provide information that would enable patients to make appropriate decisions about the continued use of a laboratory.

*Response:* We appreciate the commenters' recommendations. We will add to the Registry information on the effective date of sanction and the date of the laboratory's verified compliance. We will also publish a list of all appealed decisions and corrections of erroneous information included in the previous year's Registry.

We believe any greater specificity in regulations is not appropriate at this time. After we have gained more experience in collecting and disseminating this information we will consider collecting and disseminating additional data as long as they are not too burdensome to maintain. The registry will include appropriate explanatory information to aid in the interpretation of the data. However, we simply cannot allow each laboratory to compose its own explanatory material prior to publication because of the enormity of the task of obtaining the information and editing it to meet length and format requirements. However, as stated in § 493.1850(a)(4), included in the list of laboratories on which alternative sanctions have been imposed will be any evidence of corrective action taken by the laboratory.

In response to the commenter who is unclear about how long the information will remain in the registry, as stated in § 493.1850(b), the laboratory registry is compiled for the calendar year preceding the date the information is made available.

2. *Comment:* Several commenters believed the name of a laboratory should not be included in the laboratory registry until the result of an administrative appeal is final.

*Response:* We acknowledge that there is a significant amount of concern among the commenters with respect to publishing information about sanctioned laboratories possibly before a hearing decision has been rendered.

Nevertheless, HCFA is concerned about the difficulty the Department of Health and Human Services has encountered in bringing enforcement actions in the past, and, in particular, is concerned about cases remaining in litigation for months or years while substantial violations remain uncorrected. If there are condition-level deficiencies, HCFA will impose a sanction or sanctions, and will do so prior to a hearing in most cases, to minimize the time lapse between identification of the violations and imposition of the sanctions. This timely action is required by section 1846(b)(3) of the Act and is achievable because, with the exception of civil money penalties and principal sanctions imposed in non-immediate and serious threat cases, hearings need not be held before the imposition of the sanction. Section 353(n) of the PHS Act requires the publication of a list of the laboratories against which sanctions have been imposed, and in many instances the law allows us to impose sanctions before a hearing.

3. *Comment:* Several commenters requested a mechanism for correction of mistakes in the laboratory registry (both prior to and subsequent to publication). One commenter suggested we share a draft of the laboratory registry with all laboratories to be included in the registry to ensure that the information is accurate and no mistakes have been made. Another commenter believes State hospital associations should have access to the data prior to its release.

*Response:* It would be impossible for us to meet our statutory deadlines for publication of the Registry were we to share proposed Registry entries with individual laboratories. This is particularly true because of the huge universe of laboratories subject to CLIA, and the consequent possibility that a large number of them will be sanctioned at the same time. To safeguard against erroneous inclusion of the names of laboratories or individuals in the annual registry, prior to publication the HCFA regional offices will review their portions of the registry for verification of information. We believe this procedure should virtually prevent inaccurate reporting. However, if erroneous information is published, this information will be corrected in the next registry.

4. *Comment:* Several commenters were entirely opposed to the laboratory registry. They believe the public will be misled and only marginally served. In addition, they believe that a laboratory's credibility, once lost through inclusion on the registry, can never be regained.

*Response:* The laboratory registry is required by section 353(n) of the PHS Act. Moreover, we believe that the laboratory registry will provide a worthwhile service to physicians and the general public.

5. *Comment:* Two commenters suggested that there should be a registry of CLIA certified laboratories instead of a registry of sanctioned laboratories.

*Response:* We appreciate this comment: However, we believe the objective of the laboratory registry is to provide physicians and the general public specific information that is useful in evaluating the performance of the laboratories. If anyone is interested in knowing which laboratories in the State are certified as meeting CLIA requirements, he or she should contact the appropriate State agency or HCFA regional office.

6. *Comment:* A few commenters were of the opinion that the Registry should not include laboratories with condition level deficiencies that do not pose immediate jeopardy. Another thought that laboratories subject to the "directed plan of correction" sanction or

submission of a correction schedule should not be included because by the time the Registry is published, the corrections would have been completed. A few commenters recommended that only laboratories which did not correct deficiencies within 12 months be included in the Registry.

*Response:* Section 353(n) of the PHS Act requires the Secretary to publish a list of laboratories against which enforcement sanctions have been imposed. While a directed plan of correction is considered an alternative sanction, a correction schedule developed by the laboratory is not an alternative sanction, and when not paired with an alternative sanction, would not be subject to publication in the registry. The PHS Act does not authorize us to exclude from the Registry any laboratories that have been sanctioned.

7. *Comment:* Two commenters suggested that instructions accompany the laboratory registry with background material on the method that was used to prepare the registry as well as a guide that outlines the uses and limitations of the information. One of the commenters stated that the instructions should mention that the Federal government tends to measure a laboratory's overall performance capabilities, but does not reflect actual outcomes. They also believe the Registry should note that an adverse action taken due to a laboratory's failure to comply with Federal requirements does not necessarily mean that the quality of the laboratory's tests was poor.

*Response:* We have not yet established the administrative procedures by which the Registry will be compiled and disseminated. Nor have we developed a format for the Registry. While we believe that the Registry will be published with some general explanatory material, the extent of that information is unknown at this time. We can say at this time that, in the case of laboratories the Federal government tends to measure overall capabilities (i.e., the laboratory's capability to conduct accurate and reliable testing) rather than actual outcomes, which would be impossible to measure for many laboratories. This is contrary to recent trends in the survey and certification program for other facility types. In the case of laboratories, however, the assumption must be made that if process requirements under CLIA are followed, the outcome will be positive (i.e., accurate and reliable test results). Regarding the rationale for the imposition of adverse actions, we cannot say that noncompliance with Federal requirements and resulting

adverse action always necessarily means that the quality of laboratory testing was poor. In fact, poor quality of laboratory testing is the presumption when deficiencies in the testing process, quality assurance, quality control, and other conditions are found, remain uncorrected, and lead to adverse actions.

8. *Comment:* One commenter suggested that dentists be identified in the final rule as recipients of the Registry.

*Response:* The Registry will be available to anyone who is interested, as indicated by the term "general public". To list specific individuals might give the impression of limitations that do not exist.

9. *Comment:* One commenter suggested that if the Federal government is to publish the names of laboratories involved in false billing, fraud and kickbacks, it should publish similar information about physician and corporate users of the laboratory.

*Response:* Because section 353(n) focuses the Registry on sanctioned laboratories, we cannot follow the commenter's suggestion since it would entail adding to the Registry persons or entities that either are not laboratories or are not laboratories that have been subject to the sanctions provided by CLIA.

10. *Comment:* One commenter requested that the names of individuals who are identified as needing training or technical assistance as part of a laboratory's plan or correction, not be released in the Registry in order to avoid the risk of slander charges. The commenter also suggested that the names of laboratory instruments not be released lest the Registry become a source of information to competitors.

*Response:* Nothing in the law or regulations requires or prohibits the release of this information.

#### IV. Summary of Changes from the Proposed Rule

##### A. Definitions.

1. We have consolidated all definitions for this part at § 493.2.

2. Revised definitions: "Condition level requirement and condition-level deficiency", "HCFA agent", "Immediate jeopardy"

3. *Added definitions:* "Adverse action", "Credible allegation of compliance", "Intentional violation", "Operator", "Owner", "Principal sanction", "State-exempt laboratory", "Unsuccessful participation in proficiency testing".

**B. Imposition of Sanctions**

1. Clarify the basis for imposition of sanctions. (§ 493.1804(b))
2. Explain why HCFA does not impose alternative sanctions on laboratories with certificates of waiver (§§ 493.1804(c) and 493.1806(c))
3. Clarify the meaning of "repeat" deficiencies. (§§ 493.1804(d) and 493.1834(d)(1))
4. Make clear that HCFA may bring civil suit against any laboratory, including one that is State-exempt. (§§ 493.1806(d), 493.1812(c) and 493.1846)
5. Remove proposed alternative sanction to require refund of Medicare payments for services furnished while any other alternative sanction was in effect. (Removal of §§ 493.1807(b)(3), 493.1830, and 493.1842(a)(1)(iii))
6. Provide for—  
Including in the notice of sanction a statement as to the rationale for the sanction; and  
Giving the laboratory formal acknowledgement of any evidence or other information it submits in response to the notice of sanction. (§ 493.1810(c)(1))
7. Provide for earlier lifting of a sanction if the laboratory can show that it achieved compliance before the date of revisit. (paragraph (e) added to § 493.1810; § 493.1820(b))
8. Clarify that HCFA may later revoke a CLIA certificate that it has suspended or limited because the deficiencies posed immediate jeopardy. (§ 493.1812(b))
9. Clarify that HCFA may impose a principal sanction when deficiencies are at the condition level but do not pose immediately jeopardy. (§ 493.1814(a)(2))
10. Make clear that, in connection with suspension of all or part of Medicare payments, the laboratory's agreement must include not charging the beneficiary's private insurance carrier. (§§ 493.1826(a)(1)(ii) and 493.1828(a)(2)(ii))
11. Include information about the nature of the non-compliance in the notice to the clients of a sanctioned laboratory. (§ 493.1832(b)(2))
12. Specify limitations on authority of State monitor. (§ 493.1836(a)(1))

**C. Civil Money Penalty**

1. Clarify duration of penalty. (§ 493.1834(f)(2))
2. Clarify that, if the laboratory requests a hearing, the civil money penalty is imposed only if the hearing decision upholds the imposition. (§ 493.1834(g)(1)(ii))
3. Specify the basis for computing interest. (§ 493.1834(i)(1)(ii))

**D. Appeals Procedures**

1. Clarify definition of "prospective laboratory". (§ 493.1844(a))
2. Clarify grounds for suspending or limiting a CLIA certificate before a hearing or hearing decision. (§ 493.1844(e)(2)(ii)(B))
3. Clarify that, if an ALJ decision upholds a suspension imposed because of immediate jeopardy, the suspension becomes a revocation. (§ 493.1844(e)(4)(ii))
4. Clarify that, for prospective laboratories, request for reconsideration is the required first step in the appeals process. (§ 493.1844(f)(1))
5. Remove references to appeals procedures for determinations that affect participation in the Medicare program with respect to sanctions imposed by the OIG. (§§ 493.1844(b)(1)(ii) and (b)(5))
6. Provide that hearings for laboratories facing principal or alternative sanctions will be conducted by the Departmental Appeals Board. (§ 493.1844(a)(2))

**E. Laboratory Registry**

1. Clarify the information to be included for laboratories on which HCFA has imposed alternative sanction. (§ 493.1850(a)(4))
2. Specify that each registry will include correction of errors in the previous registry. (§ 493.1850(c))

**F. Notification of Clients**

1. Clarify that the notification of noncompliance to a laboratory's clients is discretionary with HCFA. (§ 493.1832(b)(2)(ii))

**V. Regulatory Impact Analysis****A. Executive Order 12291 and Regulatory Flexibility Act**

The Regulatory Impact Analysis contained in HSQ-176-FC, published elsewhere in this issue of the **Federal Register**, addresses the impact of the entire CLIA program. Regarding this regulation specifically, we see no reason why the enforcement procedures, as such, would have a significant effect on laboratories independent of the other effects of the CLIA reform. Presumably, some laboratories will fail to meet CLIA standards and will face sanctions. A few will be put out of business. But the cause of this will be the substantive standards themselves, not the details of the sanctions procedures. Indeed, the cost of implementing the enforcement procedures will likely involve only a few million dollars a year (in marked contrast to such other elements of CLIA as inspection procedures). Likewise, there do not appear to be enforcement

options which would significantly affect the cost of the procedures.

**B. Executive Order 12612**

Under Executive Order 12612, "Federalism," we must prepare a Federalism Assessment for any action that may have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. The enforcement system to be imposed under CLIA 88, will have a substantial effect on the relationship between the Federal government and the States in the area of clinical laboratory regulation.

Until passage of this statute, the Federal government regulated about 13,000 clinical laboratories, mainly those engaged in interstate commerce or based in hospitals participating in Medicare. The much more numerous intrastate laboratories, including those located in physician's offices, were in many, though not all cases, regulated by the States. CLIA 88 does not preclude continued State regulation and licensure. It allows HCFA to accept results of inspections performed by State licensure agencies (as well as private non-profit organizations) in lieu of meeting CLIA requirements or as proof that the laboratory can be deemed to meet requirements for a CLIA certificate. (See our proposed rule: Clinical Laboratories Improvement Act Programs; Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and State Licensure Agencies, published August 20, 1990 at 55 FR 33936). However, a realistic appraisal suggests that except for those States electing to operate within a narrowly circumscribed Federal framework, and except for the essential function of personnel licensure which is left almost entirely to the States, there will be little of the former role for States in laboratory regulation remaining under CLIA 88.

Under the regulations referred to in the preceding paragraph:

- States may be relieved of the responsibility for licensure of their laboratories but may choose to exercise such responsibility and authority at their option; and

- States approved by HCFA for exemption of their laboratories from CLIA requirements may impose user fees on the laboratories they inspect.

The Assistant Secretary for Planning and Evaluation, the designated official under the Executive Order, certifies that this rule has been assessed in light of

the principles, criteria, and requirements stated in the Executive Order.

#### VI. Paperwork Reduction Act

Sections 493.1810(b), 493.1816(a), 493.1820(d), and 493.1832(b) of this rule contain information collection requirements that are subject to OMB review under the Paperwork Reduction Act of 1980. These reporting and recordkeeping requirements are not effective until cleared by the Office of Management and Budget.

Public reporting burden for these requirements is estimated as follows:

- For preparation of written evidence against the imposition of sanctions—5 hours;
- For preparation of a plan of correction—5 hours;
- For preparation of a revised plan of correction—3 hours; and
- For completion of a list of laboratory clients—1 hour.

These estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

If you comment on this burden estimate or any other aspect of these collection of information requirements, including suggestions for reducing the burden, please send copies directly to Office of Financial Management, HCFA, P.O. Box 26684, Baltimore, Maryland 21207, and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, Attention: Allison Herron Eydt, HCFA Desk Officer. A notice will be published in the *Federal Register* when approval is obtained.

#### VII. List of Subjects in 42 CFR Part 493

Health facilities, Laboratories, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR chapter IV would be amended as set forth below.

A. The authority citation for part 493 continues to read as follows:

**Authority:** Sec. 353 of the Public Health Service Act, secs. 1102, 1861(e), the sentence following 11861(s)(11), 1861(s)(12), 1861(s)(13), 1861(s)(14), 1861(s)(15), and 1861(s)(16) of the Social Security Act (42 U.S.C. 1302, 1395–(e), the sentence following 1395x (s)(11), 1395x (s)(12), 1395x (s)(13), 1395x (s)(14), 1395x (s)(15), and 1395x (s)(16)).

B. In § 493.2 the introductory text is revised the following definitions are added in alphabetical order and the definitions for *State-exempt laboratory* is revised and placed in alphabetical order:

#### § 493.2 Definitions.

As used in this part, unless the context indicates otherwise—

*Adverse action* means the imposition of a principal or alternative sanction by HCFA.

*ALJ* stands for Administrative Law Judge.

*Alternative sanctions* means sanctions that may be imposed in lieu of or in addition to principal sanctions. The term is synonymous with "intermediate sanctions" as used in section 1846 of the Act.

*CLIA certificate* means any of the following types of certificates issued by HCFA or its agent:

(1) *Certificate* means a certificate issued to a laboratory after an inspection that finds the laboratory to be in compliance with all condition level requirements.

(2) *Certificate of accreditation* means a certificate issued on the basis of the laboratory's accreditation by an accreditation organization approved by HCFA, indicating that the laboratory is deemed to meet CLIA requirements.

(3) *Certificate of registration or registration certificate* means a certificate issued to an entity that is not qualified to receive a certificate of waiver, to enable the entity to conduct laboratory testing until the entity is determined to be in compliance through an inspection by HCFA, the State, or a HCFA agent, or is accredited by an approved accreditation organization.

(4) *Certificate of waiver* means a certificate issued to a laboratory to perform only waiver tests, that are described in § 493.15(b).

*Condition level deficiency* means noncompliance with one or more condition level requirements.

*Condition level requirements* means any of the requirements identified as "conditions" in subparts G through Q of this part.

*Credible allegation of compliance* means a statement or documentation that—

(1) Is made by a representative of a laboratory that has a history of having maintained a commitment to compliance and of taking corrective action when required;

(2) Is realistic in terms of its being possible to accomplish the required corrective action between the date of the exit conference and the date of the allegation; and

(3) Indicates that the problem has been resolved.

*HCFA's agent* means an entity with which HCFA arranges to inspect

laboratories and assess laboratory activities against CLIA conditions, and which may be a State survey agency, a professional organization, a component of the Department, or any other group that HCFA approves for this purpose. The State survey agency may not be HCFA's agent in a State in which all laboratories are exempt from CLIA requirements because HCFA has approved the State's licensure program.

*Immediate jeopardy* means a situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public. This term is synonymous with imminent and serious risk to human health and significant hazard.

*Intentional violation* means knowing and willful noncompliance with any CLIA condition.

*Operator* means the individual or group of individuals who oversee all facets of the operation of a laboratory and who bear primary responsibility for the safety and reliability of the results of all specimen testing performed in that laboratory. The term includes—

- (1) A director of the laboratory if he or she meets the stated criteria; and
- (2) The members of the board of directors and the officers of a laboratory that is a small corporation under subchapter S of the Internal Revenue Code.

*Owner* means any person who owns any interest in a laboratory except for an interest in a laboratory whose stock and/or securities are publicly traded. (That is e.g., the purchase of shares of stock or securities on the New York Stock Exchange in a corporation owning a laboratory would not make a person an owner for the purpose of this regulation.)

*Party* means a laboratory affected by any of the enforcement procedures set forth in this subpart, or HCFA or the OIG, as appropriate.

*Principal sanction* means the suspension, limitation, or revocation of any type of CLIA certificate or the cancellation of the laboratory's approval to receive Medicare payment for its services.

*Prospective laboratory* means a laboratory that is operating under a registration certificate or is seeking any

of the three other types of CLIA certificates.

*State-exempt laboratory* means a laboratory that does not require a CLIA certificate because it is licensed by a State whose licensure program has been approved by HCFA.

*Unsuccessful participation in proficiency testing* means any of the following:

(1) Unsatisfactory performance for the same analyte in two consecutive or two out of three testing events.

(2) Repeated unsatisfactory overall testing event scores for two consecutive or two out of three testing events for the same specialty or subspecialty.

(3) An unsatisfactory testing event score for those subspecialties not graded by analyte (that is, bacteriology, micobacteriology, virology, parasitology, mycology, blood compatibility, immunohematology, or syphilis serology) for the same subspecialty for two consecutive or two out of three testing events.

(4) Failure of a laboratory performing gynecologic cytology to meet the standard at § 493.855.

C. A new subpart R is added to part 493, to read as follows:

## PART 493—LABORATORY REQUIREMENTS

### Subpart R—Enforcement Procedures

- Sec.
- 493.1800 Basis and scope.
- 493.1804 General considerations.
- 493.1806 Available sanctions: All laboratories.
- 493.1807 Additional sanctions: Laboratories that participate in Medicare.
- 493.1808 Adverse action on any type of CLIA certificate: Effect on Medicare approval.
- 493.1809 Limitation on Medicaid payment.
- 493.1810 Imposition and lifting of alternative sanctions.
- 493.1812 Action when deficiencies pose immediate jeopardy.
- 493.1814 Action when deficiencies are at the condition level but do not pose immediate jeopardy.
- 493.1816 Action when deficiencies are not at the condition level.
- 493.1820 Ensuring timely correction of deficiencies.
- 493.1826 Suspension of part of Medicare payments.
- 493.1828 Suspension of all Medicare payments.
- 493.1832 Directed plan of correction and directed portion of a plan of correction.
- 493.1834 Civil money penalty.
- 493.1836 State onsite monitoring.
- 493.1838 Training and technical assistance for unsuccessful participation in proficiency testing.

- Sec.
- 493.1840 Suspension, limitation, or revocation of any type of CLIA certificate.
- 493.1842 Cancellation of Medicare approval.
- 493.1844 Appeals procedures.
- 493.1846 Civil action.
- 493.1850 Laboratory registry.

### Subpart R—Enforcement Procedures

#### § 493.1800 Basis and scope.

(a) *Statutory basis.* (1) Section 1846 of the Act—

(i) Provides for intermediate sanctions that may be imposed on laboratories that perform clinical diagnostic tests on human specimens when those laboratories are found to be out of compliance with one or more of the conditions for Medicare coverage of their services; and

(ii) Requires the Secretary to develop and implement a range of such sanctions, including four that are specified in the statute.

(2) The Clinical Laboratories Improvement Act of 1967 (section 353 of the Public Health Service Act) as amended by CLIA '88—

(i) Establishes requirements for all laboratories that perform clinical diagnostic tests on human specimens;

(ii) Requires a Federal certification scheme to be applied to all such laboratories; and

(iii) Grants the Secretary broad enforcement authority, including—

(A) Use of intermediate sanctions;

(B) Suspension, limitation, or revocation of the certificate of a laboratory that is out of compliance with one or more requirements for a certificate; and

(C) Civil suit to enjoin any laboratory activity that constitutes a significant hazard to the public health.

(3) Section 353 also—

(1) Provides for imprisonment or fine for any person convicted of intentional violation of CLIA requirements;

(ii) Specifies the administrative hearing and judicial review rights of a laboratory that is sanctioned under CLIA; and

(iii) Requires the Secretary to publish annually a list of all laboratories that have been sanctioned during the preceding year.

(b) *Scope and applicability.* This subpart sets forth—

(1) The policies and procedures that HCFA follows to enforce the requirements applicable to laboratories under CLIA and under section 1846 of the Act; and

(2) The appeal rights of laboratories on which HCFA imposes sanctions.

#### § 493.1804 General considerations.

(a) *Purpose.* The enforcement mechanisms set forth in this subpart have the following purposes:

(1) To protect all individuals served by laboratories against substandard testing of specimens.

(2) To safeguard the general public against health and safety hazards that might result from laboratory activities.

(3) To motivate laboratories to comply with CLIA requirements so that they can provide accurate and reliable test results.

(b) *Basis for decision to impose sanctions.* (1) HCFA's decision to impose sanctions is based on one or more of the following:

(i) Deficiencies found by HCFA or its agents in the conduct of inspections to certify or validate compliance with Federal requirements, or through review of materials submitted by the laboratory (e.g., personnel qualifications).

(ii) Unsuccessful participation in proficiency testing.

(2) HCFA imposes one or more of the alternative or principal sanctions specified in § 493.1806 and § 493.1807 when HCFA or HCFA's agent finds that a laboratory has condition-level deficiencies.

(c) *Imposition of alternative sanctions.* (1) HCFA may impose alternative sanctions in lieu of the principal sanctions, (HCFA does not impose alternative sanctions on laboratories that have certificates of waiver because those laboratories are not inspected for compliance with condition-level requirements.)

(2) HCFA may impose alternative sanctions other than a civil money penalty after the laboratory has had an opportunity to respond, but before the hearing specified in § 493.1844.

(d) *Choice of sanction: Factors considered.* HCFA bases its choice of sanction or sanctions on consideration of one or more factors that include, but are not limited to, the following, as assessed by the State or by HCFA, or its agents:

(1) Whether the deficiencies pose immediate jeopardy.

(2) The nature, incidence, severity, and duration of the deficiencies or noncompliance.

(3) Whether the same condition level deficiencies have been identified repeatedly.

(4) The accuracy and extent of laboratory records (e.g., of remedial action) in regard to the noncompliance, and their availability to the State, to other HCFA agents, and to HCFA.

(5) The relationship of one deficiency or group of deficiencies to other deficiencies.

(6) The overall compliance history of the laboratory including but not limited to any period of noncompliance that occurred between certifications of compliance.

(7) The corrective and long-term compliance outcomes that HCFA hopes to achieve through application of the sanction.

(8) Whether the laboratory has made any progress toward improvement following a reasonable opportunity to correct deficiencies.

(9) Any recommendation by the State agency as to which sanction would be appropriate.

(e) *Number of alternative sanctions.* HCFA may impose a separate sanction for each condition level deficiency or a single sanction for all condition level deficiencies that are interrelated and subject to correction by a single course of action.

(f) *Appeal rights.* The appeal rights of laboratories dissatisfied with the imposition of a sanction are set forth in § 493.1844.

**§ 493.1806 Available sanctions: All laboratories.**

(a) *Applicability.* HCFA may impose one or more of the sanctions specified in this section on a laboratory that is out of compliance with one or more CLIA conditions.

(b) *Principal sanction.* HCFA may impose any of the three principal CLIA sanctions, which are suspension, limitation, or revocation of any type of CLIA certificate.

(c) *Alternative sanctions.* HCFA may impose one or more of the following alternative sanctions in lieu of or in addition to imposing a principal sanction, except on a laboratory that has a certificate of waiver.

(1) Directed plan of correction, as set forth at § 493.1832.

(2) State onsite monitoring as set forth at § 493.1836.

(3) Civil money penalty, as set forth at § 493.1834.

(d) *Civil suit.* HCFA may bring suit in the appropriate U.S. District Court to enjoin continuation of any activity of any laboratory (including a State-exempt laboratory that has been found with deficiencies during a validation survey), if HCFA has reason to believe that continuation of the activity would constitute a significant hazard to the public health.

(e) *Criminal sanctions.* Under section 353(1) of the PHS Act, an individual who is convicted of intentionally violating

any CLIA requirement may be imprisoned or fined.

**§ 493.1807 Additional sanctions: Laboratories that participate in Medicare.**

The following additional sanctions are available for laboratories that are out of compliance with one or more CLIA conditions and that have approval to receive Medicare payment for their services.

(a) *Principal sanction.* Cancellation of the laboratory's approval to receive Medicare payment for its services.

(b) *Alternative sanctions.* (1) Suspension of payment for tests in one or more specific specialties or subspecialties, performed on or after the effective date of sanction.

(2) Suspension of payment for all tests in all specialties and subspecialties performed on or after the effective date of sanction.

**§ 493.1808 Adverse action on any type of CLIA certificate: Effect on Medicare approval.**

(a) *Suspension or revocation of any type of CLIA certificate.* When HCFA suspends or revokes any type of CLIA certificate, HCFA concurrently cancels the laboratory's approval to receive Medicare payment for its services.

(b) *Limitation of any type of CLIA certificate.* When HCFA limits any type of CLIA certificate, HCFA concurrently limits Medicare approval to only those specialties or subspecialties that are authorized by the laboratory's limited certificate.

**§ 493.1809 Limitation on Medicaid payment.**

As provided in section 1902(a)(9)(C) of the Act, payment for laboratory services may be made under the State plan only if those services are furnished by a laboratory that meets CLIA conditions.

**§ 493.1810 Imposition and lifting of alternative sanctions.**

(a) *Notice of noncompliance and of proposed sanction: Content.* If HCFA or its agency identifies condition level noncompliance in a laboratory, HCFA or its agent gives the laboratory written notice of the following:

(1) The condition level noncompliance that it has identified.

(2) The sanction or sanctions that HCFA or its agent proposes to impose against the laboratory.

(3) The rationale for the proposed sanction or sanctions.

(4) The projected effective date and duration of the proposed sanction or sanctions.

(5) The authority for the proposed sanction or sanctions.

(6) The time allowed (at least 10 days) for the laboratory to respond to the notice.

(b) *Opportunity to respond.* During the period specified in paragraph (a)(6) of this section, the laboratory may submit to HCFA or its agent written evidence or other information against the imposition of the proposed sanction or sanctions.

(c) *Notice of imposition of sanction—*  
(1) *Content.* HCFA gives the laboratory written notice that acknowledges any evidence or information received from the laboratory and specifies the following:

(i) The sanction or sanctions to be imposed against the laboratory.

(ii) The authority and rationale for the imposing sanction or sanctions.

(iii) The effective date and duration of sanction.

(2) *Timing.* (i) If HCFA or its agent determines that the deficiencies pose immediate jeopardy, HCFA provides notice at least 5 days before the effective date of sanction.

(ii) If HCFA or its agent determines that the deficiencies do not pose immediate jeopardy, HCFA provides notice at least 15 days before the effective date of the sanction.

(d) *Duration of alternative sanctions.* An alternative sanction continues until the earlier of the following occurs:

(1) The laboratory corrects all condition level deficiencies.

(2) HCFA's suspension, limitation, or revocation of the laboratory's CLIA certificate becomes effective.

(e) *Lifting of alternative sanctions—*  
(1) *General rule.* Alternative sanctions are not lifted until a laboratory's compliance with all condition level requirements is verified.

(2) *Credible allegation of compliance.* When a sanctioned laboratory submits a credible allegation of compliance, HCFA's agent determines whether—

(i) It can certify compliance on the basis of the evidence presented by the laboratory in its allegation; or

(ii) It must revisit to verify whether the laboratory has, in fact, achieved compliance.

(3) *Compliance achieved before the date of revisit.* If during a revisit, the laboratory presents credible evidence (as determined by HCFA or its agent) that it achieved compliance before the date of revisit, sanctions are lifted as of that earlier date.

**§ 493.1812 Action when deficiencies pose immediate jeopardy.**

If a laboratory's deficiencies pose immediate jeopardy, the following rules apply:

(a) HCFA requires the laboratory to take immediate action to remove the jeopardy and may impose one or more alternative sanctions to help bring the laboratory into compliance.

(b) If the findings of a revisit indicate that a laboratory has not eliminated the jeopardy, HCFA suspends or limits the laboratory's CLIA certificate no earlier than 5 days after the date of notice of suspension or limitation. HCFA may later revoke the certificate.

(c) In addition, if HCFA has reason to believe that the continuation of any activity by any laboratory (either the entire laboratory operation or any specialty or subspecialty of testing) would constitute a significant hazard to the public health, HCFA may bring suit and seek a temporary injunction or restraining order against continuation of that activity by the laboratory, regardless of the type of CLIA certificate the laboratory has and of whether it is State-exempt.

**§ 493.1814 Action when deficiencies are at the condition level but do not pose immediate jeopardy.**

If a laboratory has condition level deficiencies that do not pose immediate jeopardy, the following rules apply:

(a) *Initial action.* (1) HCFA may cancel the laboratory's approval to receive Medicare payment for its services.

(2) HCFA may suspend, limit, or revoke the laboratory's CLIA certificate.

(3) If HCFA does not impose a principal sanction under paragraph (a)(1) or (a)(2) of this section, it imposes one or more alternative sanctions. In the case of unsuccessful participation in proficiency testing, HCFA may impose the training and technical assistance requirement set forth at § 493.1838 in lieu of, or in addition to, one or more alternative sanctions.

(b) *Failure to correct condition level deficiencies.* If HCFA imposes alternative sanctions for condition level deficiencies that do not pose immediate jeopardy, and the laboratory does not correct the condition level deficiencies within 12 months after the last day of inspection, HCFA—

(1) Cancels the laboratory's approval to receive Medicare payment for its services, and discontinues the Medicare payment sanctions as of the day cancellation is effective.

(2) Following a revisit which indicates that the laboratory has not corrected its condition level deficiencies, notifies the laboratory that it proposes to suspend, limit, or revoke the certificate, as specified in § 493.1816(b), and the laboratory's right to hearing; and

(3) May impose (or continue, if already imposed) any alternative sanctions that do not pertain to Medicare payments. (Sanctions imposed under the authority of section 353 of the PHS Act may continue for more than 12 months from the last date of inspection, (while a hearing on the proposed suspension, limitation, or revocation of the certificate, registration certificate, or certificate of accreditation is pending.)

(c) *Action after hearing.* If a hearing decision upholds a proposed suspension, limitation, or revocation of a laboratory's CLIA certificate, HCFA discontinues any alternative sanctions as of the day it makes the suspension, limitation, or revocation effective.

**§ 493.1816 Action when deficiencies are not at the condition level.**

If a laboratory has deficiencies, that are not at the condition level, the following rules apply:

(a) *Initial action.* The laboratory must submit a plan of correction that is acceptable to HCFA in content and time frames.

(b) *Failure to correct deficiencies.* If, on revisit, it is found that the laboratory has not corrected the deficiencies within 12 months after the last day of inspection, the following rules apply:

(1) HCFA cancels the laboratory's approval to receive Medicare payment for its services.

(2) HCFA notifies the laboratory of its intent to suspend, limit, or revoke the laboratory's CLIA certificate and of the laboratory's right to a hearing.

**§ 493.1820 Ensuring timely correction of deficiencies.**

(a) *Timing of visits.* HCFA, the State survey agency or other HCFA agent may visit the laboratory at any time to evaluate progress, and at the end of the period to determine whether all corrections have been made.

(b) *Deficiencies corrected before a visit.* If during a visit, a laboratory produces credible evidence that it achieved compliance before the visit, the sanctions are lifted as of that earlier date.

(c) *Failure to correct deficiencies.* If during a visit it is found that the laboratory has not corrected its deficiencies, HCFA may propose to suspend, limit, or revoke the laboratory's CLIA certificate.

(d) *Additional time for correcting lower level deficiencies* not at the condition level. If at the end of the plan of correction period all condition level deficiencies have been corrected, and there are deficiencies, that are not at the condition level, HCFA may request a revised plan of correction. The revised

plan may not extend beyond 12 months from the last day of the inspection that originally identified the cited deficiencies.

(e) *Persistence of deficiencies.* If at the end of the period covered by the plan of correction, the laboratory still has deficiencies, the rules of § 493.1814 and § 493.1816 apply.

**§ 493.1826 Suspension of part of Medicare payments.**

(a) *Application.* (1) HCFA may impose this sanction if a laboratory—

(i) Is found to have condition level deficiencies with respect to one or more specialties or subspecialties of tests; and

(ii) Chooses to agree (in return for not having its Medicare approval cancelled immediately) not to charge Medicare beneficiaries or their private insurance carriers for the services for which Medicare payment is suspended.

(2) HCFA suspends Medicare payment for those specialties or subspecialties of tests for which the laboratory is out of compliance with Federal requirements.

(b) *Procedures.* Before imposing this sanction, HCFA provides notice of sanction and opportunity to respond in accordance with § 493.1810.

(c) *Duration and effect of sanction.*

This sanction continues until the laboratory corrects the condition level deficiencies or HCFA cancels the laboratory's approval to receive Medicare payment for its services, but in no event longer than 12 months.

(1) If the laboratory corrects all condition level deficiencies, HCFA resumes Medicare payment effective for all services furnished on or after the date the deficiencies are corrected.

**§ 493.1828 Suspension of all Medicare payments.**

(a) *Application.* (1) HCFA may suspend payment for all Medicare-approved laboratory services when the laboratory has condition level deficiencies.

(2) HCFA suspends payment for all Medicare covered laboratory services when the following conditions are met:

(i) Either—

(A) The laboratory has not corrected its condition level deficiencies included in the plan of correction within 3 months from the last date of inspection; or

(B) The laboratory has been found to have the same condition level deficiencies during three consecutive inspections; and

(ii) The laboratory has chosen (in return for not having its Medicare approval immediately cancelled), to not charge Medicare beneficiaries or their

private insurance carriers for services for which Medicare payment is suspended.

(3) HCFA suspends payment for services furnished on and after the effective date of sanction.

(b) *Procedures.* Before imposing this sanction, HCFA provides notice of sanction and opportunity to respond in accordance with § 493.1810.

(c) *Duration and effect of sanction.* (1) Suspension of payment continues until all condition level deficiencies are corrected, but never beyond twelve months.

(2) If all the deficiencies are not corrected by the end of the 12 month period, HCFA cancels the laboratory's approval to receive Medicare payment for its services.

**§ 493.1832 Directed plan of correction and directed portion of a plan of correction.**

(a) *Application.* HCFA may impose a directed plan of correction as an alternative sanction for any laboratory that has condition level deficiencies. If HCFA does not impose a directed plan of correction as an alternative sanction for a laboratory that has condition level deficiencies, it at least imposes a directed portion of a plan of correction when it imposes any of the following alternative sanctions:

- (1) State onsite monitoring.
- (2) Civil money penalty.
- (3) Suspension of all or part of Medicare payments.

(b) *Procedures—(1) Directed plan of correction.* When imposing this sanction, HCFA—

(i) Gives the laboratory prior notice of the sanction and opportunity to respond in accordance with § 493.1810;

(ii) Directs the laboratory to take specific corrective action within specific time frames in order to achieve compliance; and

(iii) May direct the laboratory to submit the names of laboratory clients for notification purposes, as specified in paragraph (b)(3) of this section.

(2) *Directed portion of a plan of correction.* HCFA may decide to notify clients of a sanctioned laboratory, because of the seriousness of the noncompliance (e.g., the existence of immediate jeopardy) or for other reasons. When imposing this sanction, HCFA takes the following steps—

(i) Directs the laboratory to submit to HCFA, the State survey agency, or other HCFA agent, within 10 calendar days after the notice of the alternative sanction, a list of names and addresses of all physicians, providers, suppliers, and other clients who have used some or all of the services of the laboratory since the last certification inspection or

within any other timeframe specified by HCFA.

(ii) Within 30 calendar days of receipt of the information, may send to each laboratory client, via the State survey agency, a notice containing the name and address of the laboratory, the nature of the laboratory's noncompliance, and the kind and effective date of the alternative sanction.

(iii) Sends to each laboratory client, via the State survey agency, notice of the rescission of an adverse action within 30 days of the rescission.

(3) *Notice of imposition of a principal sanction following the imposition of an alternative sanction.* If HCFA imposes a principal sanction following the imposition of an alternative sanction, and for which HCFA has already obtained a list of laboratory clients, HCFA may use that list to notify the clients of the imposition of the principal sanction.

(c) *Duration of a directed plan of correction.* If HCFA imposes a directed plan of correction, and on revisit it is found that the laboratory has not corrected the deficiencies within 12 months from the last day of inspection, the following rules apply:

(1) HCFA cancels the laboratory's approval for Medicare payment of its services, and notifies the laboratory of HCFA's intent to suspend, limit, or revoke the laboratory's CLIA certificate.

(2) The directed plan of correction continues in effect until the day suspension, limitation, or revocation of the laboratory's CLIA certificate.

**§ 493.1834 Civil money penalty.**

(a) *Statutory basis.* Sections 1846 of the Act and 353(h)(2)(B) of the PHS Act authorize the Secretary to impose civil money penalties on laboratories. Section 1846(b)(3) of the Act specifically provides that incrementally more severe fines may be imposed for repeated or uncorrected deficiencies.

(b) *Scope.* This section sets forth the procedures that HCFA follows to impose a civil money penalty in lieu of suspending, limiting, or revoking the certificate, registration certificate or certificate of accreditation of a laboratory that is found to have condition level deficiencies.

(c) *Basis for imposing a civil money penalty.* HCFA may impose a civil money penalty against any laboratory determined to have condition level deficiencies regardless of whether those deficiencies pose immediate jeopardy.

(d) *Amount of penalty—(1) Factors considered.* In determining the amount of the penalty, HCFA takes into account the following factors:

(i) The nature, scope, severity, and duration of the noncompliance.

(ii) Whether the same condition level deficiencies have been identified during three consecutive inspections.

(iii) The laboratory's overall compliance history including but not limited to any period of noncompliance that occurred between certifications of compliance.

(iv) The laboratory's intent or reason for noncompliance.

(v) The accuracy and extent of laboratory records and their availability to HCFA, the State survey agency, or other HCFA agent.

(2) *Range of penalty amount.*

(i) For a condition level deficiency that poses immediate jeopardy, the range is \$3,050-\$10,000 per day of noncompliance or per violation.

(ii) For a condition level deficiency that does not pose immediate jeopardy, the range is \$50-\$3,000 per day of noncompliance or per violation.

(3) *Decreased penalty amounts.* If the immediate jeopardy is removed, but the deficiency continues, HCFA shifts the penalty amount to the lower range.

(4) *Increased penalty amounts.* HCFA may, before the hearing, propose to increase the penalty amount for a laboratory that has deficiencies which, after imposition of a lower level penalty amount, become sufficiently serious to pose immediate jeopardy.

(e) *Procedures for imposition of civil money penalty—(1) Notice of intent.* (i) HCFA sends the laboratory written notice, of HCFA's intent to impose a civil money penalty.

(ii) The notice includes the following information:

(A) The statutory basis for the penalty.

(B) The proposed daily or per violation amount of the penalty.

(C) The factors (as described in paragraph (d)(1) of this section) that HCFA considered.

(D) The opportunity for responding to the notice in accordance with § 493.1810(c).

(E) A specific statement regarding the laboratory's appeal rights.

(2) *Appeal rights.* (i) The laboratory has 60 days from the date of receipt of the notice of intent to impose a civil money penalty to request a hearing in accordance with § 493.1844(g).

(ii) If the laboratory requests a hearing, all other pertinent provisions of § 493.1844 apply.

(iii) If the laboratory does not request a hearing, HCFA may reduce the proposed penalty amount by 35 percent.

(f) *Accrual and duration of penalty*—  
(1) *Accrual of penalty.* The civil money penalty begins accruing as follows:

(i) 5 days after notice of intent if there is immediate jeopardy.

(ii) 15 days after notice of intent if there is not immediate jeopardy.

(2) *Duration of penalty.* The civil money penalty continues to accrue until the earliest of the following occurs:

(i) The laboratory's compliance with condition level requirements is verified on the basis of the evidence presented by the laboratory in its credible allegation of compliance or at the time or revisit.

(ii) Based on credible evidence presented by the laboratory at the time of revisit, HCFA determines that compliance was achieved before the revisit. (In this situation, the money penalty stops accruing as of the date of compliance.)

(iii) HCFA suspends, limits, or revokes the laboratory's CLIA certificate, registration certificate, or certificate of accreditation.

(g) *Computation and notice of total penalty amount*— (1) *Computation.* HCFA computes the total penalty amount after the laboratory's compliance is verified or HCFA suspends, limits, or revokes the laboratory's CLIA certificate but in no event before—

(i) The 60 day period for requesting a hearing has expired without a request or the laboratory has explicitly waived its right to a hearing; or

(ii) Following a hearing requested by the laboratory, the ALJ issues a decision that upholds imposition of the penalty.

(2) *Notice of penalty amount and due date of penalty.* The notice includes the following information:

(i) Daily or per violation penalty amount.

(ii) Number of days or violations for which the penalty is imposed.

(iii) Total penalty amount.

(iv) Due date for payment of the penalty.

(h) *Due date for payment of penalty.*

(1) Payment of a civil money penalty is due 15 days from the date of the notice specified in paragraph (g)(2) of this section.

(2) HCFA may approve a plan for a laboratory to pay a civil money penalty plus interest, over a period of up to one year from the original due date.

(i) *Collection and settlement*—(1) *Collection of penalty amounts.* (i) The determined penalty amount may be deducted from any sums then or later owing by the United States to the laboratory subject to the penalty.

(ii) Interest accrues on the unpaid balance of the penalty, beginning on the

due date. Interest is computed at the rate specified in § 405.376(d) of this chapter.

(2) *Settlement.* HCFA has authority to settle any case at any time before the ALJ issues a hearing decision.

#### § 493.1836 State onsite monitoring.

(a) *Application.*

(1) HCFA may require continuous or intermittent monitoring of a plan of correction by the State survey agency to ensure that the laboratory makes the improvements necessary to bring it into compliance with the condition level requirements. (The State monitor does not have management authority, that is, cannot hire or fire staff, obligate funds, or otherwise dictate how the laboratory operates. The monitor's responsibility is to oversee whether corrections are made.)

(2) The laboratory must pay the costs of onsite monitoring by the State survey agency.

(i) The costs are computed by multiplying the number of hours of onsite monitoring in the laboratory by the hourly rate negotiated by HCFA and the State.

(ii) The hourly rate includes salary, fringe benefits, travel, and other direct and indirect costs approved by HCFA.

(b) *Procedures.* Before imposing this sanction, HCFA provides notice of sanction and opportunity to respond in accordance with § 493.1810.

(c) *Duration of sanction.* (1) If HCFA imposes onsite monitoring, the sanction continues until HCFA determines that the laboratory has the capability to ensure compliance with all condition level requirements.

(2) If the laboratory does not correct all deficiencies within 12 months, and a revisit indicates that deficiencies remain, HCFA cancels the laboratory's approval for Medicare payment for its services and notifies the laboratory of its intent to suspend, limit, or revoke the laboratory's certificate, registration certificate, or certificate of accreditation.

(3) If the laboratory still does not correct its deficiencies, the Medicare sanction continues until the suspension, limitation, or revocation of the laboratory's certificate, registration certificate, or certificate of accreditation is effective.

#### § 493.1838 Training and technical assistance for unsuccessful participation in proficiency testing.

If a laboratory's participation in proficiency testing is unsuccessful, HCFA may require the laboratory to undertake training of its personnel, or to obtain necessary technical assistance,

or both, in order to meet the requirements of the proficiency testing program. This requirement is separate from the principal and alternative sanctions set forth in §§ 493.1806 and 493.1807.

#### § 493.1840 Suspension, limitation, or revocation of any type of CLIA certificate.

(a) *Adverse action based on actions of the laboratory's owner, operator or employees.* HCFA may initiate adverse action to suspend, limit or revoke any CLIA certificate if HCFA finds that a laboratory's owner or operator or one of its employees has—

(1) Been guilty of misrepresentation in obtaining a CLIA certificate;

(2) Performed, or represented the laboratory as entitled to perform, a laboratory examination or other procedure that is not within a category of laboratory examinations or other procedures authorized by its CLIA certificate;

(3) Failed to comply with the certificate requirements and performance standards;

(4) Failed to comply with reasonable requests by HCFA for any information or work on materials that HCFA concludes is necessary to determine the laboratory's continued eligibility for its CLIA certificate or continued compliance with performance standards set by HCFA;

(5) Refused a reasonable request by HCFA or its agent for permission to inspect the laboratory and its operation and pertinent records during the hours that the laboratory is in operation;

(6) Violated or aided and abetted in the violation of any provisions of CLIA and its implementing regulations;

(7) Failed to comply with an alternative sanction imposed under this subpart; or

(8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked. (This provision applies only to the owner or operator, not to all of the laboratory's employees.)

(b) *Adverse action based on improper referrals in proficiency testing.* If HCFA determines that a laboratory has intentionally referred its proficiency testing samples to another laboratory for analysis, HCFA revokes the laboratory's CLIA certificate for at least one year, and may also impose a civil money penalty.

(c) *Adverse action based on exclusion from Medicare.* If the OIG excludes a laboratory from participation in Medicare, HCFA suspends the laboratory's CLIA certificate for the

period during which the laboratory is excluded.

(d) *Procedures for suspension or limitation*—(1) *Basic rule.* Except as provided in paragraph (d)(2) of this section, HCFA does not suspend or limit a CLIA certificate until after an ALJ hearing decision (as provided in § 493.1844) that upholds suspension or limitation.

(2) *Exceptions.* HCFA may suspend or limit a CLIA certificate before the ALJ hearing in any of the following circumstances:

(i) The laboratory's deficiencies pose immediate jeopardy.

(ii) The laboratory has refused a reasonable request for information or work on materials.

(iii) The laboratory has refused permission for HCFA or a HCFA agent to inspect the laboratory or its operation.

(e) *Procedures for revocation.* (1) HCFA does not revoke any type of CLIA certificate until after an ALJ hearing that upholds revocation.

(2) HCFA may revoke a CLIA certificate after the hearing decision even if it had not previously suspended or limited that certificate.

(f) *Notice to the OIG.* HCFA notifies the OIG of any violations under paragraphs (a)(1), (a)(2), (a)(6), and (b) of this section within 30 days of the determination of the violation.

#### § 493.1842 Cancellation of Medicare approval.

(a) *Basis for cancellation.* (1) HCFA always cancels a laboratory's approval to receive Medicare payment for its services if HCFA suspends or revokes the laboratory's CLIA certificate.

(2) HCFA may cancel the laboratory's approval under any of the following circumstances:

(i) The laboratory is out of compliance with a condition level requirement.

(ii) The laboratory fails to submit a plan of correction satisfactory to HCFA.

(iii) The laboratory fails to correct all its deficiencies within the time frames specified in the plan of correction.

(b) *Notice and opportunity to respond.* Before canceling a laboratory's approval to receive Medicare payment for its services, HCFA gives the laboratory—

(1) Written notice of the rationale for, effective date, and effect of, cancellation;

(2) Opportunity to submit written evidence or other information against cancellation of the laboratory's approval.

This sanction may be imposed before the hearing that may be requested by a laboratory, in accordance with the

appeals procedures set forth in § 493.1844.

(c) *Effect of cancellation.* Cancellation of Medicare approval terminates any Medicare payment sanctions regardless of the time frames originally specified.

#### § 493.1844 Appeals procedures.

(a) *General rules.* (1) The provisions of this section apply to all laboratories and prospective laboratories that are dissatisfied with any initial determination under paragraph (b) of this section.

