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# federal register

Tuesday
November 29, 1983

## Selected Subjects

**Air Carriers**
Civil Aeronautics Board

**Air Pollution Control**
Environmental Protection Agency

**Anchorage Grounds**
Coast Guard

**Aviation Safety**
Federal Aviation Administration

**Color Additives**
Food and Drug Administration

**Endangered and Threatened Species**
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**Flood Insurance**
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**Hazardous Materials Transportation**
Research and Special Programs Administration

**Hazardous Substances**
Environmental Protection Agency

**Marketing Agreements**
Agricultural Marketing Service

**Pesticides and Pests**
Environmental Protection Agency

**Radio Broadcasting**
Federal Communications Commission

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# Selected Subjects

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Civil Aeronautics Board
Environmental Protection Agency
Nuclear Regulatory Commission

**Securities**
Securities and Exchange Commission

**Television**
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## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

### 7 CFR Part 907

[Navel Orange Reg. 582]

### Navel Oranges Grown in Arizona and Designated Part of California; Limitation of Handling

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes the quantity of fresh California-Arizona navel oranges that may be shipped to market during the period December 2–December 8, 1983. Such action is needed to provide for orderly marketing of fresh navel oranges for this period due to the marketing situation confronting the orange industry.

**EFFECTIVE DATE:** December 2, 1983.

**FOR FURTHER INFORMATION CONTACT:** William J. Doyle, 202–447–5975.

**SUPPLEMENTARY INFORMATION:**

**Findings**

This rule has been reviewed under USDA procedures and Executive Order 12291 and has been designated a "non-major" rule. William T. Manley, Deputy Administrator, Agricultural Marketing Service, has certified that this action will not have a significant economic impact on a substantial number of small entities.

This regulation is issued under the marketing agreement, as amended, and Order No. 907, as amended (7 CFR Part 907), regulating the handling of navel oranges grown in Arizona and designated part of California. The agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674). This action is based upon the recommendation and information submitted by the Navel Orange Administrative Committee and upon other available information. It is hereby found that this action will tend to effectuate the declared policy of the Act.

This action is consistent with the marketing policy for 1983–84. The marketing policy was recommended by the committee following discussion at a public meeting on September 27, 1983. The committee met again publicly on November 21, 1983, at Los Angeles, California, to consider the current and prospective conditions of supply and demand and recommended a quantity of navel oranges deemed advisable to be handled during the specified week. The committee reports the demand for navel oranges is improving.

It is further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking, and postpone the effective date until 30 days after publication in the **Federal Register** (5 U.S.C. 553), because of insufficient time between the date when information became available upon which this regulation is based and the effective date necessary to effectuate the declared policy of the Act. Interested persons were given an opportunity to submit information and views on the regulation at an open meeting. It is necessary to effectuate the declared policy of the Act to make this regulatory provision effective as specified, and handlers have been apprised of such provision and the effective time.

**List of Subjects in 7 CFR Part 907**

Marketing agreements and orders, California, Arizona, Oranges (Navel).

1. § 907.882 is added as follows:

**§ 907.882 Navel Orange Regulation 582.**

The quantities of navel oranges grown in California and Arizona which may be handled during the period December 2 through December 8, 1983, are established as follows:

(a) District 1: 1,547,000 cartons;
(b) District 2: Unlimited cartons;
(c) District 3: 153,000 cartons;
(d) District 4: Unlimited cartons.

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674)

Dated: November 23, 1983.

**Russell L. Hawes,**
*Acting Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.*

[FR Doc. 83–31838 Filed 11–28–83; 8:45 am]

BILLING CODE 3410–02–M

### 7 CFR Part 989

### Raisins Produced From Grapes Grown in California; Addition of Muscat (Including Other Raisins With Seeds), Sultana, and Zante Currant Raisins to Weight Dockage System and Conforming Changes

**AGENCY:** Agricultural Marketing Service, USDA.

**ACTION:** Emergency interim final rule.

**SUMMARY:** This emergency interim final rule adds Muscat (including other raisins with seeds), Sultana and Zante Currant raisins under a weight dockage system for immaturity under the Federal marketing order for California raisins. The inclusion of these varietal types of raisins under the dockage system permits handlers of these raisins to acquire them as natural condition standard raisins even though the lot has been determined to be off-grade because of an excess of immature raisins. This action is based on a recommendation of the Raisin Administrative Committee (RAC). The RAC works with USDA in administering the order. A finding is included for determining that an emergency situation exists which warrants prompt implementation of this rule.

**DATES:** Effective with the 1983–84 crop year, which began August 1, 1983; comments must be received by December 14, 1983.

**ADDRESSES:** Send two copies of comments to the Hearing Clerk, Room 1077, South Building, U.S. Department of Agriculture, Washington, D.C. 20250, where they will be available for public inspection during regular business hours.

**FOR FURTHER INFORMATION CONTACT:** Frank M. Grasberger, Acting Chief, Specialty Crops Branch, Fruit and Vegetable Division, AMS, USDA, Washington, D.C. 20250 (202) 447–5053.

**SUPPLEMENTARY INFORMATION:** This action has been reviewed under USDA guidelines implementing Executive Order 12291 and Secretary's

Memorandum No. 1512-1 and has been classified a "non-major" rule under criteria contained therein.

William T. Manley, Deputy Administrator, Agricultural Marketing Service, has certified that this action will not have a significant economic impact on a substantial number of small entities.

It has been determined that an emergency situation exists which warrants publication of this interim final rule without prior opportunity for public comment. Handlers are acquiring 1983-84 crop Muscat (including other raisins with seeds), Sultana, and Zante Currant raisins. Handlers and producers have expressed a desire to use the weight dockage system for these varietal types this season. Therefore, prompt implementation of this action is necessary so that raisin producers and handlers can utilize the weight dockage system for the 1983-84 crop year which began August 1, 1983.

Therefore, pursuant to the administrative procedure provisions in 5 U.S.C. 553, it is found that notice of rulemaking and other public procedure with respect to this emergency interim final action are impracticable and contrary to the public interest and that good cause is found for making this emergency interim final rule effective less than 30 days after publication of this document in the **Federal Register.** Comments will be solicited for 15 days after publication of this document, and this emergency interim final action will be reviewed at that time.

The weight dockage system is contained in § 989.210 of Subpart—Supplementary Regulations (7 CFR 989.210-989.221; 48 FR 35347; 49214; 52028). Conforming changes are necessary in § 989.701 of Subpart Quality Control (7 CFR 989.701-989.703; 48 FR 49214). These subparts are operative pursuant to the marketing agreement, and Order No. 989, both as amended, regulating the handling of raisins produced from grapes grown in California (hereinafter referred to collectively as the "order"). The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674). Authority for the weight dockage system is contained in § 989.58(a) of the order.

Currently, Muscat (including other raisins with seeds), Sultana, and Zante Currant raisins are not included under a weight dockage system for immaturity. The RAC recommended that these varietal types also be included in a weight dockage system together with Natural (Sun-dried) Seedless, Dipped Seedless, Oleate and Related Seedless, Golden Seedless, and Monukka raisins. The inclusion of these three varietal types of raisins under the dockage system permits handlers to acquire them as natural condition standard raisins even though the raisins have been determined to be off-grade because of an excess of immature raisins. The immature raisins usually can be removed from the lot of raisins by the handler during normal processing so the balance of the lot meets grade requirements. The creditable weight of such lot is computed by multiplying the net weight of the lot by a dockage factor. The factor reduces the weight of the lot by an amount approximating the weight of the immature raisins needed to be removed from the lot in order for the balance of the lot to meet grade requirements.

Current minimum grade and condition requirements prescribed in § 989.701 for these three varietal types state that they shall be fairly free from immature (skinny) raisins and shall have a normal characteristic color, flavor, and odor of properly prepared raisins. The industry's interpretation of this requirement is that any lot of raisins containing 12 percent or less, by weight, of immature raisins meets this requirement. Thus, the establishment of a 12 percent minimum for a weight dockage system was recommended by the RAC in keeping with current industry practices.

Permitting handlers to acquire low maturity raisins of these three varietal types as standard raisins under this system will speed up acquisitions, save inspection costs, and save the producers of such raisins additional reconditioning costs.

Therefore, paragraph (h) is added to § 989.210 designating a dockage system applicable to Muscat (including other raisins with seeds), Sultana, and Zante Currant raisins. Also, other conforming changes are made in § 989.210 and in § 989.701 in recognition of this designation.

After consideration of all relevant matter presented, the information and recommendation submitted by the Raisin Administrative Committee and other information, it is determined that the changes hereinafter set forth will tend to effectuate the declared policy of the act.

**List of Subjects in 7 CFR Part 989**

Marketing agreements and orders, Grapes, Raisins and California.

Therefore, the emergency interim final rule is as follows:

1. Section 989.210 of Subpart — Supplementary Regulations (7 CFR 989.210-989.221; 48 FR 35347; 49214; 52028) is amended by revising the section heading paragraphs (a) through (f), and the heading for paragraph (g), and by adding a new paragraph (h) to read as follows:

## Subpart—Supplementary Regulations

### § 989.210 Handling of varietal types of raisins acquired pursuant to a weight dockage system.

(a) *General.* Subject to prior agreement between handler and tenderer, a handler may acquire as standard raisins any lot of Natural (sun-dried) Seedless, Golden Seedless, Dipped Seedless, Monukka, and Oleate and Related Seedless raisins containing more than 6 percent beginning with the 1983-84 crop year, 4 percent beginning with the 1984-85 crop year, and 2 percent beginning with the 1985-86 and subsequent crop years, by weight, of substandard raisins under a weight dockage system. A handler also may, subject to prior agreement, acquire as standard raisins any lot of Muscat (including other raisins with seeds), Sultana, and Zante Currant raisins containing more than 12 percent, by weight, of substandard raisins under a weight dockage system. The creditable weight of each lot of raisins acquired in this manner shall be that obtained by multiplying the net weight of the raisins in the lot by the applicable dockage factor from the appropriate dockage table prescribed in paragraphs (g) or (h) of this section.

(b) *Free and reserve tonnage percentages.* Whenever free and reserve percentages are designated for raisins of the varietal types specified in paragraph (a) of this section for a crop year, such percentages shall be applicable to the creditable weight of any lot of such raisins acquired by a handler pursuant to a weight dockage system.

(c) *Reserve tonnage.* A handler may hold as reserve tonnage raisins any lot, or portion thereof, of raisins of the varietal types specified in paragraph (a) of this section acquired pursuant to a weight dockage system: *Provided,* That only the creditable weight of such lot, or portion thereof, may be applied by the Committee against the handler's reserve tonnage obligation.

(d) *Assessments.* Assessments on any lot of raisins of the varietal types specified in paragraph (a) of this section acquired by a handler pursuant to a weight dockage system shall be applicable to the free tonnage portion of the creditable weight of such lot.

(e) *Payments for services on reserve tonnage.* Payment to a handler for services performed by him with respect to reserve tonnage raisins of the varietal

types specified in paragraph (a) of this section acquired pursuant to a weight dockage system shall be made on the basis of the creditable weight of such lot and at the applicable rate specified for such services in § 989.401 of Subpart—Schedule of Payments.

(f) *Identification.* Any lot of raisins of the varietal types specified in paragraph (a) of this section acquired by a handler pursuant to the weight dockage system shall be so identified by the inspection service affixing to one container on each pallet, or to each bin, in such lot, a prenumbered RAC control card (to be furnished by the Committee) which shall remain affixed to the container or bin until the raisins are processed or disposed of as natural conditions raisins. The control card shall only be removed by, or under the supervision of an inspector of the inspection service, or authorized Committee personnel.