(2) Hearings are conducted in accordance with procedures set forth in subpart D of part 498 of this chapter, except that the authority to conduct hearings and issue decisions may be exercised by ALJs assigned to, or detailed to, the Departmental Appeals Board.

(3) Any party dissatisfied with a hearing decision is entitled to request review of the decision as specified in subpart E of part 498 of this chapter, except that the authority to review the decision may be exercised by the Departmental Appeals Board.

(4) When more than one of the actions specified in paragraph (b) of this section are carried out concurrently, the laboratory has a right to only one hearing on all matters at issue.

(b) *Actions that are initial determinations.* The following actions are initial determinations and therefore are subject to appeal in accordance with this section:

(1) The suspension, limitation, or revocation of the laboratory's CLIA certificate by HCFA because of noncompliance with CLIA requirements.

(2) The denial of a CLIA certificate.

(3) The imposition of alternative sanctions under this subpart (but not the determination as to which alternative sanction or sanctions to impose).

(4) The denial or cancellation of the laboratory's approval to receive Medicare payment for its services.

(c) *Actions that are not initial determinations.* Actions that are not listed in paragraph (b) of this section are not initial determinations and therefore are not subject to appeal under this section. They include, but are not necessarily limited to, the following:

(1) The finding that a laboratory accredited by a HCFA-approved accreditation organization is no longer deemed to meet the conditions set forth in subparts G through O of this part. However, the suspension, limitation or revocation of a certificate of accreditation is an initial determination and is appealable.

(2) The finding that a laboratory determined to be in compliance with

condition-level requirements but has deficiencies that are not at the condition level.

(3) The determination not to reinstate a suspended CLIA certificate because the reason for the suspension has not been removed or there is insufficient assurance that the reason will not recur.

(4) The determination as to which alternative sanction or sanctions to impose, including the amount of a civil money penalty to impose per day or per violation.

(5) The denial of approval for Medicare payment for the services of a laboratory that does not have in effect a valid CLIA certificate.

(6) The determination that a laboratory's deficiencies pose immediate jeopardy.

(7) The amount of the civil money penalty assessed per day or for each violation of Federal requirements.

(d) *Effect of pending appeals*—(1) *Alternative sanctions.* The effective date of an alternative sanction (other than a civil money penalty) is not delayed because the laboratory has appealed and the hearing or the hearing decision is pending.

(2) *Suspension, limitation, or revocation of a laboratory's CLIA certificate*—(i) *General rule.* Except as provided in paragraph (d)(2)(ii) of this section, suspension, limitation, or revocation of a CLIA certificate is not effective until after a hearing decision by an ALJ is issued.

(ii) *Exceptions.* (A) If HCFA determines that conditions at a laboratory pose immediate jeopardy, the effective date of the suspension or limitation of a CLIA certificate is not delayed because the laboratory has appealed and the hearing or the hearing decision is pending.

(B) HCFA may suspend or limit a laboratory's CLIA certificate before an ALJ hearing or hearing decision if the laboratory has refused a reasonable request for information (including but not limited to billing information), or for work on materials, or has refused permission for HCFA or a HCFA agent to inspect the laboratory or its operation.

(3) *Cancellation of Medicare approval.* The effective date of the cancellation of a laboratory's approval to receive Medicare payment for its services is not delayed because the laboratory has appealed and the hearing or hearing decision is pending.

(4) *Effect of ALJ decision.* (i) An ALJ decision is final unless, as provided in paragraph (a)(3) of this section, one of the parties requests review by the Departmental Appeals Board within 60

days, and the Board reviews the case and issues a revised decision.

(ii) If an ALJ decision upholds a suspension imposed because of immediate jeopardy, that suspension becomes a revocation.

(e) *Appeal rights for prospective laboratories*—(1) *Reconsideration*. Any prospective laboratory dissatisfied with a denial of a CLIA certificate, or of approval for Medicare payment for its services, may initiate the appeals process by requesting reconsideration in accordance with §§ 498.22 through 498.25 of this chapter.

(2) *Notice of reopening*. If HCFA reopens an initial or reconsidered determination, HCFA gives the prospective laboratory notice of the revised determination in accordance with § 498.32 of this chapter.

(3) *ALJ hearing*. Any prospective laboratory dissatisfied with a reconsidered determination under paragraph (e)(1) of this section or a revised reconsidered determination under § 498.30 of this chapter is entitled to a hearing before an ALJ, as specified in paragraph (a)(2) of this section.

(4) *Review of ALJ hearing decisions*. Any prospective laboratory that is dissatisfied with an ALJ's hearing decision or dismissal of a request for hearing may file a written request for review by the Departmental Appeals Board as provided in paragraph (a)(3) of this section.

(f) *Appeal rights of laboratories*—(1) *ALJ hearing*. Any laboratory dissatisfied with the suspension, limitation, or revocation of its CLIA certificate, with the imposition of an alternative sanction under this subpart, or with cancellation of the approval to receive Medicare payment for its services, is entitled to a hearing before an ALJ as specified in paragraph (a)(2) of this section and has 60 days from the notice of sanction to request a hearing.

(2) *Review of ALJ hearing decisions*. Any laboratory that is dissatisfied with an ALJ's hearing decision or dismissal of a request for hearing may file a written request for review by the Departmental Appeals Board, as provided in paragraph (a)(3) of this section.

(3) *Judicial review*. Any laboratory dissatisfied with the decision to impose a civil money penalty or to suspend, limit, or revoke its CLIA certificate may, within 60 days after the decision becomes final, file with the U.S. Court of

Appeals of the circuit in which the laboratory has its principal place of business, a petition for judicial review.

(g) *Notice of adverse action*. (1) If HCFA suspends, limits, or revokes a laboratory's CLIA certificate or cancels the approval to receive Medicare payment for its services, HCFA gives notice to the laboratory, and may give notice to physicians, providers, suppliers, and other laboratory clients, according to the procedures set forth at § 493.1832. In addition, HCFA notifies the general public each time one of these principal sanctions is imposed.

(2) The notice to the laboratory—

(i) Sets forth the reasons for the adverse action, the effective date and effect of that action, and the appeal rights if any; and

(ii) When the certificate is limited, specifies the specialties or subspecialties of tests that the laboratory is no longer authorized to perform, and that are no longer covered under Medicare.

(3) The notice to other entities includes the same information except the information about the laboratory's appeal rights.

(h) *Effective date of adverse action*. (1) When the laboratory's deficiencies pose immediate jeopardy, the effective date of the adverse action is at least 5 days after the date of the notice.

(2) When HCFA determines that the laboratory's deficiencies do not pose immediate jeopardy, the effective date of the adverse action is at least 15 days after the date of the notice.

#### § 493.1846 Civil action.

If HCFA has reason to believe that continuation of the activities of any laboratory, including a State-exempt laboratory, would constitute a significant hazard to the public health, HCFA may bring suit in a U.S. District Court to enjoin continuation of the specific activity that is causing the hazard or to enjoin the continued operation of the laboratory if HCFA deems it necessary. Upon proper showing, the court shall issue a temporary injunction or restraining order without bond against continuation of the activity.

#### § 493.1850 Laboratory registry.

(a) Once a year HCFA makes available to physicians and to the general public specific information (including information provided to

HCFA by the OIG) that is useful in evaluating the performance of laboratories, including the following:

(1) A list of laboratories that have been convicted, under Federal or State laws relating to fraud and abuse, false billing, or kickbacks.

(2) A list of laboratories that have had their CLIA certificates suspended, limited, or revoked, and the reason for the adverse actions.

(3) A list of persons who have been convicted of violating CLIA requirements, as specified in section 353(1) of the PHS Act, together with the circumstances of each case and the penalties imposed.

(4) A list of laboratories on which alternative sanctions have been imposed, showing—

(i) The effective date of the sanctions;

(ii) The reasons for imposing them;

(iii) Any corrective action taken by the laboratory; and

(iv) If the laboratory has achieved compliance, the verified date of compliance.

(5) A list of laboratories whose accreditation has been withdrawn or revoked and the reasons for the withdrawal or revocation.

(6) All appeals and hearing decisions.

(7) A list of laboratories against which HCFA has brought suit under § 493.1846 and the reasons for those actions.

(8) A list of laboratories that have been excluded from participation in Medicare or Medicaid and the reasons for the exclusion.

(b) The laboratory registry is compiled for the calendar year preceding the date the information is made available and includes appropriate explanatory information to aid in the interpretation of the data. It also contains corrections of any erroneous statements or information that appeared in the previous registry.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Hospital Insurance)

Dated: December 31, 1991.

Gail R. Wilensky,  
Administrator, Health Care Financing  
Administration.

Approved: January 23, 1992.

Louis W. Sullivan,  
Secretary.

[FR Doc. 92-4050 Filed 2-20-92; 1:28 pm]

BILLING CODE 4120-03-M



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Public Health Service**
**Specific List for Categorization of Laboratory Test Systems, Assays and Examinations by Complexity**

**AGENCY:** Public Health Service, HHS.

**ACTION:** Notice with comment period.

**SUMMARY:** The Clinical Laboratory Improvement Amendments of 1988, Public Law 100-578, requires that the Secretary provide for the categorization of specific laboratory test systems, assays and examinations by level of complexity. 42 CFR 493.17, published elsewhere in this issue of the Federal Register, establishes criteria for such categorization.

It is the Department's intention to complete the categorization of all currently available clinical laboratory test systems, assays and examinations prior to the effective date of the amendments to 42 CFR Part 493 (September 1, 1992). This Notice announces the first of a series of lists containing specific clinical laboratory test systems, assays and examinations, categorized by complexity. Additional lists of test systems, assays and examinations will be published periodically. On or before September 1, 1992, a complete list of all laboratory test systems, assays and examinations, categorized by complexity, will be published in the form of a compilation of these Notices. Any clinical laboratory test system, assay or examination that is not on that final list will be considered high complexity, until categorized otherwise, as provided under 42 CFR 493.17. After publication of the compilation, applications will be taken to categorize (or recategorize) other laboratory test systems, assays and examinations following the procedures delineated in 42 CFR 493.17(d). Notices will be published periodically in the Federal Register to announce any additional test system, assay or examination that has been categorized (or re-categorized) during the preceding interval.

**DATES:** *Effective date:* This list is effective September 1, 1992.

*Comment date:* Written comments on this list of tests will be considered if they are received at the address indicated below, no later than 5 p.m. on March 30, 1992.

**ADDRESSES:** Comments on the content of this Notice—only—should be addressed to Public Health Service, Attention: CLIA Federal Register Notice, 1600

Clifton Rd. NE., (Mail Stop MLR5), Atlanta GA 30333.

Comments pertaining to the criteria for test categorization established by 42 CFR part 493 should be addressed to: Health Care Financing Administration, Attention HSQ-176-FC, P.O. Box 26678, Baltimore, MD 21207.

Due to staffing and resource limitations, we cannot accept facsimile (FAX) copies of comments. Nor can we accept comments by telephone.

**FOR FURTHER INFORMATION CONTACT:**

Miley A. Robinson, (404) 639-3153.

**SUPPLEMENTARY INFORMATION:** As described in 42 CFR 493.17, seven criteria were used to classify laboratory test systems, assays or examinations as moderate or high complexity using a grading scheme for level of complexity that assigned scores of 1, 2 or 3 within each of the seven criteria. Test systems, assays or examinations receiving total scores 12 or under were categorized as moderate complexity, while those receiving total scores of 13 through 21 were categorized as high complexity. As provided under 42 CFR 493.17, the following laboratory test systems, assays and examinations have been categorized as moderate or high complexity as noted.

Dated: January 23, 1992.

James O. Mason,

Assistant Secretary for Health.

**Specific List for Categorization of Laboratory Test Systems, Assays and Examinations by Complexity as Provided for in 42 CFR 493.17**

*Complexity:* Moderate

*Specialty/Subspecialty:* Bacteriology

*Analyte:* Aerobic Organisms from Cervical/Urethral Specimen

*Test Category:* Isolation and presumptive Identification of aerobic bacteria from cervical/urethral specimens

*Test System, Assay or Examination:* All Test Systems, Assays or Examinations

*Analyte:* Aerobic Organisms from Throat

*Test Category:* Isolation and confirmatory Identification of aerobic bacteria from throat, urine, or cervical/urethral specimens

*Test System, Assay or Examination:* All Test Systems, Assays or Examinations

*Analyte:* All Organisms

*Test Category:* Automated procedures that do not require operator intervention during the analytic process

*Test System, Assay or Examination:* Vitek Systems VITEK

Vitek Systems VITEK AMS ANA Card

Vitek Systems VITEK Anaerobe ID Card

Vitek Systems VITEK/ANI Anaerobes

Vitek Systems VITEK/Bacillus Biochem. card

Vitek Systems VITEK/EPS Enteric path. card

Vitek Systems VITEK/GNI Gram neg ID card

Vitek Systems VITEK/GPI Gram pos ID card

Vitek Systems VITEK/NHI Neisser. & Haemop.

Vitek Systems VITEK/Urine ID 3 card

*Test Category:* Gram stain

*Test System, Assay or Examination:* All Test Systems, Assays or Examinations

*Test Category:* Identification of aerobes from throat, urine, cervical or urethral specimens (e.g. Biochem/Physiol)

*Test System, Assay or Examination:*

Adams Scientific B. Cat Confirm

Adams Scientific Identicult—AE

Adams Scientific Identicult—BL

Adams Scientific Identicult—

Neisseria

Adams Scientific Mug-Indole Disc

Adams Scientific Rapid-Hippurate

Adams Scientific Stat-Urease

Analytab API 20 Streptococcus

Analytab API Laboratories Rapid E

Analytab API Laboratories Rapid NFT

Analytab API Laboratories Rapid

Strep

Analytab API StaphTrac

Analytab API Staphase III

Analytab API ZYM Microorganism

Differentiation

Analytab Quad Ferm +

Baxter Coagulase Plasma

Baxter Haemophilus/Neisseria

Identif—Panel

Baxter MicroScan Gram Neg Panels

Baxter MicroScan Gram Pos Panels

Becton Dickinson Cefinase Discs

Becton Dickinson Miniteck

Calbiochem Padac Differentiation

Discs

Calbiochem-Behring Anti-Dnase B

Carr Microbiologicals Beta Lactamase

Reagent Disc

Carr Microbiologicals CSM

Chromogenic B—Lactamase Disc

Carr Microbiologicals Hipp Microtube

Carr Microbiologicals Onpx-Indol

Microtube

Carr Microbiologicals PYR Broth

Carr Microbiologicals Pgua-Indol

Microtube

Carr Microbiologicals Phos

Microtubes

Carr Microbiologicals Pyrr Microtubes

Carr-Scarborough Rapid Glutamic

Acid Decarboxy microtube

- Diagnostic Products Corp. PathoDx  
PYR Kit
- Difco Differentiation Discs ALA  
Difco Differentiation Discs Hippurate  
Difco Differentiation Discs Nitrate  
Difco Differentiation Discs SPS  
Difco Differentiation Discs  
Spectinomycin  
Difco DrySlide Beta-Lactamase  
Difco Dryslide Oxidase  
Difco Spot Test 10% Na  
Desoxycholate  
E-Y Laboratories Strep-A-Check PYR  
E-Y Laboratories Swabzyme-Oxidase  
Innovative Diagnostic Systems Beta  
Discs  
Innovative Diagnostic Systems IDS  
Rapid SS/U System  
Innovative Diagnostic Systems IDS  
Rapid STR system  
Innovative Diagnostic Systems  
Modified IDS Rapid NH System  
Innovative Diagnostic Systems  
Oxichrome Reagent  
Innovative Diagnostic Systems  
Prophyrin Reagent  
Innovative Diagnostic Systems Rap  
NF Plus System  
Innovative Diagnostic Systems Rapid  
NF System  
Kev Connecticut Diagnostics Visi-  
Strep  
Meridian Indol Spot Test Kit  
Micro Media Systems Bacterial ID  
Panels/Gram Neg/Gram Pos  
Micro Media Systems M. Cat.  
Butyrate Disc  
Micro-Bio-Logics KWIK-LAC  
Micro-Bio-Logics Lyfo-KWIK OMI Kit  
Micro-Bio-Logics Neisseria-KWIK  
Plus  
Microbiological Specialties Beta-asc  
Tubes  
Microbiological Specialties Enzyme-  
ase I Tubes  
Microbiological Specialties Glactosid-  
ase Tubes  
Microtech Medical Systems Quadra-  
titer ID  
Pasco Labs Gram Neg ID System  
Pro-Lab Hippurate Test  
Pro-Lab Neisseria/Branhamella  
Differential Test  
Pro-Lab Rosco D'Ala Rapid Test  
Pro-Lab Rosco Pyrr  
Remel ALA Disc  
Remel Beta Lysin Disc  
Remel Beta-Lactam Disc  
Remel Bile Disc  
Remel CEPH Lactam Disc  
Remel Catarrhalis Test Strip  
Remel Coagulase Plasma  
Remel Colistin Disc  
Remel Haemophilus ID Test Kit  
Remel Hemastaph  
Remel Kanamycin Disc  
Remel Legionella ID Disc  
Remel Microdase  
Remel Nitrate Swab-Rapid Test
- Remel Novobiocin Disc  
Remel PYR Disc  
Remel PYR/Esculin Disc  
Remel Prophyrin (ALA) Disc  
Remel Pyridoxal Disc  
Remel SPS Disc  
Remel Urea-PDA Discs  
Roche Enterotube II  
Unipath Oxoid Bile Esculin Discs  
Unipath Oxoid ONPG Discs  
Unipath Oxoid Oxidase ID Sticks  
Unipath Oxoid SPS Discs  
Unipath Oxoid V Factor Discs  
Unipath Oxoid X & V Factor Discs  
Unipath Oxoid X Factor Discs  
Vitek Rapid E System  
*Test Category:* Manual procedures with  
limited steps and limited sample or  
reagent preparation  
*Test System, Assay or Examination:*  
Manual antimicrobial susceptibility  
test (KB Disc Diffus)  
*Test Category:* Manual screening  
devices for bacteriuria with limited  
steps and with limited sample or  
reagent preparation  
*Test System, Assay or Examination:*  
Analytab Uriscreeen  
Miles Diagnostic Labs MicroStix-3 ID  
Ventrex Uriscreeen  
*Test Category:* Primary culture  
inoculation  
*Test System, Assay or Examination:* All  
Test Systems, Assays or  
Examinations  
*Test Category:* Urine culture and colony  
count kits  
*Test System, Assay or Examination:*  
Culture Kits, Inc. Uri-Kit  
Medical Technology Corp. Uricult  
*Analyte:* Campylobacter  
*Test Category:* Manual procedures with  
limited steps and limited sample or  
reagent preparation  
*Test System, Assay or Examination:*  
Becton Dickinson BBL Campyslide  
Test  
Bio-Medical BIOCARD  
Campylobacter  
Meridian Diagnostics Meritec-Campy  
(JCL)  
*Analyte:* Chlamydia  
*Test Category:* Automated procedures  
that do not require operator  
intervention during the analytic  
process  
*Test System, Assay or Examination:*  
Vitek Systems Vidas Chlamydia  
(direct antigen)  
*Test Category:* Manual procedures with  
limited steps and limited sample or  
reagent preparation  
*Test System, Assay or Examination:*  
Abbott TestPack Chlamydia (EIA)  
(direct antigen)  
Analytab IDEIA (EIA) (direct antigen)  
Kodak SureCell (EIA) (direct antigen)  
Seradyn Vivid Chlamydia (direct  
antigen)
- Unipath Clearview Rapid Assay  
(direct antigen)  
*Analyte:* Clostridium difficile  
*Test Category:* Automated procedures  
that do not require operator  
intervention during the analytic  
process  
*Test System, Assay or Examination:*  
Vitek Systems Vidas C.difficile Toxin  
A Assay Kit  
*Test Category:* Manual procedures with  
limited steps and limited sample or  
reagent preparation  
*Test System, Assay or Examination:*  
Becton Dickinson Culturette CDT  
(direct antigen)  
Meridian Diagnostics Meritek (direct  
antigen)  
*Analyte:* Escherichia coli  
*Test Category:* Manual procedures with  
limited steps and limited sample or  
reagent preparation  
*Test System, Assay or Examination:*  
Bio-Medical ANI E. Coli 0157 Test  
(culture confirmation)  
Pro-Lab Diagnostics E.Coli 0157 Latex  
test (culture confirm)  
Unipath E. Coli 0157 Latex Kit (direct  
antigen)  
*Analyte:* Haemophilus influenzae, type  
a, c-f  
*Test Category:* Manual procedures with  
limited steps and limited sample or  
reagent preparation  
*Test System, Assay or Examination:*  
Karobio Phadebact Haemophilus  
(culture confirmation)  
*Analyte:* Haemophilus influenzae, type b  
*Test Category:* Manual procedures with  
limited steps and limited sample or  
reagent preparation  
*Test System, Assay or Examination:*  
Becton Dickinson Directigen  
Meningitis (direct antigen)  
Becton Dickinson Directigen  
Meningitis Combo Kit (dir. Ag)  
Karobio Phadebact CSF (direct  
antigen)  
Karobio Phadebact Haemophilus  
(culture confirmation)  
Vitek SLIDEX Meningite-Kit 5 (direct  
antigen)  
Wampole Bactigen H. influenzae type  
b (direct antigen)  
Wellcome Wellcogen Bacterial  
Antigen Kit (direct antigen)  
*Analyte:* Helicobacter pylori  
*Test Category:* Manual procedures with  
limited steps and limited sample or  
reagent preparation  
*Test System, Assay or Examination:*  
Scimedx Helicobacter pylori Test Kit  
(direct antigen)  
*Analyte:* Legionella pneumophila  
*Test Category:* Manual procedures with  
limited steps and limited sample or  
reagent preparation  
*Test System, Assay or Examination:*

- Bio-Medical BIOCARD Legionella**  
*Analyte:* Neisseria gonorrhoeae  
*Test Category:* Isolation and presumptive Identification of aerobic bacteria from cervical/urethral specimens  
*Test System, Assay or Examination:* Culture Kits, Inc. Goni-Kit  
 Medical Technology Corp. Biocult GC Culture Paddles  
 Micro-Bio-Logics GONO-KWIK  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Gen-Probe Pace2 (direct antigen)  
 Karobio Phadebact Monoclonal Gonococcus (culture confirm)  
 Meridian Diagnostics Meritec-GC (culture confirmation)  
 New Horizons Gonogen (culture confirmation)  
 New Horizons Gonogen II (culture confirmation)  
*Analyte:* Neisseria meningitidis (non-specific)  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Becton Dickinson Directigen (direct antigen)  
*Analyte:* Neisseria meningitidis, group A  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Becton Dickinson Directigen Meningitis A&Y (direct antigen)  
 Karobio Phadebact CSF (direct antigen)  
 Vitek SLIDEX Meningite-Kit 5 (direct antigen)  
 Wampole Bactigen N. meningitidis (direct antigen)  
*Analyte:* Neisseria meningitidis, group A and Y  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Becton Dickinson Directigen Meningitis Combo Kit (dir. Ag)  
*Analyte:* Neisseria meningitidis, group B  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Karobio Phadebact CSF (direct antigen)  
 Wampole Bactigen N. meningitidis (direct antigen)  
*Analyte:* Neisseria meningitidis, group B and E. coli K1  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Becton Dickinson Directigen
- Meningitis Combo Kit (dir. Ag)**  
 Vitek SLIDEX Meningite-Kit 5 (direct antigen)  
 Wellcome Wellcogen Bacterial Ag Kit Crp B/E.coli K1(dir Ag)  
*Analyte:* Neisseria meningitidis, group C  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Karobio Phadebact CSF (direct antigen)  
 Wampole Bactigen N. meningitidis (direct antigen)  
*Analyte:* Neisseria meningitidis, group C and W135  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Becton Dickinson Directigen Meningitis Combo Kit (dir. Ag)  
*Analyte:* Neisseria meningitidis, group C  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Vitek SLIDEX Meningite-Kit 5 (direct antigen)  
*Analyte:* Neisseria meningitidis, group W135  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Karobio Phadebact CSF (direct antigen)  
 Wampole Bactigen N. meningitidis (direct antigen)  
 Wellcome Wellcogen Bacterial Ag Kit(Grp A,C,Y,W135)(dir Ag)  
*Analyte:* Neisseria meningitidis, group Y  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Karobio Phadebact CSF (direct antigen)  
 Wampole Bactigen N. meningitidis (direct antigen)  
*Analyte:* Salmonella  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Ampcor Dipstick Salmonella  
 Bio-Medical ANI Salmonella Test  
*Analyte:* Staphylococcus  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Adams Scientific SeroStat II  
 Staphylococcus  
 Advanced Medical Technologies Rapi-Staph  
 Analytab Staph-Ident  
 Baxter MicroScan StaphyLatex  
 Becton Dickinson BBL Staphyloslide
- Bio-Medical ANI Staph aureus Test**  
 Carr-Scarborough Accu-Staph  
 Difco Bacto Staph Latex Test  
 Immuno-Mycologics LA-Staph  
 Innovative Diagnostic Systems IDS Staphylochrome  
 Medical Diagnostics Technologies Staph Latex  
 NCS Staphslide  
 Regional Media Lab Hemastaph  
 Remel Lysostaphin Reagent Set  
 Vitek RAPIDEX Staph  
 Wellcome Staphaurex  
*Analyte:* Streptococcus pneumoniae  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Becton Dickinson BBL Pneumoslide (culture confirmation)  
 Becton Dickinson Directigen Meningitis (direct antigen)  
 Becton Dickinson Directigen Meningitis Combo Kit (dir. Ag)  
 Karobio Phadebact CSF (direct antigen)  
 Karobio Phadebact Pneumococcus (culture confirmation)  
 Vitek SLIDEX Meningite-Kit 5 (direct antigen)  
 Wampole Bactigen S. pneumoniae (direct antigen)  
 Wellcome Wellcogen Bacterial Antigen Kit (direct antigen)  
*Analyte:* Streptococcus, (non-specific)  
*Test Category:* Isolation and confirmatory Identification of aerobic bacteria from throat, urine, or cervical/urethral specimens  
*Test System, Assay or Examination:* Culture Kits, Inc. Strep-Kit  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Bio-Medical ANI Strep Test  
*Analyte:* Streptococcus, group A  
*Test Category:* Isolation and confirmatory Identification of aerobic bacteria from throat, urine, or cervical/urethral specimens  
*Test System, Assay or Examination:* Medical Technology Corp. Respiracult—Strep  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Abbott TestPack Strep A (culture confirmation)  
 Abbott TestPack Strep A (direct antigen)  
 Adams Scientific SeroStat Streptococcus (culture confirm)  
 Antibodies Inc. Detect-A-Strep (culture confirmation)  
 Antibodies Inc. Detect-A-Strep (direct antigen)

- Baxter MicroScan Cards (direct antigen)
- Baxter MicroScan Microstrep (culture confirmation)
- Becton Dickinson BBL Strep Grouping Test (culture conf)
- Becton Dickinson Culturette Group A Strep (direct antigen)
- Becton Dickinson Directigen 1-2-3 Group A Strep (dir Ag)
- Becton Dickinson Directigen Group A Strep (direct antigen)
- Becton Dickinson Q Test Strep (direct antigen)
- Binax Equate Strep A (culture confirmation)
- Binax Equate Strep A (direct antigen)
- Clay Adams Q Test StatStrep (direct antigen)
- Diagnostic Prod PathoDx Latex Agg. Strep Group (culture con)
- Diagnostic Products Corp. PathoDx Strep A (direct antigen)
- Hybritech Concise Strep A (direct antigen)
- Hybritech Tandem Icon Strep A (direct antigen)
- Karobio Phadebact Streptococcus (culture confirmation)
- Karobio Phadirect Strep A Test (direct antigen)
- Kodak SureCell (culture confirmation)
- Kodak SureCell (direct antigen)
- Leeco Diagnostics Preview Strep A (direct antigen)
- Marion Scientific Group A Strep ID (culture confirmation)
- Marion Scientific Group A Strep ID (direct antigen)
- Medical Technology Corp. Optitec Strep A (culture confirm)
- Medical Technology Corp. Optitec Strep A (direct antigen)
- Medical Technology Corp. Respiralex (culture confirmation)
- Medical Technology Corp. Respiralex (direct antigen)
- Medix Biotech Sure-Strep A (culture confirmation)
- Medix Biotech Sure-Strep A (direct antigen)
- Meridian Diagnostics Immunocard (direct antigen)
- Meridian Diagnostics Meritec-Strep (culture confirmation)
- New Horizons Smart (direct antigen)
- New Horizons Streptogen (culture confirmation)
- Pacific Biotech Cards O.S. Strep A (direct antigen)
- Pacific Biotech Cards Strep A (direct antigen)
- Unipath Clearview Strep A (direct antigen)
- Unipath Oxoid Streptococcal Grouping Kit (culture confirm)
- V-Tech Target Strep A (direct antigen)
- V-Tech V-Trend Strep A (culture confirmation)
- V-Tech V-Trend Strep A (direct antigen)
- Ventrex Ventrescreen Strep A (direct antigen)
- Wampole Bactigen Group A Strep (direct antigen)
- Wellcome Reveal Colour Strep A (culture confirmation)
- Wellcome Reveal Colour Strep A (direct antigen)
- Wellcome Streptex A (culture confirmation)
- Analyte:* Streptococcus, group B  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Adams Scientific SeroStat Streptococcus (culture confirm)
- Baxter MicroScan Microstrep (culture confirmation)
- Becton Dickinson BBL Strep Grouping (culture confirmation)
- Becton Dickinson Directigen Group B Strep (direct antigen)
- Becton Dickinson Directigen Meningitis Combo Kit (dir. Ag)
- Binax Equate Strep B (culture confirmation)
- Binax Equate Strep B (direct antigen)
- Diagnostic Prod PathoDx Latex Agg. Strep Group (culture con)
- Diagnostic Products Corp. PathoDx Strep B (direct antigen)
- Hybritech Tandem Icon Strep B (direct antigen)
- Karobio Phadebact Streptococcus (culture confirmation)
- Marion Scientific Group B Strep ID (culture confirmation)
- Marion Scientific Group B Strep ID (direct antigen)
- Meridian Diagnostics Meritec-Strep (culture confirmation)
- Unipath Oxoid Streptococcal Grouping Kit (culture confirm)
- Wampole Bactigen Group B Strep (direct antigen)
- Wampole Bactigen Group B Strep-CS (culture confirmation)
- Wampole Bactigen Group B Strep-CS (direct antigen)
- Wellcome Streptex B (culture confirmation)
- Wellcome Wellcogen Bacterial Antigen Kit (direct antigen)
- Analyte:* Streptococcus, group C  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Adams Scientific SeroStat Streptococcus (culture confirm)
- Baxter MicroScan Microstrep (culture confirmation)
- Diagnostic Prod PathoDx Latex Agg. Strep Group (culture con)
- Karobio Phadebact Streptococcus (culture confirmation)
- Meridian Diagnostics Meritec-Strep (culture confirmation)
- Unipath Oxoid Streptococcal Grouping Kit (culture confirm)
- Wellcome Streptex C (culture confirmation)
- Analyte:* Streptococcus, group D  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Diagnostic Products Corp. PathoDx Strep D (direct antigen)
- Karobio Phadebact Streptococcus (culture confirmation)
- Unipath Oxoid Streptococcal Grouping Kit (culture confirm)
- Wellcome Streptex D (culture confirmation)
- Analyte:* Streptococcus, group F  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Adams Scientific SeroStat Streptococcus (culture confirm)
- Diagnostic Prod PathoDx Latex Agg. Strep Group (culture con)
- Karobio Phadebact Streptococcus (culture confirmation)
- Meridian Diagnostics Meritec-Strep (culture confirmation)
- Unipath Oxoid Streptococcal Grouping Kit (culture confirm)
- Wellcome Streptex F (culture confirmation)
- Analyte:* Streptococcus, group G  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Adams Scientific SeroStat Streptococcus (culture confirm)
- Baxter MicroScan Microstrep (culture confirmation)
- Diagnostic Prod PathoDx Latex Agg. Strep Group (culture con)
- Karobio Phadebact Streptococcus (culture confirmation)
- Meridian Diagnostics Meritec-Strep (culture confirmation)
- Unipath Oxoid Streptococcal Grouping Kit (culture confirm)
- Wellcome Streptex G (culture confirmation)
- Speciality/Subspeciality:* General Chemistry  
*Analyte:* 5-Hydroxyindolacetic Acid, Urine (5-HIAA)  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Abbott TDX  
Abbott TDX FLx  
*Analyte:* ALT (SGPT)

- Test Category:* Automated procedures that do not require operator intervention during the analytic process
- Test System, Assay or Examination:*
- Abbott Spectrum  
 Abbott Spectrum EPX  
 Abbott Spectrum Series II  
 Abbott Spectrum Series II CCX  
 Abbott VP  
 Abbott Vision  
 American Monitor Diagnostics Excel  
 American Monitor Diagnostics ISP 1000  
 American Monitor Diagnostics ISP 2000  
 American Monitor Diagnostics Perspective  
 Ames Seralyzer III  
 Baxter Paramax  
 Baxter Paramax 720 ZX  
 Beckman Astra Ideal  
 Beckman Synchron AS-X  
 Beckman Synchron CX 4  
 Beckman Synchron CX 5  
 Beckman Synchron CX 7  
 Boehringer Mannheim Hitachi 704  
 Boehringer Mannheim Hitachi 705  
 Boehringer Mannheim Hitachi 717  
 Boehringer Mannheim Hitachi 736  
 Boehringer Mannheim Hitachi 737  
 Boehringer Mannheim Hitachi 747  
 Ciba Corning 550 Express  
 Ciba Corning 570 Alliance  
 Ciba Corning 580 Alliance  
 Coulter Optichem 120  
 Coulter Optichem 180  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Analyst  
 Dupont Dimension  
 Dupont Dimension AR  
 Electronucleonics Gem-Profiler  
 Electronucleonics Gemini  
 Electronucleonics Gemstar  
 Electronucleonics Gemstar II  
 Instrumentation Laboratories IL Monarch  
 Instrumentation Laboratories IL Monarch Plus  
 Kodak Ektachem 400  
 Kodak Ektachem 500  
 Kodak Ektachem 700  
 Kodak Ektachem 700 XR  
 Kodak Ektachem DT SC Module  
 Olympus AU 5000  
 Olympus Demand  
 Roche Cobas FARA  
 Roche Cobas FARA II  
 Roche Cobas Mira  
 Roche Cobas Mira S  
 Technicon AXON  
 Technicon Assist  
 Technicon Chem 1  
 Technicon DAX 24  
 Technicon DAX 48  
 Technicon DAX 72  
 Technicon DAX 96
- Technicon RA 1000  
 Technicon RA 2000  
 Technicon RA 500  
 Technicon RA XT  
 Wako Diagnostics 20R  
 Wako Diagnostics 30R
- Test Category:* Whole blood measurements using teststrip meters (excluding glucose monitoring devices cleared by the FDA specifically for home use)
- Test System, Assay or Examination:*  
 Boehringer Mannheim Reflotron Plus  
 Roche Cobas Ready
- Analyte:* AST (SGOT)
- Test Category:* Automated procedures that do not require operator intervention during the analytic process
- Test System, Assay or Examination:*  
 Abbott Spectrum  
 Abbott Spectrum EPX  
 Abbott Spectrum Series II  
 Abbott Spectrum Series II CCX  
 Abbott VP  
 Abbott Vision  
 American Monitor Diagnostics Excel  
 American Monitor Diagnostics ISP 1000  
 American Monitor Diagnostics ISP 2000  
 American Monitor Diagnostics Perspective  
 Ames Clinistat  
 Ames Seralyzer  
 Ames Seralyzer III  
 Baxter Paramax  
 Baxter Paramax 720 ZX  
 Beckman Astra Ideal  
 Beckman Synchron AS-X  
 Beckman Synchron CX 4  
 Beckman Synchron CX 5  
 Beckman Synchron CX 7  
 Boehringer Mannheim Hitachi 704  
 Boehringer Mannheim Hitachi 705  
 Boehringer Mannheim Hitachi 717  
 Boehringer Mannheim Hitachi 736  
 Boehringer Mannheim Hitachi 737  
 Boehringer Mannheim Hitachi 747  
 Ciba Corning 550 Express  
 Ciba Corning 570 Alliance  
 Ciba Corning 580 Alliance  
 Coulter Optichem 120  
 Coulter Optichem 180  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Analyst  
 Dupont Dimension  
 Dupont Dimension AR  
 Electronucleonics Gem-Profiler  
 Electronucleonics Gemini  
 Electronucleonics Gemstar  
 Electronucleonics Gemstar II  
 Instrumentation Laboratories IL Monarch  
 Instrumentation Laboratories IL Monarch Plus  
 Kodak Ektachem 400  
 Kodak Ektachem 500  
 Kodak Ektachem 700  
 Kodak Ektachem 700 XR  
 Kodak Ektachem DT SC Module  
 Olympus AU 5000  
 Olympus Demand  
 Roche Cobas FARA  
 Roche Cobas FARA II  
 Roche Cobas Mira  
 Roche Cobas Mira S  
 Technicon AXON  
 Technicon Assist  
 Technicon Chem 1  
 Technicon DAX 24  
 Technicon DAX 48  
 Technicon DAX 72  
 Technicon DAX 96
- Kodak Ektachem 500  
 Kodak Ektachem 700  
 Kodak Ektachem 700 XR  
 Kodak Ektachem DT SC Module  
 Olympus AU 5000  
 Olympus Demand  
 Roche Cobas FARA  
 Roche Cobas FARA II  
 Roche Cobas Mira  
 Roche Cobas Mira S  
 Technicon AXON  
 Technicon Assist  
 Technicon Chem 1  
 Technicon DAX 24  
 Technicon DAX 48  
 Technicon DAX 72  
 Technicon DAX 96
- Test Category:* Whole blood measurements using teststrip meters (excluding glucose monitoring devices cleared by the FDA specifically for home use)
- Test System, Assay or Examination:*  
 Boehringer Mannheim Reflotron Plus  
 Roche Cobas Ready
- Analyte:* Acid Phosphatase
- Test Category:* Automated procedures that do not require operator intervention during the analytic process
- Test System, Assay or Examination:*  
 American Monitor Diagnostics Excel  
 American Monitor Diagnostics ISP 1000  
 American Monitor Diagnostics ISP 2000  
 Baxter Paramax  
 Baxter Paramax 720 ZX  
 Beckman Synchron CX 4  
 Beckman Synchron CX 5  
 Beckman Synchron CX 7  
 Boehringer Mannheim Hitachi 704  
 Boehringer Mannheim Hitachi 705  
 Boehringer Mannheim Hitachi 717  
 Boehringer Mannheim Hitachi 736  
 Boehringer Mannheim Hitachi 737  
 Boehringer Mannheim Hitachi 747  
 Ciba Corning 550 Express  
 Ciba Corning 570 Alliance  
 Ciba Corning 580 Alliance  
 Coulter Optichem 120  
 Coulter Optichem 180  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Analyst  
 Dupont Dimension  
 Dupont Dimension AR  
 Electronucleonics Gem-Profiler  
 Electronucleonics Gemini  
 Electronucleonics Gemstar  
 Electronucleonics Gemstar II  
 Instrumentation Laboratories IL Monarch  
 Instrumentation Laboratories IL Monarch Plus  
 Kodak Ektachem 400  
 Kodak Ektachem 500

Kodak Ektachem 700 XR  
 Olympus AU 5000  
 Olympus Demand  
 Technicon Assist  
 Technicon Chem 1  
 Technicon RA 1000  
 Technicon RA 500  
*Analyte:* Albumin  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott Spectrum  
 Abbott Spectrum EPX  
 Abbott Spectrum Series II  
 Abbott Spectrum Series II CCX  
 Abbott VP  
 Abbott Vision  
 American Monitor Diagnostics Excel  
 American Monitor Diagnostics ISP 1000  
 American Monitor Diagnostics ISP 2000  
 American Monitor Diagnostics Perspective  
 Baxter Paramax  
 Baxter Paramax 720 ZX  
 Beckman Array 360  
 Beckman Astra Ideal  
 Beckman Synchron AS-X  
 Beckman Synchron CX 4  
 Beckman Synchron CX 5  
 Beckman Synchron CX 7  
 Boehringer Mannheim Hitachi 704  
 Boehringer Mannheim Hitachi 705  
 Boehringer Mannheim Hitachi 717  
 Boehringer Mannheim Hitachi 736  
 Boehringer Mannheim Hitachi 737  
 Boehringer Mannheim Hitachi 747  
 Ciba Corning 550 Express  
 Ciba Corning 570 Alliance  
 Ciba Corning 580 Alliance  
 Coulter Optichem 120  
 Coulter Optichem 180  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Dimension  
 Dupont Dimension AR  
 Electronucleonics Gem-Profiler  
 Electronucleonics Gemini  
 Electronucleonics Gemstar  
 Electronucleonics Gemstar II  
 Instrumentation Laboratories IL  
 Monarch  
 Instrumentation Laboratories IL  
 Monarch Plus  
 Kodak Ektachem 400  
 Kodak Ektachem 500  
 Kodak Ektachem 700  
 Kodak Ektachem 700 XR  
 Olympus AU 5000  
 Olympus Demand  
 Roche Cobas FARA  
 Roche Cobas FARA II  
 Roche Cobas Mira  
 Roche Cobas Mira S  
 Technicon AXON

Technicon Assist  
 Technicon Chem 1  
 Technicon DAX 24  
 Technicon DAX 48  
 Technicon DAX 72  
 Technicon DAX 96  
 Technicon RA 1000  
 Technicon RA 2000  
 Technicon RA 500  
 Technicon RA XT  
 Wako Diagnostics 20R  
 Wako Diagnostics 30R  
*Analyte:* Aldolase  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Boehringer Mannheim Hitachi 717  
*Analyte:* Alkaline Phosphatase (ALP)  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott Spectrum  
 Abbott Spectrum EPX  
 Abbott Spectrum Series II  
 Abbott Spectrum Series II CCX  
 Abbott VP  
 Abbott Vision  
 American Monitor Diagnostics Excel  
 American Monitor Diagnostics ISP 1000  
 American Monitor Diagnostics ISP 2000  
 American Monitor Diagnostics Perspective  
 Baxter Paramax  
 Baxter Paramax 720 ZX  
 Beckman Astra Ideal  
 Beckman Synchron AS-X  
 Beckman Synchron CX 4  
 Beckman Synchron CX 5  
 Beckman Synchron CX 7  
 Boehringer Mannheim Hitachi 704  
 Boehringer Mannheim Hitachi 705  
 Boehringer Mannheim Hitachi 717  
 Boehringer Mannheim Hitachi 736  
 Boehringer Mannheim Hitachi 737  
 Boehringer Mannheim Hitachi 747  
 Ciba Corning 550 Express  
 Ciba Corning 570 Alliance  
 Ciba Corning 580 Alliance  
 Coulter Optichem 120  
 Coulter Optichem 180  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Analyst  
 Dupont Dimension  
 Dupont Dimension AR  
 Electronucleonics Gem-Profiler  
 Electronucleonics Gemini  
 Electronucleonics Gemstar  
 Electronucleonics Gemstar II  
 Instrumentation Laboratories IL  
 Monarch  
 Instrumentation Laboratories IL

Monarch Plus  
 Kodak Ektachem 400  
 Kodak Ektachem 500  
 Kodak Ektachem 700  
 Kodak Ektachem 700 XR  
 Kodak Ektachem DT SC Module  
 Olympus AU 5000  
 Olympus Demand  
 Roche Cobas FARA  
 Roche Cobas FARA II  
 Roche Cobas Mira  
 Roche Cobas Mira S  
 Technicon AXON  
 Technicon Assist  
 Technicon Chem 1  
 Technicon DAX 24  
 Technicon DAX 48  
 Technicon DAX 72  
 Technicon DAX 96  
 Technicon RA 1000  
 Technicon RA 2000  
 Technicon RA 500  
 Technicon RA XT  
 Wako Diagnostics 20R  
 Wako Diagnostics 30R  
*Analyte:* Alpha-Hydroxybutyrate Dehydrogenase (HBDH)  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Boehringer Mannheim Hitachi 705  
 Ciba Corning 550 Express  
 Dupont ACA IV  
 Dupont ACA V  
*Analyte:* Ammonia  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Baxter Paramax  
 Baxter Paramax 720 ZX  
 Boehringer Mannheim Hitachi 717  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Dimension  
 Instrumentation Laboratories IL  
 Monarch Plus  
 Kodak Ektachem 500  
 Kodak Ektachem 700 XR  
 Kodak Ektachem DT 60  
*Analyte:* Amylase  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott Spectrum EPX  
 Abbott Spectrum Series II  
 Abbott Spectrum Series II CCX  
 Abbott TDX  
 Abbott TDX FLx  
 Abbott VP  
 Abbott Vision  
 American Monitor Diagnostics Excel

American Monitor Diagnostics ISP  
1000  
American Monitor Diagnostics ISP  
2000

American Monitor Diagnostics  
Perspective

Baxter Paramax  
Baxter Paramax 720 ZX

Beckman Astra 8

Beckman Astra Ideal

Beckman Synchron AS-X

Beckman Synchron CX 4

Beckman Synchron CX 5

Beckman Synchron CX 7

Boehringer Mannheim Hitachi 704

Boehringer Mannheim Hitachi 705

Boehringer Mannheim Hitachi 717

Boehringer Mannheim Hitachi 736

Boehringer Mannheim Hitachi 737

Boehringer Mannheim Hitachi 747

Ciba Corning 550 Express

Ciba Corning 570 Alliance

Ciba Corning 580 Alliance

Coulter Optichem 120

Dupont ACA

Dupont ACA IV

Dupont ACA V

Dupont Analyst

Dupont Dimension

Dupont Dimension AR

Electronucleonics Gem-Profiler

Electronucleonics Gemini

Electronucleonics Gemstar

Electronucleonics Gemstar II

Instrumentation Laboratories II.

Monarch

Instrumentation Laboratories II.

Monarch Plus

Kodak Ektachem 400

Kodak Ektachem 500

Kodak Ektachem 700

Kodak Ektachem 700 XR

Kodak Ektachem DT 60

Olympus AU 5000

Olympus Demand

Roche Cobas FARA

Roche Cobas FARA II

Roche Cobas Mira

Roche Cobas Mira S

Technicon AXON

Technicon Assist

Technicon Chem 1

Technicon DAX 24

Technicon DAX 48

Technicon DAX 72

Technicon DAX 96

Technicon RA 1000

Technicon RA 2000

Technicon RA 500

Technicon RA XT

Wako Diagnostics 20R

Wako Diagnostics 30R

*Test Category:* Whole blood  
measurements using teststrip meters  
(excluding glucose monitoring  
devices cleared by the FDA  
specifically for home use)

*Test System, Assay or Examination:*

Boehringer Mannheim Reflotron Plus

*Analyte:* Bilirubin, Direct

*Test Category:* Automated procedures  
that do not require operator  
intervention during the analytic  
process

*Test System, Assay or Examination:*

Abbott Spectrum

Abbott Spectrum EPX

Abbott Spectrum Series II

Abbott Spectrum Series II CCX

Abbott VP

American Monitor Diagnostics Excel

American Monitor Diagnostics ISP

1000

American Monitor Diagnostics ISP

2000

American Monitor Diagnostics

Perspective

Baxter Paramax

Baxter Paramax 720 ZX

Beckman Astra Ideal

Beckman Synchron AS-X

Beckman Synchron CX 4

Beckman Synchron CX 5

Beckman Synchron CX 7

Boehringer Mannheim Hitachi 704

Boehringer Mannheim Hitachi 705

Boehringer Mannheim Hitachi 717

Boehringer Mannheim Hitachi 736

Boehringer Mannheim Hitachi 737

Boehringer Mannheim Hitachi 747

Ciba Corning 550 Express

Ciba Corning 570 Alliance

Ciba Corning 580 Alliance

Coulter Optichem 120

Coulter Optichem 180

Dupont ACA

Dupont ACA IV

Dupont ACA V

Dupont Dimension

Dupont Dimension AR

Electronucleonics Gem-Profiler

Electronucleonics Gemini

Electronucleonics Gemstar

Electronucleonics Gemstar II

Instrumentation Laboratories II.

Monarch

Instrumentation Laboratories II.

Monarch Plus

Kodak Ektachem 400

Kodak Ektachem 500

Kodak Ektachem 700

Kodak Ektachem 700 XR

Olympus AU 5000

Olympus Demand

Roche Cobas FARA

Roche Cobas FARA II

Roche Cobas Mira

Roche Cobas Mira S

Technicon AXON

Technicon Assist

Technicon Chem 1

Technicon DAX 24

Technicon DAX 48

Technicon DAX 72

Technicon DAX 96

Technicon RA 1000

Technicon RA 2000

Technicon RA 500

Technicon RA XT

Wako Diagnostics 20R

Wako Diagnostics 30R

*Analyte:* Bilirubin, Neonatal

*Test Category:* Automated procedures  
that do not require operator  
intervention during the analytic  
process

*Test System, Assay or Examination:*

Advanced Instruments Bilirubin

STAT Analyzer

Dupont ACA

Dupont ACA IV

Dupont ACA V

*Analyte:* Bilirubin, Total

*Test Category:* Automated procedures  
that do not require operator  
intervention during the analytic  
process

*Test System, Assay or Examination:*

Abbott Spectrum

Abbott Spectrum EPX

Abbott Spectrum Series II

Abbott Spectrum Series II CCX

Abbott VP

Abbott Vision

American Monitor Diagnostics Excel

American Monitor Diagnostics ISP

1000

American Monitor Diagnostics ISP

2000

American Monitor Diagnostics

Perspective

Ames Clinistat

Ames Seralyzer

Ames Seralyzer III

Baxter Paramax

Baxter Paramax 720 ZX

Beckman Astra Ideal

Beckman Synchron AS-X

Beckman Synchron CX 4

Beckman Synchron CX 5

Beckman Synchron CX 7

Boehringer Mannheim Hitachi 704

Boehringer Mannheim Hitachi 705

Boehringer Mannheim Hitachi 717

Boehringer Mannheim Hitachi 736

Boehringer Mannheim Hitachi 737

Boehringer Mannheim Hitachi 747

Ciba Corning 550 Express

Ciba Corning 570 Alliance

Ciba Corning 580 Alliance

Coulter Optichem 120

Coulter Optichem 180

Dupont ACA

Dupont ACA IV

Dupont ACA V

Dupont Analyst

Dupont Dimension

Dupont Dimension AR

Electronucleonics Gem-Profiler

Electronucleonics Gemini

Electronucleonics Gemstar

Electronucleonics Gemstar II

Instrumentation Laboratories II.

Monarch

Instrumentation Laboratories II.

Monarch Plus

Kodak Ektachem 400  
 Kodak Ektachem 500  
 Kodak Ektachem 700  
 Kodak Ektachem 700 XR  
 Kodak Ektachem DT 60  
 Olympus AU 5000  
 Olympus Demand  
 Roche Cobas FARA  
 Roche Cobas FARA II  
 Roche Cobas Mira  
 Roche Cobas Mira S  
 Technicon AXON  
 Technicon Assist  
 Technicon Chem 1  
 Technicon DAX 24  
 Technicon DAX 48  
 Technicon DAX 72  
 Technicon DAX 96  
 Technicon RA 1000  
 Technicon RA 2000  
 Technicon RA 500  
 Technicon RA XT  
 Wako Diagnostics 20R  
 Wako Diagnostics 30R

*Test Category:* Whole blood measurements using teststrip meters (excluding glucose monitoring devices cleared by the FDA specifically for home use)

*Test System, Assay or Examination:*  
 Boehringer Mannheim Reflotron Plus  
 Roche Cobas Ready

*Analyte:* Blood Gases

*Test Category:* Automated blood gas analyses that do not require operator intervention during the analytic process, such as instruments that have an automated process for calibration, sample intake and flushing of sample lines

*Test System, Assay or Examination:*  
 AVL 940  
 AVL 945  
 AVL 990  
 AVL 995  
 AVL 995 Hb  
 Ciba Corning 278  
 Ciba Corning 280  
 Ciba Corning 288  
 Instrumentation Laboratories BG Electrolytes  
 Instrumentation Laboratories IL 1301  
 Instrumentation Laboratories IL 1302  
 Instrumentation Laboratories IL 1303  
 Instrumentation Laboratories IL 1304  
 Instrumentation Laboratories IL 1306  
 Instrumentation Laboratories IL 1312  
 Instrumentation Laboratories IL 813  
 Mallinckrodt Gem 6 Plus  
 Mallinckrodt Gem Premier  
 Nova Stat Profile  
 Radiometer ABL 2  
 Radiometer ABL 3  
 Radiometer ABL 30  
 Radiometer ABL 300  
 Radiometer ABL 330  
 Radiometer ABL 4

*Analyte:* CK MB

*Test Category:* Automated procedures that do not require operator

intervention during the analytic process

*Test System, Assay or Examination:*  
 Abbott IMX  
 Baxter Paramax  
 Baxter Paramax 720 ZX  
 Baxter Stratus  
 Baxter Stratus II  
 Beckman Synchron CX 7  
 Boehringer Mannheim Hitachi 705  
 Boehringer Mannheim Hitachi 717  
 Boehringer Mannheim Hitachi 747  
 Ciba Corning ACS 180  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Dimension  
 Instrumentation Laboratories IL Monarch Plus  
 Kodak Ektachem 500  
 Kodak Ektachem 700 XR  
 Kodak Ektachem DT SC Module

*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation

*Test System, Assay or Examination:*  
 Hybritech ICON QSR CKMB

*Analyte:* CO<sub>2</sub>

*Test Category:* Automated procedures that do not require operator intervention during the analytic process

*Test System, Assay or Examination:*  
 AVL 986-S  
 Abbott VP  
 American Monitor Diagnostics Excel  
 American Monitor Diagnostics ISP 1000  
 American Monitor Diagnostics ISP 2000  
 American Monitor Diagnostics Perspective  
 Baxter Paramax  
 Baxter Paramax 720 ZX  
 Beckman Astra 4  
 Beckman Astra 8  
 Beckman Astra Ideal  
 Beckman E2A  
 Beckman E4A  
 Beckman Synchron AS-X  
 Beckman Synchron CX 3  
 Beckman Synchron CX 4  
 Beckman Synchron CX 5  
 Beckman Synchron CX 7  
 Beckman Synchron EL-ISE  
 Boehringer Mannheim Hitachi 704  
 Boehringer Mannheim Hitachi 705  
 Boehringer Mannheim Hitachi 717  
 Boehringer Mannheim Hitachi 736  
 Boehringer Mannheim Hitachi 737  
 Boehringer Mannheim Hitachi 747  
 Ciba Corning 550 Express  
 Ciba Corning 570 Alliance  
 Ciba Corning 580 Alliance  
 Ciba Corning 664 FAST 4  
 Coulter Optichem 120  
 Coulter Optichem 180  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V

Dupont Dimension  
 Dupont Dimension AR  
 Electronucleonics Gem-Profiler  
 Electronucleonics Gemini  
 Electronucleonics Gemstar  
 Electronucleonics Gemstar II  
 Instrumentation Laboratories IL Monarch  
 Instrumentation Laboratories IL Monarch Plus  
 Instrumentation Laboratories Phoenix  
 Kodak Ektachem 400  
 Kodak Ektachem 500  
 Kodak Ektachem 700  
 Kodak Ektachem 700 XR  
 Kodak Ektachem DTE Module  
 Olympus AU 5000  
 Olympus Demand  
 Roche Cobas FARA  
 Roche Cobas FARA II  
 Roche Cobas Mira  
 Roche Cobas Mira S  
 Technicon AXON  
 Technicon Assist  
 Technicon Chem 1  
 Technicon DAX 24  
 Technicon DAX 48  
 Technicon DAX 72  
 Technicon DAX 96  
 Technicon RA 1000  
 Technicon RA 2000  
 Technicon RA 500  
 Technicon RA XT  
 Wako Diagnostics 20R  
 Wako Diagnostics 30R

*Analyte:* Calcium, ionized

*Test Category:* Automated procedures that do not require operator intervention during the analytic process

*Test System, Assay or Examination:*  
 AVL 984-S  
 AVL 987-S  
 Beckman LABLYTE 820  
 Beckman Synchron EL-ISE  
 Ciba Corning 634  
 Coulter FLEXLYTE 3  
 Coulter FLEXLYTE 6  
 Instrumentation Laboratories BGElectrolytes  
 Mallinckrodt Gem 6 Plus  
 Mallinckrodt Gem Premier  
 Radiometer ICA 1

*Analyte:* Calcium, total

*Test Category:* Automated procedures that do not require operator intervention during the analytic process

*Test System, Assay or Examination:*  
 Abbott Spectrum  
 Abbott Spectrum EPX  
 Abbott Spectrum Series II  
 Abbott Spectrum Series II CCX  
 Abbott VP  
 Abbott Vision  
 American Monitor Diagnostics Excel  
 American Monitor Diagnostics ISP 1000

- American Monitor Diagnostics ISP 2000  
 American Monitor Diagnostics Perspective  
 Baxter Paramax  
 Baxter Paramax 720 ZX  
 Beckman Astra 8  
 Beckman Astra Ideal  
 Beckman Synchron CX 3  
 Beckman Synchron CX 4  
 Beckman Synchron CX 5  
 Beckman Synchron CX 7  
 Boehringer Mannheim Hitachi 704  
 Boehringer Mannheim Hitachi 705  
 Boehringer Mannheim Hitachi 717  
 Boehringer Mannheim Hitachi 736  
 Boehringer Mannheim Hitachi 737  
 Boehringer Mannheim Hitachi 747  
 Ciba Corning 550 Express  
 Ciba Corning 570 Alliance  
 Ciba Corning 580 Alliance  
 Coulter Optichem 120  
 Coulter Optichem 180  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Analyst  
 Dupont Dimension  
 Dupont Dimension AR  
 Electronucleonics Gem-Profiler  
 Electronucleonics Gemini  
 Electronucleonics Gemstar  
 Electronucleonics Gemstar II  
 Instrumentation Laboratories IL Monarch  
 Instrumentation Laboratories IL Monarch Plus  
 Instrumentation Laboratories Phoenix  
 Kodak Ektachem 400  
 Kodak Ektachem 500  
 Kodak Ektachem 700  
 Kodak Ektachem 700 XR  
 Kodak Ektachem DT SC Module  
 Olympus AU 5000  
 Olympus Demand  
 Roche Cobas FARA  
 Roche Cobas FARA II  
 Roche Cobas Mira  
 Roche Cobas Mira S  
 Technicon AXON  
 Technicon Assist  
 Technicon Chem 1  
 Technicon DAX 24  
 Technicon DAX 48  
 Technicon DAX 72  
 Technicon DAX 96  
 Technicon RA 1000  
 Technicon RA 2000  
 Technicon RA 500  
 Technicon RA XT  
 Wako Diagnostics 20R  
 Wako Diagnostics 30R  
*Analyte:* Carboxyhemoglobin  
*Test Category:* Automated blood gas analyses that do not require operator intervention during the analytic process, such as instruments that have an automated process for calibration, sample intake and flushing of sample lines
- Test System, Assay or Examination:*  
 AVL 912  
 AVL 995 Hb  
*Analyte:* Cerebrospinal Fluid Protein  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process
- Test System, Assay or Examination:*  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Dimension  
 Instrumentation Laboratories IL Monarch Plus  
 Kodak Ektachem 400  
 Kodak Ektachem 700 XR  
*Analyte:* Chloride  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process
- Test System, Assay or Examination:*  
 AVL 983-S  
 AVL 986-S  
 Abbott Spectrum  
 Abbott Spectrum EPX  
 Abbott Spectrum Series II  
 Abbott Spectrum Series II CCX  
 Abbott VP  
 American Monitor Diagnostics Excel  
 American Monitor Diagnostics ISP 1000  
 American Monitor Diagnostics ISP 2000  
 American Monitor Diagnostics Perspective  
 Baxter Paramax  
 Baxter Paramax 720 ZX  
 Beckman Astra 8  
 Beckman Astra Ideal  
 Beckman E2A  
 Beckman E4A  
 Beckman LABLYTE 810  
 Beckman Synchron AS-X  
 Beckman Synchron CX 3  
 Beckman Synchron CX 4  
 Beckman Synchron CX 5  
 Beckman Synchron CX 7  
 Beckman Synchron EL-ISE  
 Boehringer Mannheim Hitachi 704  
 Boehringer Mannheim Hitachi 705  
 Boehringer Mannheim Hitachi 717  
 Boehringer Mannheim Hitachi 736  
 Boehringer Mannheim Hitachi 737  
 Boehringer Mannheim Hitachi 747  
 Ciba Corning 550 Express  
 Ciba Corning 570 Alliance  
 Ciba Corning 580 Alliance  
 Ciba Corning 644  
 Ciba Corning 664 FAST 4  
 Coulter FLEXLYTE 3  
 Coulter FLEXLYTE 6  
 Coulter Optichem 120  
 Coulter Optichem 180  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Dimension  
 Dupont Dimension AR
- Electronucleonics Gem-Profiler  
 Electronucleonics Gemini  
 Electronucleonics Gemstar  
 Electronucleonics Gemstar II  
 Instrumentation Laboratories IL Monarch  
 Instrumentation Laboratories IL Monarch Plus  
 Instrumentation Laboratories Phoenix  
 Kodak Ektachem 400  
 Kodak Ektachem 500  
 Kodak Ektachem 700  
 Kodak Ektachem 700 XR  
 Kodak Ektachem DTE Module  
 Medica EasyLite Plus Ion Selective Analyzer  
 Olympus AU 5000  
 Olympus Demand  
 Roche Cobas FARA  
 Roche Cobas FARA II  
 Roche Cobas Mira  
 Roche Cobas Mira S  
 Technicon AXON  
 Technicon Chem 1  
 Technicon DAX 24  
 Technicon DAX 48  
 Technicon DAX 72  
 Technicon DAX 96  
 Technicon RA 1000  
 Technicon RA 2000  
 Technicon RA 500  
 Technicon RA XT  
 Wako Diagnostics 20R  
 Wako Diagnostics 30R  
*Analyte:* Cholesterol  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process
- Test System, Assay or Examination:*  
 Abbott Spectrum  
 Abbott Spectrum EPX  
 Abbott Spectrum Series II  
 Abbott Spectrum Series II CCX  
 Abbott TDX  
 Abbott TDX FLx  
 Abbott VP  
 Abbott Vision  
 American Monitor Diagnostics Excel  
 American Monitor Diagnostics ISP 1000  
 American Monitor Diagnostics ISP 2000  
 American Monitor Diagnostics Perspective  
 Ames Clinistat  
 Ames Seralyzer  
 Ames Seralyzer III  
 Baxter Paramax  
 Baxter Paramax 720 ZX  
 Beckman Astra Ideal  
 Beckman Synchron AS-X  
 Beckman Synchron CX 4  
 Beckman Synchron CX 5  
 Beckman Synchron CX 7  
 Boehringer Mannheim Hitachi 704  
 Boehringer Mannheim Hitachi 705  
 Boehringer Mannheim Hitachi 717

- Boehringer Mannheim Hitachi 736  
Boehringer Mannheim Hitachi 737  
Boehringer Mannheim Hitachi 747  
Ciba Corning 550 Express  
Ciba Corning 570 Alliance  
Ciba Corning 580 Alliance  
Coulter Optichem 120  
Coulter Optichem 180  
Dupont ACA  
Dupont ACA IV  
Dupont ACA V  
Dupont Analyst  
Dupont Dimension  
Dupont Dimension AR  
Electronucleonics Gem-Profiler  
Electronucleonics Gemini  
Electronucleonics Gemstar  
Electronucleonics Gemstar II  
Instrumentation Laboratories IL  
Monarch  
Instrumentation Laboratories IL  
Monarch Plus  
Kodak Ektachem 400  
Kodak Ektachem 500  
Kodak Ektachem 700  
Kodak Ektachem 700 XR  
Kodak Ektachem DT 60  
Olympus AU 5000  
Olympus Demand  
Roche Cobas FARA  
Roche Cobas FARA II  
Roche Cobas Mira  
Roche Cobas Mira S  
Technicon AXON  
Technicon Assist  
Technicon Chem 1  
Technicon DAX 24  
Technicon DAX 48  
Technicon DAX 72  
Technicon DAX 96  
Technicon RA 1000  
Technicon RA 2000  
Technicon RA 500  
Technicon RA XT  
Wako Diagnostics 20R  
Wako Diagnostics 30R
- Test Category:* Whole blood measurements using teststrip meters (excluding glucose monitoring devices cleared by the FDA specifically for home use)
- Test System, Assay or Examination:*  
Boehringer Mannheim Reflotron  
Boehringer Mannheim Reflotron Plus  
Roche Cobas Ready
- Analyte:* Cholinesterase
- Test Category:* Automated procedures that do not require operator intervention during the analytic process
- Test System, Assay or Examination:*  
American Monitor Diagnostics Excel  
Boehringer Mannheim Hitachi 705  
Boehringer Mannheim Hitachi 717  
Boehringer Mannheim Hitachi 736  
Boehringer Mannheim Hitachi 737  
Boehringer Mannheim Hitachi 747  
Ciba Corning 550 Express  
Ciba Corning 570 Alliance  
Ciba Corning 580 Alliance  
Coulter Optichem 120  
Coulter Optichem 180  
Dupont ACA  
Dupont ACA IV  
Dupont ACA V  
Dupont Dimension  
Dupont Dimension AR  
Electronucleonics Gem-Profiler  
Electronucleonics Gemini  
Electronucleonics Gemstar  
Electronucleonics Gemstar II  
Instrumentation Laboratories IL  
Monarch  
Instrumentation Laboratories IL  
Monarch Plus
- Test Category:* Automated procedures that do not require operator intervention during the analytic process
- Test System, Assay or Examination:*  
Abbott TDX  
Abbott TDX FLx  
Baxter Stratus  
Baxter Stratus II  
Boehringer Mannheim ES 300
- Analyte:* Cortisol, Urine
- Test Category:* Automated procedures that do not require operator intervention during the analytic process
- Test System, Assay or Examination:*  
Abbott TDX FLx
- Analyte:* Creatine Kinase (CK)
- Test Category:* Automated procedures that do not require operator intervention during the analytic process
- Test System, Assay or Examination:*  
Abbott Spectrum  
Abbott Spectrum EPX  
Abbott Spectrum Series II  
Abbott Spectrum Series II CCX  
Abbott VP  
Abbott Vision  
American Monitor Diagnostics Excel  
American Monitor Diagnostics ISP 1000  
American Monitor Diagnostics ISP 2000  
American Monitor Diagnostics Perspective  
Ames Clinistat  
Ames Seralyzer III  
Baxter Paramax  
Baxter Paramax 720 ZX  
Beckman Astra Ideal  
Beckman Synchron AS-X  
Beckman Synchron CX 4  
Beckman Synchron CX 5  
Beckman Synchron CX 7  
Boehringer Mannheim Hitachi 704  
Boehringer Mannheim Hitachi 705  
Boehringer Mannheim Hitachi 717  
Boehringer Mannheim Hitachi 736  
Boehringer Mannheim Hitachi 737  
Boehringer Mannheim Hitachi 747  
Ciba Corning 550 Express  
Ciba Corning 570 Alliance  
Ciba Corning 580 Alliance  
Coulter Optichem 120  
Coulter Optichem 180  
Dupont ACA  
Dupont ACA IV  
Dupont ACA V  
Dupont Dimension  
Dupont Dimension AR  
Electronucleonics Gem-Profiler  
Electronucleonics Gemini  
Electronucleonics Gemstar  
Electronucleonics Gemstar II  
Instrumentation Laboratories IL  
Monarch  
Instrumentation Laboratories IL  
Monarch Plus
- Kodak Ektachem 400  
Kodak Ektachem 500  
Kodak Ektachem 700  
Kodak Ektachem 700 XR  
Kodak Ektachem DT SC Module  
Olympus AU 5000  
Olympus Demand  
Roche Cobas FARA  
Roche Cobas FARA II  
Roche Cobas Mira  
Roche Cobas Mira S  
Technicon AXON  
Technicon Assist  
Technicon Chem 1  
Technicon DAX 24  
Technicon DAX 48  
Technicon DAX 72  
Technicon DAX 96  
Technicon RA 1000  
Technicon RA 2000  
Technicon RA 500  
Technicon RA XT  
Wako Diagnostics 20R  
Wako Diagnostics 30R
- Test Category:* Whole blood measurements using teststrip meters (excluding glucose monitoring devices cleared by the FDA specifically for home use)
- Test System, Assay or Examination:*  
Boehringer Mannheim Reflotron Plus  
Roche Cobas Ready
- Analyte:* Creatinine
- Test Category:* Automated procedures that do not require operator intervention during the analytic process
- Test System, Assay or Examination:*  
Abbott Spectrum  
Abbott Spectrum EPX  
Abbott Spectrum Series II  
Abbott Spectrum Series II CCX  
Abbott TDX  
Abbott TDX FLx  
Abbott VP  
Abbott Vision  
American Monitor Diagnostics Excel  
American Monitor Diagnostics ISP 1000  
American Monitor Diagnostics ISP 2000  
American Monitor Diagnostics Perspective  
Ames Clinistat  
Ames Seralyzer  
Ames Seralyzer III  
Baxter Paramax  
Baxter Paramax 720 ZX  
Beckman Astra 4  
Beckman Astra 8  
Beckman Astra Ideal  
Beckman Creatinine Analyzer (Original Model)  
Beckman Creatinine Analyzer 2  
Beckman Synchron AS-X  
Beckman Synchron CX 3  
Beckman Synchron CX 4  
Beckman Synchron CX 5

Beckman Synchron CX 7  
 Boehringer Mannheim Hitachi 704  
 Boehringer Mannheim Hitachi 705  
 Boehringer Mannheim Hitachi 717  
 Boehringer Mannheim Hitachi 736  
 Boehringer Mannheim Hitachi 737  
 Boehringer Mannheim Hitachi 747  
 Ciba Corning 550 Express  
 Ciba Corning 570 Alliance  
 Ciba Corning 580 Alliance  
 Coulter Optichem 120  
 Coulter Optichem 180  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Analyst  
 Dupont Dimension  
 Dupont Dimension AR  
 Electronucleonics Gem-Profiler  
 Electronucleonics Gemini  
 Electronucleonics Gemstar  
 Electronucleonics Gemstar II  
 Instrumentation Laboratories IL  
 Monarch  
 Instrumentation Laboratories IL  
 Monarch Plus  
 Instrumentation Laboratories Phoenix  
 Kodak Ektachem 400  
 Kodak Ektachem 500  
 Kodak Ektachem 700  
 Kodak Ektachem 700 XR  
 Kodak Ektachem DT 60  
 Olympus AU 5000  
 Olympus Demand  
 Roche Cobas FARA  
 Roche Cobas FARA II  
 Roche Cobas Mira  
 Roche Cobas Mira S  
 Technicon AXON  
 Technicon Assist  
 Technicon Chem 1  
 Technicon DAX 24  
 Technicon DAX 48  
 Technicon DAX 72  
 Technicon DAX 96  
 Technicon RA 1000  
 Technicon RA 2000  
 Technicon RA 500  
 Technicon RA XT  
 Wako Diagnostics 20R  
 Wako Diagnostics 30R  
*Test Category:* Whole blood  
 measurements using teststrip meters  
 (excluding glucose monitoring  
 devices cleared by the FDA  
 specifically for home use)  
*Test System, Assay or Examination:*  
 Boehringer Mannheim Reflotron  
 Boehringer Mannheim Reflotron Plus  
 Roche Cobas Ready  
*Analyte:* Estradiol  
*Test Category:* Automated procedures  
 that do not require operator  
 intervention during the analytic  
 process  
*Test System, Assay or Examination:*  
 Abbott IMX  
*Analyte:* Estradiol—Total  
*Test Category:* Automated procedures  
 that do not require operator

intervention during the analytic  
 process  
*Test System, Assay or Examination:*  
 Abbott TDX  
 Abbott TDX  
 Abbott TDX FLx  
*Analyte:* Estradiol—Unconjugated  
*Test Category:* Automated procedures  
 that do not require operator  
 intervention during the analytic  
 process  
*Test System, Assay or Examination:*  
 Abbott TDX  
 Abbott TDX FLx  
*Analyte:* Ferritin  
*Test Category:* Automated procedures  
 that do not require operator  
 intervention during the analytic  
 process  
*Test System, Assay or Examination:*  
 Abbott IMX  
 Baxter Stratus  
 Baxter Stratus II  
 Becton-Dickinson Affinity  
 Boehringer Mannheim ES 300  
 Ciba Corning ACS 180  
*Analyte:* Folate (Folic acid)  
*Test Category:* Automated procedures  
 that do not require operator  
 intervention during the analytic  
 process  
*Test System, Assay or Examination:*  
 Abbott IMX  
 Ciba Corning ACS 180  
*Analyte:* Follicle Stimulating Hormone  
 (FSH)  
*Test Category:* Automated procedures  
 that do not require operator  
 intervention during the analytic  
 process  
*Test System, Assay or Examination:*  
 Abbott IMX  
 Baxter Stratus  
 Baxter Stratus II  
 Becton-Dickinson Affinity  
 Boehringer Mannheim ES 300  
 Ciba Corning ACS 180  
 PB Diagnostics OPUS  
*Analyte:* Gamma Glutamyl Transferase  
 (GGT)  
*Test Category:* Automated procedures  
 that do not require operator  
 intervention during the analytic  
 process  
*Test System, Assay or Examination:*  
 Abbott Spectrum  
 Abbott Spectrum EPX  
 Abbott Spectrum Series II  
 Abbott Spectrum Series II CCX  
 Abbott VP  
 Abbott Vision  
 American Monitor Diagnostics Excel  
 American Monitor Diagnostics ISP  
 1000  
 American Monitor Diagnostics ISP  
 2000  
 American Monitor Diagnostics  
 Perspective  
 Baxter Paramax

Baxter Paramax 720 ZX  
 Beckman Astra Ideal  
 Beckman Synchron AS-X  
 Beckman Synchron CX 4  
 Beckman Synchron CX 5  
 Beckman Synchron CX 7  
 Boehringer Mannheim Hitachi 704  
 Boehringer Mannheim Hitachi 705  
 Boehringer Mannheim Hitachi 717  
 Boehringer Mannheim Hitachi 736  
 Boehringer Mannheim Hitachi 737  
 Boehringer Mannheim Hitachi 747  
 Ciba Corning 550 Express  
 Ciba Corning 570 Alliance  
 Ciba Corning 580 Alliance  
 Coulter Optichem 120  
 Coulter Optichem 180  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Analyst  
 Dupont Dimension  
 Dupont Dimension AR  
 Electronucleonics Gem-Profiler  
 Electronucleonics Gemini  
 Electronucleonics Gemstar  
 Electronucleonics Gemstar II  
 Instrumentation Laboratories IL  
 Monarch  
 Instrumentation Laboratories IL  
 Monarch Plus  
 Kodak Ektachem 400  
 Kodak Ektachem 500  
 Kodak Ektachem 700  
 Kodak Ektachem 700 XR  
 Kodak Ektachem DT SC Module  
 Olympus AU 5000  
 Olympus Demand  
 Roche Cobas FARA  
 Roche Cobas FARA II  
 Roche Cobas Mira  
 Roche Cobas Mira S  
 Technicon AXON  
 Technicon Assist  
 Technicon Chem 1  
 Technicon DAX 24  
 Technicon DAX 48  
 Technicon DAX 72  
 Technicon DAX 96  
 Technicon RA 1000  
 Technicon RA 2000  
 Technicon RA 500  
 Technicon RA XT  
 Wako Diagnostics 20R  
 Wako Diagnostics 30R  
*Test Category:* Whole blood  
 measurements using teststrip meters  
 (excluding glucose monitoring  
 devices cleared by the FDA  
 specifically for home use)  
*Test System, Assay or Examination:*  
 Boehringer Mannheim Reflotron Plus  
*Analyte:* Glucose  
*Test Category:* Automated procedures  
 that do not require operator  
 intervention during the analytic  
 process  
*Test System, Assay or Examination:*

Abbott Spectrum	Technicon DAX 98	intervention during the analytic process
Abbott Spectrum EPX	Technicon RA 1000	<i>Test System, Assay or Examination:</i>
Abbott TDX	Technicon RA 2000	Abbott IMX
Abbott TDX FLx	Technicon RA 500	Boehringer Mannheim ES 300
Abbott VP	Technicon RA XT	<i>Analyte:</i> Iron
Abbott Vision	Wako Diagnostics 20R	<i>Test Category:</i> Automated procedures
American Monitor Diagnostics Excel	Wako Diagnostics 30R	that do not require operator
American Monitor Diagnostics ISP 1000	Yellow Springs YSI Model 1500	intervention during the analytic process
American Monitor Diagnostics ISP 2000	Yellow Springs YSI Model 2300	<i>Test System, Assay or Examination:</i>
American Monitor Diagnostics Perspective	<i>Test Category:</i> Whole blood measurements using teststrip meters (excluding glucose monitoring devices cleared by the FDA specifically for home use)	Abbott TDX
Ames Clinistat	<i>Test System, Assay or Examination:</i>	Abbott TDX FLx
Ames Seralyzer	Boehringer Mannheim Reflotron	Abbott VP
Ames Seralyzer III	Boehringer Mannheim Reflotron Plus	American Monitor Diagnostics Excel
Baxter Paramax	Roche Cobas Ready	American Monitor Diagnostics ISP 1000
Baxter Paramax 720 ZX	<i>Analyte:</i> HCG, Serum, Qualitative	American Monitor Diagnostics ISP 2000
Beckman Astra 4	<i>Test Category:</i> Automated procedures that do not require operator intervention during the analytic process	American Monitor Diagnostics Perspective
Beckman Astra 8	<i>Test System, Assay or Examination:</i>	Baxter Paramax
Beckman Astra Ideal	Becton Dickinson Affinity	Baxter Paramax 720 ZX
Beckman Glucose Analyzer (Original Model)	<i>Test Category:</i> Manual procedures with limited steps and limited sample or reagent preparation	Beckman Synchron CX 4
Beckman Glucose Analyzer 2	<i>Test System, Assay or Examination:</i>	Beckman Synchron CX 5
Beckman Synchron AS-X	Abbott TestPack HCG-combo	Beckman Synchron CX 7
Beckman Synchron CX 3	Ampcor Quik-Dot Pregnancy Dipstick	Boehringer Mannheim Hitachi 704
Beckman Synchron CX 4	Biomerica Nimbus	Boehringer Mannheim Hitachi 705
Beckman Synchron CX 5	Hybritech Tandem ICON II	Boehringer Mannheim Hitachi 717
Boehringer Mannheim Hitachi 704	Sequoia Turner Clearview HCG	Boehringer Mannheim Hitachi 736
Boehringer Mannheim Hitachi 705	<i>Analyte:</i> HCG, Serum, Quantitative	Boehringer Mannheim Hitachi 737
Boehringer Mannheim Hitachi 717	<i>Test Category:</i> Automated procedures that do not require operator intervention during the analytic process	Boehringer Mannheim Hitachi 747
Boehringer Mannheim Hitachi 736	<i>Test System, Assay or Examination:</i>	Ciba Corning 550 Express
Boehringer Mannheim Hitachi 737	Abbott IMX	Coulter Optichem 120
Boehringer Mannheim Hitachi 747	Baxter Stratus	Coulter Optichem 180
Ciba Corning 550 Express	Baxter Stratus II	Dupont ACA
Ciba Corning 570 Alliance	Boehringer Mannheim ES 300	Dupont ACA IV
Ciba Corning 580 Alliance	Ciba Corning ACS 180	Dupont ACA V
Coulter Optichem 120	PB Diagnostics OPUS	Dupont Analyst
Coulter Optichem 180	<i>Analyte:</i> HCG, Urine	Dupont Dimension
Dupont ACA	<i>Test Category:</i> Manual procedures with limited steps and limited sample or reagent preparation	Electronucleonics Gem-Profiler
Dupont ACA IV	<i>Test System, Assay or Examination:</i>	Electronucleonics Gemini
Dupont ACA V	Abbott TestPack HCG-combo	Electronucleonics Gemstar
Dupont Analyst	Abbott TestPack Plus	Electronucleonics Gemstar II
Dupont Dimension	Ampcor Quik-Dot Pregnancy Dipstick	Instrumentation Laboratories IL Monarch
Electronucleonics Gem-Profiler	Biomerica Nimbus	Instrumentation Laboratories IL Monarch Plus
Electronucleonics Gemini	Hybritech Concise HCG	Kodak Ektachem 400
Electronucleonics Gemstar	Hybritech Tandem ICON II	Kodak Ektachem 500
Electronucleonics Gemstar II	Roche Pregnosis	Kodak Ektachem 700
Instrumentation Laboratories IL Monarch	<i>Analyte:</i> HDL Cholesterol	Kodak Ektachem 700 XR
Instrumentation Laboratories IL Monarch Plus	<i>Test Category:</i> Whole blood measurements using teststrip meters (excluding glucose monitoring devices cleared by the FDA specifically for home use)	Olympus AU 5000
Instrumentation Laboratories Phoenix	<i>Test System, Assay or Examination:</i>	Olympus Demand
Kodak Ektachem 500	Boehringer Mannheim Reflotron Plus	Roche Cobas FARA
Kodak Ektachem 700	<i>Analyte:</i> Insulin	Roche Cobas FARA II
Kodak Ektachem 700 XR	<i>Test Category:</i> Automated procedures that do not require operator	Roche Cobas MIRA
Kodak Ektachem DT 60		Roche Cobas MIRA S
Olympus AU 5000		Technicon AXON
Olympus Demand		Technicon Assist
Roche Cobas FARA		Technicon Chem 1
Roche Cobas FARA II		Technicon DAX 24
Roche Cobas MIRA		Technicon DAX 48
Roche Cobas MIRA S		Technicon DAX 72
Technicon AXON		
Technicon Assist		
Technicon Chem 1		
Technicon DAX 24		
Technicon DAX 48		
Technicon DAX 72		

- Technicon RA XT  
Wako Diagnostics 20R  
Wako Diagnostics 30R  
*Analyte:* Lactate Dehydrogenase (LDH)  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
Abbott Spectrum  
Abbott Spectrum EPX  
Abbott Spectrum Series II  
Abbott Spectrum Series II CCX  
Abbott TDX  
Abbott TDX FLx  
Abbott VP  
Abbott Vision  
American Monitor Diagnostics Excel  
American Monitor Diagnostics ISP 1000  
American Monitor Diagnostics ISP 2000  
American Monitor Diagnostics Perspective  
Ames Clinistat  
Ames Seralyzer  
Ames Seralyzer III  
Baxter Paramax  
Baxter Paramax 720 ZX  
Beckman Astra Ideal  
Beckman Synchron AS-X  
Beckman Synchron CX 4  
Beckman Synchron CX 5  
Beckman Synchron CX 7  
Boehringer Mannheim Hitachi 704  
Boehringer Mannheim Hitachi 705  
Boehringer Mannheim Hitachi 717  
Boehringer Mannheim Hitachi 736  
Boehringer Mannheim Hitachi 737  
Boehringer Mannheim Hitachi 747  
Ciba Corning 550 Express  
Ciba Corning 570 Alliance  
Ciba Corning 580 Alliance  
Coulter Optichem 120  
Coulter Optichem 180  
Dupont ACA  
Dupont ACA IV  
Dupont ACA V  
Dupont Dimension  
Dupont Dimension AR  
Electronucleonics Gem-Profiler  
Electronucleonics Gemini  
Electronucleonics Gemstar  
Electronucleonics Gemstar II  
Instrumentation Laboratories IL  
Monarch  
Instrumentation Laboratories IL  
Monarch Plus  
Kodak Ektachem 400  
Kodak Ektachem 500  
Kodak Ektachem 700  
Kodak Ektachem 700 XR  
Kodak Ektachem DT SC Module  
Olympus AU 5000  
Olympus Demand  
Roche Cobas FARA  
Roche Cobas FARA II  
Roche Cobas Mira  
Roche Cobas Mira S
- Technicon AXON  
Technicon Assist  
Technicon Chem 1  
Technicon DAX 24  
Technicon DAX 48  
Technicon DAX 72  
Technicon DAX 96  
Technicon RA 1000  
Technicon RA 2000  
Technicon RA 500  
Technicon RA XT  
Wako Diagnostics 20R  
Wako Diagnostics 30R  
*Analyte:* Lactate Dehydrogenase Heart Fraction (LDH-1)  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
Boehringer Mannheim Hitachi 717  
*Analyte:* Lactate Dehydrogenase Liver Fraction (LLDH)  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
Dupont ACA IV  
Dupont ACA V  
*Analyte:* Lactic Acid (Lactate)  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
Abbott TDX  
Abbott TDX FLx  
Baxter Paramax  
Baxter Paramax 720 ZX  
Boehringer Mannheim Hitachi 705  
Boehringer Mannheim Hitachi 717  
Dupont ACA  
Dupont ACA IV  
Dupont ACA V  
Dupont Dimension  
Kodak Ektachem 700 XR  
Yellow Springs YSI Model 1500 Sport  
Yellow Springs YSI Model 2300  
Yellow Springs YSI Model 2372  
*Analyte:* Leucine Aminopeptidase (LAP)  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
Boehringer Mannheim Hitachi 705  
Instrumentation Laboratories IL  
Monarch Plus  
*Analyte:* Lipase  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
Boehringer Mannheim Hitachi 705  
Boehringer Mannheim Hitachi 717  
Dupont ACA  
Dupont ACA IV
- Dupont ACA V  
Dupont Dimension  
Instrumentation Laboratories IL  
Monarch Plus  
Kodak Ektachem 500  
Kodak Ektachem 500  
Kodak Ektachem 700 XR  
*Analyte:* Lithium  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
AVL 985-S  
AVL 985-S1  
Abbott TDX FLx  
Amdev ISE Analyzer  
Baxter Paramax  
Baxter Paramax 720 ZX  
Beckman LABLYTE 830  
Beckman LABLYTE 830  
Beckman Synchron EL-ISE  
Ciba Corning 654  
Coulter FLEXLYTE 3  
Coulter FLEXLYTE 6  
Dupont Na, K, Li Analyzer  
*Analyte:* Luteinizing Hormone (LH)  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
Abbott IMX  
Baxter Stratus  
Baxter Stratus II  
Becton Dickinson Affinity  
Boehringer Mannheim ES 300  
Ciba Corning ACS 180  
*Analyte:* MHPG Urine  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
Abbott TDX  
Abbott TDX FLx  
*Analyte:* Magnesium  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
Abbott Spectrum  
Abbott Spectrum EPX  
Abbott Spectrum Series II  
Abbott Spectrum Series II CCX  
American Monitor Diagnostics Excel  
American Monitor Diagnostics ISP 1000  
American Monitor Diagnostics ISP 2000  
American Monitor Diagnostics Perspective  
Baxter Paramax  
Baxter Paramax 720 ZX  
Beckman Astra Ideal  
Beckman Synchron CX 4  
Beckman Synchron CX 5

Beckman Synchron CX 7  
 Boehringer Mannheim Hitachi 704  
 Boehringer Mannheim Hitachi 705  
 Boehringer Mannheim Hitachi 717  
 Boehringer Mannheim Hitachi 736  
 Boehringer Mannheim Hitachi 737  
 Boehringer Mannheim Hitachi 747  
 Ciba Corning 550 Express  
 Ciba Corning 570 Alliance  
 Ciba Corning 580 Alliance  
 Coulter Optichem 120  
 Coulter Optichem 180  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Dimension  
 Dupont Dimension AR  
 Electronucleonics Gem-Profiler  
 Electronucleonics Gemini  
 Electronucleonics Gemstar  
 Electronucleonics Gemstar II  
 Instrumentation Laboratories IL  
 Monarch  
 Instrumentation Laboratories IL  
 Monarch Plus  
 Kodak Ektachem 400  
 Kodak Ektachem 500  
 Kodak Ektachem 700  
 Kodak Ektachem 700 XR  
 Kodak Ektachem DT 60  
 Olympus AU 5000  
 Olympus Demand  
 Roche Cobas FARA  
 Roche Cobas FARA II  
 Roche Cobas Mira  
 Roche Cobas Mira S  
 Technicon AXON  
 Technicon Assist  
 Technicon Chem 1  
 Technicon DAX 24  
 Technicon DAX 48  
 Technicon DAX 72  
 Technicon DAX 96  
 Technicon RA 1000  
 Technicon RA 2000  
 Technicon RA 500  
 Technicon RA XT  
 Wako Diagnostics 20R  
 Wako Diagnostics 30R  
*Analyte:* Osmolality, Serum  
*Test Category:* Osmolality  
 measurements  
*Test System, Assay or Examination:*  
 Advanced Instruments Osmometer  
 Fiske 2400 Osmometer  
 Wescor Colloid Osmometer Model  
 4420  
 Wescor Vapor Pressure Osmometer  
*Analyte:* Osmolality, Urine  
*Test Category:* Osmolality  
 measurements  
*Test System, Assay or Examination:*  
 Advanced Instruments Osmometer  
 Fiske 2400 Osmometer  
 Wescor Colloid Osmometer Model  
 4420  
 Wescor Vapor Pressure Osmometer  
*Analyte:* Phosphatidylglycerol (PG)—  
 Amniotic Fluid

*Test Category:* Manual procedures with  
 limited steps and limited sample or  
 reagent preparation  
*Test System, Assay or Examination:*  
 Irvine Scientific Aminostat—FLM  
*Analyte:* Phosphorus  
*Test Category:* Automated procedures  
 that do not require operator  
 intervention during the analytic  
 process  
*Test System, Assay or Examination:*  
 Abbott Spectrum  
 Abbott Spectrum EPX  
 Abbott Spectrum Series II  
 Abbott Spectrum Series II CCX  
 Abbott VP  
 American Monitor Diagnostics Excel  
 American Monitor Diagnostics ISP  
 1000  
 American Monitor Diagnostics ISP  
 2000  
 American Monitor Diagnostics  
 Perspective  
 Baxter Paramax  
 Baxter Paramax 720 ZX  
 Beckman Astra Ideal  
 Beckman Synchron AS-X  
 Beckman Synchron CX 4  
 Beckman Synchron CX 5  
 Beckman Synchron CX 7  
 Boehringer Mannheim Hitachi 704  
 Boehringer Mannheim Hitachi 705  
 Boehringer Mannheim Hitachi 717  
 Boehringer Mannheim Hitachi 736  
 Boehringer Mannheim Hitachi 737  
 Boehringer Mannheim Hitachi 747  
 Ciba Corning 550 Express  
 Ciba Corning 570 Alliance  
 Ciba Corning 580 Alliance  
 Coulter Optichem 120  
 Coulter Optichem 180  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Dimension  
 Dupont Dimension AR  
 Electronucleonics Gem-Profiler  
 Electronucleonics Gemini  
 Electronucleonics Gemstar  
 Electronucleonics Gemstar II  
 Instrumentation Laboratories IL  
 Monarch  
 Instrumentation Laboratories IL  
 Monarch Plus  
 Kodak Ektachem 400  
 Kodak Ektachem 500  
 Kodak Ektachem 700  
 Kodak Ektachem 700 XR  
 Kodak Ektachem DT 60  
 Olympus AU 5000  
 Olympus Demand  
 Roche Cobas FARA  
 Roche Cobas FARA II  
 Roche Cobas Mira  
 Roche Cobas Mira S  
 Technicon AXON  
 Technicon Assist  
 Technicon Chem 1  
 Technicon DAX 24

Technicon DAX 48  
 Technicon DAX 72  
 Technicon DAX 96  
 Technicon RA 1000  
 Technicon RA 2000  
 Technicon RA 500  
 Technicon RA XT  
 Wako Diagnostics 20R  
 Wako Diagnostics 30R  
*Analyte:* Potassium  
*Test Category:* Automated procedures  
 that do not require operator  
 intervention during the analytic  
 process  
*Test System, Assay or Examination:*  
 AVL 982-S  
 AVL 983-S  
 AVL 984-S  
 AVL 985-S  
 AVL 986-S  
 AVL 987-S  
 Abbott Spectrum  
 Abbott Spectrum EPX  
 Abbott Spectrum Series II  
 Abbott Spectrum Series II CCX  
 Abbott VP  
 Amdev ISE Analyzer  
 American Monitor Diagnostics Excel  
 American Monitor Diagnostics ISP  
 1000  
 American Monitor Diagnostics ISP  
 2000  
 American Monitor Diagnostics  
 Perspective  
 Ames Clinistat  
 Ames Seralyzer  
 Ames Seralyzer III  
 Baker Ana-Lyte +1  
 Baker Ana-Lyte +2  
 Baxter Paramax  
 Baxter Paramax 720 ZX  
 Beckman Astra 8  
 Beckman Astra Ideal  
 Beckman E2A  
 Beckman E4A  
 Beckman LABLYTE 800  
 Beckman LABLYTE 810  
 Beckman LABLYTE 820  
 Beckman LABLYTE 830  
 Beckman Synchron AS-X  
 Beckman Synchron CX 3  
 Beckman Synchron CX 4  
 Beckman Synchron CX 5  
 Beckman Synchron CX 7  
 Beckman Synchron EL-ISE  
 Boehringer Mannheim Hitachi 704  
 Boehringer Mannheim Hitachi 705  
 Boehringer Mannheim Hitachi 717  
 Boehringer Mannheim Hitachi 736  
 Boehringer Mannheim Hitachi 737  
 Boehringer Mannheim Hitachi 747  
 Ciba Corning 570 Alliance  
 Ciba Corning 580 Alliance  
 Ciba Corning 614  
 Ciba Corning 644  
 Ciba Corning 654  
 Ciba Corning 664 FAST 4  
 Coulter FLEXLYTE 3

- Coulter FLEXLYTE 6  
Coulter Optichem 120  
Coulter Optichem 180  
Dupont Dimension  
Dupont Dimension AR  
Dupont Na, K, Li Analyzer  
Electronucleonics Gem-Profiler  
Electronucleonics Gemini  
Electronucleonics Gemstar  
Electronucleonics Gemstar II  
Electronucleonics Starlyte II  
Instrumentation Laboratories  
BGElectrolytes  
Instrumentation Laboratories IL 501  
Instrumentation Laboratories IL 502  
Instrumentation Laboratories IL  
Monarch  
Instrumentation Laboratories IL  
Monarch Plus  
Instrumentation Laboratories Phoenix  
Kodak Ektachem 400  
Kodak Ektachem 500  
Kodak Ektachem 700  
Kodak Ektachem 700 XR  
Kodak Ektachem DTE Module  
Mallinckrodt Gem 6 Plus  
Mallinckrodt Gem Premier  
Medica Easylite Ion Selective  
Analyzer  
Medica Easylite Plus Ion Selective  
Analyzer  
Olympus AU 5000  
Olympus Demand  
Roche Cobas FARA  
Roche Cobas FARA II  
Roche Cobas Mira  
Roche Cobas Mira S  
Technicon AXON  
Technicon Assist  
Technicon Chem 1  
Technicon DAX 24  
Technicon DAX 48  
Technicon DAX 72  
Technicon DAX 96  
Technicon RA 1000  
Technicon RA 2000  
Technicon RA 500  
Technicon RA XT  
Wako Diagnostics 20R  
Wako Diagnostics 30R
- Test Category:* Whole blood measurements using teststrip meters (excluding glucose monitoring devices cleared by the FDA specifically for home use)
- Test System, Assay or Examination:*  
Boehringer Mannheim Reflotron Plus  
*Analyte:* Progesterone  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process
- Test System, Assay or Examination:*  
Abbott IMX  
Boehringer Mannheim ES 300  
*Analyte:* Prolactin  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process
- Test System, Assay or Examination:*  
Abbott IMX  
Baxter Stratus  
Baxter Stratus II  
Becton Dickinson Affinity  
Boehringer Mannheim ES 300  
Ciba Corning ACS 180  
*Analyte:* Prostatic Acid Phosphatase  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process
- Test System, Assay or Examination:*  
Abbott IMX  
Instrumentation Laboratories IL  
Monarch Plus  
*Analyte:* Protein, Total  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process
- Test System, Assay or Examination:*  
Abbott Spectrum  
Abbott Spectrum EPX  
Abbott Spectrum Series II  
Abbott Spectrum Series II CCX  
Abbott VP  
Abbott Vision  
American Monitor Diagnostics Excel  
American Monitor Diagnostics ISP 1000  
American Monitor Diagnostics ISP 2000  
American Monitor Diagnostics Perspective  
Baxter Paramax  
Baxter Paramax 720 ZX  
Beckman Synchron AS-X  
Beckman Synchron CX 4  
Beckman Synchron CX 5  
Beckman Synchron CX 7  
Boehringer Mannheim Hitachi 704  
Boehringer Mannheim Hitachi 705  
Boehringer Mannheim Hitachi 717  
Boehringer Mannheim Hitachi 736  
Boehringer Mannheim Hitachi 737  
Boehringer Mannheim Hitachi 747  
Ciba Corning 550 Express  
Ciba Corning 570 Alliance  
Ciba Corning 580 Alliance  
Coulter Optichem 120  
Coulter Optichem 180  
Dupont ACA  
Dupont ACA IV  
Dupont ACA V  
Dupont Analyst  
Dupont Dimension  
Dupont Dimension AR  
Electronucleonics Gem-Profiler  
Electronucleonics Gemini  
Electronucleonics Gemstar  
Electronucleonics Gemstar II  
Instrumentation Laboratories IL  
Monarch  
Instrumentation Laboratories IL  
Monarch Plus  
Instrumentation Laboratories Phoenix  
Kodak Ektachem 400  
Kodak Ektachem 500
- Kodak Ektachem 700  
Kodak Ektachem 700 XR  
Kodak Ektachem DT 60  
Olympus AU 5000  
Olympus Demand  
Roche Cobas FARA  
Roche Cobas FARA II  
Roche Cobas Mira  
Roche Cobas Mira S  
Technicon AXON  
Technicon Assist  
Technicon Chem 1  
Technicon DAX 24  
Technicon DAX 48  
Technicon DAX 72  
Technicon DAX 96  
Technicon RA 1000  
Technicon RA 2000  
Technicon RA 500  
Technicon RA XT  
Wako Diagnostics 20R  
Wako Diagnostics 30R  
*Analyte:* Pseudocholinesterase, Serum  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process
- Test System, Assay or Examination:*  
Dupont ACA  
Dupont ACA IV  
Dupont ACA V  
Dupont Dimension  
*Analyte:* Sodium  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process
- Test System, Assay or Examination:*  
AVL 982-S  
AVL 983-S  
AVL 984-S  
AVL 985-S  
AVL 986-S  
AVL 987-S  
Abbott Spectrum  
Abbott Spectrum EPX  
Abbott Spectrum Series II  
Abbott Spectrum Series II CCX  
Abbott VP  
Amdev ISE Analyzer  
American Monitor Diagnostics Excel  
American Monitor Diagnostics ISP 1000  
American Monitor Diagnostics ISP 2000  
American Monitor Diagnostics Perspective  
Baker Ana-Lyte +1  
Baker Ana-Lyte +2  
Baxter Paramax  
Baxter Paramax 720 ZX  
Beckman Astra 8  
Beckman Astra Ideal  
Beckman E2A  
Beckman E4A  
Beckman LABLYTE 800  
Beckman LABLYTE 810  
Beckman LABLYTE 820