(g) *Dockage table applicable to Natural (sun-dried) Seedless, Golden Seedless, Dipped Seedless, Monukka, and Oleate and Related Seedless raisins.*

* * * * *

(h) *Dockage table applicable to Muscat (including other raisins with seeds), Sultana, and Zante Currant raisins.*

| Percent substandard | Dockage factor |
|---|---|
| 12.0 or less | (1) |
| 12.1 | .999 |
| 12.2 | .998 |
| 12.3 | .997 |
| 12.4 | .996 |
| 12.5 | .995 |
| 12.6 | .994 |
| 12.7 | .993 |
| 12.8 | .992 |
| 12.9 | .991 |
| 13.0 | .990 |

[1] No dockage.

**Note.**—Percentages in excess of the last percentage shown in the table shall be expressed in the same increments as the foregoing, and the dockage factor for each such increment shall be .001 less than the dockage factor for the preceding increment.

2. Section 989.701(d)(2), (e)(2) and (f)(2) of Subpart—Quality Control (7 CFR 989.701–989.703; 48 FR 49214) are revised to read as follows:

## Subpart—Quality Control

### § 989.701 Minimum grade and condition standards for natural condition raisins.

* * * * *

(d) * * *

(2) shall have a normal characteristic color, flavor, and odor of properly prepared raisins and shall contain not more than 12 percent, by weight, of substandard raisins (raisins that show development less than that characteristic of raisins prepared from fairly well matured grapes);

* * * * *

(e) * * *

(2) shall have a normal characteristic color, flavor, and odor of properly prepared raisins and shall contain not more than 12 percent, by weight, of substandard raisins (raisins that show development less than that characteristic of raisins prepared from fairly well matured grapes);

* * * * *

(f) * * *

(2) shall have a normal characteristic color, flavor, and odor of properly prepared raisins and shall contain not more than 12 percent, by weight, of substandard raisins (raisins that show development less than that characteristic of raisins prepared from fairly well matured grapes);

* * * * *

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674)

Dated: November 21, 1983.

**Russell L. Hawes,**

*Acting Deputy Director, Fruit and Vegetable Division.*

[FR Doc. 83-31755 Filed 11-28-83; 8:45 am]

BILLING CODE 3410-02-M

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## DEPARTMENT OF TRANSPORTATION

## Federal Aviation Administration

## 14 CFR Part 75

**[Airspace Docket No. 83-AWA-32]**

## Establishment of Jet Route J-594; Massena, NY

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule; request for comment.

**SUMMARY:** This amendment establishes new Jet Route J-594 between Massena, NY, and Toronto, ON, Canada. The Canadian Government has requested this route in order to expedite traffic between Toronto and Massena. At the present time, flight operations between Toranto and Massena are radar vectored because no charted route exists between those cities. This jet route will aid flight planning and air traffic control procedures. Messena is approximately 8 miles from the United States/Canadian boundary. This action aids Canada in establishing a jet route that improves traffic flow in that country.

**DATES:** Effective date—January 19, 1984. Comments must be received on or before January 12, 1984.

**ADDRESSES:** Send comments on the rule in triplicate to: Director, FAA, Eastern Region, Attention: Manager, Air Traffic Division, Docket No. 83-AWA-32, Federal Aviation Administration, Federal Building, John F. Kennedy International Airport, Jamaica, NY 11430.

The official docket may be examined in the Rules Docket, weekdays, except Federal holidays, between 8:30 a.m. and 5:00 p.m. the FAA Rules Docket is located in the Office of the Chief Counsel, Room 916, 800 Independence Avenue, SW., Washington, D.C.

An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division.

**FOR FURTHER INFORMATION CONTACT:** Lewis W. Still, Airspace and Air Traffic Rules Branch (AAT-230), Airspace-Rules and Aeronautical Information Division, Air Traffic Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, D.C. 20591; telephone: (202) 426-8626.

**SUPPLEMENTARY INFORMATION:**

### Request for Comments on the Rule

Although this action is in the form of a final rule, which involves establishing J-594 from Toronto, ON, Canada, to Massena, NY, on a direct route and, thus, was not preceded by notice and public procedure, comments are invited on the rule. When the comment period ends, the FAA will use the comments submitted, together with other available information, to review the regulation. After the review, if the FAA finds that changes are appropriate, it will initiate rulemaking proceedings to amend the regulation. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in evaluating the effects of the rule and determining whether additional rulemaking is needed. However, since this amendment is mainly to benefit Canada's Air Traffic Control Systems and since Massena VORTAC is approximately 8 miles from the Canadian border, the impact on the United States is very minor.

### The Rule

The purpose of this amendment to § 75.100 of Part 75 of the Federal Aviation Regulations (14 CFR Part 75) is to establish J-594 between Toronto and Massena at the request of the Canadian Government. Section 75.100 of Part 75 of the Federal Aviation Regulations was republished in Advisory Circular AC 70-3A dated January 3, 1983.

Under the circumstances presented, the FAA concludes that there is an immediate need for a regulation to establish J-594 between Toronto, ON, Canada, and Massena, NY, as requested by the Canadian Government. Since Massena, NY, is merely 8 miles from the Canadian boundary, this route has little impact on the airspace of the United States. Therefore, I find that notice and public procedure are impracticable and that good cause exists for making this amendment effective on the next charting date.

**List of Subjects in 14 CFR Part 75**

Air space, Navigation (air).

**Adoption of the Amendment**

**§ 75.100 [Amended]**

Accordingly, pursuant to the authority delegated to me, § 75.100 of Part 75 of the Federal Aviation Regulations (14 CFR Part 75) is amended, effective 0901 GMT, January 19, 1984, as follows:

**J-594 [New]**

From Massena, NY; to Toronto, ON, Canada. This airspace within Canada is excluded.

(Secs. 307(a) and 313(a), Federal Aviation Act of 1958 (49 U.S.C. 1348(a) and 1354(a)); (49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983)); and 14 CFR 11.69)

**Note.**—The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Issued in Washington, D.C., on November 18, 1983.

**B. Keith Potts,**

*Manager, Airspace-Rules and Aeronautical Information Division.*

[FR Doc. 83-31794 Filed 11-28-83; 8:45 am]

BILLING CODE 4910-13-M

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## 14 CFR Part 97

**[Docket No. 23839; Amdt. No.1256]**

## Standard Instrument Approach Procedures; Miscellaneous Amendments

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final rule.

**SUMMARY:** This amendment establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

**DATES:** An effective date for each SIAP is specified in the amendatory provisions.

**ADDRESSES:** Availability of matters incorporated by reference in the amendment is as follows:

*For Examination*—1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, D.C. 20591;

2. The FAA Regional Office of the region in which the affected airport is located; or

3. The Flight Inspection Field Office which originated the SIAP.

*For Purchase*—Individual SIAP copies may be obtained from: 1. FAA Public Inquiry Center (APA-430), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, D.C. 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

*By Subscription*—Copies of all SIAPs, mailed once every 2 weeks, are for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402

**FOR FURTHER INFORMATION CONTACT:** Donald K. Funai, Flight Procedures Standards Branch (AFO-230), Air Transportation Division, Office of Flight Operations, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, D.C. 20591; telephone (202) 426-8277.

**SUPPLEMENTARY INFORMATION:** This amendment to Part 97 of the Federal Aviation Regulations (14 CFR Part 97) prescribes new, amended, suspended, or revoked Standard Instrument Approach Procedures (SIAPs). The complete regulatory description of each SIAP is contained in official FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR Part 51, and § 97.20 of the Federal Aviation Regulations (FARs). The applicable FAA Forms are identified as FAA Forms 8260-3, 8260-4 and 8260-5. Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form document is unnecessary. The provisions of this amendment state the affected CFR (and FAR) sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

This amendment to Part 97 is effective on the date of publication and contains separate SIAPs which have compliance dates stated as effective dates based on related changes in the National Airspace System or the application of new or revised criteria. Some SIAP amendments may have been previously issued by the FAA in a National Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP amendments may require making them effective in less than 30 days. For the remaining SIAPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Approach Procedures (TERPs). In developing these SIAPs, the TERPs criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs is unnecessary, impracticable, and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

**List of Subjects in 14 CFR Part 97**

Air traffic control, Airports, Navigation (air), Weather

**Adoption of the amendment**

Accordingly, pursuant to the authority delegated to me, Part 97 of the Federal Aviation Regulations (14 CFR Part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures, effective at 0901 G.m.t. on the dates specified, as follows:

1. By Amending § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN SIAPs identified as follows:

** * * Effective January 19, 1984*

Kenia, AK—Kenai Muni, VOR RWY 19, Amdt. 12
Frankfort, KY—Capital City, VOR RWY 06, Orig.
Frankfort, KY—Capital City, VOR RWY 24, Orig.
Frankfort, KY—Capital City, VOR RWY 06, Amdt. 05, Cancelled
Frankfort, KY—Capital City, VOR RWY 24, Amdt. 06, Cancelled
Bloomington-Normal, IL—Bloomington-Normal, VOR/DME RWY 21, Orig.
Bloomington-Normal, IL—Bloomington-Normal, VOR RWY 11, Amdt. 08
Bloomington-Normal, IL—Bloomington-Normal, VOR RWY 21, Amdt. 15
Grand Rapids, MI—Kent County Intl, VOR RWY 18, Amdt. 05
Grand Rapids, MI—Kent County Intl, VOR RWY 36, Amdt. 10

** * * Effective January 5, 1984*

Elberton, GA—Elbert County-Patz Field, VOR/DME RWY 10, Amdt. 01 Norman, OK—Max Westheimer, VOR/DME RWY 03, Amdt. 01

** * * Effective December 22, 1983*

Elgin, IL—Elgin, VOR RWY 36, Amdt. 05, Cancelled
Dickinson, ND—Dickinson Muni, VOR-A, Orig.
Dickinson, ND—Dickinson Muni, VOR RWY 17, Amdt. 12, Cancelled
Dickinson, ND—Dickinson Muni, VOR/DME RWY 35, Orig., Cancelled

** * * Effective November 15, 1983*

Tallahassee, FL—Tallahassee Muni, VOR RWY 18, Amdt. 07

** * * Effective November 3, 1983*

Muscatine, IA—Muscatine Muni, VOR RWY 05, Amdt. 03
Muscatine, IA—Muscatine Muni, VOR RWY 23, Amdt. 03
Muscatine, IA—Muscatine Muni, VOR/DME RWY 12, Amdt. 03
Muscatine, IA—Muscatine Muni, VOR RWY 30, Amdt. 03

** * * Effective November 2, 1983*

Oroville, CA— Oroville Muni, VOR-A, Amdt. 03

2. By amending § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, and SDF/DME SIAPs identified as follows:

** * * Effective January 19, 1984*

Bloomington-Normal, IL—Bloomington-Normal, LOC BC RWY 11, Amdt. 05

** * * Effective January 5, 1984*

New Orleans, LA—New Orleans Intl (Moisant Field), LOC BC RWY 19, Amdt. 08
Norman, OK—Max Westheimer, LOC RWY 03, Amdt. 01

** * * Effective December 22, 1983*

Brainerd, MN—Brainerd-Crow Wing Co/Walter F. Wieland Fld, LOC RWY 23, Amdt. 01, Cancelled

** * * Effective November 15, 1983*

Tallahassee, FL—Tallahassee Muni, LOC BC RWY 18, Amdt. 13

3. By amending Part 97.27 NDB and NDB/DME SIAPs identified as follows:

** * * Effective January 19, 1984*

Frankfort, KY—Capital City, NDB RWY 24, Amdt. 08
Marshfield, MA—Marshfield, NDB RWY 06, Orig.
Grand Rapids, MI—Kent County Intl, NDB RWY 26L, Amdt. 17

** * * Effective January 5, 1984*

Norman, OK—Max Westheimer, NDB RWY 03, Amdt. 04
Shawnee, OK—Shawnee Muni, NDB RWY 17, Amdt. 04
Falfurrias, TX—Brooks County, NDB RWY 35, Amdt. 01, Cancelled
Falfurrias, TX—Brooks County, NDB-A, Orig.