Beckman LABLYTE 830  
 Beckman Synchron AS-X  
 Beckman Synchron CX 3  
 Beckman Synchron CX 4  
 Beckman Synchron CX 5  
 Beckman Synchron CX 7  
 Beckman Synchron EL-ISE  
 Boehringer Mannheim Hitachi 704  
 Boehringer Mannheim Hitachi 705  
 Boehringer Mannheim Hitachi 717  
 Boehringer Mannheim Hitachi 736  
 Boehringer Mannheim Hitachi 737  
 Boehringer Mannheim Hitachi 747  
 Ciba Corning 570 Alliance  
 Ciba Corning 580 Alliance  
 Ciba Corning 614  
 Ciba Corning 644  
 Ciba Corning 654  
 Ciba Corning 664 FAST 4  
 Coulter FLEXLYTE 3  
 Coulter FLEXLYTE 6  
 Coulter Optichem 120  
 Coulter Optichem 180  
 Dupont Dimension  
 Dupont Dimension AR  
 Dupont Na, K, Li Analyzer  
 Electronucleonics Gem-Profiler  
 Electronucleonics Gemini  
 Electronucleonics Gemstar  
 Electronucleonics Gemstar II  
 Electronucleonics Starlyte II  
 Instrumentation Laboratories  
 BGElectrolytes  
 Instrumentation Laboratories IL 501  
 Instrumentation Laboratories IL 502  
 Instrumentation Laboratories IL  
 Monarch  
 Instrumentation Laboratories IL  
 Monarch Plus  
 Instrumentation Laboratories Phoenix  
 Kodak Ektachem 400  
 Kodak Ektachem 500  
 Kodak Ektachem 700  
 Kodak Ektachem 700 XR  
 Kodak Ektachem DTE Module  
 Mallinckrodt Gem 6 Plus  
 Mallinckrodt Gem Premier  
 Medica Easylite Ion Selective  
 Analyzer  
 Medica Easylite Plus Ion Selective  
 Analyzer  
 Olympus AU 5000  
 Olympus Demand  
 Roche Cobas FARA  
 Roche Cobas FARA II  
 Roche Cobas Mira  
 Roche Cobas Mira S  
 Technicon AXON  
 Technicon Assist  
 Technicon Chem 1  
 Technicon DAX 24  
 Technicon DAX 48  
 Technicon DAX 72  
 Technicon DAX 96  
 Technicon RA 1000  
 Technicon RA 2000  
 Technicon RA 500  
 Technicon RA XT  
 Wako Diagnostics 20R

Wako Diagnostics 30R  
*Analyte:* Testosterone  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Abbott IMX  
*Analyte:* Thyroid Stimulating Hormone (TSH)  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Baxter Stratus  
 Ciba Corning ACS 180  
 PB Diagnostics OPUS  
*Analyte:* Thyroid Stimulating Hormone—high sens. (TSH-HS)  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Abbott IMX  
 Baxter Stratus  
 Becton Dickinson Affinity  
 Boehringer Mannheim ES 300  
*Analyte:* Thyroxine (T4)  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Abbott IMX  
 Abbott TDX  
 Abbott TDX FLx  
 Baxter Stratus  
 Baxter Stratus II  
 Becton Dickinson Affinity  
 Boehringer Mannheim ES 300  
 Boehringer Mannheim Hitachi 717  
 Boehringer Mannheim Hitachi 747  
 Ciba Corning ACS 180  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Dimension  
 Instrumentation Laboratories IL  
 Monarch Plus  
 PB Diagnostics OPUS  
 Technicon Chem 1  
*Analyte:* Thyroxine Binding Globulin (TGB)  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Boehringer Mannheim ES 300  
*Analyte:* Thyroxine, Free (FT-4)  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Abbott IMX  
 Baxter Stratus

Baxter Stratus II  
 Boehringer Mannheim ES 300  
 Ciba Corning ACS 180  
*Analyte:* Triglyceride  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Abbott Spectrum  
 Abbott Spectrum EPX  
 Abbott Spectrum Series II  
 Abbott Spectrum Series II CCX  
 Abbott TDX  
 Abbott TDX FLx  
 Abbott VP  
 Abbott Vision  
 American Monitor Diagnostics Excel  
 American Monitor Diagnostics ISP 1000  
 American Monitor Diagnostics ISP 2000  
 American Monitor Diagnostics Perspective  
 Ames Clinistat  
 Ames Seralyzer  
 Ames Seralyzer III  
 Baxter Paramax  
 Baxter Paramax 720 ZX  
 Beckman Astra Ideal  
 Beckman Synchron AS-X  
 Beckman Synchron CX 4  
 Beckman Synchron CX 5  
 Beckman Synchron CX 7  
 Boehringer Mannheim Hitachi 704  
 Boehringer Mannheim Hitachi 705  
 Boehringer Mannheim Hitachi 717  
 Boehringer Mannheim Hitachi 736  
 Boehringer Mannheim Hitachi 737  
 Boehringer Mannheim Hitachi 747  
 Ciba Corning 550 Express  
 Ciba Corning 570 Alliance  
 Ciba Corning 580 Alliance  
 Coulter Optichem 120  
 Coulter Optichem 180  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Analyst  
 Dupont Dimension  
 Dupont Dimension AR  
 Electronucleonics Gem-Profiler  
 Electronucleonics Gemini  
 Electronucleonics Gemstar  
 Electronucleonics Gemstar II  
 Instrumentation Laboratories IL  
 Monarch  
 Instrumentation Laboratories IL  
 Monarch Plus  
 Kodak Ektachem 400  
 Kodak Ektachem 500  
 Kodak Ektachem 700  
 Kodak Ektachem 700 XR  
 Kodak Ektachem DT 60  
 Olympus AU 5000  
 Olympus Demand  
 Roche Cobas FARA  
 Roche Cobas FARA II

Roche Cobas Mira	<i>Test System, Assay or Examination:</i>	Technicon AXON
Roche Cobas Mira S	Abbott Spectrum	Technicon Assist
Technicon AXON	Abbott Spectrum EPX	Technicon Chem 1
Technicon Assist	Abbott Spectrum Series II	Technicon DAX 24
Technicon Chem 1	Abbott Spectrum Series II CCX	Technicon DAX 48
Technicon DAX 24	Abbott TDX	Technicon DAX 72
Technicon DAX 48	Abbott TDX FLx	Technicon DAX 96
Technicon DAX 72	Abbott VP	Technicon RA 1000
Technicon DAX 96	Abbott Vision	Technicon RA 2000
Technicon RA 1000	American Monitor Diagnostics Excel	Technicon RA 500
Technicon RA 2000	American Monitor Diagnostics ISP	Technicon RA XT
Technicon RA 500	1000	Wako Diagnostics 20R
Technicon RA XT	American Monitor Diagnostics ISP	Wako Diagnostics 30R
Wako Diagnostics 20R	2000	<i>Test Category:</i> Whole blood
Wako Diagnostics 30R	American Monitor Diagnostics	measurements using teststrip meters
<i>Test Category:</i> Whole blood	Perspective	(excluding glucose monitoring
measurements using teststrip meters	Ames Clinistat	devices cleared by the FDA
(excluding glucose monitoring	Ames Seralyzer	specifically for home use)
devices cleared by the FDA	Ames Seralyzer III	<i>Test System, Assay or Examination:</i>
specifically for home use)	Baxter Paramax	Boehringer Mannheim Reflotron
<i>Test System, Assay or Examination:</i>	Baxter Paramax 720 ZX	Boehringer Mannheim Reflotron Plus
Boehringer Mannheim Reflotron Plus	Beckman Astra 4	Roche Cobas Ready
<i>Analyte:</i> Triiodothyronine (T-3) Uptake	Beckman Astra 8	<i>Analyte:</i> Uric Acid
<i>Test Category:</i> Automated procedures	Beckman Astra Ideal	<i>Test Category:</i> Automated procedures
that do not require operator	Beckman BUN Analyzer (Original	that do not require operator
intervention during the analytic	Model)	intervention during the analytic
process	Beckman BUN Analyzer 2	process
<i>Test System, Assay or Examination:</i>	Beckman Synchron AS-X	<i>Test System, Assay or Examination:</i>
Abbott IMX	Beckman Synchron CX 3	Abbott Spectrum
Abbott TDX	Beckman Synchron CX 4	Abbott Spectrum EPX
Baxter Stratus	Beckman Synchron CX 5	Abbott Spectrum Series II
Baxter Stratus II	Beckman Synchron CX 7	Abbott Spectrum Series II CCX
Becton Dickinson Affinity	Boehringer Mannheim Hitachi 704	Abbott TDX
Boehringer Mannheim ES 300	Boehringer Mannheim Hitachi 705	Abbott TDX FLx
Boehringer Mannheim Hitachi 717	Boehringer Mannheim Hitachi 717	Abbott VP
Boehringer Mannheim Hitachi 747	Boehringer Mannheim Hitachi 736	Abbott Vision
Ciba Corning ACS 180	Boehringer Mannheim Hitachi 737	American Monitor Diagnostics Excel
Dupont ACA IV	Boehringer Mannheim Hitachi 747	American Monitor Diagnostics ISP
Dupont ACA V	Ciba Corning 550 Express	1000
Dupont Dimension	Ciba Corning 570 Alliance	American Monitor Diagnostics ISP
Instrumentation Laboratories IL	Ciba Corning 580 Alliance	2000
Monarch Plus	Coulter Optichem 120	American Monitor Diagnostics
Technicon Chem 1	Coulter Optichem 180	Perspective
<i>Analyte:</i> Triiodothyronine (T3)	Dupont ACA	Ames Clinistat
<i>Test Category:</i> Automated procedures	Dupont ACA IV	Ames Seralyzer
that do not require operator	Dupont ACA V	Ames Seralyzer III
intervention during the analytic	Dupont Analyst	Baxter Paramax
process	Dupont Dimension	Baxter Paramax 720 ZX
<i>Test System, Assay or Examination:</i>	Dupont Dimension AR	Beckman Astra Ideal
Abbott IMX	Electronucleonics Gem-Profiler	Beckman Synchron AS-X
Abbott TDX	Electronucleonics Gemini	Beckman Synchron CX 4
Abbott TDX FLx	Electronucleonics Gemstar	Beckman Synchron CX 5
Baxter Stratus	Electronucleonics Gemstar II	Beckman Synchron CX 7
Baxter Stratus II	Instrumentation Laboratories IL	Boehringer Mannheim Hitachi 704
Boehringer Mannheim ES 300	Monarch	Boehringer Mannheim Hitachi 705
Ciba Corning ACS 180	Instrumentation Laboratories IL	Boehringer Mannheim Hitachi 717
PB Diagnostics OPUS	Monarch Plus	Boehringer Mannheim Hitachi 736
<i>Analyte:</i> Triiodothyronine, Free (FT-3)	Instrumentation Laboratories Phoenix	Boehringer Mannheim Hitachi 737
<i>Test Category:</i> Automated procedures	Kodak Ektachem 400	Boehringer Mannheim Hitachi 747
that do not require operator	Kodak Ektachem 500	Ciba Corning 550 Express
intervention during the analytic	Kodak Ektachem 700	Ciba Corning 570 Alliance
process	Kodak Ektachem 700 XR	Ciba Corning 580 Alliance
<i>Test System, Assay or Examination:</i>	Kodak Ektachem DT 60	Coulter Optichem 120
Ciba Corning ACS 180	Olympus AU 5000	Coulter Optichem 180
<i>Analyte:</i> Urea (BUN)	Olympus Demand	Dupont ACA
<i>Test Category:</i> Automated procedures	Roche Cobas FARA	Dupont ACA IV
that do not require operator	Roche Cobas FARA II	Dupont ACA V
intervention during the analytic	Roche Cobas Mira	Dupont Analyst
process	Roche Cobas Mira S	

Dupont Dimension  
 Dupont Dimension AR  
 Electronucleonics Gem-Profiler  
 Electronucleonics Gemini  
 Electronucleonics Gemstar  
 Electronucleonics Gemstar II  
 Instrumentation Laboratories II  
 Monarch  
 Instrumentation Laboratories II  
 Monarch Plus  
 Kodak Ektachem 400  
 Kodak Ektachem 500  
 Kodak Ektachem 700  
 Kodak Ektachem 700 XR  
 Kodak Ektachem DT 60  
 Olympus AU 5000  
 Olympus Demand  
 Roche Cobas FARA  
 Roche Cobas FARA II  
 Roche Cobas Mira S  
 Technicon AXON  
 Technicon Assist  
 Technicon Chem 1  
 Technicon DAX 24  
 Technicon DAX 48  
 Technicon DAX 72  
 Technicon DAX 96  
 Technicon RA 1000  
 Technicon RA 2000  
 Technicon RA 500  
 Technicon RA XT  
 Wako Diagnostics 20R  
 Wako Diagnostics 30R  
*Test Category:* Whole blood measurements using teststrip meters (excluding glucose monitoring devices cleared by the FDA specifically for home use)  
*Test System, Assay or Examination:* Boehringer Mannheim Reflotron  
 Boehringer Mannheim Reflotron Plus  
*Analyte:* Vitamin B12  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Abbott IMX  
 Abbott TDX FLx  
 Ciba Corning ACS 180  
*Analyte:* Zinc Protoporphyrin  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* AVIV Hematofluorometer  
 Helena Protofluor  
*Analyte:* pH  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* AVL 987-S  
 Beckman LABLYTE 820  
 Ciba Corning 634  
 Coulter FLEXLYTE 6  
*Speciality/Subspeciality:* General Immunology

*Analyte:* Allergen specific IgE  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Quidel Allergen Screen  
 Quidel Food Allergen Screen  
*Analyte:* Alpha-1-Acid Glycoprotein (orosomucoid)  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Beckman Array 360  
*Analyte:* Alpha-1-Antitrypsin  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Beckman Array 360  
 Instrumentation Laboratories II  
 Monarch Plus  
*Analyte:* Alpha-2-Macroglobulin  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Beckman Array 360  
*Analyte:* Alpha-Fetoprotein—Tumor Marker  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Abbott IMX  
*Analyte:* Aminoglycosides  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Abbott TDX  
*Analyte:* Anti-DNA Antibodies  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* General Biometrics ImmunoDot  
 Autoimmunity Screening Panel  
 Stanbio SLE Quicktest  
*Analyte:* Anti-DNP antibodies  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Ampcor SLE Test  
 Diagnostic Technology ANA Check  
 Fisher Diagnostic SLE Latex Test Kit  
 Hycor Serascan SLE  
*Analyte:* Anti-Nuclear Antibodies (ANA)  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:*

General Biometrics ImmunoDot  
 Autoimmunity Screening Panel  
 Whittaker Bioproducts RheumaStrip  
*Analyte:* Anti-RNP (Ribonucleoprotein)  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* General Biometrics ImmunoDot  
 Autoimmunity Screening Panel  
*Analyte:* Anti-SS-A/Ro  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* General Biometrics ImmunoDot  
 Autoimmunity Screening Panel  
*Analyte:* Anti-SS-B/La  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* General Biometrics ImmunoDot  
 Autoimmunity Screening Panel  
*Analyte:* Anti-Sm (Smith)  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* General Biometrics ImmunoDot  
 Autoimmunity Screening Panel  
*Analyte:* Anti-Streptolysin O (ASO)  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Ampcor Quik-Dot  
 Behring RapiTex  
 Biokit Rheumagen ASO  
 Diagnostic Technology ASO Check  
 Fisher Diagnostic LAtest ASO  
 Seradyn Color Slide  
 V-Tech V-Trend ASO Plus  
 Wampole Streptozyyme  
*Analyte:* Anti-Thyroglobulin Antibodies (ATA)  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* General Biometrics ImmunoDot  
 Thyroid Autoimmunity Panel  
*Analyte:* Anti-Thyroid Microsomal Antibodies (AMA)  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* General Biometrics ImmunoDot  
 Thyroid Autoimmunity Panel  
*Analyte:* Beta-2 microglobulin  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Abbott IMX  
*Analyte:* C-Reactive Protein (CRP)

*Test Category:* Automated procedures that do not require operator intervention during the analytic process

*Test System, Assay or Examination:*

Abbott TDX  
Abbott TDX FLx  
Abbott Vision  
Beckman Array 360  
Beckman Synchron CX 7  
Dupont ACA  
Dupont ACA IV  
Dupont ACA V  
Dupont Dimension  
Technicon Chem 1

*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation

*Test System, Assay or Examination:*

Ampcor Quik-Dot  
Amtec CRP  
Baxter ImmunoSCAN  
Behring RapiTex  
Biokit Rheumagen CRP  
Diagnostic Technology CRP Check  
Difco Bacto CRP Slide Test Set  
Fisher Diagnostic LAtest CRP  
Hycor Serascan CRP  
Sclavo CRP Latex Test  
Seradyn Color Slide  
Stanbio CRP Quicktest  
V-Tech Target CRP  
Wampole Immunex CRP

*Analyte:* Carcinoembryonic Antigen (CEA)

*Test Category:* Automated procedures that do not require operator intervention during the analytic process

*Test System, Assay or Examination:*  
Abbott IMX

*Analyte:* Ceruloplasmin

*Test Category:* Automated procedures that do not require operator intervention during the analytic process

*Test System, Assay or Examination:*  
Beckman Array 360

*Analyte:* Coccidioides Antibodies

*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation

*Test System, Assay or Examination:*  
Immuno-Mycologics LA-Cocci Antibody System

Meridian Diagnostics Coccidioides Latex Agglutination System

*Analyte:* Complement C3

*Test Category:* Automated procedures that do not require operator intervention during the analytic process

*Test System, Assay or Examination:*

Beckman Array 360  
Boehringer Mannheim Hitachi 717  
Instrumentation Laboratories IL  
Monarch Plus  
Technicon Chem 1

*Analyte:* Complement C4

*Test Category:* Automated procedures that do not require operator intervention during the analytic process

*Test System, Assay or Examination:*

Beckman Array 360  
Boehringer Mannheim Hitachi 717  
Instrumentation Laboratories IL  
Monarch Plus  
Technicon Chem 1

*Analyte:* Cytomegalovirus Antibodies (IgG/IgM)

*Test Category:* Automated procedures that do not require operator intervention during the analytic process

*Test System, Assay or Examination:*

Abbott IMX  
PB Diagnostics OPUS  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation

*Test System, Assay or Examination:*

Becton Dickinson CMV Scan  
Disease Detection International  
SeroCard CMV IgG Test  
General Biometrics ImmunoDot  
Preconception Screening Panel  
Meridian Diagnostics Immunocard Test  
V-Tech Target CMV

*Analyte:* Febrile Agglutinins

*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation

*Test System, Assay or Examination:*

Becton Dickinson BBL—Slide Test  
Difco Bacto-Slide Test  
Gamma Biologicals Slide Test

*Analyte:* Fungus Antibodies

*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation

*Test System, Assay or Examination:*

Immuno-Mycologics LA-Sporo Antibody System

*Analyte:* Haptoglobin

*Test Category:* Automated procedures that do not require operator intervention during the analytic process

*Test System, Assay or Examination:*

Beckman Array 360  
Instrumentation Laboratories IL  
Monarch Plus

*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation

*Test System, Assay or Examination:*

Behring RapiTex  
*Analyte:* Helicobacter pylori Antibodies

*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation

*Test System, Assay or Examination:*

Quidel H. pylori Test

*Analyte:* Hepatitis A Antibody (HAVAb)

*Test Category:* Automated procedures that do not require operator

intervention during the analytic process

*Test System, Assay or Examination:*

Abbott IMX

*Analyte:* Hepatitis B Core Antibody (Hb Core)

*Test Category:* Automated procedures that do not require operator intervention during the analytic process

*Test System, Assay or Examination:*

Abbott IMX

*Analyte:* Hepatitis B Surface Antigen (HBS Ag)

*Test Category:* Automated procedures that do not require operator intervention during the analytic process

*Test System, Assay or Examination:*

Abbott IMX

*Analyte:* Herpes simplex I and/or II Antibodies

*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation

*Test System, Assay or Examination:*

Disease Detection International  
SeroCard HSV IgG Test

General Biometrics ImmunoDot

Preconception Screening Panel

Meridian Diagnostics Immunocard Test

*Analyte:* Histoplasma Antibodies

*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation

*Test System, Assay or Examination:*

Immuno-Mycologics LA-Histo Antibody System

*Analyte:* Immunoglobulins IgA

*Test Category:* Automated procedures that do not require operator intervention during the analytic process

*Test System, Assay or Examination:*

Abbott TDX  
Abbott TDX FLx  
Beckman Array 360

Boehringer Mannheim Hitachi 705

Boehringer Mannheim Hitachi 717

Dupont ACA

Dupont ACA IV

Dupont ACA V

Instrumentation Laboratories IL

Monarch Plus

Technicon Chem 1

*Analyte:* Immunoglobulins IgE

*Test Category:* Automated procedures that do not require operator intervention during the analytic process

*Test System, Assay or Examination:*

Abbott IMX

Baxter Stratus

Baxter Stratus II

Boehringer Mannheim ES 300

Ciba Corning ACS 180

**Test Category:** Manual procedures with limited steps and limited sample or reagent preparation

**Test System, Assay or Examination:**

Quidel Total IgE Test

**Analyte:** Immunoglobulins IgG

**Test Category:** Automated procedures that do not require operator intervention during the analytic process

**Test System, Assay or Examination:**

Abbott TDX

Abbott TDX FLx

Beckman Array 360

Boehringer Mannheim Hitachi 705

Boehringer Mannheim Hitachi 717

Dupont ACA

Dupont ACA IV

Dupont ACA V

Instrumentation Laboratories IL

Monarch Plus

Technicon Chem 1

**Analyte:** Immunoglobulins IgM

**Test Category:** Automated procedures that do not require operator intervention during the analytic process

**Test System, Assay or Examination:**

Abbott TDX

Abbott TDX FLx

Beckman Array 360

Boehringer Mannheim Hitachi 705

Boehringer Mannheim Hitachi 717

Dupont ACA

Dupont ACA IV

Dupont ACA V

Instrumentation Laboratories IL

Monarch Plus

Technicon Chem 1

**Analyte:** Infectious Mononucleosis Antibodies (Mono)

**Test Category:** Manual procedures with limited steps and limited sample or reagent preparation

**Test System, Assay or Examination:**

Ampcor Quik-Dot

Baxter ImmunoSCAN (Latex)

Baxter ImmunoSCAN RBC

Biokit Monogen

Diagnostic Technology Infectious

Mononucleosis Check

General Biometrics ImmunoDot

Infectious Mono Syndrome Panel

Gull Laboratories Mono-Lex Test

Hybritech Concise Mono Test

Hycor Serascan Infectious

Mononucleosis Test

Leeco Diagnostics Preview Mono

Medical Technology Corp. Mono-Lisa

Medical Technology Corp. Optitec

Mono

Organon NML Monosticon

Ortho Monolert

Ortho Monospot

Pacific Biotech Cards

Sclavo Infectious Mononucleosis

Screening

Seradyn Color Slide II

Unipath Oxoid Infectious

Mononucleosis Test

V-Tech Target Mono

V-Tech V-Trend Kit IM

Ventrex

Wampole Mono-Diff

Wampole Mono-Latex

Wampole Mono-Sure

Wampole Mono-Test

**Analyte:** Kappa Light Chains

**Test Category:** Automated procedures that do not require operator intervention during the analytic process

**Test System, Assay or Examination:**

Beckman Array 360

**Analyte:** Lambda Light Chains

**Test Category:** Automated procedures that do not require operator intervention during the analytic process

**Test System, Assay or Examination:**

Beckman Array 360

**Analyte:** Lyme Disease Antibodies

(Borrelia burgdorferi Abs)

**Test Category:** Manual procedures with limited steps and limited sample or reagent preparation

**Test System, Assay or Examination:**

General Biometrics ImmunoDot Lyme

Disease Panel

Quidel Lyme Disease Test

**Analyte:** Mycoplasma pneumonia

Antibodies

**Test Category:** Manual procedures with limited steps and limited sample or reagent preparation

**Test System, Assay or Examination:**

Medical Diag Technologies

Mycoplasma pneumonia IgG Ab

Test

Meridian Diagnostics Meristar-MP

**Analyte:** Prealbumin

**Test Category:** Automated procedures that do not require operator intervention during the analytic process

**Test System, Assay or Examination:**

Beckman Array 360

**Analyte:** Properdin Factor B

**Test Category:** Automated procedures that do not require operator intervention during the analytic process

**Test System, Assay or Examination:**

Beckman Array 360

**Analyte:** Prostatic Specific Antigen

(PSA)

**Test Category:** Automated procedures that do not require operator intervention during the analytic process

**Test System, Assay or Examination:**

Abbott IMX

**Analyte:** Rheumatoid Factor (RA)

**Test Category:** Automated procedures that do not require operator intervention during the analytic process

**Test System, Assay or Examination:**

Beckman Array 360

**Test Category:** Manual procedures with limited steps and limited sample or reagent preparation

**Test System, Assay or Examination:**

Ampcor Quik-Dot

Amtec RF

Baxter ImmunoSCAN (Latex)

Baxter ImmunoSCAN RBC

Becton Dickinson Macro-vue RF

Behring RapiTex

Biokit Rheumagen RF

Diagnostic Technology RA Check

Difco Bacto RF Test

Fisher Diagnostic LAtest RF

General Biometrics ImmunoDot

Autoimmunity Screening Panel

Hycor Serascan RA test

Organon Rheumanosticon Dri-Dot

Sclavo Reuma Test

Seradyn Seratest RF Latex Test

Stanbio RA Factor Quicktest

Wampole Rheumatex

Wampole Rheumaton

**Analyte:** Rubella Antibodies, IgG/IgM

**Test Category:** Automated procedures that do not require operator intervention during the analytic process

**Test System, Assay or Examination:**

Abbott IMX

**Test Category:** Manual procedures with limited steps and limited sample or reagent preparation

**Test System, Assay or Examination:**

Becton Dickinson Rubascan

Bickit Rubagen

Disease Detection International

SeroCard Rubella IgG Test

General Biometrics ImmunoDot

Preconception Screening Panel

General Biometrics ImmunoDot

Quantitative Rubella

Meridian Diagnostics Immunocard

Test

Murex SUDS Rubella

V-Tech Target Rubella

Wampole Virogen Rubella Micro

Latex Test

Wampole Virogen Rubella Slide Test

**Analyte:** Toxoplasma gondii Antibodies (IgG/IgM)

**Test Category:** Automated procedures that do not require operator intervention during the analytic process

**Test System, Assay or Examination:**

Abbott IMX

PB Diagnostics OPUS

**Test Category:** Manual procedures with limited steps and limited sample or reagent preparation

**Test System, Assay or Examination:**

Bio-Medical BIOCARD Toxo Ab

Disease Detection International

SeroCard Toxoplasma IgG

General Biometrics ImmunoDot

Preconception Screening Panel

Meridian Diagnostics Immunocard Test  
 Murex SUDS Toxo  
*Analyte:* Transferrin  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Abbott TDX  
 Abbott TDX FLx  
 Beckman Array 360  
 Boehringer Mannheim Hitachi 717  
 Instrumentation Laboratories IL Monarch Plus  
 Technicon Chem 1  
*Analyte:* *Treponema pallidum* Antibodies  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Ampcor RPR  
 Ampcor TRUST RPR  
 Becton Dickinson Macro-vue RPR  
 Fisher Diagnostic Reagin Screen Test  
 New Horizons TRUST assay  
 Seradyn Color Slide  
*Analyte:* Varicella-Zoster Virus Antibodies  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Becton Dickinson VZV Scan  
*Speciality/Subspeciality:* Hematology  
*Analyte:* Activated Partial Thromboplastin Time (APTT)  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* American Scientific Fibrometer  
 Becton Dickinson BBL Fibrometer  
 BioData Microsample Coagulation Analyzer  
 Ciba Corning Biotrack 512  
 General Diagnostics Coag-A-Mate  
 General Diagnostics Coag-A-Mate X2  
 General Diagnostics Coag-A-Mate XC  
 Helena Cascade 480  
 Helena Laboratories Dataclot  
 Instrumentation Laboratories IL ACL 100  
 Instrumentation Laboratories IL ACL 1000  
 Instrumentation Laboratories IL ACL 200  
 Instrumentation Laboratories IL ACL 2000  
 Instrumentation Laboratories IL ACL 300  
 Instrumentation Laboratories IL ACL 3000  
 Instrumentation Laboratories IL ACL 3000 Plus  
 Instrumentation Laboratories IL ACL 810

Medical Laboratories MLA Electra 1000 C  
 Medical Laboratories MLA Electra 700  
 Medical Laboratories MLA Electra 750  
 Medical Laboratories MLA Electra 800  
 Medical Laboratories MLA Electra 900  
 Medical Laboratories MLA Electra 900 C  
 Organon Teknika Coag-A-Mate Data-Mate  
 Organon Teknika Coag-A-Mate RA4  
 Organon Teknika Coag-A-Mate X-2  
 Organon Teknika Coag-A-Mate XC  
 Organon Teknika Coag-A-Mate XC Plus  
 Organon Teknika Coag-A-Mate XM  
 Ortho Koagulab 16S  
 Ortho Koagulab 32S  
 Ortho Koagulab 40-A  
 Sigma AccuStasis 1000  
 Sigma AccuStasis 2000  
 Sysmex CA-5000  
*Analyte:* Antithrombin III (ATIII)  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Beckman Array 360  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
*Analyte:* Fibrin Split Products (Fibrin Degradation)  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Dupont ACA IV  
 Dupont ACA V  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* American Diagnostics Dimertest  
*Analyte:* Fibrinogen  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Becton Dickinson BBL Fibrometer  
 Dupont ACA IV  
 Dupont ACA V  
 General Diagnostics Coag-A-Mate X2  
 General Diagnostics Coag-A-Mate XC  
 Helena Cascade 480  
 Instrumentation Laboratories IL ACL 100  
 Instrumentation Laboratories IL ACL 200  
 Instrumentation Laboratories IL ACL 2000  
 Instrumentation Laboratories IL ACL 300  
 Instrumentation Laboratories IL ACL 3000  
 Instrumentation Laboratories IL ACL 3000 Plus  
 Instrumentation Laboratories IL ACL 810

3000 Plus  
 Instrumentation Laboratories IL ACL 810  
 Medical Laboratories MLA Electra 700  
 Medical Laboratories MLA Electra 750  
 Medical Laboratories MLA Electra 800  
 Organon Teknika Coag-A-Mate RA4  
 Organon Teknika Coag-A-Mate XC  
 Organon Teknika Coag-A-Mate XM  
 Ortho Koagulab 16S  
 Ortho Koagulab 32S  
 Ortho Koagulab 40-A  
*Analyte:* Hematocrit  
*Test Category:* Automated hematology procedures with differentials that do not require operator intervention during the analytic process and that do not require an analyst to interpret a histogram or scattegram  
*Test System, Assay or Examination:* Baker 9000  
 Coulter JS  
 Coulter JT  
 Coulter JT2  
 Coulter JT3  
 Coulter MAXM  
 Coulter S Plus IVW/DIF  
 Coulter S Plus VI/STKR  
 Coulter STKR  
 Coulter STKS  
 Coulter T540  
 Coulter T660  
 Coulter T890  
 Roche Cobas Argos  
 Roche Cobas Minos STX  
*Test Category:* Automated hematology procedures without differentials that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Baker 8000  
 Becton Dickinson QBC AutoRead  
 Coulter 530  
 Coulter 560  
 Coulter 770  
 Coulter CBC4  
 Coulter CBC5  
 Coulter M430  
 Coulter S Plus  
 Coulter S Plus II  
 Coulter S Plus III  
 Coulter S Plus IV  
 Coulter S Plus Jr.  
 Coulter S Plus V  
 Coulter S550  
 Coulter S880  
 Coulter ST  
 Electronucleonics Cellstar  
 Ortho ELT 15  
 Ortho ELT 1500  
 Ortho ELT 8  
 Ortho ELT 8/DS  
 Ortho ELT 8/WS  
 Ortho ELT 800/WS  
 Roche Cobas Minos STE  
 Sequoia Turner 1600  
 Sequoia Turner 700

- Sequoia Turner 900  
 Sysmex CC-130  
 Sysmex CC-150  
 Sysmex CC-180  
 Sysmex CC-180  
 Sysmex CC-700  
 Sysmex CC-720  
 Sysmex CC-780  
 Sysmex E-2500  
 Sysmex E-5000  
 Sysmex K-1000  
 Sysmex NE-8000  
*Analyte:* Hemoglobin  
*Test Category:* Automated hematology procedures with differentials that do not require operator intervention during the analytic process and that do not require an analyst to interpret a histogram or scattergram  
*Test System, Assay or Examination:*  
 Baker 9000  
 Coulter JS  
 Coulter JT  
 Coulter JT2  
 Coulter JT3  
 Coulter MAXM  
 Coulter S Plus IVW/DIF  
 Coulter S Plus VI/STKR  
 Coulter STKR  
 Coulter STKS  
 Coulter T540  
 Coulter T660  
 Coulter T890  
 Roche Cobas Argos  
 Roche Cobas Minos STX  
*Test Category:* Automated hematology procedures without differentials that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Baker 8000  
 Becton Dickinson QBC AutoRead  
 Coulter 530  
 Coulter 560  
 Coulter 770  
 Coulter CBC4  
 Coulter CBC5  
 Coulter M430  
 Coulter S Plus  
 Coulter S Plus II  
 Coulter S Plus III  
 Coulter S Plus IV  
 Coulter S Plus Jr.  
 Coulter S Plus V  
 Coulter S550  
 Coulter S880  
 Coulter ST  
 Electronucleonics Cellstar  
 Hemocue Hemoglobin System  
 Ortho ELT 15  
 Ortho ELT 1500  
 Ortho ELT 8  
 Ortho ELT 8/DS  
 Ortho ELT 8/WS  
 Ortho ELT 800/WS  
 Roche Cobas Minos STE  
 Sequoia Turner 1600  
 Sequoia Turner 700  
 Sequoia Turner 900
- Sysmex CC-130  
 Sysmex CC-150  
 Sysmex CC-180  
 Sysmex CC-700  
 Sysmex CC-720  
 Sysmex CC-780  
 Sysmex E-2500  
 Sysmex E-5000  
 Sysmex K-1000  
 Sysmex NE-8000  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott Vision  
 Ames Seralyzer  
 Ames Seralyzer III  
 Kodak Ektachem DT 60  
 LEO Diagnostics Hemocue  
*Test Category:* Whole blood measurements using teststrip meters (excluding glucose monitoring devices cleared by the FDA specifically for home use)  
*Test System, Assay or Examination:*  
 Boehringer Mannheim Reflotron Plus  
*Analyte:* Heparin  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Dupont ACA IV  
 Dupont ACA V  
*Analyte:* Plasminogen  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Dupont ACA IV  
 Dupont ACA V  
*Analyte:* Platelet Count  
*Test Category:* Automated hematology procedures with differentials that do not require operator intervention during the analytic process and that do not require an analyst to interpret a histogram or scattergram  
*Test System, Assay or Examination:*  
 Baker 9000  
 Coulter JS  
 Coulter JT  
 Coulter JT2  
 Coulter JT3  
 Coulter MAXM  
 Coulter S Plus IVW/DIF  
 Coulter S Plus VI/STKR  
 Coulter STKR  
 Coulter STKS  
 Coulter T540  
 Coulter T660  
 Coulter T890  
 Roche Cobas Argos  
 Roche Cobas Minos STX  
*Test Category:* Automated hematology procedures without differentials that do not require operator
- intervention during the analytic process  
*Test System, Assay or Examination:*  
 Baker 8000  
 Becton Dickinson QBC AutoRead  
 Coulter S Plus  
 Coulter S Plus II  
 Coulter S Plus III  
 Coulter S Plus IV  
 Coulter S Plus Jr.  
 Coulter S Plus V  
 Coulter S880  
 Coulter ST  
 Electronucleonics Cellstar  
 Ortho ELT 15  
 Ortho ELT 1500  
 Ortho ELT 8  
 Ortho ELT 8/DS  
 Ortho ELT 8/WS  
 Ortho ELT 800/WS  
 Roche Cobas Minos STE  
 Sequoia Turner 1600  
 Sysmex CC-130  
 Sysmex CC-150  
 Sysmex CC-700  
 Sysmex CC-720  
 Sysmex CC-780  
 Sysmex E-2500  
 Sysmex E-5000  
 Sysmex K-1000  
 Sysmex NE-8000  
*Analyte:* Prothrombin Time (PT)  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott Vision  
 American Scientific Fibrometer  
 Becton Dickinson BBL Fibrometer  
 BioData Microsample Coagulation Analyzer  
 Ciba Corning Biotrack 512  
 General Diagnostics Coag-A-Mate  
 General Diagnostics Coag-A-Mate X2  
 General Diagnostics Coag-A-Mate XC  
 Helena Cascade 480  
 Helena Laboratories Dataclot  
 Instrumentation Laboratories IL ACL 100  
 Instrumentation Laboratories IL ACL 1000  
 Instrumentation Laboratories IL ACL 200  
 Instrumentation Laboratories IL ACL 2000  
 Instrumentation Laboratories IL ACL 300  
 Instrumentation Laboratories IL ACL 3000  
 Instrumentation Laboratories IL ACL 3000 Plus  
 Instrumentation Laboratories IL ACL 810  
 Medical Laboratories MLA Electra 1000 C  
 Medical Laboratories MLA Electra 700



A,B (microwell)  
 Amtec CM-Tec Anti-A, Anti-B, Anti-A,B (tube)  
 BCA Anti-A, Anti-B, Anti-A,B (microplate)  
 BCA Anti-A, Anti-B, Anti-A,B (slide, tube)  
 BCA Anti-A1 Lectin (slide, tube)  
 Dade Anti-A, Anti-B, Anti-A,B (microplate)  
 Dade Anti-A, Anti-B, Anti-A,B (slide, tube)  
 Dade Mono-Type Anti-A, Anti-B, Anti-A + B (microplate)  
 Dade Mono-Type Anti-A, Anti-B, Anti-A + B (slide, tube)  
 Gamma Anti-A, Anti-B, Anti-A,B (slide, tube)  
 Gamma Anti-A1 Lectin (slide, tube)  
 Gamma Omni-Series II Anti-A, Anti-B, Anti-A,B (microwell)  
 Gamma Omni-Series II Anti-A, Anti-B, Anti-A,B (tube)  
 Gamma's Gamma-clone Anti-A, Anti-B, Anti-A + B (microwell)  
 Gamma's Gamma-clone Anti-A, Anti-B, Anti-A + B (slide, tube)  
 Immucor Anti-A, Anti-B, Anti-A,B (microplate)  
 Immucor Anti-A, Anti-B, Anti-A,B (slide, tube)  
 Immucor Anti-A, Anti-B, Anti-A,B—murine (microplate)  
 Immucor Anti-A, Anti-B, Anti-A,B—murine (slide, tube)  
 Immucor Anti-A1 (slide, tube)  
 Ortho Anti-A1 Lectin (slide, tube)  
 Ortho BioClone Anti-A, Anti-B, Anti-A + B (microplate)  
 Ortho BioClone Anti-A, Anti-B, Anti-A + B (slide, tube)  
*Analyte:* ABO group confirmation—Serum, Plasma  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:*  
 Amtec Serum Grouping Cells  
 BCA Confirmcells and Versa Cells  
 Dade Reverse-Cyte (microplate)  
 Dade Reverse-Cyte (tube)  
 Gamma Reverse Group (microwell)  
 Gamma Reverse Group (tube)  
 Immucor Referencells  
 Ortho Affirmagen  
*Analyte:* D(Rho) Type  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:*  
 Amtec Anti-D (slide, rapid tube)  
 Amtec CM-Tec Anti-D (microwell)  
 Amtec CM-Tec Anti-D (slide, saline tube)  
 BCA Anti-D (saline tube)  
 BCA Anti-D (slide, rapid tube)  
 BCA UltraSera Anti-D (microplate)  
 BCA UltraSera Anti-D (slide, tube)  
 Dade Anti-D (microplate)

Dade Anti-D (slide, rapid tube)  
 Dade Chemically Modified Anti-D (microplate)  
 Dade Chemically Modified Anti-D (slide, tube)  
 Gamma Anti-D (saline tube)  
 Gamma Anti-D (slide, modified tube)  
 Gamma RST/Omni-Series II Anti-D (microwell)  
 Gamma RST/Omni-Series II Anti-D (slide, saline tube)  
 Gamma's Gamma-clone Anti-D (microwell)  
 Gamma's Gamma-clone Anti-D (slide, tube)  
 Immucor Anti-D (microplate)  
 Immucor Anti-D (saline tube)  
 Immucor Anti-D (slide, tube)  
 Immucor Anti-D Chem-D (microplate)  
 Immucor Anti-D Chem-D (slide, tube)  
 Ortho Anti-D (slide, modified tube)  
 Ortho BioClone Anti-D (microplate)  
 Ortho BioClone Anti-D (slide, rapid tube)  
*Analyte:* Du (Weak D RBC antigen)  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:*  
 Amtec Anti-D  
 Amtec CM-Tec Anti-D  
 BCA Anti-D  
 BCA UltraSera Anti-D  
 Dade Anti-D  
 Dade Chemically Modified Anti-D  
 Gamma Anti-D  
 Gamma RST/Omni-Series II Anti-D  
 Gamma's Gamma-clone Anti-D  
 Immucor Anti-D  
 Immucor Anti-D Chem-D  
 Ortho Anti-D  
 Ortho BioClone Anti-D  
*Analyte:* RBC antigen type other than A or B  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:*  
 Amtec Anti-H Lectin  
 Amtec Anti-N Lectin  
 Amtec Blood Grouping Reagents (microwell)  
 Amtec Blood Grouping Reagents (slide, tube)  
 Amtec Blood Grouping Reagents for Indirect Antiglobulin  
 BCA Anti-H Lectin  
 BCA Anti-N Lectin  
 BCA Blood Grouping Reagents (slide, tube)  
 BCA Blood Grouping Reagents for Indirect Antiglobulin Test  
 Dade Blood Grouping Reagents (slide, tube)  
 Dade Blood Grouping Reagent Chemically Modified (slide, tube)  
 Dade Blood Grouping Reagents for Indirect Antiglobulin Test  
 Dade Lectin-H

Gamma Anti-H Lectin  
 Gamma Anti-N Lectin  
 Gamma Blood Grouping Reagents (slide, tube)  
 Gamma Blood Grouping Reagents for Indirect Antiglobulin  
 Gamma RST-Series Blood Grouping Reagents (slide, tube)  
 Gamma's Gamma ID-series Blood Grouping Reagents  
 Gamma's Gamma-clone Blood Grouping Reagents (microwell)  
 Gamma's Gamma-clone Blood Grouping Reagents (tube)  
 Immucor Anti-N Lectin  
 Immucor Blood Grouping Reagents (microplate)  
 Immucor Blood Grouping Reagents (slide, tube)  
 Immucor Blood Grouping Reagents—Indirect Antiglobulin  
 Ortho BioClone Blood Grouping Reagents  
 Ortho Blood Grouping Reagents (slide, tube)  
 Ortho Blood Grouping Reagents for Indirect Antiglobulin Test  
*Analyte:* Unexpected RBC antibody—detection—serum  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:*  
 Amtec Screening Cells—SAL/ALB/LISS/PEG/IAT  
 BCA Bio-Cells—SAL/ALB/LISS/PEG/IAT  
 BCA Spectrogen—SAL/ALB/LISS/PEG/IAT  
 Dade Search-Cyte—SAL/ALB/LISS/PEG/IAT  
 Dade Search-Cyte Plus—SAL/ALB/LISS/PEG/IAT  
 Dade Search-Cyte TCS—SAL/ALB/LISS/PEG/IAT  
 Gamma Duet—SAL/ALB/LISS/PEG/IAT  
 Gamma Pool—SAL/ALB/LISS/PEG/IAT  
 Gamma Trio—SAL/ALB/LISS/PEG/IAT  
 Gamma r-set—SAL/ALB/LISS/PEG/IAT  
 Immucor Hemantigen—SAL/ALB/LISS/PEG/IAT  
 Immucor Panoscreen—SAL/ALB/LISS/PEG/IAT  
 Ortho Pooled Screening Cells—SAL/ALB/LISS/PEG/IAT  
 Ortho Selectogen—SAL/ALB/LISS/PEG/IAT  
 Ortho Surgiscreen—SAL/ALB/LISS/PEG/IAT  
*Speciality/Subspeciality:*  
 Mycobacteriology  
*Analyte:* Acid-fast bacteria  
*Test Category:* Direct acid fast smear

*Test System, Assay or Examination:* All Test Systems, Assays or Examinations  
*Speciality/Subspeciality:* Mycology  
*Analyte:* All fungi  
*Test Category:* Primary culture inoculation

*Test System, Assay or Examination:* All Test Systems, Assays or Examinations  
*Analyte:* Candida  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation

*Test System, Assay or Examination:* Becton Dickinson Directigen 1-2-3 Disseminated Candidiasis  
*Analyte:* Cryptococcus  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation

*Test System, Assay or Examination:* Baxter MYCO-Immune Cryptococcal Ag Latex Agg (direct Ag)  
 Meridian Cryptococcal Antigen Latex Agg. System (dir Ag)  
 Meridian Diagnostics Premier Cryptococcal Antigen (dir Ag)  
*Analyte:* Dermatophytes  
*Test Category:* Tests using selective media for presence or absence of Dermatophytes

*Test System, Assay or Examination:* Becton Dickinson BBL Dermatophyte Test Medium  
 Carr-Scarborough Dermatophyte Test Medium  
 Hardy Diagnostics Dermatophyte Test Medium  
 Incstar Dermatophyte Test Medium  
 Medical Technology Corp. Oricult DTM  
*Analyte:* Fungal elements  
*Test Category:* Microscopic evaluation of KOH preparations

*Test System, Assay or Examination:* All Test Systems, Assays or Examinations  
*Analyte:* Yeast  
*Test Category:* Automated mycology procedures that do not require operator intervention during the analytic process

*Test System, Assay or Examination:* Vitek Systems VITEK Yeast Biochemical Card  
*Test Category:* ID of *C. albicans* (excluding semi-automated & semi-quant. procedures)

*Test System, Assay or Examination:* Analytab API 20C Yeast Identification Kits  
 Analytab API Germ Tube  
 Analytab Yeast Ident  
 Baxter MicroScan Rapid Yeast Identification Panel  
 Carr-Scarborough *C. albicans* Disc Screening Kit  
 Culture Kits, Inc. CandiKit

Innovative Diagnostic Systems IDS Rapid SS/U System  
 Medical Wire Equip. MicroRing YT  
*Test Category:* Isolation of yeast with identification limited to *Candida albicans*

*Test System, Assay or Examination:* All Test Systems, Assays or Examinations  
*Speciality/Subspeciality:* Parasitology  
*Analyte:* *Enterobius vermicularis*  
*Test Category:* Microscopic evaluation of pinworm preparations