** * * Effective December 22, 1983*

Pensacola, FL—Pensacola Regional, NDB RWY 16, Amdt. 22, Cancelled
Brainerd, MN—Brainerd-Crow Wing Co/Walter F Wieland Fld, NDB RWY 23, Amdt. 01

** * * Effective November 3, 1983*

Muscatine, IA—Muscatine Muni, NDB RWY 05, Amdt. 09
Manassas, VA—Manassas Muni/Harry P Davis Field, NDB-A, Amdt. 07

4. By amending § 97.29 ILS ILS/DME, ISMLS, MLS, MLS/DME and MLS/RNAV SIAPs identified as follows:

** * * Effective January 19, 1984*

Kenai, AK—Kenai Muni, ILS RWY 19, Amdt. 03
Bloomington-Normal, IL—Bloomington-Normal, ILS RWY 29, Amdt. 06

** * * Effective December 22, 1983*

Brainerd, NM—Brainerd-Crow Wing Co/Walter F Wieland Fld, ILS RWY 23, Orig.
Longview, TX—Gregg County, ILS RWY 13, Amdt. 07

5. By amending § 97.31 RADAR SIAPs identified as follows:

** * * Effective January 19, 1984*

Grand Rapids, MI—Kent County Intl. RADAR-1, Amdt. 08

6. By amending § 97.33 RNAV SIAPs identified as follows:

** * * Effective January 5, 1984*

Norman, OK—Max Westheimer, RNAV RWY 03, Amdt. 03
Shawnee, OK—Shawnee Muni, RNAV RWY 17, Amdt. 01

** * * Effective December 22, 1983*

Elgin, IL—Elgin, RNAV RWY 18, Amdt. 06, Cancelled

(Secs. 307, 313(a), 601, and 1110, Federal Aviation Act of 1958 (49 U.S.C. 1348, 1354(a), 1421, and 1510); 49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983); and 14 CFR 11.49(b)(3))

**Note.**—The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Issued in Washington, D.C. on November 25, 1983.

**Note.**—The incorporation by reference in the preceding document was approved by the Director of the Federal Register on December 31, 1980, and reapproved as of January 1, 1982.

**Kenneth S. Hunt,**
*Director of Flight Operations.*

[FR Doc. 83-31792 Filed 11-28-83; 8:45 am]
BILLING CODE 4910-13-M

## CIVIL AERONAUTICS BOARD

## 14 CFR Part 201

**[Regulation ER-1366; Economic Regulations Amdt. No. 8 to Part 201]**

## Information Collection Requirements Submitted to OMB for Review; Approval

**AGENCY:** Civil Aeronautics Board.

**ACTION:** Final rule.

**SUMMARY:** This final rule gives notice that the Office of Management and Budget (OMB) has approved the information collection requirements contained in Part 201 of the Board's Economic Regulations, which establishes procedures for applications for certificates of public convenience and necessity for U.S. carriers to engage in air transportation, as required by Section 401 of the Federal Aviation Act of 1958, as amended. Approval has been granted through November 30, 1986. OMB approval is required under the Paperwork Reduction Act of 1980.

**DATES:** November 23, 1983.

Effective: November 8, 1983.

**FOR FURTHER INFORMATION CONTACT:** Linda K. Koman, Data Requirements Section, Information Management Division, Office of Comptroller, Civil Aeronautics Board, 1825 Connecticut Avenue, NW., Washington, D.C. 20428, (202) 673-6042.

**List of Subjects in 14 CFR Part 201**

Air carriers.

Accordingly, the Civil Aeronautics Board amends Part 201 of its Economic Regulations (14 CFR Part 201) by adding a note at the end of the table of contents to Part 201 to read:

Note.—The information collection requirements contained in §§ 201.2 and 201.4 have been approved by the Office of Management and Budget under number 3024-0069.

This amendment is issued by the undersigned pursuant to delegation of authority from the Board to the Secretary in 14 CFR Sec. 385.24(b). (Sec. 204 of the Federal Aviation Act of 1958, as amended, 72 Stat. 743; 49 U.S.C. 1324).

By the Civil Aeronautics Board.

**Phyllis T. Kaylor,**

*Secretary.*

[FR Doc. 83-31885 Filed 11-28-83; 8:45 am]

BILLING CODE 6320-01-M

## 14 CFR Part 314

## Extension of Reporting and Recordkeeping Requirements

**AGENCY:** Civil Aeronautics Board.

**ACTION:** Notice of approval of extension of reporting requirements by the Office of Management and Budget.

**SUMMARY:** The Civil Aeronautics Board has extended the reporting requirements in Part 314 of the Board's Procedural Regulations governing applications by airline employees for federal payments under the employee protection program in section 43 of the Airline Deregulation Act. The Office of Management and Budget approved the extension of these requirements through November 30, 1986, under OMB No. 3024-0053. OMB approval is required under the Paperwork Reduction Act of 1980.

**DATES:** Effective: November 8, 1983.

Dated: November 23, 1983.

**FOR FURTHER INFORMATION CONTACT:** Bernard Davis, Data Requirements Section, Information Management Division, Office of Comptroller, Civil Aeronautics Board, 1825 Connecticut Avenue, NW., Washington, D.C. 20428, (202) 673-6042.

**SUPPLEMENTARY INFORMATION:**

**List of Subjects in 14 CFR Part 314**

Air carriers, Employment and labor.

**Phyllis T. Kaylor,**

*Secretary.*

[FR Doc. 83-31886 Filed 11-28-83; 8:45 am]

BILLING CODE 6320-01-M

## SECURITIES AND EXCHANGE COMMISSION

## 17 CFR Parts 200, 240, 241 and 249

**[Released No. 34-20409; File No. S7-1003]**

## SECO Programs; Direct Regulation of Certain Broker-Dealers; Elimination

**AGENCY:** Securities and Exchange Commission.

**ACTION:** Final rulemaking.

**SUMMARY:** The Commission announces the rescission and modification of certain of its rules in light of amendments to the Securities Exchange Act of 1934 which eliminate the Commission's program of direct regulation of certain broker-dealers, the SECO Program. In addition, the Commission has amended one of its rules to exempt certain exchange members from the requirement to join a registered securities association.

**EFFECTIVE DATE:** December 6, 1983.

**DATE:** Comments on the amendment of Rule 15b9-1 should be submitted on or before January 3, 1984.

**ADDRESS:** Comments should be submitted in triplicate to: George A. Fitzsimmons, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, D.C. 20549. Comment letters should refer to File No. S7-1003. All comments received will be available for public inspection and copying in the Commission's Public Reference Room, Room 1026, 450 Fifth Street, NW., Washington, D.C. 20549.

**FOR FURTHER INFORMATION CONTACT:** Katherine A. England, Esq., (202) 272-2411, Room 5204, Division of Market Regulation, Securities and Exchange Commission, Washington, D.C. 20549.

**SUPPLEMENTARY INFORMATION:** The Securities and Exchange Commission ("Commission") announces (1) The rescission of fifteen rules and their related forms which are no longer necessary due to the elimination of the SECO Program; (2) technical amendments to six rules which delete references to nonmember broker-dealers [1] and remove unnecessary cross-references; (3) amendments to Rule 15b9-1 to exempt certain exchange members from the requirement to join a registered securities association and (4) withdrawal of Securities Exchange Act Release No. 9420 (December 20, 1971), 37 FR 3050 (February 11, 1972), which provides staff interpretive advice concerning the application of National Association of Securities Dealers, Inc. ("NASD") rules to SECO broker-dealers.

### I. Discussion

On June 6, 1983, the Securities Exchange Act of 1934 ("Act") was amended by Pub. L. 98-38 ("Legislation") [2] to eliminate direct regulation of broker-dealers by the Commission through the SECO Program and to require any broker-dealer engaged in an over-the-counter ("OTC") securities business to join a registered securities association effective December 6, 1983. The Commission, therefore, is rescinding the rules and forms which apply exclusively to SECO broker-dealers and amending its rules which refer to nonmember broker-dealers. These amendments will become effective December 6, 1983.

The Commission has determined to adopt these amendments without affording prior notice and opportunity for comment because it finds, for good cause, that prior notice and opportunity for public comment are unnecessary under Section 553(b)(B) of the Administrative Procedure Act ("APA") [5 U.S.C. 553(b)(B)]. The rule changes merely eliminate requirements that, as a result of the Legislation, will not have any application after December 6, 1983. In addition, the amendment of Rule 15b9-1 merely conforms an existing exemptive provision with the new legislative framework.[3]

All SECO broker-dealers are required to be in compliance with the current rules until their expiration. Therefore, any violation of these rules as currently in effect which occurs on or before their

[1] The term nonmember is used in the Act and rules thereunder to refer to those broker-dealers in the SECO Program.

[2] 97 Stat. 205 [1983].

[3] The Commission also believes that pursuant to paragraph (d)(1) of Section 553 of the APA, it is not necessary to publish these amendments 30 days prior to their effective date because the rules being rescinded relieve restrictions on broker-dealers and the one substantive amendment recognizes an exemption for certain broker-dealers from the requirement to join a registered national securities association. Moreover, the Commission also finds that, in any event, good cause exists for dispensing with the 30 day publication requirement because the rule rescissions and withdrawals are necessary to conform those rules with statutory changes which take effect on December 6, 1983, and unless the exemption provided in Rule 15b9-1 is effective on that date, broker-dealers who would be eligible for the exemption would be in violation of Section 15(b)(8) of the Act.

expiration will be subject to appropriate administrative, civil and criminal actions even if discovery of the violation occurs after the expiration of the rules.[4] In addition, although the Commission is rescinding the SECO recordkeeping rule, Rule 15b10–6 under the Act, a broker-dealer who leaves the SECO Program must continue to retain appropriate records pursuant to Rule 17a–4 under the Act or the applicable rules of the SRO which it joins.[5]

A. *Rules and Forms to be Rescinded.* The Commission is rescinding the following rules adopted under Section 15 of the Act.

Rule 15b8–1 establishes qualification requirements for SECO broker-dealers and their associated persons.

Rule 15b8–2 provides that no registered broker or dealer or associated person of a SECO firm will be deemed qualified pursuant to Section 15(b)(7) of the Act if a registered national securities association or exchange has taken disciplinary action against such broker, dealer or an associated person of a SECO firm which resulted in a suspension, expulsion or a bar from an exchange or association.

Rule 15b9–2 sets out the mechanics for the annual assessments which SECO broker-dealers are required to pay. Although the Commission is entitled to collect an annual assessment from broker-dealers who were in the SECO Program from October 1, 1983, until December 5, 1983, the Commission has decided not to collect such fees because of the de minimis amount of money involved and the cost involved in collecting the fees.

Rule 15b10–1 defines terms for use in the 15b10 series of rules.

Rule 15b10–2 establishes a general business conduct standard for SECO broker-dealers.

Rule 15b10–3 establishes a suitability requirement for SECO broker-dealers and their associated persons.

Rule 15b10–4 establishes supervision requirements for associated persons of SECO broker-dealers.

Rule 15b10–5 provides standards for the exercise of discretionary authority by SECO broker-dealers and their associated persons.

Rule 15b10–6 establishes recordkeeping requirements for SECO broker-dealers and requires that the records be maintained for a six year period. Although this rule will be deleted, all broker-dealers are required to maintain appropriate records in accordance with Rule 17a–4 under the Act. Specifically, customer account records required by paragraph (a)(1)(i) of Rule 15b10–6 must be maintained for a period of six years pursuant to paragraph (c) of Rule 17a–4. The remaining records must be kept for a three year period under paragraph (b) of Rule 17a–4. The NASD has recordkeeping requirements which are similar to the requirements of Rule 15b10–6 which will apply to broker-dealers who become NASD members.

Rule 15b10–7 exempts a limited group of exchange members from the requirements of Rules 15b10–1 through 15b10–5.

Rule 15b10–8 establishes standards for SECO broker-dealers which participate in a public offering of securities.

Rule 15b10–9, the self-underwriting rule, establishes standards for SECO broker-dealers which underwrite or participate in the Distribution of their own or an affilate's securities.

Rule 15b10–10 establishes guidelines for the execution of investment company portfolio transactions by SECO broker-dealers.

Rule 15b10–11 requires a SECO broker-dealer to carry a fidelity bond if it is a member of the Securities Investor Protection Corporation and has employees.

Rule 15b10–12 exempts the municipal securities transactions of SECO broker-dealers from the 15b10 series of rules.

Reg. § 249.502 Form U–4, is the registration form for associated persons of SECO broker-dealers. The Commission receives these forms exclusively from SECO associated persons.

Reg. § 249.502a, Form SECO–2F, is a certification form for associated persons of SECO broker-dealers engaged in securities activities outside of the jurisdiction of the United States who do not deal or act for any United States resident or national.

Reg. § 249.504q, Form SECO–4–83, is the annual assessment and information form for SECO broker-dealers.[6]

Reg. § 249.505, Form SECO–5, is the initial assessment and information form for SECO broker-dealers.

B. *Rules to be Amended.* The Commission is amending three rules to remove references to nonmember broker-dealers, amending two rules to delete unnecessary cross-references to rules which have been deleted, and amending the rule which delegates authority to the Director of the Division of Market Regulation.

Rule 11Aa3–1 requires exchange members, NASD members and SECO broker-dealers to have transaction reporting plans and to disseminate, pursuant to those plans, transaction reports or last sale data, as appropriate.

Rule 11Aa3–2 provides the framework for the filing of a national market system plan and the mechanics relating to the operation of such a plan by exchange members, NASD members and SECO broker-dealers.

Rule 11Ac1–2 provides requirements for the display of transaction reports, last sale data and quotation information.

Rule 19h–1 provides procedures for a self-regulatory organization ("SRO") to follow when dealing with a statutorily disqualified person. The rescission of Rule 15b8–2 necessitates the removal of cross-references to Rule 15b8–2 found in Rule 19h–1.

Rule 30–3 (17 CFR 200.30–3) provides for the delegation of authority to the Director of the Division of Market Regulation ("Division") to perform certain specified functions. Paragraph (a)(26) of Rule 30–3 delegates authority to the Director of the Division to grant exemptions from Rule 15b10–9, the SECO self-underwriting rule. The removal of Rule 15b10–9 eliminates the need for the delegation of authority contained in paragraph (a)(26).

Rule 80 (17 CFR 200.80) describes how Commission records and information are to be handled for purposes of public access to such information. Paragraph (b)(6) contains a cross-reference to Rule 15b8–1 under the Act which is being withdrawn by this Release therefore, the cross-reference is being removed.

C. *Exemption for Certain Exchange Members.* The Commission is amending Rule 15b9–1 to provide a limited exemption for broker-dealers which belong to a national securities exchange and engage in very limited securities activities other than on such exchange.[7]

Section 15(b)(9) of the Act, as amended by Public Law No. 98–38, authorized the Commission to conditionally or unconditionally exempt any broker or dealer or class of brokers or dealers engaged in an OTC securities business from the statutory requirement of joining a registered national securities association when such exemption is consistent with the public interest and the protection of investors.[8] Currently,

[4] *See* 1 U.S.C. 109.

[5] 17 CFR 240.17a–4.

[6] The Commission also is rescinding Reg. §§ 249.504n, form SECO–4–80; 249.504o, Form SECO–4–81; and 249.504p, Form SECO–4–82; the annual assessment forms for 1980, 1981 and 1982, respectively.

[7] Rule 15b9–1 presently establishes registration and fee requirements for SECO broker-dealers and their associated persons. The Commission is eliminating paragraphs (a) through (d) and paragraph (f) of Rule 15b9–1 which relate to SECO broker-dealers.

[8] 15 U.S.C. 78*o*(b).

paragraph (e) of Rule 15b9-1 provides an exemption from the requirement to join either SECO or the NASD for a limited group of exchange member broker-dealers doing minimal securities business other than on such exchange. The Commission believes that it is appropriate to retain an exemption of this type. Accordingly, a broker-dealer will be exempt from the requirement to join a registered securities association if (1) It is a member of a national securities exchange, (2) it carries no customer accounts and (3) the annual gross income derived from securities transactions off an exchange where membership is held is less than $1,000. Transactions effected for a broker-dealer's own account with or through another broker or dealer would not be included in the $1,000 gross income limitation. In addition, income derived from transactions through the Intermarket Trading System will not be subject to the $1,000 income limitation. In this regard, the Commission specifically requests comments on whether the $1,000 limit should be increased and, if so, what amount is viewed as appropriate.

D. *Withdrawal of Release.* The Commission is withdrawing Securities Exchange Act Release No. 9420 (December 20, 1971), 37 FR 3050 (February 11, 1972), ("Release No. 9420"), which addresses the comparability of NASD and SECO regulation and the relevance of published NASD standards and rules of conduct to nonmember broker-dealers and their associated persons. The elimination of the SECO Program makes this release unnecesssary.[9]

## II. Effects on Competition

Section 23(a)(2) of the Act [10] requires the Commission, in adopting rules under the Act, to consider the anti-competitive effects of such rules, if any, and to balance any anti-competitive impact against the regulatory benefits gained in terms of furthering the purposes of the Act. In light of the legislative elimination of the SECO Program, these rule changes do not impose any unnecessary or inappropriate burden on competition.

[9] While the Commission has determined to withdraw Release No. 9420 because, in large part, it addresses the applicability of NASD rules to SECO broker-dealers, the more general views expressed in the release regarding the duty of a broker-dealer to follow just and equitable principles of trade continue in effect.

[10] 15 U.S.C. 78w(a).

## III. List of Subjects

*17 CFR Part 200*

Administrative practice and procedure, Freedom of Information, Privacy, Securities.

*17 CFR Part 240*

Brokers, Confidential business information, Fraud, Reporting and recordkeeping requirements, Securities

*17 CFR Part 241*

Reporting and recordkeeping requirements, Securities

*17 CFR Part 249*

Brokers, Reporting and recordkeeping requirements, Securities

## IV. Text of Amendments

The commission hereby amends Chapter II of Title 17 of the Code of Federal Regulations, pursuant to its authority under the Act, [(15 U.S.C. 78a *et seq.*, as amended by Pub. L. 84-29 (June 4, 1975) and by Pub. L. 98-38 (June 6, 1983)], particularly Sections 11A, 15, 19 and 23 thereof [15 U.S.C. 78k-1, 78*o*, 78s and 78w], as follows:

## PART 200—ORGANIZATION; CONDUCT AND ETHICS; AND INFORMATION AND REQUESTS

**§ 200.30-3 [Amended]**

1. By removing and reserving paragraph (a)(26) of § 200.30-3.

2. By revising paragraph (b)(6) of § 200.80 as follows:

**§ 200.80 Commission records and information.**

* * * * *

(b) * * *

(6) Personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, including those concerning all employees of the Commission and those concerning persons subject to regulation by the Commission.

* * * * *

## PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

**§§ 240.15b8-1, 240.15b8-2, 240.15b9-2, 240.15b10-1, through 240.15b10-12 [Removed]**

1. By removing the following sections of Part 240:

§ 240.15b8-1, § 240.15b8-2, § 240.15b9-2, § 240.15b10-1, § 240.15b10-2, § 240.15b10-3, § 240.15b10-4, § 240.15b10-5, § 240.15b10-6, § 240.15b10-7, § 240.15b10-8, § 240.15b10-9, § 240.15b10-10, § 240.15b10-11, § 240.15b10-12. [Removed].

2. By removing paragraph (b)(2), redesignating paragraph (b)(3) as (b)(2) and (b)(4) as (b)(3), and revising new paragraph (b)(2)(iii) of § 240.11Aa3-1 as follows:

**§ 240.11Aa3-1 Dissemination of transaction reports and last sale data with respect to transactions in reported securities.**

* * * * *

(b) * * *

(2) * * *

(iii) The manner such transaction reports reported pursuant to such plan are to be consolidated with transaction reports from exchanges and associations reported pursuant to any other effective transaction reporting plan;

* * * * *

3. By revising paragraphs (a)(1)(ii), (a)(6), (d) and (f) and removing paragraph (a)(9) of § 240.11Aa3-2 as follows:

**§ 240.11Aa3-2 Filing and amendment of national market system plans.**

(a) * * *

(1) * * *

(ii) The development and implementation of procedures and/or facilities designed to achieve compliance by self-regulatory organizations and their members with any section of this subpart promulgated pursuant to Section 11A of the Act.

* * * * *

(6) The term "participants," when used in connection with a national market system plan, shall mean any self-regulatory organization which has agreed to act in accordance with the terms of the plan but which is not a signatory of such plan.

* * * * *

(d) *Compliance with terms of national market system plans.* Each self-regulatory organization shall comply with the terms of any effective national market system plan of which it is a sponsor or a participant. Each self-regulatory organization also shall, absent reasonable justification or excuse, enforce compliance with any such plan by its members and persons associated with its members.

* * * * *

(f) *Exemptions.* The Commission may exempt from the provisions of this section, either unconditionally or on specified terms and conditions, any self-regulatory organization, member thereof, or specified security, if the Commission determines that such exemption is consistent with the public interest, the

protection of investors, the maintenance of fair and orderly markets and the removal of impediments to, and perfection of the mechanisms of, a national market system.

4. By revising paragraph (a)(1) of § 240.11Ac1-2 as follows:

**§ 240.11Ac1-2 Display of transaction reports, last sale data and quotation information.**

(a) * * * (1) The terms "transaction report," "effective transaction reporting plan," "moving ticker," "last sale data," "market minder" and "interrogation device" shall have the meaning provided in § 240.11Aa3-1 (Rules 11Aa3-1 under the Act).

* * * * *

5. By revising § 240.15b9-1 to read as follows:

**§ 240.15b9-1 Exemption for certain exchange members.**

(a) Any broker or dealer required by Section 15(b)(8) of the Act to become a member of a registered national securities association shall be exempt from such requirement if it: (1) Is a member of a national securities exchange, (2) carries no customer accounts, and (3) has annual gross income derived from purchases and sales of securities otherwise than on a national securities exchange of which it is a member in an amount no greater than $1,000.

(b) The gross income limitation contained in paragraph (a) of this section, shall not apply to income derived from transactions (1) for the dealer's own account with or through another registered broker or dealer or (2) through the Intermarket Trading System.

(c) For purposes of this section, the term "Intermarket Trading System" shall mean the intermarket communications linkage operated jointly by certain self-regulatory organizations pursuant to a plan filed with, and approved by, the Commission pursuant to § 240.11Aa3-2 (Rule 11Aa3-2 under the Act).