*Test System, Assay or Examination:* All Test Systems, Assays or Examinations  
*Analyte:* Intestinal parasites  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation

*Test System, Assay or Examination:* Alexon Biomedical ProSpect Giardia Antibodies Inc. Giard EIA  
*Test Category:* Microscopic evaluation of direct wet mount preparations

*Test System, Assay or Examination:* All Test Systems, Assays or Examinations  
*Analyte:* *Trichomonas*  
*Test Category:* Microscopic evaluation of direct wet mount preparations

*Test System, Assay or Examination:* All Test Systems, Assays or Examinations  
*Speciality/Subspeciality:* Toxicology/TDM  
*Analyte:* Acetaminophen  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process

*Test System, Assay or Examination:* Abbott ADX  
 Abbott TDX  
 Abbott TDX FLx  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
 Instrumentation Laboratories IL  
 Monarch Plus  
*Analyte:* Amikacin  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process

*Test System, Assay or Examination:* Abbott TDX  
 Abbott TDX FLx  
 Baxter Stratus  
 Baxter Stratus II  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
 Instrumentation Laboratories IL  
 Monarch Plus  
 Roche Cobas FARA  
 Roche Cobas FARA II  
 Roche Cobas Mira  
 Roche Cobas Mira S

*Analyte:* Amphetamines  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process

*Test System, Assay or Examination:* Abbott ADX  
 Abbott TDX  
 Abbott TDX FLx  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Dimension  
 Instrumentation Laboratories IL  
 Monarch Plus  
*Analyte:* Barbiturates  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process

*Test System, Assay or Examination:* Abbott ADX  
 Abbott TDX  
 Abbott TDX FLx  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Dimension  
 Instrumentation Laboratories IL  
 Monarch Plus  
*Analyte:* Benzodiazepines  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process

*Test System, Assay or Examination:* Abbott ADX  
 Abbott TDX  
 Abbott TDX FLx  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Dimension  
 Instrumentation Laboratories IL  
 Monarch Plus  
*Analyte:* Cannabinoids  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process

*Test System, Assay or Examination:* Abbott ADX  
 Abbott TDX  
 Abbott TDX FLx  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Dimension  
 Instrumentation Laboratories IL  
 Monarch Plus  
*Analyte:* Carbamazepine  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process

*Test System, Assay or Examination:* Abbott TDX  
 Abbott TDX FLx  
 Amès Seralyzer III  
 Baxter Stratus  
 Baxter Stratus II  
 Beckman Array 360

Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Dimension  
 Instrumentation Laboratories II.  
 Monarch Plus  
 PB Diagnostics OPUS  
 Roche Cobas FARA  
 Roche Cobas FARA II  
 Roche Cobas Mira  
 Roche Cobas Mira S  
*Analyte:* Carbamazepine, Free  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott TDX  
 Abbott TDX FLx  
*Analyte:* Cocaine Metabolites  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott ADX  
 Abbott TDX  
 Abbott TDX FLx  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Dimension  
 Instrumentation Laboratories II.  
 Monarch Plus  
*Analyte:* Cyclosporine  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott TDX  
 Abbott TDX FLx  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
*Analyte:* Digitoxin  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott TDX  
 Abbott TDX FLx  
 Baxter Stratus  
 Baxter Stratus II  
 Dupont ACA IV  
 Dupont ACA V  
*Analyte:* Digoxin  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott TDX  
 Abbott TDX FLx  
 Ames Clinimate—TDA  
 Ames Seralyzer III  
 Baxter Stratus  
 Baxter Stratus II  
 Beckman Synchron CX 4

Beckman Synchron CX 5  
 Becton Dickinson Affinity  
 Boehringer Mannheim ES 300  
 Ciba Corning ACS 180  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Dimension  
 Instrumentation Laboratories II.  
 Monarch Plus  
 PB Diagnostics OPUS  
 Technicon Chem 1  
*Analyte:* Disopyramide  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott TDX  
 Abbott TDX FLx  
*Analyte:* Drugs of Abuse in Urine  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abuscreen ONTRAK  
*Analyte:* Ethanol (Alcohol)  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott ADX  
 Abbott TDX  
 Abbott TDX FLx  
 Baxter Paramax  
 Baxter Paramax 720 ZX  
 Boehringer Mannheim Hitachi 705  
 Boehringer Mannheim Hitachi 717  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Dimension  
 Instrumentation Laboratories II.  
 Monarch Plus  
 Kodak Ektachem 700 XR  
*Analyte:* Ethosuximide  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott TDX  
 Abbott TDX FLx  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
 Instrumentation Laboratories II.  
 Monarch Plus  
*Analyte:* Flecainide  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott TDX  
 Abbott TDX FLx  
 Beckman Synchron CX 4

*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott TDX  
 Abbott TDX FLx  
 Baxter Stratus  
 Baxter Stratus II  
 Beckman Array 360  
 Beckman Synchron CX 4  
 Beckman Synchron CX 5  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Dimension  
 Instrumentation Laboratories II.  
 Monarch Plus  
 Roche Cobas FARA  
 Roche Cobas FARA II  
 Roche Cobas Mira  
 Roche Cobas Mira S  
 Technicon Chem 1  
*Analyte:* Kanamycin  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott TDX  
 Abbott TDX FLx  
*Analyte:* Lidocaine  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott TDX  
 Abbott TDX FLx  
*Analyte:* Methadone  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott ADX  
 Abbott TDX FLx  
 Instrumentation Laboratories II.  
 Monarch Plus  
*Analyte:* Methamphetamine  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott ADX  
 Abbott TDX  
 Abbott TDX FLx  
*Analyte:* Methaqualone  
*Test Category:* Automated procedures that do not require operator

intervention during the analytic process  
*Test System, Assay or Examination:*  
 Instrumentation Laboratories IL  
 Monarch Plus  
*Analyte:* Methotrexate  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott TDX  
 Abbott TDX FLx  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
*Analyte:* N-Acetylprocainamide (NAPA)  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott TDX  
 Abbott TDX FLx  
 Baxter Stratus  
 Baxter Stratus II  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
 Instrumentation Laboratories IL  
 Monarch Plus  
 Roche Cobas FARA  
 Roche Cobas FARA II  
 Roche Cobas Mira  
 Roche Cobas Mira S  
*Analyte:* Netilmycin  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott TDX  
 Abbott TDX FLx  
*Analyte:* Opiates  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott ADX  
 Abbott TDX  
 Abbott TDX FLx  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Dimension  
 Instrumentation Laboratories IL  
 Monarch Plus  
*Analyte:* Phencyclidine  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott ADX  
 Abbott TDX  
 Abbott TDX FLx  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Dimension

Instrumentation Laboratories IL  
 Monarch Plus  
*Analyte:* Phenobarbital  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott TDX  
 Abbott TDX FLx  
 Ames Seralyzer  
 Ames Seralyzer III  
 Baxter Stratus  
 Baxter Stratus II  
 Beckman Array 360  
 Beckman Synchron CX 4  
 Beckman Synchron CX 5  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Dimension  
 Instrumentation Laboratories IL  
 Monarch Plus  
 PB Diagnostics OPUS  
 Roche Cobas FARA  
 Roche Cobas FARA II  
 Roche Cobas Mira  
 Roche Cobas Mira S  
 Technicon Chem 1  
*Analyte:* Phenytoin  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott TDX  
 Abbott TDX FLx  
 Ames Seralyzer  
 Ames Seralyzer III  
 Baxter Stratus  
 Baxter Stratus II  
 Beckman Array 360  
 Beckman Synchron CX 4  
 Beckman Synchron CX 5  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Dimension  
 Instrumentation Laboratories IL  
 Monarch Plus  
 PB Diagnostics OPUS  
 Roche Cobas FARA  
 Roche Cobas FARA II  
 Roche Cobas Mira  
 Roche Cobas Mira S  
 Technicon Chem 1  
*Analyte:* Phenytoin, Free  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott TDX  
 Abbott TDX FLx  
*Analyte:* Primidone  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process

*Test System, Assay or Examination:*  
 Abbott TDX  
 Abbott TDX FLx  
 Baxter Stratus  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
 Instrumentation Laboratories IL  
 Monarch Plus  
 Roche Cobas FARA  
 Roche Cobas FARA II  
 Roche Cobas Mira  
 Roche Cobas Mira S  
*Analyte:* Procainamide  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott TDX  
 Abbott TDX FLx  
 Baxter Stratus  
 Baxter Stratus II  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
 Instrumentation Laboratories IL  
 Monarch Plus  
 Roche Cobas FARA  
 Roche Cobas FARA II  
 Roche Cobas Mira  
 Roche Cobas Mira S  
*Analyte:* Propoxyphene  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Instrumentation Laboratories IL  
 Monarch Plus  
*Analyte:* Quinidine  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott TDX  
 Abbott TDX FLx  
 Baxter Stratus  
 Baxter Stratus II  
 Beckman Array 360  
 Dupont ACA  
 Dupont ACA IV  
 Dupont ACA V  
 Dupont Dimension  
 Instrumentation Laboratories IL  
 Monarch Plus  
 Roche Cobas FARA  
 Roche Cobas FARA II  
 Roche Cobas Mira  
 Roche Cobas Mira S  
*Analyte:* Salicylates  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott ADX

- Abbott TDX  
Abbott TDX FLx  
Baxter Paramax  
Baxter Paramax 720 ZX  
Boehringer Mannheim Hitachi 705  
Boehringer Mannheim Hitachi 717  
Dupont ACA  
Dupont ACA IV  
Dupont ACA V  
Dupont Dimension  
Instrumentation Laboratories IL  
Monarch Plus  
Kodak Ektachem 500  
Kodak Ektachem 700 XR  
*Analyte:* Streptomycin  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Abbott TDX  
Abbott TDX FLx  
*Analyte:* Theophylline  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Abbott TDX  
Abbott TDX FLx  
Ames Clinimate—TDA  
Ames Seralyzer  
Ames Seralyzer III  
Baxter Stratus  
Baxter Stratus II  
Beckman Array 360  
Beckman Synchron CX 4  
Beckman Synchron CX 5  
Ciba Corning Biotrack 518  
Dupont ACA  
Dupont ACA IV  
Dupont ACA V  
Dupont Dimension  
Instrumentation Laboratories IL  
Monarch Plus  
Kodak Ektachem 500  
Kodak Ektachem 700 XR  
Kodak Ektachem DT SC Module  
PB Diagnostics OPUS  
Roche Cobas FARA  
Roche Cobas FARA II  
Roche Cobas Mira  
Roche Cobas Mira S  
Technicon Chem 1  
*Analyte:* Tobramycin  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Abbott TDX  
Abbott TDX FLx  
Baxter Stratus  
Baxter Stratus II  
Beckman Array 360  
Dupont ACA  
Dupont ACA IV  
Dupont ACA V  
Dupont Dimension
- Instrumentation Laboratories IL  
Monarch Plus  
Roche Cobas FARA  
Roche Cobas FARA II  
Roche Cobas Mira  
Roche Cobas Mira S  
Technicon Chem 1  
*Analyte:* Tricyclic Antidepressants  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Abbott ADX  
Abbott TDX  
Abbott TDX FLx  
Dupont ACA IV  
Dupont ACA V  
*Analyte:* Valproic Acid  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Abbott TDX  
Abbott TDX FLx  
Dupont ACA  
Dupont ACA IV  
Dupont ACA V  
Instrumentation Laboratories IL  
Monarch Plus  
PB Diagnostics OPUS  
Roche Cobas FARA  
Roche Cobas FARA II  
Roche Cobas Mira  
Roche Cobas Mira S  
*Analyte:* Valproic Acid, Free  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Abbott TDX  
Abbott TDX FLx  
*Analyte:* Vancomycin  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Abbott TDX  
Abbott TDX FLx  
Dupont ACA IV  
Dupont ACA V  
Dupont Dimension  
Instrumentation Laboratories IL  
Monarch Plus  
*Speciality/Subspeciality:* Urinalysis  
*Analyte:* Qualitative Urine Dipstick/  
Tablet Analytes  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Ames Clinitek 100  
Ames Clinitek 200 Plus  
Behring Rapidmat II  
Behring Rapidmat II T
- Analyte:* Specific Gravity  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Behring Rapidmat II Digital Refractometer  
*Analyte:* Urinary Sediment Microscopic Elements  
*Test Category:* Microscopic analysis of urinary sediment  
*Test System, Assay or Examination:* All Test Systems, Assays or Examinations  
*Speciality/Subspeciality:* Virology  
*Analyte:* Adenovirus  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Analytab Adenovirus Test Kit (EIA) (direct antigen)  
Analytab Adenovirus Type 40 & 41 (EIA) (direct antigen)  
Cambridge Biotech Adenoclone (EIA) (direct antigen)  
Cambridge Biotech Adenoclone-type 40/41 (EIA) (dir Ag)  
*Analyte:* Herpes simplex  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Fairleigh Dickinson Lab ELISA for H. Simplex (dir Ag)  
Kodak SureCell (direct antigen)  
Wampole Virogen Herpes latex slide test (direct antigen)  
*Analyte:* Respiratory syncytial virus  
*Test Category:* Automated procedures that do not require operator intervention during the analytic process  
*Test System, Assay or Examination:* Vitek Systems Vidas RSV (direct antigen)  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Abbott Test Pack RSV (EIA) (direct antigen)  
Becton Dickinson Directigen RSV (EIA) (direct antigen)  
Sanofi/Kallestad Pathfinder RSV (direct antigen)  
*Analyte:* Respiratory viruses (Influenza A&B, parainfluenza)  
*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation  
*Test System, Assay or Examination:* Becton Dickinson Directigen Flu A (direct antigen)  
*Analyte:* Rotavirus

*Test Category:* Manual procedures with limited steps and limited sample or reagent preparation

*Test System, Assay or Examination:*

Abbott Rotazyme II Diagnostic Kit (direct antigen)  
 Analytab API Rotavirus Test Kit (direct antigen)  
 Bio-Medical ANI Biocard Rotovirus (direct antigen)  
 Cambridge Biotech Rotaclone (direct antigen)  
 Isolab RotaVirus EIA (direct antigen)  
 Medical Technology Corp Rotalex (direct antigen)  
 Meridian Diag. Meritec Rotavirus Latex (direct antigen)  
 Sanofi/Kallestad Pathfinder Rotavirus (direct antigen)  
 V-Tech Target Rotavirus (direct antigen)  
 Vitek SLIDEX Rota-kit 2 (direct antigen)  
 Wampole Virogen Rotatest (direct antigen)  
 Wellcome Rotavirus Latex Test (direct antigen)

*Complexity:* High

*Specialty/Subspecialty:* Bacteriology

*Analyte:* All Organisms

*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process

*Test System, Assay or Examination:*

Abbott MS-2/Advantage  
 Abbott Quantum II System  
 Analytab API UniScept System  
 Baxter AutoSCAN Walk/Away  
 Baxter MicroScan AutoSCAN 4  
 Baxter MicroScan Rapid Anaerobe ID Panel  
 Biolog GN Microplate/ES Microplate  
 Difco Pasco Tri Panel  
 Organon Autobac Series II  
 Radiometer Sensititre  
 Radiometer Sensititre Gram neg bacteria

*Test Category:* Identification of aerobes or anaerobes from specimens not in moderate complexity (e.g. Biochem/Physiol)

*Test System, Assay or Examination:*

Adams Scientific B. Cat Confirm  
 Adams Scientific Identicult—AE  
 Adams Scientific Identicult—BL  
 Adams Scientific Identicult—Neisseria  
 Adams Scientific Mug-Indole Disc  
 Adams Scientific Rapid-Hippurate  
 Adams Scientific Stat-Urease  
 American Biomedical Prod. B. Fragtex  
 Anaerobe Systems Bile Differential Disk  
 Anaerobe Systems Colistin 10 mcg. Differential Disk  
 Anaerobe Systems Kanamycin 1000 mcg Differential Disk

Anaerobe Systems Vancomycin 5 mcg Differential Disk  
 Analytab API 20 Streptococcus  
 Analytab API 20-A  
 Analytab API An-Ident  
 Analytab API Laboratories Rapid E  
 Analytab API Laboratories Rapid NFT  
 Analytab API Laboratories Rapid Strep  
 Analytab API StaphTrac  
 Analytab API Staphase III  
 Analytab API ZYM Microorganism Differentiation  
 Analytab Quad Ferm +  
 Baxter Coagulase Plasma  
 Baxter Haemophilus/Neisseria Identif—Panel  
 Baxter MicroScan Gram Neg Panels  
 Baxter MicroScan Gram Pos Panels  
 Becton Dickinson Cefinase Discs  
 Becton Dickinson Miniteck  
 Calbiochem Padac Differentiation Discs  
 Calbiochem-Behring Anti-Dnase B  
 Carr Microbiologicals Beta Lactamase Reagent Disc  
 Carr Microbiologicals CSM Chromogenic B-Lactamase Disc  
 Carr Microbiologicals Hipp Microtube  
 Carr Microbiologicals Onpx-Indol Microtube  
 Carr Microbiologicals PYR Broth  
 Carr Microbiologicals PYR Discs  
 Carr Microbiologicals Pgua-Indol Microtube  
 Carr Microbiologicals Phos Microtubes  
 Carr Microbiologicals Pro Discs  
 Carr Microbiologicals Pyrr Microtubes  
 Carr-Scarborough ALN Differentiation Discs  
 Carr-Scarborough Acridine Orange Stain  
 Carr-Scarborough Rapid Glutamic Acid Decarboxy Microtube  
 Diagnostic Products Corp. PathoDx PYR Kit  
 Difco Differentiation Discs ALA  
 Difco Differentiation Discs Colistin 10 mcg  
 Difco Differentiation Discs Erythromycin 60 mcg  
 Difco Differentiation Discs Hippurate  
 Difco Differentiation Discs Kanamycin 1000 mcg  
 Difco Differentiation Discs Nitrate  
 Difco Differentiation Discs Penicillin G 2 units  
 Difco Differentiation Discs Rifampin 15 mcg  
 Difco Differentiation Discs SPS  
 Difco Differentiation Discs Spectinomycin  
 Difco Differentiation Discs Vancomycin 5 mcg  
 Difco DrySlide Beta-Lactamase  
 Difco Dryslide Oxidase  
 Difco Spot Test 10% Na Desoxycholate

Difco Spot Test Acridine Orange Stain  
 E-Y Laboratories Strep-A-Check PYR  
 E-Y Laboratories Swabzyme-Oxidase  
 Innovative Diagnostic Systems Beta Discs  
 Innovative Diagnostic Systems IDS Rapid SS/U System  
 Innovative Diagnostic Systems IDS Rapid STR System  
 Innovative Diagnostic Systems Modified IDS Rapid NH System  
 Innovative Diagnostic Systems Oxichrome Reagent  
 Innovative Diagnostic Systems Prophyrin Reagent  
 Innovative Diagnostic Systems Rap ANA II System  
 Innovative Diagnostic Systems Rap NF Plus System  
 Innovative Diagnostic Systems Rapid NF System  
 Kev Connecticut Diagnostics Visi-Strep  
 Meridian Indol Spot Test Kit  
 Micro Media Systems Bacterial ID Panels/Gram Neg/Gram Pos  
 Micro Media Systems M. Cat. Butyrate Disc  
 Micro-Bio-Logics KWIK-LAC  
 Micro-Bio-Logics Lyfo-KWIK OMI Kit  
 Micro-Bio-Logics Neisseria-KWIK Plus  
 Microbiological Specialties Beta-ase Tubes  
 Microbiological Specialties Enzyme-ase I Tubes  
 Microbiological Specialties Glactosid-ase Tubes  
 Microtech Medical Systems Quadrater ID  
 Pasco Labs Gram Neg ID System  
 Pro-Lab Hippurate Test  
 Pro-Lab Neisseria/Branhamella Differential Test  
 Pro-Lab Rosco D'Ala Rapid Test  
 Pro-Lab Rosco Pyrr  
 Remel ALA Disc  
 Remel Acridine Orange Stain  
 Remel Beta Lysin Disc  
 Remel Beta-Lactam Disc  
 Remel Bile Disc  
 Remel CEPH Lactam Disc  
 Remel Catarrhalis Test Strip  
 Remel Coagulase Plasma  
 Remel Colistin Disc  
 Remel Haemophilus ID Test Kit  
 Remel Hemastaph  
 Remel Kanamycin Disc  
 Remel Legionella ID Disc  
 Remel Microdase  
 Remel Nitrate Swab-Rapid Test  
 Remel Novobiocin Disc  
 Remel PYR Disc  
 Remel PYR/Esculin Disc  
 Remel Prophyrin (ALA) Disc  
 Remel Pyridoxal Disc  
 Remel SPS Disc  
 Remel Urea-PDA Discs

- Roche Enterotube II  
Unipath Oxoid Bile Esculin Discs  
Unipath Oxoid ONPG Discs  
Unipath Oxoid Oxidase ID Sticks  
Unipath Oxoid SPS Discs  
Unipath Oxoid V Factor Discs  
Unipath Oxoid X & V Factor Discs  
Unipath Oxoid X Factor Discs  
Vitek Rapid E System  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Manual antimicrobial susceptibility testing (MIC)  
Unipath Oxoid Diagnostic Reagent PET-RPLA  
Unipath Oxoid Diagnostic Reagent TST-RPLA  
Unipath Oxoid Diagnostic Reagent VET-RPLA  
*Analyte:* Bacterial organisms  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Manual Nucleic Acid analysis  
*Test Category:* Serogrouping or typing  
*Test System, Assay or Examination:* All Test Systems, Assays or Examinations  
*Analyte:* Chlamydia  
*Test Category:* Antigen or toxin test procedures or kits requiring microscopic evaluations  
*Test System, Assay or Examination:* Analytab IMAGEN  
Baxter Bartels Chlamydiae Fluorescent Monoclonal Antibody  
Baxter Bartels Chlamydiae Immunoperoxidase Test Kit  
Cellabs Diagnostics Chlamydia-Cel TWAR IFA Test  
Diagnostic Products Corp. Chlamydia-Check  
Diagnostic Products Corp. PathoDx Chlamydia Trachomatis  
Difco Chlamydia Direct Detection System  
Incstar Chlamydia Direct Test System  
Ortho Chlamydia (DFA)  
Ortho Cultureset Chlamydia Identification Kit (FA)  
Ortho Cultureset Chlamydia Identification Kit (PAP)  
Sanofi/Kallestad Pathfinder (FA)  
Scimedx Chlamydia Test Kit  
Syva Microtrak Culture confirmation  
Syva Microtrak Direct Specimen  
Wellcome Chlamysel  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* ADI Diagnostics Visuwel Chlamydia (direct antigen)  
Abbott Chlamydiazyme (EIA) (direct antigen)  
Baxter Bartels Chlamydia (EIA) (direct antigen)  
Ciba Corning Magic Lite Chlamydia (direct antigen)  
Ortho Chlamydia Antigen ELISA Test (direct antigen)  
Sanofi/Kallestad Pathfinder Chlamydia Microplate (dir. Ag)  
Syva Microtrak Chlamydia EIA (direct antigen)  
*Analyte:* Clostridium difficile  
*Test Category:* Antigen or toxin test procedures or kits requiring microscopic evaluations  
*Test System, Assay or Examination:* Advanced Clinical Diag. CDT Toxin Test  
Baxter C. difficile Toxin Assay Kit  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Baxter C. difficile Toxin A (EIA)  
Cambridge Biotech Cytoclone A & B (EIA)  
*Analyte:* Legionella  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Binax Equate Legionella Urinary Antigen Kit  
*Analyte:* Legionella pneumophila  
*Test Category:* Antigen or toxin test procedures or kits requiring microscopic evaluations  
*Test System, Assay or Examination:* Genetic Systems Legionella IFA Test Kit  
Litton Legionella/DFA  
Medical Diagnostics Technologies Legionella  
Scimedx Legionella Test Kit/DFA  
Zeus Legionella/DFA & IFA  
*Analyte:* Neisseria gonorrhoeae  
*Test Category:* Antigen or toxin test procedures or kits requiring microscopic evaluations  
*Test System, Assay or Examination:* Baxter Bartels N. gonorrhoeae Direct Fluorescent  
Incstar N.gonorrhoeae Fluoro-Kit  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Abbott Gonozyme (direct antigen)  
*Analyte:* Salmonella  
*Test Category:* Serogrouping or typing  
*Test System, Assay or Examination:* Analytab API Serum Immure Salmonella Test Kit  
Wellcome Wellcolex Colour Salmonella Test  
*Analyte:* Shigella  
*Test Category:* Serogrouping or typing  
*Test System, Assay or Examination:* Wellcome Wellcolex Colour Shigella Test  
*Analyte:* Streptococcus, group A  
*Test Category:* Antigen or toxin test procedures or kits requiring microscopic evaluations  
*Test System, Assay or Examination:* Incstar Group A Streptococcus Fluoro-Kit (DFA test)  
Zeus Group A Strep/DFA  
*Speciality/Subspeciality:* General Chemistry  
*Analyte:* ALT (SGPT)  
*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process  
*Test System, Assay or Examination:* Abbott Bichromatic ABA 100  
Abbott Bichromatic ABA 200  
American Monitor KDA  
American Monitor Parallel  
Technicon SMAC  
*Analyte:* AST (SGOT)  
*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process  
*Test System, Assay or Examination:* Abbott Bichromatic ABA 100  
Abbott Bichromatic ABA 200  
American Monitor KDA  
American Monitor Parallel  
Technicon SMA 12/60  
Technicon SMAC  
*Analyte:* Albumin  
*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process  
*Test System, Assay or Examination:* American Monitor KDA  
American Monitor Parallel  
Technicon SMA 12/60  
Technicon SMAC  
*Analyte:* Alkaline Phosphatase (ALP)  
*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process  
*Test System, Assay or Examination:* Abbott Bichromatic ABA 100  
Abbott Bichromatic ABA 200  
American Monitor KDA  
American Monitor Parallel  
*Analyte:* Alpha-Fetoprotein—Maternal Serum  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Abbott AFP EIA  
Hybritech Tandem-E  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:* Amersham Amerlex  
Clinical Assays GammaDab  
*Analyte:* Apolipoprotein B  
*Test Category:* Gel based immunochemical procedures  
*Test System, Assay or Examination:*

- Behring M-partigen Kit**  
*Analyte:* Bilirubin, Direct  
*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 American Monitor KDA  
 American Monitor Parallel  
 Technicon SMA 12/60  
 Technicon SMAC
- Analyte: Bilirubin, Total**  
*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 American Monitor KDA  
 American Monitor Parallel  
 Technicon SMA 12/60  
 Technicon SMAC
- Analyte: Blood Gases**  
*Test Category:* Automated or semi-auto blood gas analyses requiring operator intervention to calibrate instrument, equilibrate gas supplies, introduce sample into measuring chamber or flush sample line  
*Test System, Assay or Examination:*  
 Ciba Corning 158  
 Ciba Corning 168  
 Ciba Corning 170  
 Ciba Corning 178
- Analyte: Blood Lead**  
*Test Category:* Anodic stripping voltametry  
*Test System, Assay or Examination:* All Test Systems, Assays or Examinations  
*Test Category:* Atomic absorption  
*Test System, Assay or Examination:* All Test Systems, Assays or Examinations
- Analyte: CO<sub>2</sub>**  
*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Technicon SMA 6/60  
 Technicon SMAC
- Analyte: Calcium, total**  
*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 American Monitor KDA  
 American Monitor Parallel  
 Technicon SMA 12/60  
 Technicon SMAC
- Analyte: Chloride**  
*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Buchler Chloridometer  
 Technicon SMA 6/60
- Technicon SMAC**  
*Analyte:* Chloride, Sweat (Cystic Fibrosis Sweat Test)  
*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Advanced Instruments Cystic Fibrosis Analyzer
- Analyte: Cholesterol**  
*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 American Monitor KDA  
 American Monitor Parallel  
 Technicon SMA 12/60  
 Technicon SMAC
- Analyte: Cortisol**  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:*  
 Amersham Amerlite  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:*  
 Amersham Amerlex  
 Becton Dickinson Corti-Cote  
 Bio-Rad Quantimune  
 Ciba Corning Magic (MGC)  
 Clinical Assays GammaCoat  
 Diagnostic Products Corp. Double Antibody  
 Micromedic Systems CONCEPT 4  
 Organon NML  
 Sanofi/Kallestad Quanticcoat
- Analyte: Creatine Kinase (CK)**  
*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott Bichromatic ABA 100  
 Abbott Bichromatic ABA 200  
 American Monitor KDA  
 American Monitor Parallel  
 Technicon SMA 12/60  
 Technicon SMAC
- Analyte: Creatinine**  
*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process  
*Test System, Assay or Examination:*  
 Abbott Bichromatic ABA 100  
 Abbott Bichromatic ABA 200  
 American Monitor KDA  
 American Monitor Parallel  
 Technicon SMA 12/60  
 Technicon SMA 6/60  
 Technicon SMAC
- Analyte: Estradiol**  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:*  
 Amersham Amerlite
- Analyte: Estriol-Total**  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:*  
 Amersham Amerlex  
 Clinical Assays GammaDab  
 Diagnostic Products Corp. Coat-A-Count
- Analyte: Estriol-unconjugated**  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:*  
 Amersham Amerlex  
 Diagnostic Products Corp. Coat-A-Count
- Analyte: Ferritin**  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:*  
 Amersham Amerlite  
 Hybritech Tandem-E  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:*  
 Amersham Amerlex  
 Becton Dickinson MAB  
 Becton Dickinson Monoclonal Solid Phase Coated Tube  
 Bio-Rad Quantimune  
 Diagnostic Products Corp. Coat-A-Count  
 Hybritech Tandem-R  
 Nichols Institute Allegro  
 Ramco IRMA
- Analyte: Folate (Folic acid)**  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:*  
 Becton Dickinson Simultrac  
 Becton Dickinson Simultrac S  
 Becton Dickinson Simultrac SNB  
 Bio-Rad Quantphase  
 Ciba Corning Magic (MGC)  
 Ciba Corning Magic Boil  
 Ciba Corning Magic/NB (no boil)  
 Clinical Assays No Boil  
 Clinical Assays Solid Phase  
 Diagnostic Products Corp. Charcoal Boil  
 Diagnostic Products Corp. Dualcount Charcoal  
 Diagnostic Products Corp. Dualcount No Boil  
 Diagnostic Products Corp. Dualcount Solid Phase Boil  
 Diagnostic Products Corp. Solid Phase/No Boil  
 Micromedic Combostat II
- Analyte: Follicle Stimulating Hormone (FSH)**  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:*  
 Amersham Amerlite
- Analyte: Gamma Glutamyl Transferase (GGT)**  
*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process

*Test System, Assay or Examination:*

American Monitor KDA  
American Monitor Parallel  
Technicon SMAC

*Analyte:* Glucose

*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process

*Test System, Assay or Examination:*

Abbott Bichromatic ABA 100  
Abbott Bichromatic ABA 200  
American Monitor KDA  
American Monitor Parallel  
Technicon SMA 12/60  
Technicon SMA 6/60  
Technicon SMAC

*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process

*Test System, Assay or Examination:*

Sclavo  
Seradyn  
Stanbio

*Analyte:* Glycosylated Hemoglobin

*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process

*Test System, Assay or Examination:*

Binax Equate Glycohemoglobin

*Analyte:* HCG, Serum, Quantitative

*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process

*Test System, Assay or Examination:*

Abbott Beta-HCG 15/15  
Amersham Amerlite  
Diamedix Microassay Test Set  
Hybritech Tandem-E

*Test Category:* Radioimmunoassays*Test System, Assay or Examination:*

Amersham Amerlex-M  
Becton Dickinson MAB  
Becton Dickinson Solid Phase Coated Tube

Bio-Rad Cotube  
Ciba Corning Magic (MGC)  
Clinical Assays GammaDab  
Diagnostic Products Corp. Coat-A-Count  
Diagnostic Products Corp. Double Antibody  
Hybritech Tandem-R  
Nichols Institute Allegro  
Organon NML  
Serono HCG MAIA Clone

*Analyte:* HDL Cholesterol (post-precipitation VLDL & LDL)

*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process

*Test System, Assay or Examination:*

Abbott Spectrum  
Abbott Spectrum EPX  
Abbott Spectrum Series II  
Abbott Spectrum Series II CCX  
Abbott TDX  
Abbott TDX FLx

## Abbott VP

Abbott Vision  
American Monitor Diagnostics Excel  
American Monitor Diagnostics ISP 1000

American Monitor Diagnostics ISP 2000

American Monitor KDA  
American Monitor Parallel  
Ames Clinistat

Ames Seralyzer III

Baxter Paramax

Baxter Paramax 720 ZX

Beckman Synchron CX 4

Beckman Synchron CX 5

Beckman Synchron CX 7

Boehringer Mannheim Hitachi 704

Boehringer Mannheim Hitachi 705

Boehringer Mannheim Hitachi 717

Boehringer Mannheim Hitachi 736

Boehringer Mannheim Hitachi 737

Boehringer Mannheim Hitachi 747

Ciba Corning 550 Express

Ciba Corning 570 Alliance

Ciba Corning 580 Alliance

Dupont ACA

Dupont ACA IV

Dupont ACA V

Dupont Analyst

Dupont Dimension

Dupont Dimension AR

Electronucleonics Gem-Profiler

Electronucleonics Gemini

Electronucleonics Gemstar

Electronucleonics Gemstar II

Instrumentation Laboratories IL

Monarch

Instrumentation Laboratories IL

Monarch Plus

Kodak Ektachem 400

Kodak Ektachem 500

Kodak Ektachem 700

Kodak Ektachem 700 XR

Kodak Ektachem DT 60

Olympus AU 5000

Olympus Demand

Roche Cobas FARA

Roche Cobas FARA II

Roche Cobas Mira

Roche Cobas Mira S

Technicon AXON

Technicon Assist

Technicon Chem 1

Technicon DAX 24

Technicon DAX 48

Technicon DAX 72

Technicon DAX 98

Technicon RA 1000

Technicon RA 2000

Technicon RA 500

Technicon RA XT

*Analyte:* Insulin

*Test Category:* Radioimmunoassays

*Test System, Assay or Examination:*

Ciba Corning Magic (MGC)

Diagnostic Products Corp. Coat-a-

Count

Incstar Insulin

Pharmacia Insulin Test

*Analyte:* Iron

*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process

*Test System, Assay or Examination:*

American Monitor KDA  
American Monitor Parallel  
Technicon SMAC

*Analyte:* Iron Binding Capacity (post saturation/separation)

*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process

*Test System, Assay or Examination:*

Abbott TDX  
Abbott TDX FLx  
Abbott VP  
American Monitor Diagnostics Excel  
American Monitor Diagnostics ISP 1000

American Monitor Diagnostics ISP 2000

American Monitor KDA  
American Monitor Parallel

Baxter Paramax

Baxter Paramax 720 ZX

Beckman Synchron CX 4

Beckman Synchron CX 5

Beckman Synchron CX 7

Boehringer Mannheim Hitachi 704

Boehringer Mannheim Hitachi 705

Boehringer Mannheim Hitachi 717

Boehringer Mannheim Hitachi 736

Boehringer Mannheim Hitachi 737

Boehringer Mannheim Hitachi 747

Dupont ACA

Dupont ACA IV

Dupont ACA V

Dupont Dimension

Dupont Dimension AR

Electronucleonics Gem-Profiler

Electronucleonics Gemini

Electronucleonics Gemstar

Electronucleonics Gemstar II

Instrumentation Laboratories IL

Monarch

Instrumentation Laboratories IL

Monarch Plus

Kodak Ektachem 400

Kodak Ektachem 500

Kodak Ektachem 700

Kodak Ektachem 700 XR

Olympus AU 5000

Olympus Demand

Technicon Assist

Technicon Chem 1

Technicon RA 1000

Technicon RA 500

*Analyte:* Lactate Dehydrogenase (LDH)

*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process

*Test System, Assay or Examination:*

Abbott Bichromatic ABA 100

Abbott Bichromatic ABA 200

- American Monitor KDA  
American Monitor Parallel  
Technicon SMA 12/60  
Technicon SMAC  
*Analyte:* Lithium  
*Test Category:* Atomic absorption  
*Test System, Assay or Examination:*  
Instrumentation Laboratories AA  
Spectro  
Perkin Elmer  
*Test Category:* Flame photometry  
*Test System, Assay or Examination:*  
Beckman Flame Photometer  
Ciba Corning Flame Photometer  
Instrumentation Laboratories IL Flame  
Photometer/Elect  
Radiometer Flame Photometer  
*Analyte:* Luteinizing Hormone (LH)  
*Test Category:* Manual procedures with  
multiple steps in sample/reagent  
preparation or analytic process  
*Test System, Assay or Examination:*  
Amersham Amerlite  
NMS Pharmaceuticals COT Ovulation  
Test  
*Analyte:* Magnesium  
*Test Category:* Automated or semi-  
automated procedures that do  
require operator intervention during  
the analytic process  
*Test System, Assay or Examination:*  
American Monitor KDA  
American Monitor Parallel  
*Analyte:* Phosphorus  
*Test Category:* Automated or semi-  
automated procedures that do  
require operator intervention during  
the analytic process  
*Test System, Assay or Examination:*  
American Monitor KDA  
American Monitor Parallel  
Technicon SMA 12/60  
Technicon SMAC  
*Analyte:* Potassium  
*Test Category:* Automated or semi-  
automated procedures that do  
require operator intervention during  
the analytic process  
*Test System, Assay or Examination:*  
Technicon SMA 6/60  
Technicon SMAC  
*Test Category:* Flame photometry  
*Test System, Assay or Examination:*  
Beckman Flame Photometer  
Instrumentation Laboratories IL Flame  
Photometer/Elect  
Radiometer Flame Photometer  
*Analyte:* Progesterone  
*Test Category:* Manual procedures with  
multiple steps in sample/reagent  
preparation or analytic process  
*Test System, Assay or Examination:*  
Amersham Amerlite  
*Analyte:* Prolactin  
*Test Category:* Manual procedures with  
multiple steps in sample/reagent  
preparation or analytic process  
*Test System, Assay or Examination:*  
Amersham Amerlite
- Hybritech Tandem-E  
*Analyte:* Prostatic Acid Phosphatase  
*Test Category:* Manual procedures with  
multiple steps in sample/reagent  
preparation or analytic process  
*Test System, Assay or Examination:*  
Abbott PAP EIA  
Hybritech Tandem-E  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:*  
Clinical Assays GammaDab  
Dupont RIANEN  
Hybritech Tandem-R  
Yang Laboratories RIA  
*Analyte:* Protein, Total  
*Test Category:* Automated or semi-  
automated procedures that do  
require operator intervention during  
the analytic process  
*Test System, Assay or Examination:*  
Technicon SMA 12/60  
Technicon SMAC  
*Analyte:* Retinol binding protein  
*Test Category:* Gel based  
immunochemical procedures  
*Test System, Assay or Examination:*  
Behring LC-partigen Kit  
*Analyte:* Sodium  
*Test Category:* Automated or semi-  
automated procedures that do  
require operator intervention during  
the analytic process  
*Test System, Assay or Examination:*  
Technicon SMA 6/60  
Technicon SMAC  
*Test Category:* Flame photometry  
*Test System, Assay or Examination:*  
Beckman Flame Photometer  
Instrumentation Laboratories IL Flame  
Photometer/Elect  
Radiometer Flame Photometer  
*Analyte:* Thyroid Stimulating Hormone  
(TSH)  
*Test Category:* Manual procedures with  
multiple steps in sample/reagent  
preparation or analytic process  
*Test System, Assay or Examination:*  
Amersham Amerlite  
Ciba Corning Magic Lite  
Diamedix Microassay Test Set  
Hybritech Tandem-E  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:*  
Abbott RIA Bead  
Becton Dickinson MAB  
Bio-Rad Cotube  
Bio-Rad Echoclonal  
Ciba Corning MAB (monoclonal)  
Ciba Corning Magic (MGC)  
Clinical Assays GammaDab  
Diagnostic Products Corp. Coat-A-  
Count  
Hybritech Tandem-R  
Nichols Institute Allegro  
Organon NML  
Organon NML L.E.S.  
Sanofi/Kallestad Quanticlone  
Serono Maiacalone  
Ventrex
- Analyte:* Thyroid Stimulating Hormone  
(TSH) (Neonatal)  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:*  
Diagnostic Products Corp. Double  
Antibody  
*Analyte:* Thyroid Stimulating  
Hormone—high sens. (TSH-HS)  
*Test Category:* Manual procedures with  
multiple steps in sample/reagent  
preparation or analytic process  
*Test System, Assay or Examination:*  
Hybritech Tandem-E  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:*  
Clinical Assays GammaCoat  
Hybritech Tandem-R  
*Analyte:* Thyroxine (T4)  
*Test Category:* Manual procedures with  
multiple steps in sample/reagent  
preparation or analytic process  
*Test System, Assay or Examination:*  
Amersham Amerlite  
Diamedix Microassay Test Set  
Syva Emit  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:*  
Becton Dickinson Monoclonal Solid  
Phase Coated Tube  
Ciba Corning Magic (MGC)  
Clinical Assays GammaCoat  
Diagnostic Products Corp. Coat-a-  
Count  
Micromedic Systems CONCEPT 4  
Organon NML Tetra Tab  
Organon NML Tetra Tube  
Sanofi/Kallestad Quanticcoat  
Ventrex Coated Tube  
*Analyte:* Thyroxine, Free (FT-4)  
*Test Category:* Manual procedures with  
multiple steps in sample/reagent  
preparation or analytic process  
*Test System, Assay or Examination:*  
Amersham Amerlite  
Ciba Corning Magic Lite  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:*  
Amersham Amerlex-M  
Becton Dickinson MAB  
Becton Dickinson Simultrac  
Becton Dickinson Solid Phase Coated  
Tube  
Ciba Corning Magic (MGC)  
Clinical Assays Direct FT4  
Clinical Assays Two Step  
Diagnostic Products Corp. Coat-a-  
Count  
*Analyte:* Triglyceride  
*Test Category:* Automated or semi-  
automated procedures that do  
require operator intervention during  
the analytic process  
*Test System, Assay or Examination:*  
American Monitor KDA  
American Monitor Parallel  
Technicon SMA 12/60  
Technicon SMAC  
*Analyte:* Triiodothyronine (T-3) Uptake

**Test Category:** Manual procedures with multiple steps in sample/reagent preparation or analytic process

**Test System, Assay or Examination:**  
Amersham Amerlite  
Ciba Corning Magic Lite  
Diamedix Microassay Test Set

**Test Category:** Radioimmunoassays

**Test System, Assay or Examination:**

Abbott Triobead 125  
Becton Dickinson Solid Phase  
Ciba Corning Magic (MGC) (25-35 normal range)  
Ciba Corning Magic (MGC) (35-45 normal range)

Clinical Assays GammaCoat  
Diagnostic Products Corp. Coat-a-Count

Microgenics

Micromedic Systems CONCEPT

Organon NML Tri Tab

Organon NML Tri Tube T3U

Sanofi/Kallestad Quanticoat

**Analyte:** Triiodothyronine (T3)

**Test Category:** Manual procedures with multiple steps in sample/reagent preparation or analytic process

**Test System, Assay or Examination:**  
Amersham Amerlite

**Test Category:** Radioimmunoassays

**Test System, Assay or Examination:**

Abbott RIA Bead  
Amersham Amerlex-M  
Becton Dickinson Solid Phase  
Bio-Rad Quantimune II  
Ciba Corning Magic (MGC)  
Clinical Assays GammaCoat  
Diagnostic Products Corp. Coat-A-Count

Diagnostic Products Corp. Double Antibody

Micromedic Systems CONCEPT 4

Organon NML

Sanofi/Kallestad Quanticoat

**Analyte:** Triiodothyronine, Free (FT-3)

**Test Category:** Manual procedures with multiple steps in sample/reagent preparation or analytic process

**Test System, Assay or Examination:**  
Amersham Amerlite

**Test Category:** Radioimmunoassays

**Test System, Assay or Examination:**

Amersham Amerlex-M  
Diagnostic Products Corp. Coat-a-Count

**Analyte:** Urea (BUN)

**Test Category:** Automated or semi-automated procedures that do require operator intervention during the analytic process

**Test System, Assay or Examination:**

Abbott Bichromatic ABA 100  
Abbott Bichromatic ABA 200  
American Monitor KDA  
American Monitor Parallel  
Technicon SMA 12/60  
Technicon SMA 6/60  
Technicon SMAC

**Test Category:** Manual procedures with multiple steps in sample/reagent preparation or analytic process

**Test System, Assay or Examination:**  
Seradyn

**Analyte:** Uric Acid

**Test Category:** Automated or semi-automated procedures that do require operator intervention during the analytic process

**Test System, Assay or Examination:**

American Monitor KDA  
American Monitor Parallel  
Technicon SMAC

**Test Category:** Manual procedures with multiple steps in sample/reagent preparation or analytic process

**Test System, Assay or Examination:**  
Seradyn

**Analyte:** Vitamin B12

**Test Category:** Radioimmunoassays

**Test System, Assay or Examination:**

Becton Dickinson Simultrac  
Becton Dickinson Simultrac S  
Becton Dickinson Simultrac SNB  
Bio-Rad Quantphase  
Ciba Corning Magic (MGC)  
Ciba Corning Magic Boil  
Ciba Corning Magic/NB (no boil)  
Clinical Assays No-Boil  
Clinical Assays Solid Phase  
Diagnostic Products Corp. Charcoal Boil

Diagnostic Products Corp. Dualcount Charcoal

Diagnostic Products Corp. Dualcount No Boil

Diagnostic Products Corp. Dualcount Solid Phase Boil

Diagnostic Products Corp. Solid Phase/N Boil

Micromedic Combostat II

**Speciality/Subspeciality:** General Immunology

**Analyte:** Adenovirus Antibodies

**Test Category:** Manual procedures with multiple steps in sample/reagent preparation or analytic process

**Test System, Assay or Examination:**  
Virotech ELISA Antibody Test

**Analyte:** Albumin

**Test Category:** Gel based immunochemical procedures

**Test System, Assay or Examination:**

Behring LC-partigen Kit  
Behring Nor-partigen Kit  
Kallestad Endoplate RID  
Kallestad Quantiplate RID

**Analyte:** Allergen specific IgE

**Test Category:** Manual procedures with multiple steps in sample/reagent preparation or analytic process

**Test System, Assay or Examination:**  
3M Allergen Specific IgE FAST-Plus Test

3M IgE FASTSCREEN Assay  
Alercheck Flipscreen II Visual Allergy Test

Alercheck Flipscreen quantitative

Allergy Tests

Diagnostic Products Corp. AlaSTAT  
MAST Allergy Systems  
(chemiluminescence)

**Analyte:** Allergen specific IgG

**Test Category:** Manual procedures with multiple steps in sample/reagent preparation or analytic process

**Test System, Assay or Examination:** 3M

Allergen Specific IgG4 FAST Test

**Analyte:** Alpha-1-Acid Glycoprotein (orosomuroid)

**Test Category:** Gel based immunochemical procedures

**Test System, Assay or Examination:**

Behring Nor-partigen Kit  
Hycor Accuplate

Kent Radial Immunodiffusion Test

**Analyte:** Alpha-1-Antitrypsin

**Test Category:** Gel based immunochemical procedures

**Test System, Assay or Examination:**

Behring Nor-partigen Kit  
Helena Laboratories Quiplate System for RID

Hycor Accuplate

Kallestad Endoplate RID

Kallestad Quantiplate RID

Kent Radial Immunodiffusion Test

**Analyte:** Alpha-2-Macroglobulin

**Test Category:** Gel based immunochemical procedures

**Test System, Assay or Examination:**

Behring Nor-partigen Kit

Kent Radial Immunodiffusion Test

**Analyte:** Alpha-Fetoprotein—Tumor Marker

**Test Category:** Manual procedures with multiple steps in sample/reagent preparation or analytic process

**Test System, Assay or Examination:**

Hybritech Tandem-E

**Test Category:** Radioimmunoassays

**Test System, Assay or Examination:**

Amersham Amerlex

Clinical Assays GammaDab

**Analyte:** Anti-Adrenal Antibodies

**Test Category:** Immunoassay methods requiring microscopic evaluations

**Test System, Assay or Examination:**

Scimedx Anti-adrenal Test System

**Analyte:** Anti-Brush Border Antibodies

**Test Category:** Immunoassay methods requiring microscopic evaluations

**Test System, Assay or Examination:**

Incstar Fluoro-Kit

**Analyte:** Anti-Canalicular Antibodies

**Test Category:** Immunoassay methods requiring microscopic evaluations

**Test System, Assay or Examination:**

Incstar Fluoro-Kit

**Analyte:** Anti-Cardiac Muscle

Antibodies

**Test Category:** Immunoassay methods requiring microscopic evaluations

**Test System, Assay or Examination:**

Scimedx CMA Test System

**Analyte:** Anti-Cardioplin Antibodies

*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process

*Test System, Assay or Examination:*

BioHyTech EIA Kit

Reaads Medical Products Anti-cardiolipin Semi-quant. Test

Sanofi/Kallestad Anti-cardiolipin Kit (EIA)

TheraTest Laboratories EL-ACA Test

*Analyte:* Anti-DNA Antibodies

*Test Category:* Immunoassay methods requiring microscopic evaluations

*Test System, Assay or Examination:*

Antibodies Inc. CrithiDNA Test Kit

Behring AFT System II

Incstar nDNA Fluoro-Kit

MarDx Anti-nDNA Antibody Test System

MeDiCa A-nDNA-A Test Kit

MeDiCa ANA/A-nDNA-A Test Kit

MeDiCa Multiple Antibody Test Kit

Sanofi/Kallestad Quantifluor Kit

Scimedx nDNA Test System

Virgo Anti-nDNA IFA Test

Zeus Anti-DNA Test System

*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process

*Test System, Assay or Examination:*

BioHyTech EIA Kit

Diamedix Microassay Test Set

Hemagen DNA

Reaads Medical Products Anti-ds DNA Semi-quantitative Test

Sigma EIA

TheraTest Laboratories EL-ANA

Profiles Test

Whittaker Bioproducts FIAX System

Whittaker Bioproducts RheumELISA kit

Whittaker Bioproducts dsDNA STAT

*Analyte:* Anti-DNP antibodies

*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process

*Test System, Assay or Examination:*

BioHyTech EIA Kit

Diamedix Microassay Test Set

Sigma EIA

*Analyte:* Anti-Histone Antibodies

*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process

*Test System, Assay or Examination:*

BioHyTech EIA Kit

*Analyte:* Anti-Jo-1

*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process

*Test System, Assay or Examination:*

Hemagen ENA

*Analyte:* Anti-Mitochondrial Antibodies (AMTA)

*Test Category:* Immunoassay methods requiring microscopic evaluations

*Test System, Assay or Examination:*

Behring AFT System I

Incstar Fluoro-Kit

MarDx Autoimmune IFA Screening Test System

MarDx Mitochondrial Antibodies Test System

MeDiCa AMA Test Kit

MeDiCa Multiple Antibody Test Kit

Sanofi/Kallestad Quantifluor Kit

Scimedx Auto Screen Test System

Scimedx MA Test System

Virgo AMA IFA Test

Zeus MA Test System

*Analyte:* Anti-Neutrophil Cytoplasm Antibodies

*Test Category:* Immunoassay methods requiring microscopic evaluations

*Test System, Assay or Examination:*

Scimedx Anti-Neutrophil Cytoplasm Antibody IFA Test System

*Analyte:* Anti-Nuclear Antibodies (ANA)

*Test Category:* Immunoassay methods requiring microscopic evaluations

*Test System, Assay or Examination:*

Amico ANA Test System

Antibodies Inc.