6. By revising the first sentence of paragraph (d)(3), paragraph (e)(9), and paragraph (f)(1)(iii) of § 240.19h-1 to read as follows:

**§ 240.19h-1 Notice by a self-regulatory organization of proposed admission to or continuance in membership or participation or association with a member of any person subject to a statutory disqualification and applications to the Commission for relief therefrom.**

(d) * * *

(3) Will deem such person qualified pursuant to Rule G-4 of the Municipal Securities Rulemaking Board under the Act.

* * * * *

(e) * * *

(9) Such other matters as the organization or person deems relevant.

If the application contains assertions of material facts not a matter of record before the organization, such facts shall be sworn to by affidavit of the person or organization offering such facts for Commission consideration.

(f) * * *

(1) * * *

(iii) A failure under the provisions of Rule G-4 of the Municipal Securities Rulemaking Board under the Act, to meet qualifications standards, and such failure may be remedied by a finding or determination by the Commission pursuant to such rule(s) that the person affected nevertheless meets such standards.

* * * * *

## PART 241—INTERPRETATIVE RELEASES RELATING TO THE SECURITIES EXCHANGE ACT OF 1934 AND GENERAL RULES AND REGULATIONS THEREUNDER

1. By amending Part 214 by removing the following release:

Statement of policy by the Commission's Director of the Division of Trading and Markets on the relevance of NASD standards and rules of conduct to nonmember broker-dealers. February 11, 1972 (37 FR 3050).

## PART 249—FORMS, SECURITIES EXCHANGE ACT OF 1934

1. By removing § 249.502.

**§ 249.502 [Removed]**

2. By removing § 249.502a.

**§ 249.502a [Removed]**

3. By removing § 249.504n.

**§ 249.504n [Removed]**

4. By removing § 249.504o.

**§ 249.504o [Removed]**

5. By removing § 249.504p.

**§ 249.504p [Removed]**

6. By removing § 249.504q.

**§ 249.504q [Removed]**

7. By removing § 249.505.

**§ 249.505 [Removed]**

George A. Fitzsimmons,

*Secretary.*

Dated: November 22, 1983.

[FR Doc. 83-31912 Filed 11-28-83; 8:45 am]

BILLING CODE 8010-01-M

## 17 CFR Part 241

[Release No. 34-20396; File No. S7-987]

## Phase-in Program for Options on Narrow-Based Stock Indices

**AGENCY:** Securities and Exchange Commission.

**ACTION:** Statement of general policy.

**SUMMARY:** To provide for the orderly introduction of options on narrow-based stock indices, the Commission is limiting each self-regulatory organization seeking to trade narrow-base index options to a maximum of two such contracts until February 1, 1984

**EFFECTIVE DATE:** November 29, 1983.

**FOR FURTHER INFORMATION CONTACT:** Alden Adkins, Esq. (202) 272-2418, Division of Market Regulation, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, D.C. 20549.

**SUPPLEMENTARY INFORMATION:**

### I. Introduction

On August 12, 1983, the Commission proposed a phase-in program for the introduction of narrow-based index options that would limit each self-regulatory organization ("SRO"), seeking to trade narrow-based index options, to a maximum of two contracts until February 1, 1984.[1] The Commission proposal was prompted by concerns with the potentially unlimited proliferation of such products [2] and by the consequent possibility that the development of such products might outstrip the capacity of the industry and the public to understand them and to adjust operationally to their introduction.[3]

[1] Securities Exchange Act Release No. 20076, August 12, 1983; 48 FR 37664, August 19, 1983 (the "Proposing Release").

[2] On the same day as it issued the Proposing Release, the Commission approved two narrow-based index options proposed by the American Stock Exchange, Inc. ("Amex") (Securities Exchange Act Release No. 20075, 48 FR 37556, August 18, 1983). On that date, an Amex proposal to trade an additional nine narrow-based index options (File No. SR-Amex-82-22), and Chicago Board Options Exchange, Incorporated ("CBOE") proposals to trade five such products (File Nos. SR-CBOE-83-14 through 18) were pending. Since the issuance of the Proposing Release, the Commission has authorized trading in two of the narrow-based index options proposed by the CBOE. Securities Exchange Act Release Nos. 20125 and 20178, August 26 and September 13, 1983. There also are proposals on file or anticipated for a number of other narrow-based index options. *See* n. 7, *infra*.

[3] These concerns were voiced by the Options and Derivative Products Committee of the Securities Industry Association (the "SIA Options Committee") in letters sent to each of the SROs trading or proposing to trade options on instruments other than individual equity securities. Responses

Continued

The Commission proposed that the phase-in program remain in effect only until January 31, 1984, and that after that date narrow-based index options could be introduced without restriction, so long as they are consistent with the Securities Exchange Act of 1934.[4] The Commission also indicated that it intended to determine whether a proposed index option was narrow or broad-based for purposes of the phase-in program on a case-by-case basis. Finally, the Commission determined, preliminarily, that any burdens on competition imposed by the proposed phase-in program are outweighed by the benefits to the public, the broker-dealer community and to the exchanges of an orderly introduction of narrow-based index options. The Commission, nevertheless, solicited comment on this and any other issues raised by the proposed phase-in program.

## II. Comments Received

The Commission received comments regarding the proposed phase-in program from Merrill Lynch & Co., Inc. ("Merrill Lynch"), the SIA Options Committee, the National Association of Securities Dealers, Inc. ("NASD"), the Phlx, and the CBOE.[5] With the exception of the CBOE, all of the commentators supported the proposal. As discussed above, the Amex also has previously suggested that the Commission adopt a phase-in program.

In Merrill Lynch's view, a phase-in program will help broker-dealers deal with the current strain on their operational capacities caused by the multiplicity of new products, and will give registered representatives and customers sufficient time to assimilate the possible uses and risks entailed in trading these new products. Merrill Lynch also suggested that the forces of competition be allowed to function once more following the proposed January 31, 1984 end of the phase-in period.

The SIA Options Committee reaffirmed its belief that the proliferation of new products "has raised questions of the ability of the member firm to devote the manpower and financial resources necessary to . . . train sales forces and compliance staffs in the nuances and special requirements of the new instruments." The SIA, however, urged that the phase-in program be broadened in two respects, by: (1) Extending the period of orderly introductions of new options products beyond January 1984, in six month intervals, for as long as is necessary; and (2) including all new option products within these phase-in periods.

The NASD also supported the Commission's proposal, but expressed concern that Commission approval of any exchange proposed narrow-based index option based solely upon NASDQ securities would place the NASD at a competitive disadvantage because the Commission has not yet acted on the NASD's own options program. Thus, the NASD's support of the Commission's phase-in proposal was conditioned upon the Commission's giving prompt consideration to the NASD's NASDAQ options proposal and its withholding of approval of any exchange option that is either identical to or substantially comparable to that envisioned by the proposed NASDAQ options program.

Similarly, the Phlx, while supporting the proposed phase-in program, also suggested: (1) That the program should be expanded beyond January 31, 1984 and that it should continue to provide for an allocation of the number of index options which each SRO may introduce over a given time period; (2) that the Commission, with the input of the industry, should periodically evaluate the trading activity in these options to assess whether any resulting fragmentation, competition and proliferation are harmful to the public interest;[6] and (3) that the program should apply to all index options.

The CBOE opposed the proposed phase-in program on the ground that, "it would severely harm CBOE's competitive position, without any regulatory justification." According to CBOE, the proposed program would damage CBOE's competitive position by allowing the three other competing options exchanges to trade a total of six options on narrow-based indices dominated by stocks on which CBOE trades the individual options, while CBOE could only trade two such narrow-based index options. This would in CBOE's view threaten its share of the market in the individual stock options. In this regard, CBOE suggested that the Commission's choice of two such contracts per exchange is arbitrary and ignores differences in the individual characteristics of each exchange.

The CBOE also stated that, with trading in some classes of narrow-based index options having commenced, the addition of new classes of this type of option will not entail significant new operational adjustments. In addition, CBOE indicated that the two-week waiting period the Commission has imposed, in the past, between the announcement of the date upon which trading will begin and actual trading, is enough time to educate the public regarding the composition of each new index. CBOE stated that market forces will effectively restrain SROs from introducing new products for which there is no demand. Thus, it concluded that there is no regulatory justification for the proposed phase-in program.

## III. Discussion

The Commission continues to feel that a phase-in program for narrow-based index options will help avoid the possible public confusion, operational and related concerns raised by the unchecked introduction of options on narrow-based index options. As the Commission noted in the Proposing Release, unlike other categories of new options products, where there would appear to be only a limited number of potentially attractive underlying instruments, there are a substantial number of possible industry indices that could conceivably serve as the basis for index options contracts. In particular, it appears possible that competing SROs could develop options on a variety of different, yet overlapping, index options contracts.[7] The Commission does not

by the Amex, CBOE, and the New York Stock Exchange, Inc. ("NYSE") to the SIA Options Committee echoed to some extent these concerns. In addition, the Amex in a comment letter to the Commission regarding its own proposal to trade narrow-based index options specifically proposed a phase-in program similar to the one proposed by the Commission. *See* the Proposing Release.

[4] The Commission expressly rejected an Amex suggestion that a phase-in program should limit each self-regulatory organization to options on two narrow-based indices not substantially similar to competing products offered by other SROs.

[5] Letter dated September 30, 1983, from Robert Rittereiser, Executive Vice President, Merrill Lynch, to George A. Fitzsimmons, Secretary, SEC; letter dated September 14, 1983, from Howard Brenner, Chairman, SIA Options Committee, to George A. Fitzsimmons, Secretary, SEC; letter dated September 22, 1983, from S. William Broka, Secretary, NASD to George A. Fitzsimmons, Secretary, SEC; letter dated September 20, 1983 from Nicholas A. Giordano, President, Phlx, to George A. Fitzsimmons, Secretary, SEC; and letter dated September 15, 1983, from Walter E. Auch, Chairman, CBOE, to George A. Fitzsimmons, Secretary, SEC.

[6] Specifically, the Phlx suggested that the Commission evaluate the extent to which index options trading draws volume away from the equity options market ("market fragmentation"), as well as the effect on capital formation of index options trading. In addition, the Phlx suggested that the Commission should monitor competition among SROs in new options products with "particular reference to the ability of a smaller exchange to effectively establish a market in an index [option] without fear of losing it to a larger self-regulatory organization once that self-regulatory organization senses the public's interest in that index."

[7] In addition to the narrow-based index options proposals from the Amex, CBOE, NASD and possibly the PSE pending at the time of the Proposing Release, the Commission notes that the Phlx has submitted a proposal to trade two narrow-

Continued

share CBOE's view that once one narrow-based index option is introduced, the subsequent introduction of other such products does not create any additional operational problems. The Commission feels that the simultaneous introduction of numerous new products would create operational problems that can be avoided by allowing a limited number of such products to trade for an initial phase-in period. In addition, the Commission feels that a phase-in period until February 1, 1984 will provide the time necessary to develop the type of educational efforts needed for a new product. The two-week waiting period required for each such product may be sufficient to educate brokers and investors already familiar with industry index options, generally, of the particular characteristics of a specific new contract. The Commission does not believe, however, that this waiting period would suffice to keep brokers and the public apprised if myriad similar and possibly overlapping products were to be introduced at one time prior to any substantial trading experience.