Behring AFT System I

Bion ANA Test Kit

Clinical Sciences

Hemagen

INOVA Diagnostics, Inc.

Immuno Concepts

Incstar ANA Colorimetric Kit

Incstar ANAFAST Kit

Incstar ANAFLUOR Kit

Incstar ANAZYME Kit

Incstar RL Fluoro-Kit ANA

Fluorescent test

MarDx ANA Test System

MarDx Autoimmune IFA Screening Test System

MeDiCa ANA Test Kit

MeDiCa ANA/A-nDNA-A Test Kit

MeDiCa Multiple Antibody Test Kit

Ortho Fluoraset ANA

Quidel ANA IFA kit

Sanofi/Kallestad Quantifluor Kit

Scimedx ANA Test System

Scimedx Auto Screen Test System

Virgo ANA IFA Test

Zeus ANA Test

*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process

*Test System, Assay or Examination:*

BioHyTech EIA Kit

Whittaker Bioproducts FIAX System

*Analyte:* Anti-Parietal Cell Antibodies

*Test Category:* Immunoassay methods requiring microscopic evaluations

*Test System, Assay or Examination:*

Incstar Fluoro-Kit

MarDx Autoimmune IFA Screening Test System

MarDx Parietal Cell Antibody Test System

MeDiCa APCA Test Kit

MeDiCa Multiple Antibody Test Kit

Sanofi/Kallestad Quantifluor Kit

Scimedx Auto Screen Test System

Scimedx PCA Test System

*Analyte:* Anti-RNP (Ribonucleoprotein)

*Test Category:* Gel based immunochemical procedures

*Test System, Assay or Examination:*

Behring ENA I Test

Scimedx ENA Detect I Test System

Scimedx ENA Detect II Test System

Scimedx ENA Detect III Test System

Zeus Poly-ENA Assay

*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process

*Test System, Assay or Examination:*

BioHyTech EIA Kit

Diamedix Microassay Test Set

General Biometrics ImmunoWELL

Sm/RNP Antibody Test

Hemagen ENA

Reaads Medical Products Anti-ENA

(Sm/RNP complex) Qual Test

TheraTest Laboratories EL-ANA

Profiles Test

Whittaker Bioproducts RheumELISA kit

*Analyte:* Anti-Reticulin Antibodies

*Test Category:* Immunoassay methods requiring microscopic evaluations

*Test System, Assay or Examination:*

Incstar Fluoro-Kit

Scimedx Auto Screen Test System

*Analyte:* Anti-Ribosomal Antibodies

*Test Category:* Immunoassay methods requiring microscopic evaluations

*Test System, Assay or Examination:*

Incstar Fluoro-Kit

*Analyte:* Anti-SS-A/Ro

*Test Category:* Gel based

immunochemical procedures

*Test System, Assay or Examination:*

Behring ENA II Test

Scimedx ENA Detect III Test System

Zeus Poly-ENA Assay

*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process.

*Test System, Assay or Examination:*

Diamedix Microassay Test Set

General Biometrics ImmunoWELL SS-

A (Ro) Antibody Test

Hemagen ENA

TheraTest Laboratories EL-ANA

Profiles Test

Whittaker Bioproducts RheumELISA kit

*Analyte:* Anti-SS-B/La

*Test Category:* Gel based

immunochemical procedures

*Test System, Assay or Examination:*

Behring ENA II Test

Scimedx ENA Detect II Test System

Scimedx ENA Detect III Test System

Zeus Poly-ENA Assay

*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process

*Test System, Assay or Examination:*

Diamedix Microassay Test Set

- General Biometrics ImmunoWELL SS-B (La) Antibody Test  
Hemagen ENA  
TheraTest Laboratories EL-ANA Profiles Test  
Whittaker Bioproducts RheumELISA kit  
*Analyte:* Anti-Scl-70  
*Test Category:* Gel based immunochemical procedures  
*Test System, Assay or Examination:* Behring ENA III Test  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Diamedix Microassay Test Set Hemagen ENA  
*Analyte:* Anti-Skin Antibodies  
*Test Category:* Immunoassay methods requiring microscopic evaluations  
*Test System, Assay or Examination:* MarDx Anti-Skin Antibody Test System  
MeDiCa ASA Test Kit  
Scimedx ASA Test System  
Zeus Anti-Skin Antibody Test System  
*Analyte:* Anti-Sm (Smith)  
*Test Category:* Gel based immunochemical procedures  
*Test System, Assay or Examination:* Behring ENA I Test  
Scimedx ENA Detect I Test System  
Scimedx ENA Detect II Test System  
Scimedx ENA Detect III Test System  
Zeus Poly-ENA Assay  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* BioHyTech EIA Kit  
Diamedix Microassay Test Set  
General Biometrics ImmunoWELL Sm Antibody Test  
Hemagen ENA  
Reaads Medical Products Anti-ENA (Sm/RNP complex) Qual Test  
Reaads Medical Products Anti-SM Qualitative Test  
TheraTest Laboratories EL-ANA Profiles Test  
Whittaker Bioproducts RheumELISA kit  
*Analyte:* Anti-Smooth Muscle Antibodies (ASMA)  
*Test Category:* Immunoassay methods requiring microscopic evaluations  
*Test System, Assay or Examination:* Behring AFT System I  
Incstar Fluoro-Kit  
MarDx Autoimmune IFA Screening Test System  
MarDx Smooth Muscle Antibody Test System  
MeDiCa ASMA Test Kit  
MeDiCa Multiple Antibody Test Kit  
Sanofi/Kallestad Quantifluor Kit  
Scimedx SMA Test System  
Zeus SMA Test System
- Analyte:* Anti-Thyroglobulin Antibodies (ATA)  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Ames Sera-tek  
General Biometrics Thyroglobulin Antibody Test  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:* Kronus Kalibre-R Thyroglobulin Antibody RIA Kit  
*Analyte:* Anti-Thyroid Antibodies  
*Test Category:* Immunoassay methods requiring microscopic evaluations  
*Test System, Assay or Examination:* Incstar MT Fluoro-Kit  
MarDx Anti-Thyroid Antibody Test System  
MeDiCa ATA Test Kit  
Sanofi/Kallestad Quantifluor Kit  
Scimedx TA Test System  
Zeus TA Test System  
*Analyte:* Anti-Thyroid Microsomal Antibodies (AMA)  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Ames Sera-tek  
General Biometrics  
Microsomal(Recombinant TPO) Ab Test  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:* Kronus Kalibre TPO Antibody RIA Kit  
*Analyte:* Bordetella pertussis Antibodies  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Labsystems Bordetella pertussis IgG EIA Kit  
*Analyte:* C-Reactive Protein (CRP)  
*Test Category:* Gel based immunochemical procedures  
*Test System, Assay or Examination:* Behring LC-partigen Kit  
Hycor Accuplate  
Kent Radial Immunodiffusion Test  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Whittaker Bioproducts FIAX System  
*Analyte:* Candida albicans Antibodies  
*Test Category:* Gel based immunochemical procedures  
*Test System, Assay or Examination:* Immuno-Mycologics ID-Candida Antibody System  
Meridian Diagnostics Candida Immunodiffusion System  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process
- Test System, Assay or Examination:* Immuno-Mycologics Candi-Sphere EIA (CEIA)  
*Analyte:* Carcinoembryonic Antigen (CEA)  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Abbott CEA-EIA Monoclonal  
Abbott CEA-EIA One-Step  
Hybritech Tandem-E  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:* Abbott RIA Monoclonal  
Hybritech Tandem-R  
*Analyte:* Ceruloplasmin  
*Test Category:* Gel based immunochemical procedures  
*Test System, Assay or Examination:* Behring Nor-partigen Kit  
Kent Radial Immunodiffusion Test  
*Analyte:* Chlamydia Trachomatis Antibodies  
*Test Category:* Immunoassay methods requiring microscopic evaluations  
*Test System, Assay or Examination:* Amico Amizyme Chlamydia Trachomatis Antibody Test  
Incstar Fluoro-Kit  
Virgo Chlamydia trachomatis IFA Test  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Whittaker Bioproducts CHLAMYDELISA II  
Whittaker Bioproducts CHLAMYDIA STAT  
*Analyte:* Coccidioides Antibodies  
*Test Category:* Gel based immunochemical procedures  
*Test System, Assay or Examination:* Immuno-Mycologics ID-Cocci Antibody System  
*Analyte:* Complement C1 inhibitor  
*Test Category:* Gel based immunochemical procedures  
*Test System, Assay or Examination:* Kent Radial Immunodiffusion Test  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Quidel C1-Inhibitor EIA  
*Analyte:* Complement C1q  
*Test Category:* Gel based immunochemical procedures  
*Test System, Assay or Examination:* Kent Radial Immunodiffusion Test  
*Analyte:* Complement C2  
*Test Category:* Gel based immunochemical procedures  
*Test System, Assay or Examination:* Kent Radial Immunodiffusion Test  
*Analyte:* Complement C3

- Test Category:* Gel based immunochemical procedures  
*Test System, Assay or Examination:* Behring Nor-partigen Kit  
 Helena Laboratories Quiplate System for RID  
 Hycor Accuplate  
 Kallestad Endoplate RID  
 Kallestad Quantiplate RID  
 Kent Radial Immunodiffusion Test  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Whittaker Bioproducts FIAX System  
*Analyte:* Complement C4  
*Test Category:* Gel based immunochemical procedures  
*Test System, Assay or Examination:* Behring Nor-partigen Kit  
 Helena Laboratories Quiplate System for RID  
 Hycor Accuplate  
 Kallestad Endoplate RID  
 Kallestad Quantiplate RID  
 Kent Radial Immunodiffusion Test  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Whittaker Bioproducts FIAX System  
*Analyte:* Complement C5  
*Test Category:* Gel based immunochemical procedures  
*Test System, Assay or Examination:* Kent Radial Immunodiffusion Test  
*Analyte:* Cytomegalovirus Antibodies (IgG/IgM)  
*Test Category:* Immunoassay methods requiring microscopic evaluations  
*Test System, Assay or Examination:* Amico Amizyme CMV Ab Test  
 Bion CMV-G Antibody Test System  
 Gull Laboratories CMV IgM Test  
 Gull Laboratories CMV Test  
 Incstar Fluoro-Kit  
 Virgo Cytomegalovirus IFA Test  
 Zeus CMV Test System  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Abbott CMV Total AB EIA  
 Diamedix Microassay Test Set  
 Gull Laboratories CMV IgG ELISA  
 Gull Laboratories CMV IgM ELISA  
 Immucor Capture CMV  
 Incstar Clin-ELISA Test System  
 Labsystems CMV IgG EIA Kit  
 Labsystems CMV IgM EIA Kit  
 Sigma EIA  
 Virotech ELISA Antibody Test  
 Whittaker Bioproducts CMV CAP-M  
 Whittaker Bioproducts CMV STAT  
 Whittaker Bioproducts CMV STAT M  
 Whittaker Bioproducts  
 CYTOMEGELISA II
- Whittaker Bioproducts FIAX System  
 Zeus CMV IgG ELISA  
*Analyte:* Entamoeba histolytica Antibodies  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Sigma EIA  
*Analyte:* Epstein-Barr virus Antibodies  
*Test Category:* Immunoassay methods requiring microscopic evaluations  
*Test System, Assay or Examination:* Amico Amizyme EBV Ab Test  
 Bion EBV-G (VCA) Antibody Test System  
 Bion EBV-M (VCA) Antibody Test System  
 Diagnostic Technology EBNA Check  
 Diagnostic Technology EBV Check  
 Diagnostic Technology EBV/EA Check  
 Diagnostic Technology EBV/IgM Check  
 Granbio Inc. EBNA Anti-complement IFA  
 Granbio Inc. Epstein-Barr EA IgG IFA  
 Granbio Inc. Epstein-Barr VCA IgG IFA  
 Granbio Inc. Epstein-Barr VCA IgM IFA  
 Gull Laboratories EBV IgM Test  
 Gull Laboratories EBV Test  
 Gull Laboratories EBV-EA Test  
 Gull Laboratories EBV-NA Test  
 Organon Teknika EB-VCA IFA Kit II  
 Organon Teknika EBNA ACIF Kit  
 Organon Teknika EBV-EA IFA Kit  
 Organon Teknika EBV-M Kit  
 Virgo Epstein-Barr Virus—VCA Antibody IFA Test  
 Zeus EBV-EA Test System  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Granbio Inc. Epstein-Barr VCA IgG EIA  
 Granbio Inc. Epstein-Barr VCA IgM EIA  
 Gull Laboratories EBV IgG ELISA  
 Gull Laboratories EBV IgM ELISA  
 Incstar Clin-ELISA Test System  
 Ortho EBNA IgG Antibody ELISA  
 Ortho Epstein-Barr Virus VCA-IgG Antibody ELISA  
 Ortho Epstein-Barr Virus VCA-IgM Antibody ELISA  
 Whittaker Bioproducts EB VCA STAT  
 Whittaker Bioproducts EB VCA STAT M  
 Whittaker Bioproducts EBNA STAT  
 Whittaker Bioproducts FIAX System  
*Analyte:* Febrile Agglutinins  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Becton Dickinson BBL—Tube Test
- Difco Bacto-Tube Test  
 Gamma Biologicals Tube Test  
*Analyte:* Fungus Antibodies  
*Test Category:* Gel based immunochemical procedures  
*Test System, Assay or Examination:* Immuno-Mycologics ID-Fungal Antibody System  
 Meridian Diagnostics Fungal Immunodiffusion System  
*Analyte:* HIV Antibody  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Abbott HIVAB HIV-1 EIA  
 Cambridge Biotech Recombigen (env. & gag) HIV-1 EIA  
 Cellular Products Retro-Tek HIV-1 ELISA  
 Dupont HIV-1 ELISA  
 Electronucleonics HIV-1 IgG EIA  
 Genetic Systems HIV-1/HIV-2 EIA  
 Genetic Systems HIV-2 EIA  
 Genetic Systems LAV EIA  
 Organon Teknika Bioenzabead HIV  
 Organon Teknika Vironostilca HIV  
 Ortho Diagnostics HIV-1 ELISA  
 Syva Microtrak HIV-1 (env & gag) EIA  
 United Biomedical HIV-1 EIA  
*Test Category:* Western blot  
*Test System, Assay or Examination:* Bio-Rad Novapathe HIV-1 Immunoblot  
 Cambridge Biotech HIV-1 WB  
 Organon Teknika Epiblot HIV  
*Analyte:* HIV Antigen  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Abbott HIVAG-1  
*Analyte:* HTLV Antibody  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Abbott HTLV-1 EIA  
 Cellular Products Retro-Tek HTLV-1 ELISA  
 Dupont HTLV-1 ELISA  
*Analyte:* Haptoglobin  
*Test Category:* Gel based immunochemical procedures  
*Test System, Assay or Examination:* Behring Nor-partigen Kit  
 Hycor Accuplate  
 Kallestad Endoplate RID  
 Kallestad Quantiplate RID  
 Kent Radial Immunodiffusion Test  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Whittaker Bioproducts FIAX System  
*Analyte:* Helicobacter pylori Antibodies

- Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Whittaker Bioproducts FIAX System  
 Whittaker Bioproducts PYLORI STAT  
*Analyte:* Hemopexin  
*Test Category:* Gel based immunochemical procedures  
*Test System, Assay or Examination:* Behring Nor-partigen Kit  
*Analyte:* Hepatitis A Antibody (HAVAb)  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Abbott HAVAB EIA  
 Organon Teknika Hepanostika Anti-HAV Microelisa System  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:* Abbott HAVAB  
 Sorin Biomedica AB-HAVK  
*Analyte:* Hepatitis A Antibody—IgM  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* ADI Diagnostics Anti-HAV IgM EIA (Heprofile)  
 Abbott HAVAB-M EIA  
 Organon Teknika Hepanostika Anti-HAV IgM Microelisa System  
 Sorin Biomedica ETI-HA-IgMK  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:* Abbott HAVAB-M RIA  
 Sorin Biomedica HA-IgMK (IRMA)  
*Analyte:* Hepatitis B Core Antibody (Hb Core)  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Abbott CORZYME  
 Genetic Systems Anti-HBc EIA  
 Organon Teknika Hepanostika ANTICORE Microelisa System  
 Ortho HBc ELISA  
 Sorin Biomedica ETI-AB-COREK (EIA)  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:* Abbott CORAB  
 Sorin Biomedica AB-COREK, AB-COREK J  
*Analyte:* Hepatitis B Core Antibody—IgM  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Abbott CORZYME-M  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:* Abbott CORAB-M  
 Sorin Biomedica CORE-IgMK (IRMA)  
*Analyte:* Hepatitis B Surface Antibody
- Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Abbott AUSAB Quantitation Panel  
 Abbott AUSAB-EIA  
 Organon Teknika Microplate Anti-HBs EIA  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:* Abbott AUSAB  
 Abbott AUSAB Quantitation Panel  
 Sorin Biomedica AB-AUK-3 (RIA)  
*Analyte:* Hepatitis B Surface Antigen (HBS Ag)  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Abbott AUSCELL (RPHA)  
 Abbott AUSCELL Confirmatory Test (RPHA)  
 Abbott AUSZYME (EIA)  
 Abbott AUSZYME Confirmatory Test  
 Genetic Systems HBsAg Confirmatory Test  
 Genetic Systems HBsAg EIA  
 Organon NML ELISA HBsAg Confirmatory Test  
 Organon NML ELISA HBsAg Screening Test  
 Ortho Antibody to HBsAg ELISA Confirmatory Test  
 Ortho Antibody to HBsAg ELISA Test System II  
 Pharmacia Hepatitis B Surface Antigen Confirmatory Test  
 Pharmacia Hepatitis B Surface Antigen-AntiHBs ELISA  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:* Abbott AUSRIA  
 Organon NML RIA HBsAg Confirmatory Test  
 Organon NML RIA HBsAg Screening Test  
 Sorin Biomedica AUK-3, AUK 3J (RIA)  
 Sorin Biomedica Confirmatory Test  
*Analyte:* Hepatitis Be Antibody  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Abbott HBe (rDNA) EIA  
 Organon Teknika Hepanostika HBeAg/Anti-HBe Microelisa  
 Sorin Biomedica ETI-EBK (EIA)  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:* Abbott HBe  
 Sorin Biomedica EBK (RIA)  
*Analyte:* Hepatitis Be Antigen  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Abbott HBe (rDNA) EIA  
 Organon Teknika Hepanostika
- HBeAg/Anti-HBe Microelisa  
 Sorin Biomedica ETI-EBK (EIA)  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:* Abbott HBe RIA  
 Sorin Biomedica EBK (RIA)  
*Analyte:* Hepatitis C Virus Antibody  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Abbott HCV-EIA  
 Ortho HCV ELISA  
*Analyte:* Hepatitis delta Antibody  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Abbott Anti-delta-EIA  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:* Abbott Anti-delta  
*Analyte:* Herpes simplex I and/or II Antibodies  
*Test Category:* Immunoassay methods requiring microscopic evaluations  
*Test System, Assay or Examination:* Amico Amizyme HSV Ab Test  
 Bion HSV1-G or HSV2-G Test System  
 Diagnostic Technology HSV Check  
 Cull Laboratories HSV IgM Test  
 Gull Laboratories HSV Test  
 Incstar Fluoro-Kit  
 Ortho Herpes simplex virus Antibodies Fluoraset  
 Virgo Herpes Simplex Virus Type 1 Antibody IFA Test  
 Virgo Herpes Simplex Virus Type 2 Antibody IFA Test  
 Zeus HSV Antibody Test System  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Diamedix Microassay Test Set  
 Gull Laboratories HSV-1 IgG ELISA  
 Gull Laboratories HSV-1 IgM ELISA  
 Gull Laboratories HSV-2 IgG ELISA  
 Gull Laboratories HSV-2 IgM ELISA  
 Incstar Clin-ELISA Test System  
 Sigma EIA  
 Whittaker Bioproducts FIAX System  
 Whittaker Bioproducts HERPELISA II  
 Whittaker Bioproducts HERPES 1&2 STAT  
 Whittaker Bioproducts HERPES STAT  
 Zeus HSV-1 and HSV-2 ELISA  
*Analyte:* Histoplasma Antibodies  
*Test Category:* Gel based immunochemical procedures  
*Test System, Assay or Examination:* Immuno-Mycologics ID-Histo Antibody System  
*Analyte:* Immune complexes (CIC)  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:*

- Diamedix Microassay Test Set  
 Quidel CIC-C1q EIA  
 Quidel CIC-Raji Cell Replacement EIA  
 Sigma EIA  
*Analyte:* Immunoglobulins—  
 monoclonal/polyclonal  
*Test Category:* Electrophoresis  
*Test System, Assay or Examination:*  
 Helena Laboratories Titan Gel  
 ImmunoFix  
 Helena Laboratories Titan Gel  
 Immunoelectrophoresis  
 Kallestad Immunoelectrophoresis  
 System  
*Analyte:* Immunoglobulins IgA  
*Test Category:* Gel based  
 immunochemical procedures  
*Test System, Assay or Examination:*  
 Behring LC-partigen Kit  
 Behring Nor-partigen Kit  
 Helena Laboratories Quiplate System  
 for RID  
 Hycor Accuplate  
 Kallestad Endoplate RID  
 Kallestad Quantiplate RID  
 Kent Radial Immunodiffusion Test  
*Test Category:* Manual procedures with  
 multiple steps in sample/reagent  
 preparation or analytic process  
*Test System, Assay or Examination:*  
 Whittaker Bioproducts FIAX  
 System  
*Analyte:* Immunoglobulins IgD  
*Test Category:* Gel based  
 immunochemical procedures  
*Test System, Assay or Examination:*  
 Helena Laboratories Quiplate System  
 for RID  
 Hycor Accuplate  
 Kallestad Endoplate RID  
 Kallestad Quantiplate RID  
 Kent Radial Immunodiffusion Test  
*Analyte:* Immunoglobulins IgE  
*Test Category:* Manual procedures with  
 multiple steps in sample/reagent  
 preparation or analytic process  
*Test System, Assay or Examination:*  
 3M Total IgE II FAST Test  
 Alercheck Flipscreen Total IgE  
 Diagnostic Products Corp. AlaSTAT  
 Total IgE  
 Nichols Institute Allegro IgE  
 Whittaker Bioproducts FIAX System  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:*  
 Leeco Diagnostics IgE Quant  
*Analyte:* Immunoglobulins IgG  
*Test Category:* Gel based  
 immunochemical procedures  
*Test System, Assay or Examination:*  
 Behring LC-partigen Kit  
 Behring Nor-partigen Kit  
 Helena Laboratories Quiplate System  
 for RID  
 Hycor Accuplate  
 Kallestad Endoplate RID  
 Kallestad Quantiplate RID  
 Kent Radial Immunodiffusion Test
- Test Category:* Manual procedures with  
 multiple steps in sample/reagent  
 preparation or analytic process  
*Test System, Assay or Examination:*  
 Whittaker Bioproducts FIAX System  
*Analyte:* Immunoglobulins IgG  
 subclasses  
*Test Category:* Manual procedures with  
 multiple steps in sample/reagent  
 preparation or analytic process  
*Test System, Assay or Examination:*  
 Janssen Biochimica IgG subclasses  
 ELISA Kit  
*Analyte:* Immunoglobulins IgM  
*Test Category:* Gel based  
 immunochemical procedures  
*Test System, Assay or Examination:*  
 Behring LC-partigen Kit  
 Behring Nor-partigen Kit  
 Helena Laboratories Quiplate System  
 for RID  
 Hycor Accuplate  
 Kallestad Endoplate RID  
 Kallestad Quantiplate RID  
 Kent Radial Immunodiffusion Test  
*Test Category:* Manual procedures with  
 multiple steps in sample/reagent  
 preparation or analytic process  
*Test System, Assay or Examination:*  
 Whittaker Bioproducts FIAX System  
*Analyte:* Influenza A Antibodies  
*Test Category:* Manual procedures with  
 multiple steps in sample/reagent  
 preparation or analytic process  
*Test System, Assay or Examination:*  
 Virotech ELISA Antibody Test  
*Analyte:* Influenza B Antibodies  
*Test Category:* Manual procedures with  
 multiple steps in sample/reagent  
 preparation or analytic process  
*Test System, Assay or Examination:*  
 Virotech ELISA Antibody Test  
*Analyte:* Legionella Antibodies  
*Test Category:* Immunoassay methods  
 requiring microscopic evaluations  
*Test System, Assay or Examination:*  
 MarDx Legionella IFA Test System  
 Organon Teknika Legionella IFA Kit I  
 Scimedx Lyme Detect Test System  
 Zeus Legionella IFA  
*Analyte:* Lyme Disease Antibodies  
 (Borrelia burgdorferi Abs)  
*Test Category:* Immunoassay methods  
 requiring microscopic evaluations  
*Test System, Assay or Examination:*  
 MarDx Lyme Disease IgG IFA Test  
 System  
 MarDx Lyme Disease IgM IFA Test  
 System  
 Scimedx Lyme Detect Test System  
 Zeus Lyme Disease Antibody Test  
 System  
*Test Category:* Manual procedures with  
 multiple steps in sample/reagent  
 preparation or analytic process  
*Test System, Assay or Examination:*  
 3M IgG/IgM FASTLYME Test  
 Cambridge Biotech Human Lyme EIA  
 Diamedix Microassay Test Set
- General Biometrics Borrelia (Lyme)  
 Test*  
*General Biometrics Recombinant P39  
 (Lyme) Test*  
 Gull Laboratories Lyme IgM ELISA  
 MarDx Lyme Disease EIA (IgM & IgG)  
 MarDx Lyme Disease EIA IgG  
 MarDx Lyme Disease EIA IgM  
 Sigma EIA  
 Whittaker Bioproducts FIAX System  
 Whittaker Bioproducts LYME STAT  
 Whittaker Bioproducts LYME STAT  
 M  
 Zeus Lyme ELISA  
 Zeus Lyme IgG ELISA  
 Zeus Lyme IgM ELISA  
*Analyte:* Mumps Antibodies  
*Test Category:* Immunoassay methods  
 requiring microscopic evaluations  
*Test System, Assay or Examination:*  
 Virgo Mumps Antibody IFA Test  
*Test Category:* Manual procedures with  
 multiple steps in sample/reagent  
 preparation or analytic process  
*Test System, Assay or Examination:*  
 Whittaker Bioproducts FIAX System  
 Whittaker Bioproducts MUMPSTAT  
*Analyte:* Mycoplasma pneumonia  
 Antibodies  
*Test Category:* Immunoassay methods  
 requiring microscopic evaluations  
*Test System, Assay or Examination:*  
 Zeus MP IgM Test System  
 Zeus MP Test System  
*Test Category:* Manual procedures with  
 multiple steps in sample/reagent  
 preparation or analytic process  
*Test System, Assay or Examination:*  
 Incstar IgM-MP Reverse ELISA Kit  
 Incstar Mp Test IgM/IgG MA Reverse  
 ELISA Kit  
 Seradyn Color Vue  
 Whittaker Bioproducts FIAX System  
 Whittaker Bioproducts  
 MYCOPLASMA STAT  
 Whittaker Bioproducts  
 MYCOPLASMELISA II  
*Analyte:* Plasminogen  
*Test Category:* Gel based  
 immunochemical procedures  
*Test System, Assay or Examination:*  
 Helena Laboratories Quiplate System  
 for RID  
*Analyte:* Prealbumin  
*Test Category:* Gel based  
 immunochemical procedures  
*Test System, Assay or Examination:*  
 Behring M-partigen Kit  
 Kent Radial Immunodiffusion Test  
*Analyte:* Properdin Factor B  
*Test Category:* Gel based  
 immunochemical procedures  
*Test System, Assay or Examination:*  
 Kent Radial Immunodiffusion Test  
*Analyte:* Prostatic Specific Antigen  
 (PSA)

- Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Hybritech Tandem-E  
*Analyte:* Protein Fractions  
*Test Category:* Electrophoresis  
*Test System, Assay or Examination:* Helena Laboratories Super Z Serum Protein Kit  
 Helena Laboratories Titan Gel High Resolution Protein Kit  
*Analyte:* Respiratory syncytial virus Antibodies  
*Test Category:* Immunoassay methods requiring microscopic evaluations  
*Test System, Assay or Examination:* Gull Laboratories RSV Test  
 Virgo RSV Antibody IFA Test  
*Analyte:* Rheumatoid Factor (RA)  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Alercheck RF Assay  
 Diamedix Microassay Test Set  
 Hemagen RF  
 Sigma EIA  
 Whittaker Bioproducts FIAX System  
*Analyte:* Rubella Antibodies, IgG/IgM  
*Test Category:* Immunoassay methods requiring microscopic evaluations  
*Test System, Assay or Examination:* Virgo Rubella Antibody IFA Test  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Abbott Rubazyme  
 Abbott Rubazyme-M  
 Diamedix Microassay Test Set  
 Gull Laboratories Rubella IgG ELISA  
 Gull Laboratories Rubella IgM ELISA  
 Incstar Clin-ELISA Test System  
 Labsystems Rubella IgM EIA Kit  
 Sigma EIA  
 Whittaker Bioproducts FIAX System  
 Whittaker Bioproducts RUBECAP-M  
 Whittaker Bioproducts RUBELISA II  
 Whittaker Bioproducts RUBESTAT  
 Whittaker Bioproducts RUBESTAT M  
 Zeus Rubella IgG ELISA  
*Analyte:* Rubeola Antibodies (measles)  
*Test Category:* Immunoassay methods requiring microscopic evaluations  
*Test System, Assay or Examination:* Bion Measles-G Antibody Test System  
 Bion Measles-M Antibody Test System  
 Gull Laboratories Rubeola Test  
 Virgo Measles Antibody IFA Test  
 Zeus Measles Test System  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Diamedix Microassay Test Set  
 Gull Laboratories Rubeola IgG ELISA  
 Gull Laboratories Rubeola IgM ELISA  
 Incstar Clin-ELISA Test System  
 Virotech ELISA Antibody Test  
 Whittaker Bioproducts FIAX System  
 Whittaker Bioproducts MEASELESTAT M  
 Whittaker Bioproducts MEASELESTAT II  
*Analyte:* Schistosoma Antibodies  
*Test Category:* Immunoassay methods requiring microscopic evaluations  
*Test System, Assay or Examination:* Amico Amizyme Schistosoma species Ab Test System  
*Analyte:* TSH Receptor Antibody  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:* Kronus Kalibre-R TSH Receptor (TRAb) Kit  
*Analyte:* Tetanus toxoid Antibodies  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Labsystems Tetanus Toxoid EIA Test Kit  
*Analyte:* Toxoplasma gondii Antibodies (IgG/IgM)  
*Test Category:* Immunoassay methods requiring microscopic evaluations  
*Test System, Assay or Examination:* Amico Amizyme Toxoplasma gondii Ab Test System  
 Diagnostic Technology Toxo/IgM Check  
 Gull Laboratories Toxo IgM Test  
 Gull Laboratories Toxo Test  
 Incstar Fluoro-Kit  
 Organon Teknika Toxo IFA Kit I  
 Virgo Toxoplasma gondii Antibody IFA Test  
 Zeus IFA Toxoplasma Test System  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Abbott Toxo-G EIA Kit  
 Abbott Toxo-M EIA Kit  
 Diamedix Microassay Test Set  
 Gull Laboratories Toxo IgG ELISA  
 Gull Laboratories Toxo IgM ELISA  
 Incstar Clin-ELISA Test System  
 Labsystems Toxoplasma gondii IgG EIA Kit  
 Sigma EIA  
 Whittaker Bioproducts FIAX System  
 Whittaker Bioproducts TOXOCAP-M  
 Whittaker Bioproducts TOXOELISA II  
 Whittaker Bioproducts TOXOSTAT  
 Whittaker Bioproducts TOXOSTAT M  
 Zeus TOXO ELISA IgG  
 Zeus TOXO IgM ELISA  
*Analyte:* Transferrin  
*Test Category:* Gel based immunochemical procedures  
*Test System, Assay or Examination:* Behring Nor-partigen Kit  
 Helena Laboratories Quipate System  
 for RID  
 Hycor Accuplate  
 Kallestad Endoplate RID  
 Kallestad Quantiplate RID  
 Kent Radial Immunodiffusion Test  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Whittaker Bioproducts FIAX System  
*Analyte:* Treponema pallidum Antibodies  
*Test Category:* Immunoassay methods requiring microscopic evaluations  
*Test System, Assay or Examination:* Incstar Fluoro-Kits (FTA-ABS)  
 MarDx FTA-ABS Test System  
 Scimedx FTA-ABS Test System  
 Virgo FTA-ABS IFA Test  
 Zeus FTA-ABS Test System  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* ADI Diagnostics Visuwell Reagin  
 Difco Bacto VDRL  
 Fisher Diagnostic VDRL  
*Analyte:* Varicella-Zoster Virus Antibodies  
*Test Category:* Immunoassay methods requiring microscopic evaluations  
*Test System, Assay or Examination:* Gull Laboratories VZV Test  
 Virgo Varicella-zoster Antibody IFA Test  
 Zeus VZ IgG IFA Test System  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Diamedix Microassay Test Set  
 Incstar Clin-ELISA Test System  
 Sigma EIA  
 Whittaker Bioproducts FIAX System  
 Whittaker Bioproducts VARICELISA II  
 Whittaker Bioproducts VARICELLA STAT  
*Speciality/Subspeciality:* Hematology  
*Analyte:* Activated Partial Thromboplastin Time (APTT)  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Manual coagulation assays  
*Analyte:* Antithrombin III (ATIII)  
*Test Category:* Gel based immunochemical procedures  
*Test System, Assay or Examination:* Behring Nor-partigen Kit  
 Helena Laboratories Quipate System for RID  
 Kent Radial Immunodiffusion Test  
*Analyte:* Fibrinogen  
*Test Category:* Gel based immunochemical procedures  
*Test System, Assay or Examination:*

- Behring Nor-partigen Kit**  
*Analyte:* Hematocrit  
*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process  
*Test System, Assay or Examination:* Technicon H 6000 Technicon H1  
*Analyte:* Hemoglobin  
*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process  
*Test System, Assay or Examination:* Technicon H 6000 Technicon H1  
*Analyte:* Hemoglobin F  
*Test Category:* Gel based immunochemical procedures  
*Test System, Assay or Examination:* Helena Laboratories Quipate System for RID  
*Analyte:* Platelet Count  
*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process  
*Test System, Assay or Examination:* Technicon H 6000 Technicon H1  
*Test Category:* Manual cell counts  
*Test System, Assay or Examination:* All Test Systems, Assays or Examinations  
*Analyte:* Pleural Fluid Microscopic Elements  
*Test Category:* Manual cell counts  
*Test System, Assay or Examination:* All Test Systems, Assays or Examinations  
*Analyte:* Prothrombin Time (PT)  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Manual coagulation assays  
*Analyte:* Red Blood Cell Count (Erythrocyte Count)  
*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process  
*Test System, Assay or Examination:* Technicon H 6000 Technicon H1  
*Analyte:* Reticulocyte Count  
*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process  
*Test System, Assay or Examination:* Sysmex R1000  
*Test Category:* Manual reticulocyte counts  
*Test System, Assay or Examination:* All Test Systems, Assays or Examinations  
*Analyte:* White Blood Cell (WBC) Differential
- Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process  
*Test System, Assay or Examination:* Technicon H 6000 Technicon H1  
*Test Category:* Manual white blood cell differential counts when the analyst is required to identify atypical cells  
*Test System, Assay or Examination:* All Test Systems, Assays or Examinations  
*Analyte:* White Blood Cell Count (Leukocyte Count)  
*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process  
*Test System, Assay or Examination:* Technicon H 6000 Technicon H1  
*Speciality/Subspeciality:* Immunohematology  
*Analyte:* ABH secretor status—Saliva  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Amtec Anti-H Lectin—qualitative BCA Anti-H Lectin—qualitative Dade Lectin-H—qualitative Dade Lectin-H—quantitative Gamma Anti-H Lectin—qualitative Gamma Anti-H Lectin—quantitative  
*Analyte:* ABO group—RBC  
*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process  
*Test System, Assay or Examination:* Gamma STS-M Automated Blood Grouping Instrument Olympus PK1700 Automated Pretransfusion Blood Testing System  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Adsorption/Elution Procedures  
*Analyte:* ABO group confirmation—Serum, Plasma  
*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process  
*Test System, Assay or Examination:* Gamma STS-M Automated Blood Grouping Instrument Olympus PK1700 Automated Pretransfusion Blood Testing System  
*Analyte:* D(Rho) Type  
*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process  
*Test System, Assay or Examination:* Gamma STS-M Automated Blood
- Grouping Instrument**  
Olympus PK1700 Automated Pretransfusion Blood Testing System  
*Analyte:* Donor/Recipient Compatibility  
*Test Category:* Compatibility testing including when performed to determine donor/recipient compatibility; recipient & donor ABO group/D(Rho) type/antigen typing, direct antiglobulin test, tests for unexpected antibody detection & identification, & crossmatch procedures  
*Test System, Assay or Examination:* All Test Systems, Assays or Examinations  
*Analyte:* Du (Weak D RBC antigen)  
*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process  
*Test System, Assay or Examination:* Olympus PK1700 Automated Pretransfusion Blood Testing System  
*Analyte:* Fetal RBCs—Maternal Blood (fetal-maternal bleed)  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Du procedures with microscopic exam for mixed field agglut. Gamma Fetal Bleed Screening Test Indicator Cell Rosette Test Ortho FETALSCREEN  
*Analyte:* Isohemagglutinins  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Dade Neutr-AB Reagent—screen Dade Neutr-AB Reagent—titration Titration procedures  
*Analyte:* RBC antigen type other than A or B  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Adsorption/Elution Procedures Gamma Arachis hypogea Lectin Gamma Lectin System  
*Analyte:* Unexpected RBC antibody—detection—serum  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* 1 Stage Enzyme Procedures 2 Stage Enzyme Procedures Amtec Ficin Treated Screening Cells 1,2,3 Dade Rap-I.D. Polycation Potentiator System Direct Antiglobulin Test (tube) Gamma Ficin-Duet System Gamma Ficin-Pool Immucor Capture-R Ready-Screen

- Immucor Panoscreen I and II, Ficin-Treated  
*Analyte:* Unexpected RBC antibody—identification  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* All Test Systems, Assays or Examinations  
*Speciality/Subspeciality:* Mycobacteriology  
*Analyte:* Acid-fast bacteria  
*Test Category:* Antimycobacterial susceptibility testing  
*Test System, Assay or Examination:* All Test Systems, Assays or Examinations  
*Test Category:* Concentration, smear & primary culture inoculation  
*Test System, Assay or Examination:* All Test Systems, Assays or Examinations  
*Test Category:* Identification of Mycobacteria  
*Test System, Assay or Examination:* Becton Dickinson Bactec NAP TB Differentiation Test  
*Test Category:* Isolation and identification techniques  
*Test System, Assay or Examination:* All Test Systems, Assays or Examinations  
*Analyte:* Mycobacterium avium  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Manual Nucleic Acid analysis  
*Analyte:* Mycobacterium avium complex  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Gen-Probe AccuProbe (w/culture) Syngene Snap Culture ID Diagnostic Kit  
*Analyte:* Mycobacterium avium specific  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Gen-Probe AccuProbe (w/culture)  
*Analyte:* Mycobacterium gordonae  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Gen-Probe AccuProbe (w/culture)  
*Analyte:* Mycobacterium intracellulare  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Manual Nucleic Acid analysis  
*Analyte:* Mycobacterium intracellulare specific  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process
- Test System, Assay or Examination:* Gen-Probe AccuProbe (w/culture)  
*Analyte:* Mycobacterium kansasii  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Gen-Probe AccuProbe (w/culture)  
*Analyte:* Mycobacterium tuberculosis complex  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Gen-Probe AccuProbe (w/culture) Manual Nucleic Acid analysis Syngene Snap Culture ID Diagnostic Kit  
*Speciality/Subspeciality:* Mycology  
*Analyte:* All fungi  
*Test Category:* Isolation and identification of all fungi not specified in moderate complexity  
*Test System, Assay or Examination:* All Test Systems, Assays or Examinations  
*Analyte:* Blastomyces Dermatitidis  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Gen-Probe AccuProbe (w/culture)  
*Analyte:* Coccidioides immitis  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Gen-Probe AccuProbe (w/culture)  
*Analyte:* Cryptococcus  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Baxter MYCO—Immune Cryptococcal Ag Latex Agg (semi-quant) Gen-Probe AccuProbe (w/culture) Meridian Cryptococcal Antigen Latex Agg. (semi-quant) Meridian Diagnostics Premier Cryptococcal Ag (semi-quant)  
*Analyte:* Histoplasma capsulatum  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Gen-Probe AccuProbe (w/culture)  
*Analyte:* Systemic fungi  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Immuno-Mycologics Exo-Antigen ID System  
*Analyte:* Yeast  
*Test Category:* Automated or semi-automated procedures that do require operator intervention during the analytic process  
*Test System, Assay or Examination:*
- Abbott Quantum II Yeast ID system  
*Test Category:* Identification of Yeast not specified in moderate complexity  
*Test System, Assay or Examination:* Analytab API 20C Yeast Identification Kits  
 Analytab API Germ Tube  
 Analytab Yeast Ident  
 Baxter MicroScan Rapid Yeast Identification Panel  
 Carr-Scarborough C. albicans Disc Screening Kit  
 Innovative Diagnostic Systems IDS Rapid SS/U System  
 Medical Wire Equip. MicroRing YT  
*Speciality/Subspeciality:* Other  
*Analyte:* Eye Cornea Integrity  
*Test Category:* Eye bank microscopy procedures  
*Test System, Assay or Examination:* Slit Lamp Biomicroscopy  
 Specular Microscopy  
*Speciality/Subspeciality:* Parasitology  
*Analyte:* Blood, tissue & intestinal parasites  
*Test Category:* Concentration or differential stain techniques  
*Test System, Assay or Examination:* All Test Systems, Assays or Examinations  
*Analyte:* Intestinal parasites  
*Test Category:* Antigen or toxin test procedures or kits requiring microscopic evaluations  
*Test System, Assay or Examination:* Genetic Systems Pneumocystis Carinii IFA Test Kit  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Trend Scientific Giardia lamblia Direct Detection System  
*Speciality/Subspeciality:* Toxicology/TDM  
*Analyte:* Acetaminophen  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Syva Emit  
*Analyte:* Amikacin  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Ames TDA  
 Syva Emit  
*Analyte:* Carbamazepine  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Ames TDA  
 Syva Emit  
*Analyte:* Carbamazepine, Free

*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Syva Emit  
*Analyte:* Digoxin  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Syva Emit  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:* Abbott RIA Bead  
 Ciba Corning Magic (MGC)  
 Clinical Assays GammaCoat  
 Diagnostic Products Corp. Coat-a-Count  
 Sanofi/Kallestad Quanticat  
 Ventrex Coated Tube  
*Analyte:* Disopyramide  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Syva Emit  
*Analyte:* Ethosuximide  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Ames TDA  
 Syva Emit  
*Analyte:* Gentamicin  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Ames TDA  
 Syva Emit  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:* Clinical Assays GammaDab  
 Diagnostic Products Corp. Coat-a-Count  
*Analyte:* Lidocaine  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Syva Emit  
*Analyte:* Methotrexate  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Syva Emit  
*Analyte:* N-Acetylprocainamide (NAPA)  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Ames TDA  
 Syva Emit  
*Analyte:* Phenobarbital  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:*

Ames TDA  
 Syva Emit  
*Analyte:* Phenytoin  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Ames TDA  
 Syva Emit  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:* Clinical Assays GammaCoat  
*Analyte:* Phenytoin, Free  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Syva Emit  
*Analyte:* Primidone  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Ames TDA  
 Syva Emit  
*Analyte:* Procainamide  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Ames TDA  
 Syva Emit  
*Analyte:* Quinidine  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Ames TDA  
 Syva Emit  
*Analyte:* Theophylline  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Ames TDA  
 Syva Emit  
*Test Category:* Radioimmunoassays  
*Test System, Assay or Examination:* Clinical Assays GammaDab  
*Analyte:* Tobramycin  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Ames TDA  
 Syva Emit  
*Analyte:* Valproic Acid  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Ames TDA  
*Analyte:* Valproic Acid  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Syva Emit  
*Speciality/Subspeciality:* Virology

*Analyte:* Adenovirus  
*Test Category:* Antigen or toxin test procedures or kits requiring microscopic evaluations  
*Test System, Assay or Examination:* Analytab Adenovirus Test Kit (IFA)  
 Cambridge Biotech Adenoclone (IFA)  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Analytab Adenovirus Test Kit (EIA) (culture confirmation)  
 Analytab Adenovirus Type 40 & 41 (EIA) (culture confirm)  
 Cambridge Biotech Adenoclone (EIA) (culture confirmation)  
*Analyte:* All viruses  
*Test Category:* Isolation and identification techniques  
*Test System, Assay or Examination:* All Test Systems, Assays or Examinations  
*Analyte:* Cytomegalovirus  
*Test Category:* Antigen or toxin test procedures or kits requiring microscopic evaluations  
*Test System, Assay or Examination:* Baxter Bartels CMV Immediate Early Antigen IFA Direct  
 Baxter Bartels Direct CMV Kit  
 Ortho CMV Identification Reagent  
 Syva Microtrak CMV Culture Identification Kit  
*Analyte:* Herpes simplex  
*Test Category:* Antigen or toxin test procedures or kits requiring microscopic evaluations  
*Test System, Assay or Examination:* Baxter Bartels HSV FA Monoclonal Antibody Kit  
 Baxter Bartels HSV FA Test for ID & Diff. HSV I & II  
 Diagnostic Products Corp. PathoDx Herpes Typing  
 Ortho Cultureset HSV Isolation and ID System  
 Ortho HSV 1 & 2 Dichromatic Typing Reagent  
 Sanofi/Kallestad Pathfinder H simplex 1&2 D. Ant Det Sys  
 Syva Microtrak Syva HSV-1/HSV-2 Typing Test/Culture Confir  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Kodak SureCell (culture confirmation)  
 Wampole Virogen Herpes latex slide test (culture confirm)  
*Analyte:* Respiratory syncytial virus  
*Test Category:* Antigen or toxin test procedures or kits requiring microscopic evaluations  
*Test System, Assay or Examination:* Analytab Imagen RSV  
 Baxter Bartels RSV  
 Ortho RSV (IFA)

*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Sanofi/Kallestad Pathfinder RSV (spectrophotometric)  
*Analyte:* Respiratory viruses (Influenza A&B, parainfluenza)  
*Test Category:* Antigen or toxin test procedures or kits requiring microscopic evaluations  
*Test System, Assay or Examination:* Analytab IMAGEN Influenza—Virus A&B

*Baxter Bartels Viral Respiratory Kit*  
*Analyte:* Rotavirus  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Abbott Rotazyme II Diagnostic Kit (photometric)  
*Sanofi/Kallestad Pathfinder Rotavirus (spectrophotometric)*  
*Analyte:* Varicella-Zoster viruses  
*Test Category:* Antigen or toxin test procedures or kits requiring microscopic evaluations

*Test System, Assay or Examination:* Ortho Varicella-Zoster Virus Identification Reagent  
*Analyte:* Viruses  
*Test Category:* Manual procedures with multiple steps in sample/reagent preparation or analytic process  
*Test System, Assay or Examination:* Manual Nucleic Acid analysis  
[FR Doc. 92-4051 Filed 2-20-92; 12:29 pm]  
BILLING CODE 4120-03-M

# **Federal Register**

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**Friday  
February 28, 1992**

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## **Part IV**

### **Department of the Interior**

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**Bureau of Indian Affairs**

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**Tribal-State Compacts Approval; Class III  
(Casino) Gambling: Omaha Tribe, NE;  
Notice**

**DEPARTMENT OF THE INTERIOR****Bureau of Indian Affairs****Indian Gaming**

February 24, 1992.