The Commission does not feel that it would be appropriate at this time to expand the proposed phase-in program beyond January 31, 1984 or to include other new options products. As the Commission acknowledged in the Proposing Release, the phase-in program may impose a burden on competition on any SRO that would like to trade more than the prescribed number of narrow-based index options contracts. The longer a phase-in program lasts, the greater this competitive concern becomes. Thus, while the Commission continues to believe that it is important that public confusion and operational and other problems be minimized in connection with the start-up of narrow-based index options trading, it remains of the view that a phase-in program through January 31, 1984, should be sufficient to permit the industry and the public to adjust to these new options products. The Commission, however, will monitor carefully trading in these index products to assess whether serious operational or public investor protection concerns occur.[8] The Commission also does not believes that the phase-in needs to be expanded to include other new options products because there is no indication of any potential proliferation of such products similar to that which has been evidenced for narrow-based index options.

As proposed, each SRO will be allowed to decide whether to offer, during the phase-in period, options on industry indices substantially similar to or competing with, products offered by other SROs.[9] The Commission will continue to decide on a case-by-case basis whether any particular proposed index option is broad or narrow-based.

As noted above, the Commission recognizes that the phase-in program may burden competition among market participants. The Commission does not agree with CBOE, however, that the phase-in will burden competition among participants in the market for individual stock options. The CBOE envisions that narrow-based index options could trade as surrogates for dominant component securities and, thus, compete with options on such securities. In the absence of actual trading experience, the Commission continues to have doubts about the extent of such a phenomenon. Most of the narrow-based index options have enjoyed only limited trading volume.[10] While trading activity may increase as registered representatives and their customers become more familiar with the products, any substantial increase in activity prior to February 1, 1984 appears unlikely. Therefore, any transitory competitive burdens placed on the CBOE appear extremely small. Furthermore, the Commission has required a regulatory structure for narrow-based index options comparable to that required of options on individual securities in order to ensure that competition between options products will be fair. If this competition effects CBOE more than other SROs, it is because CBOE is the dominant force in the market for individual stock options, not because the phase-in program discriminates against CBOE. Finally, the Commission finds that any temporary burden on competition imposed by the proposal is outweighed by the benefits to the public, the broker-dealer community and to the SROs of an orderly introduction of narrow-based index options.[11]

## IV. Findings and Conclusions

The Commission adopts as a statement of general policy the phase-in program for the introduction of narrow-based index options, under which, as proposed and described above, it intends not to permit any SRO to trade more than two narrow-based index options contracts until February 1, 1984.[12] The Commission finds for the reasons discussed above, that the general policy announced today is consistent with Sections 6, 9 and 15A of the Act in that it is designed to protect investors and the public interest and will not impose any burden on competition not necessary or appropriate in furtherance of the Act.

## List of Subjects in 17 CFR Part 241

Reporting and recordkeeping requirements, Securities.

By the Commission.

Dated: November 18, 1983.

**George A. Fitzsimmons,**

*Secretary.*

[FR Doc. 83-31767 Filed 11-28-83; 8:45 am]

BILLING CODE 8010-01-M

based index options contracts (*see* File No. SR-Phlx-83-17); and the NYSE has submitted a proposal to trade 13 such contracts (*see* File No. SR-NYSE-83-52). In addition, the CBOE has indicated that it may seek to introduce options on as many as 18 additional sub-industry indices. *See* Wall Street Letter, October 17, 1983.

[8] As to the potential problems that the Phlx suggests the Commission should monitor, the Commission notes that it continues to be skeptical about the potential "market fragmentation" effect of index options trading in the absence of actual trading experience indicating such fragmentation (*see* Securities Exchange Act Release No. 20076, August 12, 1983, the release approving Amex's two narrow-based index options). Nevertheless, it concurs that it would be useful for the Commission and the options exchanges to monitor narrow-based index options trading in this regard. Second, the Commission shares Phlx's concerns about the effect on capital formation of these options, as well as a variety of other new options products and financial instruments that have been introduced in recent years. The Commission believes, however, that the Congressionally mandated study of these products currently being undertaken by the Commission, the Commodity Futures Trading Commission and the Federal Reserve Board is the appropriate vehicle for examining the effect on capital formation of index options trading.

[9] In this regard, the Commission notes that the two narrow-based index options already being traded by both Amex and CBOE are both in the computer and the oil and gas industries.

[10] The Amex Computer Technology Index Option has been, by far, the most actively traded narrow-based index, averaging over 5,000 contracts daily. Notwithstanding this success, CBOE's options on IBM averaged 28,107 contracts per day during September 1983, the month after the introduction of Amex's Computer Technology Index Option, as compared with 27,803 average daily volume for all of 1982.

[11] The Commission does not feel it is necessary at this time to address the NASD's comment regarding the possible precedent set by the narrow-based index options approved to date by the Commission.

[12] As discussed above, the Commission will continue to monitor the trading in these products over the next several months. We expect to be in a position in January 1984 to begin discussing with the SROs their proposals for introducing additional narrow-based index options after January 31, 1984.

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### 18 CFR Parts 125, 225, and 356

[Docket No. RM83-40-000]

### Revisions to Regulations on Retention of Records by Natural Gas Companies, Public Utilities, Licensees, and Oil Pipeline Companies

**AGENCY:** Federal Energy Regulatory Commission, DOE.

**ACTION:** Temporary suspension of effective date of final rule.

**SUMMARY:** The Federal Energy Regulatory Commission is suspending temporarily the effective date on the final rule in Docket No. RM83-40-000, issued September 27, 1983, amending regulations on the retention of records by natural gas companies, public utilities, licensees and oil pipeline companies. The effective date is being suspended because the Commission has not yet received OMB approval.

**FOR FURTHER INFORMATION CONTACT:** Kenneth J. Malloy, Office of the General Counsel, 825 North Capitol Street, NE., Washington, D.C. 20426, (202) 357-8033.

**SUPPLEMENTARY INFORMATION:** The Paperwork Reduction Act, 44 U.S.C. 3501-3520 (Supp. V 1981) and the Office of Management and Budget's (OMB) regulations, 5 CFR Part 1320 (1983), require that OMB review certain information collection requirements imposed by agency rule. Upon approval, OMB issues a control number.

On September 27, 1983, the Federal Energy Regulatory Commission (Commission) issued a final rule in Docket No. RM83-40-000 (Order No. 335) amending its regulations on retention of records by public utilities, licensees, natural gas companies, and oil pipeline companies. Revisions to Regulations on Retention of Records by Natural Gas Companies, Public Utilities, Licensees and Oil Pipeline Companies, 48 FR 44,477 (September 29, 1983). The Commission therein stated that the rule would be effective on November 28, 1983, unless the Commission did not receive OMB's approval by that time, in which case the Commission would temporarily suspend the effective date of the rule. The Commission has not yet received OMB's approval. The Commission is, therefore, suspending the effective date of this rule until it publishes in the **Federal Register** notice of the receipt of OMB's approval, which it expects will be no later than December 23, 1983.

The Commission also finds, for good cause, that in light of the nesessity and imminence of an OMB response it is impracticable and unnecessary to allow notice and comment prior to suspending the effective date of this rule. 5 U.S.C. 553(d) (1976).

Issued November 22, 1983.

**Kenneth Plumb,**

*Secretary.*

[FR Doc. 83-31727 Filed 11-28-83; 8:45 am]

BILLING CODE 6717-01-M

### 18 CFR Parts 271 and 274

[Docket Nos. RM83-3-000 and RM81-12-000]

### Reduction in Filing Requirements for Well Category Applications Under Sections 102, 103, 107 and 108 of the Natural Gas Policy Act of 1978; Regulations for Temporary Pressure Buildup Determinations Under Section 108 of the Natural Gas Policy Act

**AGENCY:** Federal Energy Regulatory Commission, DOE.

**ACTION:** Temporary suspension of effective date of final rule.

**SUMMARY:** The Federal Energy Regulatory Commission is suspending temporarily the effective date on the final rule issued in Docket Nos. RM83-3-000 and RM81-12-000, issued September 27, 1983. These rules relate to filing requirements for well category determinations under the Natural Gas Policy Act of 1978, and adopting regulations for temporary pressure buildup determinations under the Act. These rules are being suspended because OMB approval has not yet been obtained.

**FOR FURTHER INFORMATION CONTACT:** Nancy M. Rizzo, Office of the General Counsel, 825 North Capitol Street, NE., Washington, D.C. 20426 (202) 357-8033.

**SUPPLEMENTARY INFORMATION:** The Paperwork Reduction Act, 44 U.S.C. 3501-3520 (Supp. V 1981) and the Office of Management and Budget's (OMB) regulations, 5 CFR Part 1320 (1983), require that OMB review certain information collection requirements imposed by agency rule. Upon approval, OMB issues a control number.

On September 27, 1983, the Federal Energy Regulatory Commission (Commission) issued a final rule in Docket Nos. RM83-3-000 and RM81-12-000 (Order No. 336) amending its regulations relating to filing requirements for well category determinations and adopting regulations for temporary pressure buildup determinations under the Natural Gas Policy Act of 1978. Reduction in Filing Requirements for Well Category Applications Under Sections 102, 103, 107 and 108 of the Natural Gas Policy Act of 1978; Regulations for Temporary Pressure Buildup Determinations Under Section 108 of the Natural Gas Policy Act, 48 FR 44,508 (September 29, 1983). The Commission therein stated that the rule would be effective on November 28, 1983, unless the Commission did not receive OMB's approval by that time, in which case the Commission would temporarily suspend the effective date of the rule. The Commission has not yet received OMB's approval. The Commission is, therefore, suspending the effective date of this rule until it publishes in the **Federal Register** notice of the receipt of OMB's approval, which it expects will be no later than December 23, 1983.

The Commission also finds, for good cause, that in light of the necessity and imminence of an OMB response it is impracticable and unnecessary to allow notice and comment prior to suspending the effective date of this rule. 5 U.S.C. 553(d) (1976).

Issued: November 22, 1983.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 83-31728 Filed 11-28-83; 8:45 am]

BILLING CODE 6717-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 81

[Docket No. 76N-0366]

### Provisional Listing of FD&C Red No. 3 and of FD&C Yellow No. 5 in Externally Applied Drugs and Cosmetics and of Their Lakes in Food and Ingested Drugs; Provisional Listing of D&C Red No. 8, D&C Red No. 9, and D&C Red No. 33 in Drugs and Cosmetics; Postponement of Closing Date

**AGENCY:** Food and Drug Administration.

**ACTION:** Final rule

**SUMMARY:** The Food and Drug Administration (FDA) is postponing the closing dates for the provisional listing of FD&C Red No. 3 and of FD&C Yellow No. 5 for use in coloring externally applied drugs and cosmetics and of the lakes of these color additives for use in coloring food and ingested drugs; of D&C Red No. 8, D&C Red No. 9, and D&C Red No. 33 for use in drugs and cosmetics. The new closing date for the provisional listing of all of these color

additives will be February 3, 1984. This postponement will provide additional time for the agency to determine the applicability of the statutory standard for the listing of color additives to the results of the scientific investigations of FD&C Red No. 3, FD&C Yellow No. 5, D&C Red No. 8, D&C Red No. 9, and D&C Red No. 33.

**DATES:** Effective November 29, 1983, the new closing date for FD&C Red No. 3 and its lakes, FD&C Yellow No. 5 and its lakes, D&C RED No. 8, D&C Red No. 9, and D&C Red No. 33 will be February 3, 1984.

**FOR FURTHER INFORMATION CONTACT:** Gerad McCowin, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204, 202-472-5676.