**AGENCY:** Bureau of Indian Affairs, Interior.

**ACTION:** Notice of approved Tribal-State Compact.

**SUMMARY:** Pursuant to 25 U.S.C. 2710, of the Indian Gaming Regulatory Act of 1988 (Pub. L. 100-497), the Secretary of

the Interior shall publish, in the **Federal Register**, notice of approved Tribal-State Compacts for the purpose of engaging in Class III (casino) gambling on Indian reservations. The Assistant Secretary—Indian Affairs, Department of the Interior, through his delegated authority has approved a Tribal-State Compact between the Omaha Tribe of Nebraska and the State of Iowa executed on December 30, 1991.

**DATES:** This action is effective February 28, 1992.

**ADDRESSES:** Office of Tribal Services, Bureau of Indian Affairs, Department of the Interior, MS/MIB 4603, 1849 C Street NW., Washington, DC 20240.

**FOR FURTHER INFORMATION CONTACT:** Joyce Grisham, Bureau of Indian Affairs, Washington, DC 20240, (202) 208-7445.

Dated: February 24, 1992.

**Eddie F. Brown,**

*Assistant Secretary—Indian Affairs.*

[FR Doc. 92-4634 Filed 2-27-92; 8:45 am]

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# **federal register**

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**Friday  
February 28, 1992**

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**Part V**

**Department of Labor**

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**Office of the Secretary**

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**Use of Alternative Dispute Resolution  
and Negotiated Rulemaking Procedures  
by the Department of Labor; Notice**

**DEPARTMENT OF LABOR****Office of the Secretary****Use of Alternative Dispute Resolution and Negotiated Rulemaking Procedures by the Department of Labor****AGENCY:** Office of the Secretary.**ACTION:** Notice of interim ADR policy.

**SUMMARY:** The Department has developed an interim policy to implement two important amendments to the Administrative Procedure Act and certain provisions of the Executive Order on Civil Justice Reform (E.O. 12778). The two amendments are the Administrative Dispute Resolution Act (ADR Act), Public Law 101-552, and the Negotiated Rulemaking Act, Public Law 101-648. Both of these acts authorize and encourage agencies to use arbitration, mediation, negotiated rulemaking, and other consensual methods of dispute resolution. E.O. 12778, among other things, requires agencies to consider ADR methods wherever appropriate in litigation. The Department is issuing this interim policy, in conjunction with a planned regional pilot test of ADR, recognizing that refinements likely will be needed based on the experience gained with these techniques.

Section 3(a) of the ADR Act requires the Department to adopt a formal policy as to how it intends to implement that statute in each of the following areas: (a) Formal and informal adjudications; (b) rulemakings; (c) enforcement actions; (d) issuing approvals and variances; (e) contract administration; (f) litigation brought against or by any part of the Department; and (g) other Departmental actions.

**FOR FURTHER INFORMATION CONTACT:** Roland Droitsch, Deputy Assistant Secretary for Policy, U.S. Department of Labor. Telephone 202-523-6197.

**SUPPLEMENTARY INFORMATION:** In response to a requirement of the Administrative Dispute Resolution Act, Public Law 101-552 (ADR Act), the Department of Labor is developing a general policy on the use of alternative dispute resolution techniques to encourage their use whenever the parties involved agree to them and it is practical to do so in light of the requirements of other statutes. Among the alternative dispute resolution techniques mentioned in the ADR Act is the use of negotiated rulemaking under appropriate circumstances, the criteria for which are set forth in more detail in companion legislation, the Negotiated Rulemaking Act, Public Law 101-648.

While notice and comment is not required for statements of policy or procedural rules, such a course has been recommended by the Administrative Conference of the United States for ADR policy statements. Implementing the ADR Act: Guidance for Agency Dispute Resolution Specialists, Office of the Chairman, Administrative Conference of the United States, Feb. 1992, pp. 19-22. Accordingly, the Department published a notice in the *Federal Register* on May 22, 1991 (56 FR 23599), inviting interested parties to submit comments on the Department's May 22 notice, and the comment period was subsequently extended (56 FR 28177, June 19, 1991) to August 23, 1991.

The *Federal Register* notices encouraged interested parties to provide specific comments that relate to activities of the Department; and, most particularly, to bring to the attention of the Department any prior experience with ADR or negotiated rulemaking activities of the Department, areas of the Department's operations which might readily benefit from the use of such techniques, areas in which such techniques should be limited or not used at all, or any other matters which they believed would be of interest to the Department as it developed its policy in these areas.

In enacting the ADR Act, the Congress expressed concern that traditional forms of dispute resolution proceedings used to resolve disputes between agencies and members of the public have become too formal and lengthy, and asserted that alternative procedures may, in at least some instances, be faster, less contentious, and more economical. However, ADR techniques are not appropriate in every situation. The statute itself provides (5 U.S.C. 582(b)):

An agency shall consider not using a dispute resolution proceeding if—

(1) A definitive or authoritative resolution of the matter is required for precedential value, and such a proceeding is not likely to be accepted generally as an authoritative precedent;

(2) The matter involves or may bear upon significant questions of Government policy that require additional procedures before a final resolution may be made, and such a proceeding would not likely serve to develop a recommended policy for the agency;

(3) Maintaining established policies is of special importance, so that variations among individual decisions are not increased and such a proceeding would not likely reach consistent results among individual decisions;

(4) The matter significantly affects persons or organizations who are not parties to the proceeding;

(5) A full record of the proceeding is important, and a dispute resolution proceeding cannot provide such a record; and

(6) The agency must maintain continuing jurisdiction over the matter with authority to alter the disposition of the matter in the light of the changed circumstances, and a dispute resolution proceeding would interfere with the agency's fulfilling that requirement.

Within the limitations set forth in the statute, the Department plans to intensively explore whether and where the use of ADR techniques will, in fact, result in fairer, faster, less contentious, or more economical resolutions of disputes, and to consider modifying any of its current procedures and rules, as necessary and if appropriate, to allow for greater use of ADR. Initial explorations will, however, be performed with due regard for limited agency familiarity with the full range of ADR techniques, and limited familiarity of the DOL community with respect to the use of such techniques in DOL programs, so as not to disrupt agency operations. The Department's first effort will be a pilot program for the Philadelphia region which will test the use of in-house mediators, trained by the Federal Mediation and Conciliation Service, to assist in the resolution of the full range of cases arising within that region in situations where traditional agency conciliation and settlement efforts do not appear to be effective.

On October 23, 1991, the President signed Executive Order 12778 on Civil Justice Reform. Among other provisions, the Executive Order requires Federal litigation counsel to consider the use of an ADR process if warranted in the context of the particular Federal court case, and if ADR will contribute to the prompt, fair, and efficient resolution of the claim. The approach the Department is taking does not limit ADR use to matters before litigation counsel for possible Federal court adjudication, but rather contemplates its consideration in the widest variety of disputes in which the Department may be involved and at the earliest possible time resolution is appropriate and feasible. This approach, and the decision by the Department to implement ADR use through a process of careful pilot testing, is fully consistent with the requirements of the Executive Order.

In enacting the Negotiated Rulemaking Act, the Congress indicated its concern that traditional notice and comment rulemaking procedures may

discourage agreement among the potentially affected parties and the Federal government. The procedures explicitly authorized by the Act are designed to facilitate the search for potential agreement while the Department is still developing a proposed rule. While this may require the initial commitment of more resources than formal notice and comment rulemaking, the ultimate saving of resources can be very significant if the result is a more technically accurate, legally sound regulation which is likely to be acceptable to the regulated community and other affected interests and less likely to be challenged and delayed in litigation. Thus, while the Department recognizes the difficulties that interested parties may face in committing the resources required for such negotiations, particularly if the Federal government is engaged in multiple projects of this type in which some parties may have an interest, it believes that such efforts should be considered where feasible and will encourage its component agencies to begin experimenting with this approach in situations they identify as likely to produce positive results. A fully articulated negotiated rulemaking policy will be issued by the Department at a later date.

The Department developed this interim ADR policy in consultation with the Administrative Conference of the United States (ACUS) and the Federal Mediation and Conciliation Service (FMCS) as required by section 3(a) of the ADR Act.

The Department has designated its ADR Specialist, the Assistant Secretary for Policy, as required by section 3(b) of the ADR Act, to serve as liaison with ACUS and FMCS and as coordinator of the Department's ADR implementation. The Department has also established an ADR Steering Committee, consisting of the Assistant Secretary of Policy (as chair), the Solicitor of Labor, the Assistant Secretary for Administration and Management, the Inspector General, and the Director of the Department's Training Academy. Other established mechanisms will be used to implement negotiated rulemaking.

The Department has also undertaken an initial survey of all its agencies and programs to begin to identify the types of disputes encountered, the current procedures used to resolve such disputes, and any statutory, regulatory and procedural requirements that are "barriers" to the use of ADR. The Department's intention is to closely review such barriers and to seek to remove those—and only those—that do

not serve other legislative, policy or practical purpose.

Implementation by DOL of ADR will at all times observe the requirements of the various program statutes and applicable regulations.

#### Analysis of Comments

Comments on the Department's May 22 and June 19 Federal Register notices were received from (listed alphabetically):

AFL-CIO, Washington, DC,  
 Associated General Contractors of America, Washington, DC,  
 Building and Construction Trades Department, AFL-CIO, Washington, DC  
 Butler Aviation, Irving, TX,  
 Endispute, Inc., Cambridge, MA,  
 Freund, Mr. David, Silver Spring, MD,  
 International Brotherhood of Teamsters, Chauffeurs, Warehousemen & Helpers, AFL-CIO, Washington, DC,  
 Joint Conference Board of the Construction Employers Association and the Chicago and Cook County Building and Construction Trades Council, Chicago, IL,  
 Judicial Services, Inc., Philadelphia, PA,  
 Pension Rights Center, Washington, DC,  
 South Plains Association of Governments, Lubbock, TX,  
 Standing Committee on Dispute Resolution, American Bar Association, Washington, DC,  
 State of New Mexico Department of Labor, Albuquerque, NM,  
 State of New York Department of Labor, Albany, NY,  
 State of Utah Industrial Commission, Salt Lake City, UT,  
 State of Wisconsin Department of Industry, Labor and Human Relations, Madison, WI.

The Utah Industrial Commission stated that it uses in-house mediators to resolve wage claim and discrimination cases where appropriate and is exploring ways to expand the use of ADR to reduce delays in their case-loads. The Commission cautioned that the Department must be careful in using negotiated rulemaking so as to ensure that such rulemakings include all interested parties.

The Department believes a regional pilot test using in-house mediators will be helpful in identifying the types of disputes in which ADR, and particularly this type of ADR, may be most effective. The Department agrees that negotiated rulemaking procedures should only be used in instances where all interested parties can be adequately represented.

The New York Department of Labor stated that it had used pre-hearing compliance conferences, administrative

hearings, mediation, conciliation and other techniques which have successfully resolved disputes without formal adjudication. The comments also stressed the need to provide orientation and education to outside parties who will be invited to participate in resolving disputes through these techniques.

The Department has contracted with FMCS to assist in the design of the regional pilot. An important component of that effort will be to develop procedures for communicating information about the Department's ADR program to outside parties who will be invited to participate in resolving disputes through these techniques. While the pilot will focus initially on the technique of mediation, other ADR methods may be explored as the Department gains more experience in this area.

The Wisconsin Department of Industry, Labor and Human Relations commented that it had used ADR successfully in obtaining early resolution of complaints under the State's fair employment law. Wisconsin also commented that the States would welcome the prompt resolution of issues in conjunction with federal rulemaking, noting that State agencies can face serious difficulties as a result of long delays in the issuance of federal regulations.

The Department hopes that in appropriate cases, negotiated rulemaking can be used to reduce the long delays in the issuance of federal regulations caused by litigation.

The New Mexico Department of Labor commented that it successfully uses informal methods to resolve internal employee grievances and certain types of grievances of participants in programs they operate using funds supplied under the Job Training Partnership Act.

The Department notes that it too is already utilizing alternative dispute resolution methods to help resolve grievances by its own employees. Moreover, while the exact types of disputes arising under programs administered by New Mexico and other State and local governments may not be identical to those normally faced by the U.S. Department of Labor, their positive experience with informal dispute resolution techniques suggests that such approaches should be widely explored by the Department.

The South Plains Association of Governments, located in Lubbock, TX, operates a Dispute Resolution Center which processes judicial and non-judicial disputes. The association commented that many States and local

jurisdictions have established public agency ADR facilities and programs which Federal agencies should consider as alternatives to in-house programs. It indicated that the State and local programs could provide a ready source of neutrals at minimal cost to the Federal Government.

The Department is very interested in identifying economical sources for neutrals. The availability of State and local resources, as well as resources that might be available from other Federal agencies, will be reviewed as the DOL agencies gain familiarity with basic ADR concepts.

The Associated General Contractors of America (AGC) stated its support for the objectives of the legislation. The association indicated the Department's policy could reduce the cost of resolving disputes with DOL's separate agencies and recommended experimenting with a pilot ADR program. The AGC stated the importance of ensuring that participation in ADR is entirely voluntary and that participants retain their rights to formal proceedings. It suggested that DOL might wish to develop a separate set of procedures and a separate roster of impartial experts for each enforcement agency. Also, the AGC recommended that DOL carefully consider who for the Department will decide which cases will be referred for ADR, indicating the need to avoid decisions by those who may have a professional or other conflict of interest in ADR. With respect to negotiated rulemaking, the AGC noted the importance of agency consultation with affected parties prior to proposing rules. However, it expressed concern that the negotiated rulemaking procedures themselves could present a new obstacle to such informal consultation. The association stated that DOL should use negotiated rulemaking procedures in those cases meeting the statutory conditions when less formal consultations fail to produce a consensus yet reveal that a consensus may be possible. Finally, the AGC recommended that DOL take steps to avoid enforcement disputes that arise as a result of ambiguities about regulatory requirements by establishing a national hot-line for each enforcement agency for requesting advance written opinions on specific situations.

The Department agrees with many of these comments, including the recommendation of a pilot and the policy that participation in ADR must be completely voluntary and must not affect any party's right to subsequent formal proceedings. The Department also agrees that negotiated rulemaking

should enhance, rather than diminish, opportunities for interested parties to participate meaningfully in rulemakings consistent with the requirements of the Administrative Procedure Act. Finally, with respect to comments about ambiguous regulatory requirements, Executive Order 12778, in addition to its ADR provisions, imposes new requirements on agencies to draft regulations that establish clear, unambiguous standards for compliance by regulated parties.

The AFL-CIO commented that ADR should not be used in enforcement actions by the Department because, it maintained, negotiations for settlements undermine existing laws and their prescribed penalties. With respect to OSHA enforcement proceedings, the AFL-CIO stated, workers and their representatives have been allowed party status only to contest the date that OSHA mandates for violations to be abated and have not been permitted to participate in settlement agreements reached between the agency and companies. If the Department chooses to proceed with ADR in OSHA enforcement proceedings more vigorously, the AFL-CIO argued, it must take steps to assure that workers or their representatives are given notice of the proceeding and advised of their rights to be involved in the process.

The Department is sensitive to the full range of its obligations and missions, and is adopting a policy toward ADR which should avoid the types of concerns raised by the AFL-CIO, including certain limitations on the types of cases where ADR will be used. As a general matter, the use of ADR by the Department will neither constitute a new procedure nor a new approach to violations of the laws administered by the various agencies of the Department, including OSHA. In the case of the pilot project in Philadelphia, for example, the Department's participation in a structured mediation effort does not involve turning over any decision-making authority to the mediator; rather, any ADR techniques utilized by the Department will simply provide the Department's agencies with another resource to use in resolving a case through settlement. As with the informal settlement discussions and negotiations currently undertaken by agencies of the Department, agencies are always free to decline to enter into a settlement which they do not believe adequately satisfies the Department's obligations and mission. To the extent that parties or potential parties currently have rights to challenge the Department's actions in this regard, those rights will remain

unchanged; the Department's participation in an ADR proceeding does not create nor require the creation of any new grant of party or other special status. (Only if binding arbitration were to be used does the Act, in section 591(b)(1), give nonparties a limited opportunity to challenge the outcome pursuant to 9 U.S.C. section 10(b).) The Department believes that all of its actions in OSHA cases must be taken with an eye toward furthering the occupational safety and health of all workers, including those immediately affected by the case being resolved.

Moreover, as a matter of resource considerations, all government enforcement agencies have to make judgments about which cases to bring to trial and which to settle. The Department hopes that the pilot project in the Philadelphia region will help ascertain those situations in which the use of ADR may strengthen its enforcement programs by satisfactorily resolving more cases in a fair manner and a quicker period of time with less expenditure of resources than current methods. To the extent the pilot suggests it can achieve this goal, ADR will be relied upon to complement the Department's enforcement strategy of vigorously pursuing willful and criminal violators of labor statutes. Where it turns out to be not valuable or counterproductive, ADR will not be used.

The AFL-CIO commented that negotiated rulemaking on its own is not a panacea to the lengthy and cumbersome rulemaking process. The AFL-CIO specifically expressed concern about the use of this technique in developing OSHA standards, noting that its prior participation in two negotiated OSHA rulemakings (benzene and methylene dianiline) and two EPA rulemakings (asbestos abatement in schools and farmworker protection) had produced mixed results. The AFL-CIO commented that the negotiated rulemaking process does allow for more open and direct exchange of views and positions than the traditional rulemaking process. However, it suggested a number of steps the Department should take if DOL decides to use this process. Specifically, it explained, DOL must be willing to commit the resources and time necessary to actively participate in developing the draft rule and the Department must promulgate the draft in the form negotiated. With respect to OSHA, the AFL-CIO stated the Department should rely on the advisory committee for input on whether the use negotiated rulemaking and for determining who should participate in

the negotiations. It maintained DOL should use the existing advisory committee to develop safety and health standards rather than setting up an additional structure for negotiated rulemaking.

The Department agrees with the comments of the AFL-CIO (and the Teamsters, as noted below) that the existing advisory committees should be used where appropriate in developing safety and health standards. The Department notes, however, that ad hoc advisory committees are also a well recognized approach to obtain guidance on issues requiring special expertise or experience. The Department intends that its continued experimentation with negotiated rulemaking will be consistent with these established practices.

The Building and Construction Trades Department of the AFL-CIO requested an extension on the time for filing comments. In its reply, the Department indicated its desire to have the Building Trades' comments and expressed the hope that it could file them quickly in light of the time constraints under which DOL needed to develop its ADR policy.

The Teamsters Union recommended that negotiated rulemaking be used extensively as a means to produce regulations that are realistic and constructive. It commented that in the OSHA area, standards advisory committees are recognized in the Act and should be revitalized. With respect to ADR, the union stated that it favors less formal procedures and less litigation. It noted that in an OSHA case a company has only 15 days to appeal a citation, and, consequently, ADR is unlikely to avoid appeals. However, the union stated that ADR procedures may more effectively accommodate and protect OSHA whistleblowers than the current formal process. With respect to programs in the Office of Labor-Management Standards, the union commented that to what extent ADR, particularly arbitration, would be useful is questionable. However, it suggested that mediation or negotiation could prove useful in union officer election and removal cases, depending on the particular facts. Finally, the union stated that if ADR is presented as an attractive alternative, rather than a process in which the parties have no choice, it may be a success.

The Department thinks many of these comments may have merit. The regional pilot test of ADR is intended to provide a sound basis on which to make judgments about which disputes and which programs can benefit most from the use of ADR.

The Standing Committee on Dispute Resolution of the American Bar

Association submitted comments supporting the Department's efforts and offering its assistance in implementing the legislation.

The Department appreciates the Committee's offer and will seek its assistance as it proceeds in its efforts to implement ADR.

The Joint Conference Board is a group of labor and management representatives that informally resolves trade union jurisdictional disputes in the Chicago area construction industry. The board stated that since established in 1913, it has successfully resolved work assignment disputes quickly and economically. This process, the board stated, ensures that projects stick close to schedule and budget by avoiding work stoppages due to jurisdictional disputes and promotes productivity, efficiency and improved labor relations. The board's comments strongly endorsed the concept of ADR and encouraged the Department to explore its use in resolving disputes.

Butler Aviation commented that it had experience using ADR to settle disputes with the Government and had found it to be useful and time saving. The comments indicated the company's full support for ADR.

Judicial Services, Inc., a mediation and arbitration service, and Mr. David Freund, a private mediator and arbitrator, filed comments strongly supporting the Department's experimentation with ADR. Mr. Freund commented that he had learned of ADR initiatives underway in a number of DOL offices, and indicated that coordination among these offices was important. He suggested that DOL establish a central location responsible for maintaining a list of qualified neutral volunteers who would be available as needed to serve as mediators or arbitrators.

The Department has established a Steering Committee to coordinate ADR initiatives underway in the Department. The Administrative Conference of the United States is developing a roster of neutrals pursuant to a provision of the ADR Act. The Department does not intend to develop its own roster of neutrals pending the results of the pilot program.

Endispute, Inc., a private ADR consulting company, commented on the Department's ongoing survey of internal and external disputes. The company stated that other public and private organizations had found such analysis to be essential in ADR planning. Their comments recommended that the survey be used to produce a catalog of the types of disputes that provide opportunities to test ADR, and

specifically identified as likely ADR opportunities disputes involving vendor and contract agreements, internal management-employee relations, internal management disputes, and disputes arising with programs administered by DOL. In the case of program disputes, Endispute commented that a number of States, including Michigan, Connecticut and Wisconsin, have successfully used ADR to resolve workers' compensation claims and recommended that DOL consider ADR in federal employee compensation cases.

The Department agrees that the ongoing survey may produce significant information about potential areas for using ADR. For purposes of the regional pilot, however, the approach adopted is to provide as much flexibility as possible for experienced DOL field personnel to test ADR in a wide variety of disputes. Their experience will then be evaluated, along with the initial survey results, to develop recommendations for further implementation. At the same time, however, the Department has decided not to include in its regional pilot test of ADR those workers' compensation programs it administers, i.e., the Federal Employees' Compensation Program (FECA), the Black Lung Benefits Program (BL), and the Longshore and Harbor Workers' Compensation Program (LHWCA). Under FECA, the Department of Labor by law makes the final compensation decision; accordingly, we are a decisionmaker in this program, not a disputant. Moreover, FECA was deliberately designed as a nonadversarial system; thus, the employing agencies who might be considered to have a "dispute" with a claimant have no party status in the process. LHWCA and BL involve the use of an administrative hearing and review process to determine claims for compensation, pursuant to a detailed statutory structure. As intensive conciliation efforts are already made by the Department at each stage of the process, and because the disputes involved tend to be over the application of legal eligibility criteria to an agreed upon set of facts, the Department decided to narrow the broad scope of the pilot effort by placing these programs outside its reach.

Endispute also recommended that DOL take a careful look at areas in which the Department is already using ADR, such as conciliation efforts at resolving disputes in connection with Executive Order 11246. Endispute's comments suggested that the survey would prove useful in identifying

organizational obstacles to ADR. For example, it commented that in areas where litigation has been the dominant mode for resolving disputes, ADR may be perceived as reducing the scope of litigators' authority. The company recommended that DOL consider using consensus-building processes, including the use of outside neutrals, to overcome such obstacles and build consensus around the use of ADR techniques. With respect to DOL's ADR policy, the company indicated that such a policy should highlight and promote mediation rather than arbitration for a number of reasons, including the fact that in mediation the parties remain fully in control of the final outcome. The ADR policy, the company commented, should avoid setting limits on the use of these techniques, such as a limitation on the amount of money in dispute. It recommended that the policy should include a pilot program in which DOL actively encourages the use of ADR in a limited group of cases and thereby gains data on the effectiveness of these techniques. Finally, the company commented that the ADR policy should be reviewed and evaluated on a regular basis and that this evaluation should include a methodology for comparing the costs of ADR with the costs of current procedures.

The Department agrees with most of these comments and believes the regional pilot will address many of these recommendations. The pilot is intended to develop internal consensus on the use of ADR and to build experience and confidence in these techniques. The pilot will not include the use of arbitration, but will focus on the technique of mediation. As indicated above, the pilot encourages field staff in a single region to explore the use of ADR in a wide variety of cases. Finally, the pilot will include a methodology for assessing the effectiveness of ADR and comparing its costs with those of traditional procedures.

The Pension Rights Center, a non-profit organization working in the area of pension plan issues, commented that the Department should implement an ADR program for resolving pension benefit claims disputes using the resources of the pension bar to serve as neutrals. Using a grant from the National Institute for Dispute Resolution, the Center has developed a plan for an ERISA Early Expert Evaluation program, a copy of which was included with its comments. This program would attempt to settle pension benefit disputes by providing the parties with a neutral expert's evaluation of the relative merits of their positions and the

likely outcome of litigation. The Center's proposal was among the subjects covered in a September 12, 1991 public hearing of the Department's Advisory Council on Employee Welfare and Pension Benefit Plans' Enforcement Work Group.

The Department appreciates these comments. However, the regional pilot will focus only on disputes in which DOL agencies currently have program responsibility.

In summary, the Department agrees with the comments that the use of informal dispute resolution techniques may, at least in some cases, result in fairer, faster and more economical case resolutions. However, the Department wants to proceed cautiously and deliberately in implementing ADR to avoid any potential misuse. Specifically, the Department intends to test these techniques in various programs and types of disputes to identify where ADR has the greatest potential to produce satisfactory settlements more quickly and economically than traditional procedures and litigation. Once the most fruitful program areas and types of cases are identified, the Department intends to implement ADR on a broad scale in those areas.

#### **Alternative Dispute Resolution (ADR) Interim Policy**

The Department's interim ADR policy is predicated on the ADR statute which requires, among other things, the consideration of alternative dispute resolution methods as vehicles for avoiding protracted administrative procedures and litigation. In adopting its interim policy on ADR, the Department intends to explore the use of such techniques to the extent, and only to the extent, that they can improve and enhance the fairness, effectiveness and efficiency of its actions.

It is the Department's policy to implement or expand the use of ADR techniques wherever such informal dispute resolution methods have a likelihood of proving useful. To study the potential impact of ADR generally, the Department will initiate at least one pilot study of such techniques, as discussed below, in a regional office, to test the applicability and utility of ADR in disputes. In addition, the Department will continue to encourage its staff to avail itself of training in ADR techniques and negotiation skills. During the course of the regional pilot, the ADR Steering Committee will consider other invitations to participate in an ADR proceeding by another party, where requested by a court or other adjudicative authority, or where an agency otherwise believes that there is

merit in initiating an alternative approach to resolving a particular dispute in which the Department is a party. With respect to rulemaking activity, the Department will continue to experiment with the use of negotiated rulemaking.

The Department intends to use the regional pilot to meet its initial responsibilities under Executive Order 12778, as well. The Executive Order requires Federal litigation counsel that conduct or otherwise participate in civil litigation on behalf of the United States in Federal court—which, in the case of Department of Labor programs, may include attorneys in the Office of the Solicitor, the Office of the Department's Inspector General, and Attorneys who represent the Department's positions but who do not work for the Department (e.g., the U.S. Attorneys)—to adhere to certain guidelines during the conduct of such litigation (with certain enumerated exceptions). Among these guidelines is to make reasonable attempts to resolve a dispute expeditiously and properly (or confirm that the referring agency has done so) before proceeding to trial in Federal court, including the use of ADR in appropriate cases.

The regional pilot test of ADR does not limit ADR use to matters before litigation counsel for possible Federal court adjudication, but rather contemplates its consideration in the widest variety of disputes in which the Department may be involved and at the earliest possible time resolution is appropriate and feasible, the pilot test will include cases of the type covered by the Executive Order. The Department believes the pilot will provide its litigation counsel with significant insight into where ADR processes may be appropriate in cases covered by the Executive Order. Those litigation counsel participating in the pilot test in Philadelphia with respect to cases covered by the Executive Order will do so in a fashion consistent with any other requirements of the Order. This interim policy on ADR shall be considered as part of the Department's internal guidance on implementation of the Order pursuant to section 4(b) of the Order.

The Department will not use ADR:

- (1) Where statutes or regulations preclude the use of such techniques;
- (2) Where the dispute is not suitable for ADR on consideration of the factors set forth in 5 U.S.C. 582(b);
- (3) Where the responsible DOL program agency, in consultation with the Office of the Solicitor, believes a dispute involves a willful or criminal violation of law; or

(4) Where, for any reason, the responsible DOL program agency, in consultation with the Office of the Solicitor, believes it is necessary or preferable to proceed with traditional litigation in light of the facts of the case.

#### Regional Pilot Test of ADR

For the reasons indicated above, after consulting with the Administrative Conference of the United States (ACUS) and the Federal Mediation and Conciliation Service (FMCS), the Department has decided to conduct a pilot test of ADR in the Philadelphia Region. The Department believes that such a regional pilot test is the best possible means to determine the effectiveness of ADR in resolving disputes arising within its jurisdiction.

ACUS and FMCS will provide training for the regional staff in the background of ADR and in mediation skills, and will assist in developing plans for the pilot. Trained in-house mediators will be available to serve as neutrals in resolving disputes outside of their program area responsibilities. Each case handled through mediation will be carefully evaluated at its conclusion to determine whether ADR is helpful in the particular program and type of dispute involved.

The Department has made a deliberate decision not to limit the potential scope of the pilot by constraining in advance types of cases in which ADR may be utilized: e.g. type of program, type of case, seriousness of offense, or any other such criteria. Rather, experienced agency staff in the Philadelphia region are being trained to recognize the types of disputes which may be amenable to ADR processes, and encouraged to refer cases from their programs for consideration of possible ADR use. Thus, the Department hopes to evaluate ADR's utility as a supplement to informal dispute resolution efforts already undertaken by DOL agencies by selecting cases from a broad pool of disputes to which the Department is a party: Disputes over employer obligations to pay particular wages and restrict working hours, provide safe and healthful workplaces, meet planned benefit and affirmative active duties; disputes over the obligations of union officials to conduct their activities in accordance with Federal law; disputes with government contractors; and disputes among agency personnel. DOL agencies will, however, exercise caution to avoid the use of ADR in those cases for which the Department's interim policy precludes the use of ADR techniques. Moreover, the Department has decided not to include workers' compensation cases in the pilot for

various reasons peculiar to the various workers' compensation programs operated by the Department.

The in-house mediators will not serve as decision-makers, but will serve to facilitate settlement negotiations between the parties. No DOL employee who serves as a mediator in a particular dispute may participate in any way in any subsequent further action or litigation over that dispute, absent the agreement of the parties or an order of a court. Specifically, the mediator will be required to recuse himself or herself from any meetings, discussions, recommendations, or decisions about any subsequent action in the dispute.

An important consideration in ADR is to assure that the designated representatives of the parties will have full authority to settle the dispute without extensive supervisory review or concurrence. No DOL staff who represent the Department in such proceedings shall be subject to any adverse whatsoever, including any adverse performance evaluation, based solely or in part on the outcome of settlement negotiations entered into under this pilot test.

Outside parties in the Philadelphia Region who are involved in disputes with the Department (e.g., contract disputes, grant disputes, or enforcement actions) may be offered, solely at the DOL program agency's discretion, the opportunity to submit the dispute to mediation. In addition, such parties may request such an opportunity to try mediation.

If an outside party to a dispute wishes to try mediation but does not want to use a DOL employee as mediator, the DOL agency may offer, at its own discretion, the opportunity to submit the dispute to another mediator (public or private). In no event will the DOL agency agree to the use of such an outside mediator unless the costs are shared equally with the outside party.

The agreement to participate in mediation shall not constitute a waiver of any party's statutory or regulatory right to an administrative proceeding or court action. However, to the extent permitted by law, DOL agencies are authorized to enter into agreements to waive filing deadlines for appeals by an outside party, or to obtain the voluntary waiver by an outside party of any statute of limitations, for the duration of the mediation procedure.

After an adequate number of cases have been mediated, the pilot will be evaluated and decisions will be made about whether to modify how ADR is used, undertake new pilot projects, extend the use of the ADR in some form

throughout the Department, or abandon it use.

#### Negotiated Rulemaking

It is the Department's policy to continue to experiment with the use of negotiated rulemaking wherever such a process has the potential to result in a rule which is more technically accurate, clear and specific, and less likely to be challenged in litigation by interested parties than a rule produced by traditional notice and comment procedures.

Proponents of the negotiated rulemaking process recognize that it takes a substantial initial investment of time and resources by the agency and by interested parties. Therefore, the Department will only use negotiated rulemaking for regulations where such time and resource investment (public and private) is expected to be prudent and efficient. An important factor in this determination will be an analysis by an independent convener of whether representatives of all parties who are likely to assert an interest in the subject of the negotiation effort, including the appropriate representatives of the government, appear to have access to adequate resources to sustain the required level of participation in the negotiation effort.

To assist it in such analysis, the Department will make efforts to use conveners with special skills in negotiated rulemaking and mediators with special skills in the technical aspects of the particular rule that may be involved. The Department will rely on the expertise of the Administrative Conference of the United States and the experience of other agencies in assisting it to develop appropriate mechanisms in this regard.

A more articulated policy on the use of negotiated rulemaking will be issued at a later date.

#### Further Policy Development

The Department intends to closely evaluate the results of its pilot project and other ADR activities under this interim policy prior to nationwide implementation. Suggestions on the implementation of Department's interim ADR policy, particularly from those who participate in or are affected by activities undertaken pursuant to this interim policy, are welcome.

Suggestions on negotiated rulemaking should be directed to Marshall J. Breger, Solicitor of Labor, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210. Suggestions on the Philadelphia pilot project and other aspects of ADR should be directed to

Nancy Risque Rohrbach, Assistant  
Secretary for Policy, U.S. Department of  
Labor, at the same address.

Signed at Washington, DC, this 25th day of  
February 1992.

Lynn Martin,  
*Secretary of Labor.*

[FR Doc. 92-4629 Filed 2-27-92; 8:45 am]

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# **Federal Register**

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**Friday  
February 28, 1992**

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## **Part VI**

### **Department of Education**

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**34 CFR Part 212**

**Elementary and Secondary Education:  
Even Start Program; Proposed Rule**

## DEPARTMENT OF EDUCATION

## 34 CFR Part 212

RIN: 1810-AA64

## Even Start

AGENCY: Department of Education.

ACTION: Notice of proposed rulemaking.

**SUMMARY:** The Secretary proposes to amend the regulations governing the Even Start program. Even Start is authorized by part B, chapter 1, of title I of the Elementary and Secondary Education Act of 1965. The National Literacy Act of 1991 (Pub. L. 102-73) contains amendments to Even Start. These proposed regulations would amend current Even Start regulations to: (1) Reflect the statutory changes to Even Start contained in the National Literacy Act; (2) include provisions needed to govern the program when it becomes State-administered; and (3) make related changes to the migrant education component of the Even Start program.

**DATES:** Comments must be received on or before March 30, 1992.

**ADDRESSES:** All comments concerning these proposed regulations should be addressed to Mary Jean LeTendre, Director, Compensatory Education Programs, U.S. Department of Education, 400 Maryland Avenue, SW., room 2043, Washington, DC 20202-6132. Telephone: (202) 401-1692. Deaf and hearing impaired individuals may call (202) 732-4538 for TDD services.

A copy of any comments that concern information collection requirements should also be sent to the Office of Management and Budget at the address listed in the Paperwork Reduction Act section of this preamble.

**FOR FURTHER INFORMATION CONTACT:** Patricia McKee, Chief, Discretionary Grants Branch, Compensatory Education Programs, U.S. Department of Education, 400 Maryland Avenue, SW., room 2043, Washington, DC 20202, Telephone: (202) 401-1692. Deaf and hearing impaired individuals may call (202) 732-4538 for TDD services. For questions about the Migrant Education Even Start program, contact Howard Essl, Chief, Policy and Planning Branch, Office of Migrant Education, Office of Elementary and Secondary Education, U.S. Department of Education, 400 Maryland Avenue, SW., room 2149, Washington, DC 20202-6135, Telephone: (202) 401-1611. Deaf and hearing impaired individuals may call (202) 732-4538 for TDD services.

## SUPPLEMENTARY INFORMATION:

## A. Background

The regulations governing the Even Start program (34 CFR part 212) were published in the *Federal Register* on March 23, 1989. Subpart F of those regulations, governing the Migrant Education Even Start program, was published in the *Federal Register* on May 25, 1989. These proposed amendments to the regulations reflect statutory changes to Even Start contained in the National Literacy Act of 1991 (Pub. L. 102-73). In accordance with the statutory changes, these regulations: (1) Make community-based organizations, in cooperation with local educational agencies, eligible to apply for grants (§§ 212.2 and 212.6); (2) expand eligibility for Even Start funds to include Indian tribes, tribal organizations, and the Nation's insular areas (territories) (§ 212.2); (3) expand the age of children eligible for Even Start to include those from birth through age 7 (§ 212.7); (4) provide that families that otherwise would be ineligible due to one or more participants having become ineligible under the statute may continue to participate until all family members become ineligible (§ 212.7); (5) revise the selection criteria for making discretionary grants to eligible entities (§ 212.21); (6) provide a method for applying the priorities contained in the amendments to the discretionary grant selection process (§ 212.21); (7) specify conditions for waiving the requirement relating to the source of the local contribution of funds (§ 212.25); (8) contain provisions regarding State administration of the program, which will begin in fiscal year (FY) 1992 (§§ 212.30-212.34); and (9) make conforming changes to regulations governing the Migrant Education Even Start program (§§ 212.50-212.58).

Even Start supports AMERICA 2000, the President's strategy to help America move toward achieving the six National Education Goals. Because it integrates early childhood education and adult education by involving parents who have limited basic education skills in the education of their young children, Even Start helps States and localities directly address two of the National Education Goals. Goal 1 calls for all children in America to start school ready to learn. An objective of Goal 1 is for every parent to be a child's first teacher, to devote time each day to helping his or her preschool child learn, and to have access to training and support. Even Start also contributes to achieving Goal 5—that every adult American will be literate and will possess the knowledge and skills necessary to compete in a global

economy and exercise the rights and responsibilities of citizenship.

These proposed regulations are necessary to bring current regulations into conformity with legislative amendments, and to establish procedures that will govern the program when it becomes State-administered in FY 1992.

## B. Issues

## Priority Points

The proposed regulations would implement the new requirement in section 1057 of the statute that certain applicants be given priority when applying for grants. That provision requires that the review panel appointed by the Secretary or the State, as the case may be, give priority to the following applicants: (1) Those that demonstrate a high degree of need for Even Start services in the area to be served; and (2) those that demonstrate an ability to operate an effective program.

In the amendments to the Even Start law, the Congress also included the first factor (need) as one of the regular selection criteria. The second factor is similar to an existing selection criterion that judges an applicant's likelihood of success in meeting the Even Start goals. Therefore, in § 212.21 of the proposed regulations, the Secretary proposes to implement the priorities by assigning additional points to applicants as follows:

1. For the first factor, "need," the Secretary would assign 10 additional points to applicants that demonstrate a severity of need, by substantial objective documentation, using several of the need-related indicators contained in § 212.21(b).

2. For the second factor, "ability to operate," the proposed regulations would first add a new subelement to § 212.21(a), "Likelihood of Success in Meeting the Even Start Goals." The subelement would give five points for: (1) Objective evidence that the eligible entity has had past success in operating programs that served any or all of the Even Start target groups (adults, young children, or families); or (2) information supporting the applicability of a certain model to the local site, with descriptions of the model and its proposed implementation (§ 212.21(a)(1)(viii)). In cases where the applicant is a nonprofit organization, evidence of past success may be provided by its collaborating local educational agency (LEA).

The five points added to paragraph (a) of § 212.21 would be taken from paragraph (e), "Promise as a Model." The points for the subelements in

paragraph (e) would be changed as follows: (1) Evaluation plan—from 8 to 5 points; (2) basis of project components—from 5 to 3 points; and (3) willingness to serve as a model—remains at 2 points.

For the priority points, the review panel would assign 10 additional points to applicants that receive 35 or more points out of the 40 points now possible under § 212.21(a) of the regulations, and, in addition, receive 5 points on the new subelement (§ 212.21(a)(1)(viii)) if based on evidence of past success in operating a program. An applicant providing information concerning implementation of a model, rather than evidence of past success, can receive up to five points on the new subelement, but would not qualify for the ten priority points.

#### *State Requirements*

Section 212.30 (a) and (b) of the proposed regulations would require that, in order for a State to receive funds for the first three fiscal years in which the program is State-administered, it must submit a State plan to the Secretary. State plans are needed to insure full understanding and implementation of Even Start statutory and administrative requirements that govern the program after it converts from Federal to State operation. State plans would provide a systematic means for communication between the Department and each State about those requirements and would help the Department provide appropriate technical assistance to all States. The Department discourages States from filing lengthy documents. A concise plan outlining the basic elements requested will suffice.

After the three-year period, it is expected that State plans would no longer be as necessary. Thereafter, as proposed in § 212.30(c), States would be required only to file appropriate assurances with the Department.

The proposed regulations require that States submit the reports and information as the Secretary may require (§ 212.33). The Secretary plans to develop a performance report form specific to Even Start that States will submit annually. The performance report would ask for information on various aspects of program operations, such as information about subgrant awards, services provided, numbers of children and adults served, information concerning the amount of funds spent on State administration and technical assistance, and outcomes achieved.

The proposed regulations also contain provisions that would govern State procedures for awarding subgrants. Section 1052(b) of the amended statute requires that States make subgrants of

at least \$75,000 each. Sections 212.31 and 212.32 of the proposed regulations would require that, in addition, subgrants be of sufficient size, scope, and quality to give reasonable promise of meeting the purposes of Even Start. The Secretary proposes this requirement to emphasize the fact that the statutory minimum should not also be used as a maximum, and that subgrant awards should be large enough to help ensure successful Even Start projects.

For continuation awards, to ensure a smooth transition and avoid overlapping Federal and State grants in FY 1992 when Even Start converts to a State program, the beginning date of an award made by a State should be the day after the expiration of the Federal grant. In the event that the Federal project grant ends before a State grant begins, a grantee may request an extension of the Federal grant period from the Department.

#### *Applicability of General Chapter 1 Provisions*

The Even Start program is contained in part B of chapter 1 of title I of the Elementary and Secondary Education Act of 1965 (chapter 1). Several of the provisions in parts E and F of chapter 1 will affect the States in their administration of the Even Start program. Others are inapplicable to Even Start. Those that do apply to Even Start, and are directed to the States rather than the Department, are identified in § 212.34 of the proposed regulations.

Section 1404 of the Act (Payments for State Administration) concerns payments to the States for performance of their duties under chapter 1. These funds may be used for administration of Even Start, if needed, in addition to the five percent of Even Start funds that the State is authorized to use under section 1052(b) of the Act.

Section 1432(b) of the Act (Availability of Appropriations), containing limitations on carryover of funds, does not apply to Even Start. This provision is interpreted to apply only to basic and concentration grants under the chapter 1 LEA program. Those grants are distributed to LEAs by formula. The carryover limits were designed to provide yearly consistency of expenditures among those LEAs that have an expectation of yearly funding. Because Even Start is a discretionary program with funds made available to eligible entities on a competitive basis, eligible entities receiving funds have no legitimate expectation of continuation of funding. Therefore, carryover limits do not apply.

The "Tydings" provision in section 412(b) of the General Education Provisions Act (Availability of Appropriations on Academic or School Year Basis) does, however, apply to Even Start when the program is State-administered, so that Even Start funds that States receive will remain available for obligation during the fiscal year succeeding the fiscal year for which they are appropriated. States may allow eligible entities to carry over unobligated funds from State grants for the remaining time available, and reduce the amount of future awards by the carryover amount.

Section 1438 of the Act (Application of General Education Provisions Act), providing that the General Education Provisions Act (GEPA) applies except for certain superseded or excepted provisions, applies to Even Start. Note that, even though section 436 of GEPA, governing LEA applications to the State, is mostly inapplicable, section 1056 of the Even Start statute specifically requires eligible entities to submit applications to States containing the detailed information listed in the statute.

Section 1451 of the Act (State Regulations), which requires, among other things, that a Committee of Practitioners review any proposed State rules governing the program, applies to Even Start as well. The proposed regulations in § 212.5(b)(10) adopt the regulation in 34 CFR 200.70 interpreting and implementing the provisions of section 1451. However, some provisions of 34 CFR 200.70 are not appropriate for Even Start and are excepted. Although some States may wish to use, for Even Start, the same Committee of Practitioners already in place for the basic LEA program, others may wish to develop a committee solely for Even Start. States are encouraged to consider, in addition to the committee members required by statute, persons knowledgeable about the various aspects of education that Even Start addresses: adult education, family literacy, and early childhood education.

Section 1453 (Assignment of Personnel) applies to the extent that Even Start personnel are paid entirely with Even Start funds and perform their duties in an elementary school setting, i.e., teach Even Start children in kindergarten through grade 12 in a public school. For this Even Start purpose, § 212.5(b)(10) of the proposed regulations adopts the regulation in 34 CFR 200.39 that interprets the statutory requirements.

*Applicability of Certain of the Education Department General Administrative Regulations*

Section 212.5 of the proposed regulations lists those sections of part 76 of the Education Department General Administrative Regulations (EDGAR) that do not apply to Even Start. In addition, the Department plans to amend part 76 to include Even Start as a program covered by 34 CFR 76.102 (Definition of "State plan" for Part 76), and 34 CFR 76.125 (What is the purpose of these regulations?) governing consolidated applications from insular areas.

The proposed regulations provide that Part 80 of the EDGAR will continue to apply to Even Start when the program is State-administered.

*Allocation of Funds—Migratory Children, Indian Tribes and Organizations, and Territories*

In fiscal years for which Congress appropriates \$50 million or more, section 1053 of the statute, as amended, requires the Secretary first to reserve five percent of the Even Start appropriation for migratory children, the territories (Guam, American Samoa, the Virgin Islands, Northern Mariana Islands and Palau), and Indian tribes and tribal organizations, to be allocated according to their relative need. The amount reserved for programs for migratory children must be at least the amount reserved in the preceding fiscal year.

A review of data available on which to base relative need among the three groups has yielded only one data set on which common information is available: The number of school-aged children (ages 5-17) in each group. Reliable data on the number of children ages birth through seven (the group of children eligible to be served under the statute), are not available for all three groups. The Secretary assumes that the number of children in these groups ages birth through seven is likely to be proportional to the number of children ages 5-17. The Secretary recognizes that, as groups, children who are migratory, Indian, or residents of the territories all have substantial need for Even Start program services, and that use of child-count data alone to determine how the five percent set-aside should be apportioned among these groups is less than ideal. However, the Secretary proposes to use the 5-17 child count because it appears to be the best available proxy for "need," given the substantial difficulty in obtaining, for these groups, other reliable and comparable data for need-related

indicators such as poverty, illiteracy, and unemployment.