**SUPPLEMENTARY INFORMATION:** FDA established the current closing date of December 2 and December 5, 1983, respectively, for the provisional listing of FD&C Red No. 3 and of FD&C Yellow No. 5 for use in externally applied drugs and in cosmetics and for the provisional listing of the use of the lakes of FD&C Red No. 3 and of FD&C Yellow No. 5 in food and ingested drugs by rules published in the **Federal Register** of October 4 and October 7, 1983 (48 FR 45237 for FD&C Red No. 3, see that **Federal Register** for a full procedural history of this matter; 48 FR 45760 for FD&C Yellow No. 5). FDA had previously extended the closing date for FD&C Yellow No. 5 in the **Federal Register** of March 27, 1981 (46 FR 18954).

Additionally, the agency established the current closing date of November 29, 1983, for the provisional listing of D&C Red No. 8 and D&C Red No. 9 and of D&C Red No. 33 for use in drugs and cosmetics by final rules published in the **Federal Register** of September 20, 1983 (48 FR 42807 for D&C Red No. 8 and D&C Red No. 9) and of September 30, 1983 (48 FR 44773 for D&C Red No. 33), respectively (see the preamble to those rules for a full procedural history of the provisional listing of these color additives).

FDA extended the closing dates for the provisional listing of each of these color additives and of the lakes of FD&C Red No. 3 and of FD&C Yellow No. 5 to permit the agency to consider the scientific and legal aspects of the data concerning the safety of their provisionally listed uses. FDA expected that these closing dates would provide time for the agency to prepare and to publish appropriate regulations in the **Federal Register** regarding the agency's final decision on the petitions for the permanent listing of the aforementioned uses of these color additives and of the lakes of FD&C Red No. 3 and of FD&C Yellow No. 5.

FDA's review and evaluation of the data relevant to the provisionally listed uses of FD&C Red No. 3 and FD&C Yellow No. 5 and their lakes, D&C Red No. 8, D&C Red No. 9, and D&C Red No. 33 have required more time than anticipated, however. The agency finds that it still needs additional time to determine the applicability of the statutory standard for listing color additives to D&C Red No. 8, D&C Red No. 9, D&C Red No. 33, as well as to FD&C Red No. 3 and FD&C Yellow No. 5 and their lakes. The regulations set forth below will postpone the November 29, December 2, and December 5, 1983 closing dates for the provisionally listed uses of these color additives until February 3, 1984. This postponement will also provide additional time for the agency to prepare and to publish the appropriate **Federal Register** documents setting forth its decision on the petitions for the permanent listing of FD&C Red No. 3 and of FD&C Yellow No. 5 for use in coloring externally applied drugs and cosmetics and of the lakes of FD&C Red No. 3 and of FD&C Yellow No. 5 for use in coloring food and ingested drugs and for the permanent listing of D&C Red No. 8, D&C Red No. 9, and D&C Red No. 33 for use in coloring drugs and cosmetics. The continued use of these color additives for the short time needed for the adequate evaluation of the data and for the preparation of the **Federal Register** documents will not pose a hazard to the public health.

Because of the short time until the November 29, December 2, and December 5, 1983 closing dates, FDA concludes that notice and public procedure on these amendments are impracticable, and that good cause exists for issuing this postponement as a final rule. This final rule will permit the uninterrupted use of D&C Red No. 8, D&C Red No. 9, D&C Red No. 33, as well as FD&C Red No. 3 and FD&C Yellow No. 5 and their lakes until February 3, 1984. To prevent any interruption in the provisional listing of D&C Red No. 8, D&C Red No. 9, D&C Red No. 33, as well as FD&C Red No. 3 and FD&C Yellow No. 5 and their lakes and in accordance with 5 U.S.C. 553(d) (1) and (3), this regulation is being made effective on November 29, 1983.

**List of Subjects in 21 CFR Part 81**

Color additives, Color additives provisional list, Food, Cosmetics, Drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 701, 706 (b), (c), and (d), 52 Stat. 1055-1056 as amended, 74 Stat. 399-403 (21 U.S.C. 371, 376 (b), (c), and (d))) and the transitional provisions of the Color Additive Amendments of 1960 (Title II, Pub. L. 86-618, sec. 203, 74 Stat. 404-407 (21 U.S.C. 376, note)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 81 is amended as follows:

## PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

**§ 81.1 [Amended]**

1. In § 81.1 *Provisional lists of color additives,* by revising the closing dates for "FD&C Yellow No. 5" and "FD&C Red No. 3" in paragraph (a) to read "February 3, 1984" and by revising the closing dates for "D&C Red No. 8," "D&C Red No. 9." and "D&C Red No. 33" in paragraph (b) to read "February 3, 1984."

**§ 81.27 [Amended]**

2. In § 81.27 *Conditions of provisional listing,* by revising the closing dates for "FD&C Yellow No. 5," "FD&C Red No. 3," "D&C Red No. 8," "D&C Red No. 9," and "D&C Red No. 33" in paragraph (d) to read "February 3, 1984" and by revising the closing date for "D&C Red No. 33" in paragraph (e) to read "February 3, 1984."

*Effective date.* This final rule is effective November 29, 1983.

(Secs. 701, 706 (b), (c), and (d), 52 Stat. 1055-1056 as amended, 74 Stat. 399-403 (21 U.S.C. 371, 376 (b), (c), and (d)); sec. 203, 74 Stat. 404-407 (21 U.S.C. 376, note))

Dated: November 17, 1983.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 83-31604 Filed 11-25-83; 1:06 pm]

BILLING CODE 4160-01-M

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**21 CFR Part 81**

**[Docket No. 76N-0366]**

## Provisional Listing of D&C Orange No. 17, D&C Red No. 19, and D&C Red No. 37 for Use in Externally Applied Drugs and Cosmetics; Postponement of Closing Dates

**AGENCY:** Food and Drug Administration.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is postponing the closing date for the provisional listing of D&C Orange No. 17, D&C Red No. 19, and D&C Red No. 37 for use as color additives in externally applied drugs

and cosmetics. The new closing date will be February 3, 1984. This postponement will provide additional time for determining the applicability of the statutory standard for the listing of noningested color additives to the results of the scientific investigations of D&C Orange No. 17, D&C Red No. 19, and D&C Red No. 37.

**DATES:** Effective November 29, 1983, the new closing date for D&C Orange No. 17, D&C Red No. 19, and D&C Red No. 37 will be February 3, 1984.

**FOR FURTHER INFORMATION CONTACT:** Gerad McCowin, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204, 202-472-5676.

**SUPPLEMENTARY INFORMATION:** FDA established the current closing date of November 29, 1983, for the provisional listing of D&C Orange No. 17 and December 2, 1983, for the provisional listing of D&C Red No. 19 and D&C Red No. 37 for use in externally applied drugs and cosmetics by final rules published in the **Federal Register** of September 30 and October 31, 1983, respectively (48 FR 44774, 50076). The agency had previously extended the closing dates for these color additives on several occasions. For a full procedural history of the provisional listing of these color additives, see 48 FR 38814 for D&C Red No. 19 and D&C Red No. 37 and 48 FR 44774 for D&C Orange No. 17.

The agency extended the closing date for the provisional listing of these color additives on these occasions to permit it to consider the scientific and legal aspects of the submissions by the petitioner, the Cosmetic, Toiletry and Fragrance Association, Inc., in support of the safety of the external uses of these color additives. Although D&C Orange No. 17, D&C Red No. 19, and D&C Red No. 37 have been shown to be animal carcinogens upon ingestion the agency believes that somewhat different questions are raised by the request to list these color additives for noningested use. It has taken more time to evaluate the data involved in resolving these questions than the agency anticipated. FDA finds that it still needs additional time to determine the applicability of the statutory standard for the listing of color additives for noningested use to D&C Orange No. 17, D&C Red No. 19, and D&C Red No. 37. The regulations set forth below will postpone the November 29 and December 2, 1983 closing dates for the provisionally listed uses of these color additives until February 3, 1984. This postponement will also provide additional time for the agency to prepare and to publish **Federal Register** documents setting forth its final decision on the petitions for the permanent listing of these color addditives for external use. The continued use of these color additives in externally applied products for the short time needed for the adquate evaluation of the data and for preparation of the **Federal Register** documents will not pose a hazard to the public health.

Because of the short time until the November 29 and December 2, 1983 closing dates, FDA concludes that notice and public procedure on these amendments are impracticable, and that good cause exists for issuing the postponement as a final rule. This final rule will permit the uninterrupted use of these color additives until February 3, 1984. To prevent any interruption in the provisional listing of D&C Orange No. 17, D&C Red No. 19, and D&C Red No. 37, and in accordance with 5 U.S.C. 553 (d) (1) and (3), this final rule is being made effective November 29, 1983.

**List of Subjects in 21 CFR Part 81**

Color additives, Color additives provisional list, Cosmetics, Drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 701, 706 (b), (c), and (d), 52 Stat. 1055-1056 as amended, 74 Stat. 399-403 (21 U.S.C. 371, 376 (b), (c) and (d))) and under the transitional provisions of the Color Additive Amendments of 1960 (Title II, Pub. L. 86-618; sec. 203, 74 Stat. 404-407 (21 U.S.C. 376, note)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 81 is amended as follows:

## PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

**§ 81.1 [Amended]**

1. In § 81.1 *Provisional lists of color additives,* by revising the closing date for "D&C Orange No. 17," "D&C Red No. 19," and "D&C Red No. 37" in paragraph (b) to read "February 3, 1984."

**§ 81.27 [Amended]**

2. In § 81.27 *Conditions of provisional listing,* by revising the closing date for "D&C Orange No. 17," "D&C Red No. 19," and "D&C Red No. 37" in paragraph (d) to read "February 3, 1984."

*Effective date.* This final rule shall be effective November 29, 1983.

(Secs. 701, 706, (b), (c), and (d), 52 Stat. 1055-1056 as amended, 74 Stat. 399-403 (21 U.S.C. 371, 376 (b), (c), and (d)); sec. 203, 74 Stat. 404-407 (21 U.S.C. 376, note))

Dated: November 10, 1983.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 83-31805 Filed 11-25-83; 1:06 pm]

BILLING CODE 4160-01-M

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## DEPARTMENT OF TRANSPORTATION

## Coast Guard

## 33 CFR Part 110

**[CCGD 8-82-19]**

## Anchorage Regulations, Lower Mississippi River

**AGENCY:** Coast Guard, DOT.

**ACTION:** Final rule.

**SUMMARY:** The Coast Guard has amended the anchorage regulations on the Lower Mississippi River by establishing two permanent anchorages in the vicinity of Venice, Louisiana called the Upper Venice Anchorage and the Lower Venice Anchorage. This action was necessary to provide needed additional anchorage space for deep draft vessels.

**EFFECTIVE DATE:** December 29, 1983.

**FOR FURTHER INFORMATION CONTACT:** Lcdr. R. E. Ford, Port Safety Officer, Captain of the Port, New Orleans, LA, U.S. Coast Guard, 4640 Urquhart Street, New Orleans, LA 70117, Tel: (504) 589-7118.

**SUPPLEMENTARY INFORMATION:** On February 10, 1983 the Coast Guard published a Notice of Proposed Rulemaking in the **Federal Register** for this regulation (48 FR 6136). Interested persons were requested to submit comments and one comment was received.

**Drafting Information**

The Drafters of this regulation are Lt. T. L. McCarty, USCG, Project Officer, c/o Commander, Eighth Coast Guard District (mps) and Cdr. R. A. Brunell, USCG, Project Attorney, c/o Commander, Eighth Coast Guard District (dl), Hale Boggs Federal Building, 500 Camp Street, New Orleans LA 70130.