In estimating the number of children ages 5-17 in each group, the Secretary will use the most recent data that are available. In determining the set-aside for each group, the Secretary plans to apply these child-count figures proportionately to the five percent set-aside and round to the nearest half percent. By doing so, for FY 1992, three percent of the Even Start appropriation would be reserved for programs for migratory children (the same as the statutorily required reservation when the program is federally administered); one and one-half percent would be reserved for programs for Indian tribes and tribal organizations; and one-half percent would be reserved for Guam, American Samoa, the Virgin Islands, the Commonwealth of the Northern Marianas, and Palau. When the underlying data yield different percentages or better measures of relative need become available, the Secretary will notify the public of the new allocation percentages.

Funds reserved for Indian tribes and tribal organizations would be competitively awarded. The Secretary would apply the regular Even Start selection criteria contained in the regulations that include "need" as one of the factors (§ 212.23(a)). Migrant Education Even Start funds would also be awarded competitively, with selection criteria modified as described in the following section. Funds reserved for the territories would be allocated to them in proportion to each territory's Chapter 1 basic grant (§ 212.23(b)). Territories could either submit a consolidated grant application or submit a State plan for the first three fiscal years of State administration.

*Migrant Education Even Start Program*

Proposed subpart F of the Even Start regulations would modify the existing regulations for the Migrant Education Even Start program to reflect both the new statutory requirements in the National Literacy Act of 1991 as they would apply to a program for migratory children and their parents, and technical changes that are needed in the subpart F regulations. For clarity, the following discussion focuses first on significant differences between regulations that would govern the regular Even Start program and those that would govern the Migrant Education Even Start program.

Under §§ 212.51 and 212.57(b), as proposed, the Secretary would continue to make grants on a competitive basis to State educational agencies (SEAs) (as has been the practice since the Even

Start program began). SEAs may then make subgrants to eligible entities that include local operating agencies or institutions for Even Start projects that serve migratory children and parents. The principal change involves selection criteria.

First, § 212.55(a) would tailor the criterion contained in § 212.21(b), as proposed (Need for the project), to emphasize that a State's need for a Migrant Education Even Start project depends on the relative numbers or percentages of currently migratory children and parents who reside in the area to be served for the period of time the project would operate. As with the regular Even Start program, a high need for Migrant Education Even Start services could be shown by comparison with other areas of the State or the Nation as a whole. Defining need in this way would permit applications from those "receiving" States in which large numbers or high percentages of migratory children and parents reside for only a portion of the calendar year to be evaluated fairly alongside applications from the "sending" States in which currently migratory children and parents reside for most of the year.

Second, § 212.55(b) would alter the regular Even Start application's description of interagency planning, contained in § 212.21(c)(2) (Degree of cooperation and coordination), to reflect the overall requirements in § 212.50(b) that Migrant Education Even Start projects provide services on an interstate or intrastate basis.

Third, § 212.55(c), which identifies the number of points that may be awarded to applicants under each Migrant Education Even Start selection criterion, would assign values to several of the criteria that differ from those provided under the regular Even Start program. Rather than provide for priority points, as would § 212.21(b)(3) (Need for the project), § 212.55(c)(2) simply would assign up to 20 points for this criterion. In addition, in view of the particular importance of awarding Migrant Education Even Start grants to applicants whose projects show promise as a model, § 212.55(c) would continue to provide applicants up to 20 points, rather than the 10 points in § 212.21(e), for projects that are expected to meet this criterion. In order for the total number of points that may be awarded under the Migrant Education Even Start program to be 120, as under the regular Even Start program, § 212.55(c)(1) would reduce from 40 to 32 the number of points that may be awarded under the criterion, Likelihood of success in meeting the Even Start goals. Similarly,

§ 212.55(c)(4) would reduce from ten to eight the number of points that may be awarded for the criterion, Reasonableness of budget.

Proposed subpart F also would make several technical changes in existing regulations for the Migrant Education Even Start program. First, §§ 212.52 and 212.53(b) would adopt the new requirements proposed for the regular Even Start program in §§ 212.7 and 212.25 regarding expanded eligibility and waiver of the source of local contribution. Section 212.54(b) would change the maximum number of points that can be awarded under the Migrant Education Even Start selection criteria to 120. Under § 212.56(a)(2), like its counterpart in § 212.22(a)(1) of the proposed regulations in the regular Even Start program, the Secretary would ensure that, in awarding new grants, projects will build on existing community resources to create services that integrate the early childhood and adult education components into a unified program. In addition, §§ 212.57(a)(4) and 212.58 would clarify that the SEA may make subgrants to an eligible entity that includes, for purposes of Migrant Education Even Start, any agency that could receive Migrant Education Program funds under 34 CFR part 201.

Finally, in keeping with the requirement in section 1052(b)(3) of the Act that States use no more than five percent of their Even Start grants for the costs of administration and technical assistance when the program is State-administered, § 212.58(b) would apply this same limitation to SEAs that subgrant the operation of a Migrant Education Even Start program to an eligible entity.

#### *Executive Order 12291*

These proposed regulations have been reviewed in accordance with Executive Order 12291. They are not classified as major because they do not meet the criteria for major regulations established in the order.

#### *Regulatory Flexibility Act Certification*

The Secretary certifies that these proposed regulations would not have a significant economic impact on a substantial number of small entities.

The small entities that would be affected by these proposed regulations are small LEAs and community-based organizations receiving Federal funds under this program. However, the regulations would not have a significant economic impact on the small entities affected because the regulations would not impose excessive regulatory burdens or require unnecessary Federal

supervision. The regulations would impose minimal requirements to ensure the proper expenditure of program funds.

#### *Paperwork Reduction Act of 1980*

Sections 212.10, 212.11, 212.12, 212.13, 212.21, 212.22, 212.25, 212.30, 212.32, 212.33, 212.53, and 212.55 contain information collection requirements. As required by the Paperwork Reduction Act of 1980, the Department of Education will submit a copy of these sections to the Office of Management and Budget for its review. (44 U.S.C. 3504(h))

States and territories are required, for three years, to submit a State plan under these regulations. The Department needs and uses the information to facilitate the Department's oversight of the program with regard to the States' compliance with the statute and regulations. Annual public reporting burden for this collection of information is estimated to average 15 hours per response for 57 respondents (who meet the definition of a State or territory for purposes of Even Start), including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

For purposes of the Migrant Education Even Start program, annual public reporting burden for this collection of information is estimated to average 17.33 hours per response for 60 respondents, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. In addition, for Indian tribes that will submit applications for discretionary grants, the annual public reporting burden for this collection of information is estimated to average 20 hours per response for 30 respondents, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Organizations and individuals desiring to submit comments on the information collection requirements should direct them to the Office of Information and Regulatory Affairs, room 3002, New Executive Office Building, Washington, DC 20503, Attention: Daniel J. Chenok.

#### *Intergovernmental Review*

When this program is administered by the Secretary as a direct grant program, it is subject to the requirements of Executive Order 12372 and the

regulations in 34 CFR part 79. The Migrant Education Even Start program is also subject to these requirements. The objective of the Executive Order is to foster an intergovernmental partnership and a strengthened federalism by relying on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

In accordance with the order, this document is intended to provide early notification of the Department's specific plans and actions for this program.

#### *Invitation to Comment*

Interested persons are invited to submit comments and recommendations regarding these proposed regulations. The Secretary is particularly interested in views concerning: (1) The proposed application of the statutory priorities to the selection process; (2) the proposed use of the child-count data, described in the preamble, to allocate funds among Indian tribes and tribal organizations, territories, and projects serving migratory children; (3) the proposed three-year requirement of a State plan; and (4) whether the territories should be permitted to make subgrants.

All comments submitted in response to these proposed regulations will be available for public inspection, during and after the comment period, in room 2043, 400 Maryland Avenue, SW., Washington, DC, between the hours of 8:30 and 4 p.m., Monday through Friday of each week except Federal holidays.

To assist the Department in complying with the specific requirements of Executive Order 12291 and the Paperwork Reduction Act of 1980 and their overall requirement of reducing regulatory burden, the Secretary invites comment on whether there may be further opportunities to reduce any regulatory burdens found in these proposed regulations.

#### *List of Subjects in 34 CFR Part 212*

Adult education, Education, Education of disadvantaged children, Elementary and secondary education, Family, Family-centered education, Grant program—education, Indians—education, Reporting and recordkeeping requirements.

(Catalog of Federal Domestic Assistance Number 84.213, The Even Start program)

Dated: February 21, 1992.

Lamar Alexander,  
Secretary of Education.

The Secretary proposes to amend chapter II, title 34 of the Code of Federal Regulations by revising part 212 to read as follows:

**PART 212—EVEN START****Subpart A—General**

- Sec.
- 212.1 What is the Even Start program?
- 212.2 Who is eligible for a grant?
- 212.3 What activities may the Secretary or States fund?
- 212.4 What is the duration of a project?
- 212.5 What regulations apply?
- 212.6 What definitions apply?
- 212.7 Who are eligible participants in an Even Start project?

**Subpart B—How Does an Applicant Apply for a Grant?**

- 212.10 To whom does an eligible entity submit an application?
- 212.11 What requirements apply to eligible entities for submitting an application to the Secretary for a new grant?
- 212.12 How does an Indian tribe or tribal organization apply for assistance?
- 212.13 How does a territory apply for assistance?

**Subpart C—How Does the Secretary Make a Grant?****New Grants**

- 212.20 How does the Secretary evaluate an application from an eligible entity for a new grant?
- 212.21 What selection criteria are used in making new grants to eligible entities?
- 212.22 What additional factors does the Secretary consider in making new grants to eligible entities?
- 212.23 How does the Secretary make a grant to Indian tribes and tribal organizations, and to territories?
- 212.24 What is the portion of an Even Start grant that eligible entities are required to contribute?
- 212.25 When may the Secretary waive the requirement concerning the source of the local contribution of funds?

**Continuation Awards**

- 212.26 How does the Secretary make continuation awards if there are insufficient appropriations to fund all requests fully?
- 212.27 What actions may the Secretary take if a grantee does not make sufficient progress toward meeting its projects objectives?

**Subpart D—State Administration**

- 212.30 How does a State apply for Even Start funds?
- 212.31 What requirements must a State meet in making subgrants?
- 212.32 What selection criteria does a State use in making new subgrants?
- 212.33 What reporting requirements apply to States?
- 212.34 Which of the general Chapter 1 provisions apply to States in their administration of Even Start?

**Subpart E—Transition Provisions**

- 212.40 How are grants made when responsibility for making grants to applicants transfers between the Department and the SEAs?

**Subpart F—Migrant Education Even Start**

- 212.50 What is the Migrant Education Even Start program?
- 212.51 Who is eligible for a grant?
- 212.52 Who may be served?
- 212.53 What applications does the Secretary consider?
- 212.54 How does the Secretary evaluate an application for a new grant?
- 212.55 What selection criteria does the Secretary use in making new grants?
- 212.56 What additional factors does the Secretary consider in making new grants?
- 212.57 What other provisions in this part apply?
- 212.58 May an SEA make a subgrant to an eligible entity?

Authority: 20 U.S.C. 2741–2749, 2831, unless otherwise noted.

**Subpart A—General****§ 212.1 What is the Even Start program?**

(a) The Even Start program grants funds for the Federal share of the cost of providing family-centered education projects to help parents become full partners in the education of their children, to assist children in reaching their full potential as learners, and to provide literacy training for their parents.

(b) The Secretary implements the Even Start program by assisting cooperative projects that build on existing community resources to create a new range of services, integrating early childhood education and adult education for parents.

(Authority: 20 U.S.C. 2741, 2744(a))

**§ 212.2 Who is eligible for a grant?**

(a) If the Secretary makes direct grants under section 1052(a) of the Act, the Secretary makes grants to—

- (1) Eligible entities or consortia of eligible entities;
- (2) Territories; and
- (3) Indian tribes and tribal organizations.

(b) If the Secretary makes grants to States under section 1052(b) of the Act—

- (1) The Secretary provides funds to—
  - (i) States through their respective State educational agencies (SEAs);
  - (ii) Territories; and
  - (iii) Indian tribes and tribal organizations; and
- (2) States make subgrants to eligible entities.

(Authority: 20 U.S.C. 2742)

**§ 212.3 What activities may the Secretary or States fund?**

The Secretary or each SEA, as the case may be, funds family-centered education projects that comply with section 1054 of the Act, and that include

all of the program elements required by section 1054(b) of the Act.

(Authority: 20 U.S.C. 2744)

**§ 212.4 What is the duration of a project?**

No project operated by an eligible entity may exceed four years.

(Authority: 20 U.S.C. 2747(d))

**§ 212.5 What regulations apply?**

The following regulations apply to the Even Start program:

(a) When the Secretary makes direct grants under section 1052(a) of the Act, the following parts of the Education Department General Administrative Regulations (EDGAR):

(1) 34 CFR part 74 (Administration of Grants to Institutions of Higher Education, Hospitals and Nonprofit Organizations) for grants to nonprofit organizations.

(2) 34 CFR part 75 (Direct Grant Programs) except for grants to territories.

(3) CFR part 76 (State-Administered Programs) for grants to territories.

(4) 34 CFR part 77 (Definitions that Apply to Department Regulations).

(5) 34 CFR part 79 (Intergovernmental Review of Department of Education Programs and Activities).

(6) 34 CFR part 80 (Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments) for grants to State and local governments (including territories), and Indian tribes and tribal organizations.

(7) 34 CFR part 81 (General Education Provisions Act—Enforcement).

(8) 34 CFR part 82 (New Restrictions on Lobbying).

(9) 34 CFR part 85 (Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)).

(10) 34 CFR part 86 (Drug-Free Schools and Campuses) for grants to institutions of higher education, SEAs, LEAs, and territories.

(b) When the Secretary makes grants under section 1052(b) of the Act, the following parts of EDGAR and sections of 34 CFR part 200 (for grants to States):

(1) 34 CFR part 75 (Direct Grant Programs) for grants to Indian tribes and tribal organizations, and to SEAs under subpart F of this part.

(2)(i) 34 CFR part 76 (State-Administered Programs) for grants to States and territories, except for the following sections:

(A) Section 76.301 (Local educational agency general application).

(B) Sections 76.560 through 76.563 (Indirect Cost Rates).

(C) Section 76.684 (Day care services).

(ii) In addition, after the first three consecutive fiscal years in which section 1052(b) of the Act applies, the following sections also do not apply:

(A) Sections 76.100 through 76.106 (State Plans and Applications);

(B) Sections 76.140 through 76.142 (Amendments);

(C) Section 76.201 (A State plan must meet all statutory and regulatory requirements); and

(D) Section 76.202 (Opportunity for a hearing before a State plan is disapproved).

(3) 34 CFR part 77 (Definitions that Apply to Department Regulations).

(4) 34 CFR part 79 (Intergovernmental Review of Department of Education Programs and Activities) for grants to States and territories.

(5) 34 CFR part 80 (Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments).

(6) 34 CFR part 81 (General Education Provisions Act—Enforcement).

(7) Part 82 (New Restrictions on Lobbying).

(8) Part 85 (Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)).

(9) 34 CFR part 86 (Drug Free Schools and Campuses).

(10) The following sections of 34 CFR part 200 for grants to States:

(i) Section 200.39 (How may personnel be assigned non-chapter 1 duties?), with the term "chapter 1" interpreted as "Even Start."

(ii) Section 200.70 (Does a State have authority to issue State regulations for the chapter 1 LEA program?), with the term "chapter 1" interpreted as "Even Start," and "this part" interpreted as "part 212," except for the following:

(A) Section 200.70(c)(1).

(B) Section 200.70(e)(3)(i)(E) and (e)(3)(iii).

(iii) Section 200.73 through 200.75 (Complaint Procedures of the SEA), with the term "chapter 1 LEA program" interpreted as "Even Start."

#### § 212.6 What definitions apply?

(a) *Definitions in the Act.* The following terms used in this part are defined in section 1471 of the Act: Community-based organization, Elementary school, Equipment, Local educational agency, Parent, Secretary, State educational agency.

(b) *Definitions in EDGAR.* The following terms used in this part are defined in 34 CFR 77.1: Applicant, Application, Award, Department,

Facilities, Fiscal year, Grant, Grant period, Grantee, Nonprofit, Project.

(c) *Other definitions.* The following definitions also apply to this part:

*Act* means the Elementary and Secondary Education Act of 1965, as amended.

*Eligible entity* means—(i) An LEA applying in collaboration with a community-based organization, public agency, institution of higher education, or other nonprofit organization; or

(ii) A community-based organization or other nonprofit organization of demonstrated quality applying in collaboration with an LEA.

*Indian tribe* means any Indian tribe, band, nation, or other organized group or community, including any Alaska Native village or regional or village corporation as defined in or established pursuant to the Alaska Native Claims Settlement Act (85 Stat. 688) (43 U.S.C. 1601 *et seq.*) that is recognized as eligible for the special programs and services provided by the United States to Indians because of their status as Indians.

*State* means any of the 50 States, the District of Columbia, and the Commonwealth of Puerto Rico.

*Territory* means Guam, America Samoa, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, and Palau (until the compact of Free Association with Palau takes effect pursuant to section 101(a) of Pub. L. 99-658).

*Tribal organization* means the recognized governing body of any Indian tribe, and any legally established organization of Indians that is controlled, sanctioned, or chartered by the governing body or is democratically elected by the adult members of the Indian community to be served by the organization and that includes the maximum participation of Indians in all phases of its activities.

(Authority: 20 U.S.C. 2742(d), 2743, 2831(a))

#### § 212.7 Who are eligible participants in an Even Start project?

(a) Except as provided in paragraph (b) of this section, eligible participants are—

(1) A parent of a child described in paragraph (a)(2) of this section, if the parent is eligible for participation in an adult education program under the Adult Education Act, 20 U.S.C. 1201a(1) and (2); and

(2) A child, from birth to age 7, inclusive, of any eligible parent, who resides in an elementary school attendance area designated for participation in programs under part A of chapter 1 of title I of the Act.

(b)(1) A family that has been participating in an Even Start program and would become ineligible for participation as a result of one or more family members becoming ineligible may continue to participate in the program until all family members become ineligible.

(2) In the situation described in paragraph (b)(1) of this section, any family member who would be ineligible under paragraph (a) of this section may continue to participate in appropriate family literacy activities, provided that projects may not provide these family members special activities different from those already provided for other Even Start participants.

(Authority: 20 U.S.C. 2745)

#### Subpart B—How Does an Applicant Apply for a Grant?

##### § 212.10 To whom does an eligible entity submit an application?

An eligible entity shall submit an application to the Secretary under section 1052(a) of the Act, in the form required by the Secretary, or to the SEA under section 1052(b) of the Act, in the form required by the SEA, as the case may be.

(Authority: 20 U.S.C. 2746(a))

##### § 212.11 What requirements apply to eligible entities for submitting an application to the Secretary for a new grant?

Before submitting an application to the Secretary for a new grant under section 1052(a) of the Act, an eligible entity shall—

(a) Give reasonable notice of the general public's opportunity to testify or otherwise comment at an open meeting regarding the subject matter of the application;

(b) Hold the open meeting; and

(c) Consider comments obtained at the meeting in developing the final application.

(Authority: 20 U.S.C. 3386)

##### § 212.12 How does an Indian tribe or tribal organization apply for assistance?

An Indian tribe or tribal organization shall submit an application to the Secretary in the form required by the Secretary.

(Authority: 20 U.S.C. 2743(a))

##### § 212.13 How does a territory apply for assistance?

A territory shall—

(a) For the first three consecutive fiscal years in which section 1052(b) of the Act applies, submit a State plan to

the Secretary in accordance with 34 CFR part 76 and subpart D of this part; or

(b) Submit a consolidated grant application to the Secretary in accordance with the provisions in 34 CFR part 76.

(Authority: 20 U.S.C. 2743(a), 48 U.S.C. 1469(a))

### Subpart C—How Does the Secretary Make a Grant? New Grants

#### § 212.20 How does the Secretary evaluate an application from an eligible entity for a new grant?

(a) *Review Panel.* (1) The Secretary appoints a panel to review applications in accordance with section 1057 of the Act.

(2)(i) The panel evaluates an application for a new grant on the basis of the criteria in § 212.21.

(ii) The panel gives up to 120 points for these criteria.

(iii) The maximum possible score for each complete criterion in § 212.21 is indicated in parentheses.

(3) The panel indicates whether the applicant has adequately demonstrated its ability to provide the additional funding required by section 1054(c) of the Act.

(b) *Additional factors.* The Secretary then applies the additional considerations in § 212.22 to make grants.

(Authority: 20 U.S.C. 2747)

#### § 212.21 What selection criteria are used in making new grants to eligible entities?

The following criteria are used to evaluate an application for a new grant to an eligible entity:

(a) *Likelihood of success in meeting the Even Start goals* (40 total points plus possible 10 priority points). (1) The Secretary reviews each application to determine the extent to which the proposed project will provide a family-centered education program that includes activities to promote literacy of participating parents, train parents to support the educational growth of their children, and prepare children for success in regular school programs. In applying this criterion the Secretary determines the extent to which the project described in the application—

(i) Contains clear, attainable, measurable objectives against which the progress and success of the project will be measured (5 points);

(ii) Includes appropriate activities, services, and timelines to achieve those objectives (5 points);

(iii) Designates responsibilities to specific personnel who are qualified to administer and implement the project and to provide special training

necessary to prepare staff for the program (5 points);

(iv) Includes an effective plan to ensure proper and efficient administration of the project (5 points);

(v) Is based on sound research in the areas of early childhood education, adult literacy, and parenting education (5 points);

(vi) Contains instructional and developmental activities appropriate to the level of the participants to be served (5 points);

(vii) Provides for continuity of services to maintain progress by, for example, providing continuous services through the summer months (5 points); and

(viii) Provides—

(A) Objective evidence, including quantitative data on the educational and related outcomes of the program, that the applicant, or its collaborating LEA, has had past success in operating a literacy program, an adult education program, an early childhood education program, or a parenting education program; or

(B) A description of the specific family literacy model that the applicant proposes to implement (including quantitative data on the model's effectiveness), information supporting the applicability of the model to the local site, and a detailed description of how the model will be implemented in the proposed project (5 points).

(2) The Secretary gives 10 additional points to applicants that—

(i) Receive at least 35 out of 40 points under paragraph (a) of this section; and

(ii) Receive 5 points under paragraph (a)(1)(viii) of this section, based on paragraph (a)(1)(viii)(A) of this section (0 or 10 points).

(Authority: 20 U.S.C. 2744(b)(7), 2747, 2831(a))

(b) *Need for the project* (10 points plus possible 10 priority points). (1) The Secretary reviews each application to determine the extent to which the applicant demonstrates that the area to be served has a high percentage or large number of children and parents in need of Even Start services.

(2) For purposes of paragraph (b)(1) of this section, need for Even Start services must be shown by demonstrating the following:

(i) High levels of poverty, illiteracy, unemployment, limited English proficiency, or other need-related indicators. High levels of need may be shown by comparison with other areas of the State or the United States.

(ii) The unavailability of comprehensive family literacy services for the target population that could be provided by other programs. If similar

programs serve the same population, applicants may provide evidence of waiting lists or other indicators that local demand exceeds the ability of those programs to meet the needs.

(3) The Secretary gives 10 additional points to applicants providing substantial objective documentation of need in more than one of the indicators listed in paragraph (b)(2)(i) of this section (0 or 10 points).

(c) *Degree of cooperation and coordination* (30 total points). The Secretary reviews each application to determine the extent to which cooperation and coordination will take place in all phases of the proposed project among a variety of relevant service providers, including those funded under the programs listed in section 1054(b)(7) of the Act. The Secretary considers the extent to which—

(1) The applicant has made a survey of all relevant providers and is fully aware of similar and related services, including State and locally funded programs, being provided to eligible children and adults (5 points);

(2) The applicant has, in planning the project, engaged various providers in discussions that have resulted in firm agreements for specific cooperative activities (10 points);

(3) The plan of operation includes specific provision for additional cooperative efforts with other service providers, including State and locally funded providers, throughout the duration of the project (5 points); and

(4) Services offered by the applicant will build upon, but not duplicate, those being provided to project participants by the applicant or other service providers (10 points).

(d) *Reasonableness of budget* (10 points). The Secretary reviews each application to determine the extent to which the budget submitted for the entire cost of the proposed project appears reasonable, given the scope of the project. The Secretary considers the extent to which—

(1) Costs are reasonable in relation to expected outcomes;

(2) The applicant will make use of currently available resources such as facilities and equipment; and

(3) The budget provides sufficient information to support the requested amount of funds.

(e) *Promise as a model* (10 total points). The Secretary reviews each application to determine the extent to which the proposed project shows promise in providing a model that may be transferred to other eligible entities.

The Secretary considers the extent to which—

- (1) The preliminary evaluation plan described in the application—
  - (i) Measures the progress and success of the project in achieving its clearly stated and attainable objectives;
  - (ii) Utilizes concrete and quantifiable means of measurement; and
  - (iii) Includes, if possible, comparisons with appropriate control groups (5 points);
- (2) The general components of the project are readily understandable and usable by other entities, and are based on research or models that have proven to be adaptable to various circumstances (3 points); and
- (3) The applicant shows a willingness to serve as a model and to disseminate detailed information about the project to the Department and to other eligible entities (2 points).

(Authority: 20 U.S.C. 2744(b)(7), 2747, 2831(a))

**§ 212.22 What additional factors does the Secretary consider in making new grants to eligible entities?**

(a) The Secretary, in approving grants to eligible entities, ensures that—

- (1) Each project builds on existing community resources in a cooperative effort to create a new range of services integrating early childhood education and adult education for parents into a unified program; and
- (2)(i) Grants are made to eligible entities that are representative of urban and rural regions of the United States.
- (ii) Grant funds are distributed equitably among the States and among urban and rural areas of the United States.

(b)(1) For purposes of this section, urban eligible entities are those within Metropolitan Areas (MAs), as most recently designated by the United States Department of Commerce, Bureau of Census, and rural eligible entities are those outside the boundaries of MAs.

(2) If an eligible entity includes areas both within and outside of an MA, the applicant shall designate the category in which the majority of expected participants reside.

(c) To the extent that acceptable applications are received from the various States, the Secretary does not give grants to eligible entities in one State in amounts that, in total, exceed the amount that the State would be allocated under section 1053(b) of the Act if the appropriation for the Even Start program equals \$50 million.

(Authority: 20 U.S.C. 2741, 2747(a)(1)(F), (c), (d)(2))

**§ 212.23 How does the Secretary make a grant to Indian tribes and tribal organizations, and to territories?**

(a)(1) The Secretary provides funds to Indian tribes and tribal organizations by making grants based on applications submitted under § 212.12.

(2) The Secretary applies the following sections of this part in making new grants to Indian tribes and tribal organizations:

(i) Section 212.20, with the exception of § 212.20(a)(2).

(ii) Section 212.21.

(iii) Section 212.22(a)(1).

(b)(1) The Secretary provides funds to the territories by making grants based on applications submitted under § 212.13, according to the relative need of each territory.

(2) The relative need of each territory is considered to be in proportion to the amount of funds received by the territory under part A of chapter 1 of title I of the Act.

(Authority: 20 U.S.C. 2743(a))

**§ 212.24 What is the portion of an Even Start grant that eligible entities are required to contribute?**

(a) An Even Start grant to an eligible entity is comprised of a Federal portion of funds and a portion contributed by the eligible entity.

(b) The eligible entity's portion of an Even Start grant is—

(1) In the first year of the project's funding, at least 10 percent of the total cost of the project;

(2) In the second year of the project's funding, at least 20 percent of the total cost of the project;

(3) In the third year of the project's funding, at least 30 percent of the total cost of the project.

(4) In the fourth year and any subsequent year of the project's funding, at least 40 percent of the total cost of the project.

(c) The eligible entity's portion may be obtained from any source other than funds made available for programs under Chapter 1 of Title I of the Act, and may be provided in cash or in kind, fairly evaluated.

(Authority: 20 U.S.C. 2744)

**§ 212.25 When may the Secretary waive the requirement concerning the source of the local contribution of funds?**

The Secretary may waive in whole or in part the requirement that the local share of the cost of the project be obtained from sources other than funds under chapter 1 of title I of the Act if—

(a) An eligible entity demonstrates that, due to its own financial situation and the lack of any other sources of funding—

(1) It otherwise would not be able to conduct an Even Start project; or

(2) It otherwise would not be able to continue its project at the level previously maintained, if it is a grantee applying for a continuation grant;

(b) The demonstration required by paragraph (a) of this section is supported by detailed financial data and is accompanied by a signed statement from a responsible official that all possible sources of funding, including cooperating entities, have been explored;

(c) The applicant designates the specific funds under chapter 1 of the title I of the Act that it intends to use for its local share; and

(d) The applicant negotiates an agreement with the Secretary with respect to the amount of the local contribution to which the waiver would be applicable.

(Authority: 20 U.S.C. 2744(c))

**§ 212.26 How does the Secretary make continuation awards if there are insufficient appropriations to fund all requests fully?**

(a) If funds are insufficient for the Secretary to fund all continuation requests in the amounts at which each request would otherwise be funded ("approvable grant" amounts), the Secretary reduces the approvable grant amounts for continuation requests on a pro rata basis.

(b) The Secretary does not reduce funding for a project for any fiscal year more than 25 percent below its approvable grant amount, subject to paragraph (c) of this section.

(c) If funds are insufficient to fund all continuation awards at 75 percent of their approvable grant amounts, the Secretary—

(1) Ranks all continuation requests based on the criteria in § 212.21, taking into account information collected throughout the project period, including yearly progress reports, the application submitted in the first year, and revisions to that application; and

(2) Funds continuation requests, based on that rank ordering, at 75 percent of approvable grant amounts until funds are exhausted.

(d) If the ranking procedure in paragraph (c) of this section does not result in the distribution of awards consistent with the requirements of § 212.22(a), the Secretary adjusts the selection process so as to meet those requirements.

(Authority: 20 U.S.C. 2831(a))

**§ 212.27 What actions may the Secretary take if a grantee does not make sufficient progress toward meeting its project objectives?**

If the Secretary finds, after the first, second, or third year of a project, that the grantee has not made sufficient progress toward meeting its project objectives, the Secretary may—

(a) Approve revisions to the project, proposed by the grantee, if those revisions would enable the grantee to meet its project objectives; or

(b) After affording the grantee notice and an opportunity for a hearing, refuse to make a continuation award to the grantee for that project.

(Authority: 20 U.S.C. 2747(d)(1))

**Subpart D—State Administration**

**§ 212.30 How does a State apply for Even Start funds?**

(a) In order to receive assistance for the first fiscal year in which section 1052(b) of the Act applies, a State must provide to the Secretary a State plan, that must include the following:

(1) The certifications required by 34 CFR 76.104.

(2) A description of the selection criteria to be used in making subgrants to eligible entities if the State does not adopt the selection criteria in § 212.21.

(3) A description of how the SEA will coordinate Even Start activities with appropriate offices at the State level, including the following:

(i) Those dealing with adult education and early childhood education.

(ii) Those administering the Federal programs listed in section 1054(b)(7) of the Act.

(iii) Other appropriate Statewide organizations, such as Statewide literacy councils.

(4) A description of how the State will ensure, through such means as monitoring, that grantees will meet the requirements of sections 1054–1057 of the Act.

(5) An assurance that the State will meet the requirements in section 435(b)(2) and (5) of the General Education Provisions Act (GEPA) relating to fiscal control and fund accounting procedures.

(6) An assurance that the State will comply with all applicable Federal laws in implementing the program.

(b) In order to receive assistance for the second and third consecutive fiscal years in which section 1052(b) of the Act applies, a State shall submit to the Secretary an update or amendment to the plan submitted under paragraph (a) of this section, if there have been any changes to information submitted in that plan.

(c) In order to receive assistance for the fourth and following fiscal years in which section 1052(b) of the Act applies, a State shall submit to the Secretary assurances that it—

(1) Will coordinate Even Start activities with appropriate offices at the State level, including the following:

(i) Those dealing with adult education and early childhood education.

(ii) Those administering the Federal programs listed in section 1054(b)(7) of the Act.

(iii) Other appropriate Statewide organizations, such as Statewide literacy councils.

(2) Will ensure that its LEAs comply with all the applicable statutory and regulatory requirements.

(3) Will meet the requirements in section 435(b)(2) and (5) of GEPA relating to fiscal control and fund accounting procedures.

(4) Will comply with all applicable Federal laws in implementing the program.

(Authority: 20 U.S.C. 2747(d), 2831(a))

**§ 212.31 What requirements must a State meet in making subgrants?**

(a) Projects supported by subgrants must—

(1) Be funded at no less than \$75,000;

(2) Be of sufficient size, scope, and quality to give reasonable promise of meeting the purposes of Even Start; and

(3) Make maximum use of the resources available at the local level.

(b) Before making subgrants, a State must—

(1) Determine the effectiveness and financial needs of the currently funded projects within the State;

(2) Consider a current grantee to have an acceptable continuation application if—

(i) The grantee shows that it is making sufficient progress toward meeting the objectives of the project; and

(ii) The grantee meets applicable State requirements for continuation awards; and

(3) Determine, for each current grantee with an acceptable continuation application, an award amount that will ensure the project's continuity of services for the next fiscal year, provided that sufficient funds exist for the State to continue all projects.

(c)(1) A State may permit a grantee to retain funds from State grants that are unobligated by the grantee in one project year, in which case the SEA shall deduct from the subsequent year's continuation award an amount equal to the unobligated funds.

(2) After making continuation awards, the SEA shall use any remaining funds to make grants to new applicants, subject to paragraph (a) of this section.

(d) A State shall ensure a representative distribution of assistance between urban and rural areas of the State.

(Authority: 20 U.S.C. 2742(b), 2747(c)(2), (d)(2), 2831(a))

**§ 212.32 What selection criteria does a State use in making new subgrants?**

In making new subgrants under section 1052(b) of the Act, a State may—

(a) Apply the criteria contained in § 212.21; or

(b) Apply its own criteria, provided the criteria are consistent with section 1057 of the Act.

(Authority: 20 U.S.C. 2747)

**§ 212.33 What reporting requirements apply to States?**

In any fiscal year in which section 1052(b) of the Act applies, States shall annually report such information about program operations as may be required by the Secretary.

(Authority: 20 U.S.C. 1232f(a), 2852)

**§ 212.34 Which of the general Chapter 1 provisions apply to States in their administration of Even Start?**

The following sections of parts E and F of chapter 1 of title I of the Act apply to States in their administration of Even Start:

(a) Section 1404 of the Act (Payments for State Administration).

(b) Section 1433 of the Act (Withholding of Payments).

(c) Section 1434 of the Act (Judicial Review).

(d) Section 1438 of the Act (Application of General Education Provisions Act).

(e) Section 1451 of the Act (State Regulations).

(f) Section 1452 of the Act (Records and Information).

(g) Section 1453 of the Act (Assignment of Personnel), to the extent the Even Start personnel are paid entirely with Even Start funds and perform their duties in an elementary school setting.

(h) Section 1454 of the Act (Prohibition Regarding State Aid).

(i) Section 1471 of the Act (Definitions).

(Authority: 20 U.S.C. 2824, 2833, 2834, 2838, 2851–2854, 2891)

**Subpart E—Transition Provisions****§ 212.40 How are grants made when responsibility for making grants to applicants transfers between the Department and the SEAs?**

When the responsibility for administering the Even Start program transfers from the Department to the SEAs, or vice versa—

(a) The Secretary applies—

(1) 34 CFR 75.253 with the exception of 34 CFR 75.253 (a)(2);

(2) Section 212.27; and

(3) Section 212.26, if necessary;

(b) A State applies §§ 212.31 and 212.32; and

(c) The Federal share limitations contained in section 1054(c) of the Act are determined from the original year of the project grant award.

(Authority: 20 U.S.C. 2747(d), 2831(a))

**Subpart F—Migrant Education Even Start****§ 212.50 What is the Migrant Education Even Start program?**

(a) The Migrant Education Even Start program supports grants to eligible SEAs for the cost of providing family-centered education projects to help parents of currently migratory children (as defined in 34 CFR 201.3) become full partners in the education of their children, to assist currently migratory children in reaching their full potential as learners, and to provide literacy training for their parents.

(b) The Secretary makes grants for family centered education projects that provide services on an intrastate or interstate basis, and that include all of the program elements required by section 1054(b) of the Act.

(Authority: 20 U.S.C. 2741, 2743, 2831)

**§ 212.51 Who is eligible for a grant?**

An SEA or a consortium of SEAs that applies under section 1053(a) of the Act is eligible to receive a grant under the Migrant Education Even Start program.

(Authority: 20 U.S.C. 2743, 2831)

**§ 212.52 Who may be served?**

(a) Except as provided in paragraph (b) of this section, eligible participants under this subpart are—

(1) A parent of a child described in paragraph (b) of this section, if the parent is eligible for participation in an adult basic education program under the Adult Education Act, 20 U.S.C. 1201(a)(1) and (2); and

(2)(i) As a first priority, a currently migratory child, as defined in 34 CFR 201.3, from birth to age 7, inclusive; and

(ii) As a second priority and, if space is available, a formerly migratory child,

as defined in 34 CFR 201.3, from birth to age 7, inclusive.

(b)(1) A family that would become ineligible for participation as a result of one or more family members becoming ineligible may continue to participate in the program until all family members become ineligible.

(2) In the situation described in paragraph (b)(1) of this section, to the extent possible, any family member who would be ineligible under paragraph (a) of this section may continue to be involved in appropriate family literacy activities, provided that projects may not provide these family members special activities different from those already provided for other Migrant Education Even Start participants.

(Authority: 20 U.S.C. 2743, 2745, 2831)

**§ 212.53 What applications does the Secretary consider?**

(a) The Secretary considers an application that—

(1) Meets the purposes of the Migrant Education Even Start program as provided in § 212.50; and

(2) Adequately demonstrates the applicant's ability to provide the additional funding required by section 1054(c) of the Act.

(b) As provided in § 212.25, the Secretary may waive the requirement in section 1054(c) of the Act concerning the source of the local contribution of funds.

(Authority: 20 U.S.C. 2743, 2744)

**§ 212.54 How does the Secretary evaluate an application for a new grant?**

(a) The Secretary uses the criteria in § 212.55 to evaluate an application.

(b) The Secretary awards up to 120 possible points for these criteria.

(c) The maximum number of points for each criterion is indicated in § 212.55(c).

(Authority: 20 U.S.C. 2743, 2747)

**§ 212.55 What selection criteria does the Secretary use in making new grants?**

The Secretary uses the criteria in § 212.21 in evaluating an application, except that—

(a) The criteria in § 212.21(b) (1) and (2) (regarding *Need for the project*) do not apply. Instead, for purposes of this subpart, the Secretary uses the criterion in paragraphs (a) (1) and (2) of this section to evaluate the need for the project.

(1) The Secretary reviews each application to determine the extent to which the applicant demonstrates that, during the period in which the project would operate in a particular location, the areas to be served have high percentages or large numbers of currently migratory children and their

parents in need of Migrant Education Even Start services.

(2) For purposes of paragraph (a)(1) of this section—

(i) Need for Migrant Education Even Start services must be shown by demonstrating high levels of poverty, illiteracy, unemployment, limited English proficiency, or other need-related indicators; and

(ii) High levels of need during the period in which the project would operate in a particular location may be shown by comparison with other areas of the State or of the United States.

(b)(1) The criterion in § 212.21(c)(2) (regarding the *Degree of cooperation and coordination*) does not apply.

(2) Instead, for purposes of this subpart, the Secretary considers, as a criterion, the extent to which the applicant has, in planning the interstate or intrastate project, engaged various providers in all locations in which the project would operate, in discussions that have resulted in firm agreements for specific cooperative activities.

(c) The maximum number of points that an applicant may receive for each selection criterion is:

(1) *Likelihood of success in meeting the Even Start goals*—32 points plus a possible 10 priority points. The Secretary awards up to four points for each criterion contained in § 212.21(a)(1)(i) through (a)(1)(viii).

(2) *Need for the project*—20 points.

(3) *Degree of cooperation and coordination*—30 points. The Secretary distributes these points as follows: § 212.21(c)(1)—5 points, § 212.55(b)—10 points, § 212.21(c)(3)—5 points, and § 212.21(c)(4)—10 points.

(4) *Reasonableness of budget*—8 points.

(5) *Promise as a model*—20 points. The Secretary distributes these points as follows: § 212.21(e)(1)—(9 points), § 212.21(e)(2)—(9 points), and § 212.21(e)(3)—(2 points).

(Authority: 20 U.S.C. 2743, 2831)

**§ 212.56 What additional factors does the Secretary consider in making new grants?**

(a) In addition to applying the criteria in §§ 212.21 and 212.55, the Secretary ensures that—

(1) Grants are made to projects that ensure coordination and cooperation between States (or areas of a State) in which participating children and parents reside during the year;

(2) Each project will build on existing community resources in a cooperative effort to create a new range of services integrating early childhood education and adult education for parents into a unified program; and

(3) To the extent possible, grants are distributed equitably among the States in the three migrant streams, as defined in paragraph (c) of this section.

(b) In order to meet the requirements of paragraph (a)(3) of this section, the Secretary—

(1) Separates applications into three groups representing the three migrant streams; and

(2) Awards grants to applicants in each stream that are ranked the highest as a result of the process in § 212.54, provided that there is one or more acceptable applications from an SEA or consortium of SEAs in that stream.

(c) For the purposes of this section, the States comprising each stream are the following:

#### EASTERN STREAM—

Alabama	New York
Connecticut	North Carolina
Delaware	Pennsylvania
Florida	Puerto Rico
Georgia	Rhode Island
Kentucky	South Carolina
Maine	Tennessee
Maryland	Vermont
Massachusetts	Virginia
Mississippi	West Virginia
New Hampshire	District of Columbia
New Jersey	

#### CENTRAL STREAM—

Arkansas	Missouri
Illinois	Nebraska
Indiana	North Dakota
Iowa	Ohio
Kansas	Oklahoma
Louisiana	South Dakota
Michigan	Texas
Minnesota	Wisconsin

#### WESTERN STREAM—

Alaska	New Mexico
Arizona	Oregon
California	Utah
Colorado	Washington
Idaho	Wyoming
Montana	Mariana Islands
Nevada	

(Authority: 20 U.S.C. 2743, 2831)

#### § 212.57 What other provisions in this part apply?

(a) In addition to the provisions in this subpart, the following provisions in this part apply to the Migrant Education Even Start program:

(1) Section 212.3.

(2) Section 212.4.

(3) Section 212.5, except for § 212.5(b)(10). In the place of § 212.5(b)(10), paragraphs (a)(3) (i) through (iii) of this section apply.

(i) The following sections of 34 CFR part 201 apply to the Migrant Education Even Start program:

(A) Section 201.46 (State rulemaking and other SEA responsibilities.), except for § 201.46(e)(3)(i)(E).

(B) Section 201.47 (Complaint procedures for an SEA.).

(C) Section 201.49 (Persons to be assigned non-Chapter 1 duties.).

(ii) In §§ 201.46, 201.47, and 201.49, "chapter 1" or "chapter 1—Migrant Education Program" are interpreted as "Migrant Education Even Start."

(iii) Paragraphs (a)(3) (i) and (ii) of this section also apply when the Secretary makes direct grants under section 1052(a) of the Act.

(4) Section 212.6, except for the definition of *Eligible entity* in § 212.6(c). For the purposes of the Migrant Education Even Start program, except as noted in paragraph (b) and (c) of this section, *Eligible entity* means—

(i) An LEA or other operating agency as defined in 34 CFR 201.3 applying in collaboration with a community-based organization, public agency, institutions of higher education, or other nonprofit organization; or

(ii) A community-based organization or other nonprofit organization of

demonstrated quality applying in collaboration with an LEA or other operating agency as defined in 34 CFR 201.3.

(5) Section 212.23.

(6) Section 212.24.

(7) Section 212.25.

(8) Section 212.26, except that for the purposes of the Migrant Education Even Start program, the appropriate cross-references in § 212.26 (c) and (d) to §§ 212.21 and 212.22(a) are to §§ 212.55 and 212.56, respectively.

(9) Section 212.27.

(b) For the purposes of the Migrant Education Even Start program, in §§ 212.21, 212.24(a) and 212.25 an "eligible entity" means an SEA.

(c) For the purposes of the Migrant Education Even Start program, in § 212.24 (b) and (c) an "eligible entity" means an SEA or eligible entity.

(Authority: 20 U.S.C. 2743)

#### § 212.58 May an SEA make a subgrant to an eligible entity?

(a) Notwithstanding the prohibition of subgrants in 34 CFR 75.708(a), an SEA that receives a grant under the Migrant Education Even Start program may make a subgrant of funds to one or more eligible entities, as defined in § 212.57(a)(4), provided that program funds are used as the SEA's approved project application specifies.

(b) An SEA that makes a subgrant of funds to one or more eligible entities may use not more than 5 percent of its Migrant Education Even Start grant for the costs of administration and technical assistance.

(Authority: 20 U.S.C. 2743, 2831)

[FR Doc. 92-4577 Filed 2-27-92; 8:45 am]

BILLING CODE 4000-01-M

# **federal register**

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**Friday  
February 28, 1992**

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**Part VII**

## **The President**

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**Proclamation 6406—American Red Cross  
Month, 1992**



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# Presidential Documents

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Title 3—

Proclamation 6406 of February 26, 1992

The President

American Red Cross Month, 1992

By the President of the United States of America

**A Proclamation**

Since its founding in 1881, the American Red Cross has earned the respect and trust of millions of people around the world—many of whom have benefitted directly from its outstanding humanitarian programs. This month, we salute and thank the more than 1,000,000 volunteers and 23,000 staff members who conduct the life-saving work of today's Red Cross.

In addition to offering valuable health and safety information to the public, the American Red Cross has long brought vital aid and services to victims of natural disasters and other emergencies, to persons in need of blood, and to members of the Armed Forces. The past year was extraordinarily eventful by any standard, and we owe a special debt to the members of the Red Cross, who rose to the challenges it presented.

One of the most significant events of 1991, of course, was the war in the Persian Gulf, and members of the American Red Cross were there. At the outset of Operation Desert Storm, the Red Cross shipped 10,000 pints of blood to the Gulf. As our troops fought to liberate Kuwait and repel Iraqi aggression, Red Cross workers provided them with an important link to their families, relaying emergency messages from home. In the United States, Red Cross staff and volunteers helped to counsel spouses, established support groups, and provided emergency loans and grants to ease the burden of separation on military families.

In keeping with its commitment to serving people in need without regard to race, creed, or national origin, the Red Cross remained in the region to assist refugees and other persons affected by the war. In Kuwait a 50-member medical team recruited by the Red Cross delivered emergency care for hundreds of patients in a war-ravaged hospital. Team members also operated a camp on the Iraq-Kuwait border providing refuge and medical care for tens of thousands of men, women, and children driven or fleeing from their homes.

Despite the demands of its overseas operations in 1991, the American Red Cross continued to maintain a high level of activity at home. During a year that saw an unprecedented series of tornadoes, floods, and other natural disasters, thousands of Red Cross workers operated shelters, served meals, and provided financial assistance to individuals and families in need. On average, the Red Cross helps victims of about 55,000 disasters—from house fires to hurricanes—each year.

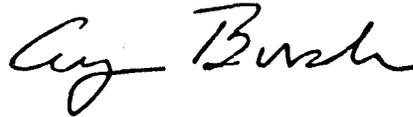
During the past year, the Red Cross continued its health and safety programs, training thousands of Americans in first aid, cardiopulmonary resuscitation (CPR), and water safety. Red Cross workers also continued to collect, process, and distribute more than half of our Nation's blood supply—some 6,000,000 units—thereby ensuring countless Americans of life-saving transfusions.

Because so many people place their trust in the American Red Cross, the Red Cross is working to ensure that it will always meet the highest standards of performance and accountability. For example, it has launched a far-reaching modernization of its blood services programs to produce a state-of-the-art operation to meet the challenge of 21st century medicine. This month, as we

recognize the outstanding contributions of Red Cross volunteers and staff, we also thank them for their commitment to even greater accomplishments in the future.

NOW, THEREFORE, I, GEORGE BUSH, President of the United States of America and Honorary Chairman of the American National Red Cross, by virtue of the authority vested in me by the Constitution and laws of the United States, do hereby proclaim the month of March 1992 as American Red Cross Month. I urge all Americans to continue their generous support of the work of the American Red Cross and its local chapters.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-sixth day of February, in the year of our Lord nineteen hundred and ninety-two, and of the Independence of the United States of America the two hundred and sixteenth.



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Friday, February 28, 1992

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This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with "P L U S" (Public Laws Update Service) on 202-523-6641. The text of laws is not published in the **Federal Register** but may be ordered in individual pamphlet form (referred to as "slip laws") from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202-512-2470).

**H.R. 2927/P.L. 102-247**

Omnibus Insular Areas Act of 1992. (Feb. 24, 1992; 106 Stat. 33; 7 pages) Price: \$1.00

Last List February 21, 1992