**Discussion of Comment**

Comments were received from one commenter. The commenter felt that .2 miles distance between the Upper and Lower Anchorages was insufficient to safeguard the pipeline located at mile 9.8 AHOP. The commenter recommended that a larger spacing of .5

miles be adopted. The Coast Guard acknowledges that a larger spacing is desirable and has doubled the spacing between the anchorages to .4 miles by decreasing the length of each anchorage by .1 mile. The Coast Guard feels that this provides an acceptable margin of safety, while not decreasing the capacity of the anchorages. A Precautionary Note has also been added.

The commenter also recommended the area across the river from a navigable channel known as "The Jump" (approximately mile 10.5 AHOP) be declared a "Non-Anchorage Area" due to the heavy usage of that navigable channel by small vessels. Since the anchorage is across the river from the channel and because those vessels generally using the channel are small, highly maneuverable craft, the Coast Guard does not feel that navigation will be adversely affected. Accordingly, the commenter's second recommendation was not adopted.

**Economic Assessment and Certification**

These regulations are considered to be nonsignificant in accordance with DOT Policies and Procedures for Simplification, Analysis, and Review of Regulation (DOY Order 2100.5 of 5-22-80). Their economic impact is expected to be minimal. Any economic effects will be positive, however, as this anchorage will result in lower operating costs for vessels. It is also certified in accordance with section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 605(b) that this regulation will not have a significant economic impact on a substantial number of entities. This regulation has been reviewed in accordance with Executive Order 12291 of February 17, 1981, on Federal Regulation and has been determined not to be a major rule under the terms of that order.

**List of Subjects in 33 CFR Part 110**

Anchorage grounds.

**Final Regulation**

In consideration of the foregoing, Part 110 of Title 33, Code of Federal Regulations, is amended as follows:

## PART 110—[AMENDED]

1. 33 CFR 110.195 is amended by redesignating (a)(2) through (a)(27) as (a)(4) through (a)(29) and by adding two new paragraphs (a)(2) and (a)(3) to read as follows:

**§ 110.195 Mississippi River below Baton Rouge, LA, including south and southwest passes.**

(a) * * *

(2) *Lower Venice Anchorage.* An area 1.6 miles in length along the left descending bank of the river from mile 8.0 to mile 9.6 above Head of Passes with the west limit 1,200 feet from the ALWP of the right descending bank.

(3) *Upper Venice Anchorage.* An area 1.2 miles in length along the left descending bank of the river from mile 10.0 to mile 11.2 above Head of Passes with the west limit 1,200 feet from the ALWP of the right descending bank.

2. By addition of a Cautionary Note after § 110.195(a)(2) to read as follows:

**Caution:** A pipeline crossing exists at mile 9.8 AHOP. Mariners are urged to use caution between mile 9.6 AHOP and mile 10.0 AHOP.

(33 U.S.C. 471; 49 U.S.C. 1655(g)(1); 49 CFR 1.46(c)(1): 33 CFR 1.05-1(g))

Dated: November 22, 1983.

**C. M. Holland,**

*Captain, U.S. Coast Guard, Executive Secretary, Marine Safety Council.*

[FR Doc. 83-31785 Filed 11-28-83; 8:45 am]

BILLING CODE 4910-14-M

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

**[AD-FRL 2479-3; EPA Action NE 1122]**

### Approval and Promulgation of Implementation Plans; Nebraska Lead Plan

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** The State of Nebraska has submitted a State Implementation Plan (SIP) for lead as required by Section 110 of the Clean Air Act and the October 5, 1978, promulgation of national ambient air quality standards (NAAQS) for lead (43 FR 46246). The plan was proposed for approval for all areas of the State, except Omaha, on August 29, 1983 (48 FR 39084). The purpose of today's notice is to take final action on the submission as proposed.

**EFFECTIVE DATE:** This action is effective December 29, 1983.

**ADDRESSES:** Copies of the state submission and the technical support material which explain EPA's actions are available for review at the following locations: Environmental Protection Agency, Air Branch, 324 East 11th Street, Kansas City, Missouri 64106; Environmental Protection Agency, Public Information Reference Unit, 401 M Street, S.W., Washington, D.C. 20460; The Office of the Federal Register, 1100 L Street, N.W., Room 8401, Washington, D.C.; and State of Nebraska, Department of Environmental Control, 301 Centennial Mall South, Lincoln, Nebraska 68509.

**FOR FURTHER INFORMATION CONTACT:** Dewayne E. Durst at (816) 374-3791 (FTS: 758-3791).

**SUPPLEMENTARY INFORMATION:** On January 9, 1981, the Governor of Nebraska submitted the State's SIP for attainment and maintenance of the NAAQS for lead. The state submitted additional information on August 5, 1981, and January 11, 1983. The SIP contained a summary of the statewide inventory of lead emissions. Only two point sources of lead in Omaha have lead emissions greater than five tons per year. Monitoring data show the only violations of the standard are near these two sources. There are no other significant lead point sources identified in the state. The SIP included a mobile source inventory for the area where violations of the standard occurred.

The SIP contained dispersion modeling for the area in Omaha where violations of the standard had been measured. The modeling indicated that mobile source contributions are small. The two point sources in the area were identified as the major cause of the high levels of lead. The modeling results in the SIP did not predict attainment of the lead standard.

Because the SIP did not predict attainment of the lead standard in Omaha by a specific date, the state requested a two year extension for that area. The basis for the request was lack of control technology to provide sufficient control to meet the standard, and the fact that all available interim control measures were being applied.

The SIP also contained Nebraska Pollution Control Rules 3 and 4 which provide for review of new or modified lead sources with greater than 5 tons of lead emissions per year. These rules give the State the authority to prevent construction or modification of such sources if they would cause a violation of the applicable control strategy or interfere with maintenance of the NAAQS for lead. Also, Federal regulations pertaining to lead phase down in gasoline will contribute to continued maintenance of the lead standard in areas of the State not affected by lead point sources.

On August 29, 1983, EPA proposed to approve Nebraska Rules 3 and 4 as they pertain to review of lead sources (48 FR 39084). Additionally, EPA proposed to approve the control strategy for all portions of the State, except Omaha. As was discussed in EPA's proposed approval of the Nebraska lead SIP

published on August 29, 1893 (48 FR 39084), the schedule for submission of the control strategy for Omaha is subject to the Agreement established in *NRDC v. Ruckelshaus* No. 82-2137 (D.D.C.), described in the **Federal Register** of August 10, 1983 (48 FR 36250). The reader is referred to the proposal of August 29 for further discussion of the contents of the Nebraska lead plan. EPA has received no public comments as a result of that proposal.

*Action:* EPA has evaluated the Nebraska lead SIP and determined that, with the exception of the portion of the implementation plan for the Omaha area, it meets the requirements of Section 110(a) of the Clean Air Act and 40 CFR Part 51, Subparts B and E. EPA believes the SIP is adequate to attain and maintain the NAAQS for lead and is therefore approving the plan, except for the Omaha area.

Under Executive Order 12291, today's action is not "Major." It has been submitted to the Office of Management and Budget (OMB) for review. Any comments from OMB to EPA, and any EPA response, are available for public inspection at the EPA Region VII office.

Under Section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by (60 days from today). This action may not be challenged later in proceedings to enforce its requirements. (See 307(b)(2).)

Incorporation by reference of the State Implementation Plan for the State of Nebraska was approved by the Director of the Federal Register on July 1, 1982.

This notice of final rulemaking is issued under the authority of Section 110(a) of the Clean Air Act, 42 U.S.C. 7410(a).

**List of Subjects in 40 CFR Part 52:**

Intergovernmental relations, Air pollution control, Ozone, Sulfur oxides, Nitrogen dioxide, Lead, Particulate matter, Carbon monoxide, Hydrocarbons.

Dated: November 17, 1983.

**William D. Ruckelshaus,**

*Administrator.*

## PART 52—[AMENDED]

Part 52 of Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

### Subpart CC—Nebraska

1. Section 52.1420 is amended by adding a new paragraph (c)(28) to read as follows:

**§ 52.1420 Identification of Plan**

* * * * *

(c) The plan revisions listed below were submitted on the dates specified.

* * * * *

(28) A plan revision for attaining and maintaining the National Ambient Air Quality Standard for Lead in the State of Nebraska was submitted to EPA on January 9, 1981, by the Governor. Additional material was submitted by the State on August 5, 1981 and January 11, 1983. All portions of the submittals are approved except the control strategy for Omaha and the request for a two year extension to attain the lead standard in Omaha.

[FD Doc 83-31833 Filed 11-28-83; 8:45 am]

BILLING CODE 6560-50-M

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## FEDERAL EMERGENCY MANAGEMENT AGENCY

### 44 CFR Part 64

**[Docket No. FEMA 6573]**

### Suspension of Community Eligibility Under the National Flood Insurance Program; Pennsylvania, et al.

**AGENCY:** Federal Emergency Management Agency, FEMA.

**ACTION:** Final rule.

**SUMMARY:** This rule lists communities, where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP), that are suspended on the effective dates listed within this rule because of noncompliance with the flood plain management requirements of the program. If FEMA receives documentation that the community has adopted the required flood plain management measures prior to the effective suspension date given in this rule, the suspension will be withdrawn by publication in the **Federal Register.**

**EFFECTIVE DATES:** The third date ("Susp.") listed in the fourth column.

**FOR FURTHER INFORMATION CONTACT:** Richard W. Krimm, Assistant Associate Director, Office of Natural and Technological Hazards Programs (202) 287-0176, 500 C Street, SW., FEMA—Room 506, Washington, D.C. 20472.

**SUPPLEMENTARY INFORMATION:** The National Flood Insurance Program (NFIP), enables property owners to purchase flood insurance at rates made reasonable through a Federal subsidy. In return, communities agree to adopt and administer local flood plain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended (42 U.S.C. 4022) prohibits flood insurance coverage as authorized under the National Flood Insurance Program (42 U.S.C. 4001-4128) unless an appropriate public body shall have adopted adequate flood plain management measures with effective enforcement measures. The communities listed in this notice no longer meet that statutory requirement for compliance with program regulations (44 CFR Part 59 et seq.). Accordingly, the communities are suspended on the effective date in the fourth column, so that as of that date flood insurance is no longer available in the community. However, those communities which, prior to the suspension date, adopt and submit documentation of legally enforceable flood plain management measures required by the program, will continue their eligibility for the sale of insurance. Where adequate documentation is received by FEMA, a notice withdrawing the suspension will be published in the **Federal Register.**

In addition, the Director of Federal Emergency Management Agency has identified the special flood hazard areas in these communities by publishing a Flood Hazard Boundary Map. The date of the flood map, if one has been published, is indicated in the fifth column of the table. No direct Federal financial assistance (except assistance pursuant to the Disaster Relief Act of 1974 not in connection with a flood) may legally be provided for construction or acquisition of buildings in the identified special flood hazard area of communities not participating in the NFIP and identified for more than a year, on the Federal Emergency Management Agency's initial flood insurance map of the community as having flood prone areas. (Section 202(a) of the Flood Disaster Protection Act of 1973 (Pub. L. 93-234), as amended.) This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column.

The Director finds that notice and public procedure under 5 U.S.C. 533(b) are impracticable and unnecessary because communities listed in this final rule have been adequately notified. Each community receives a 6-month, 90-day, and 30-day notification addressed to the Chief Executive Officer that the community will be suspended unless the

required flood plain management measures are met prior to the effective suspension date. For the same reasons, this final rule may take effect within less than 30 days.

Pursuant to the provision of 5 U.S.C. 605(b), the Associate Director of State and Local Programs and Support, to whom authority has been delegated by the Director, Federal Emergency Management Agency, hereby certifies that this rule if promulgated will not have a significant economic impact on a substantial number of small entities. As stated in Section 2 of the Flood Disaster Protection Act of 1973, the establishment of local flood plain management together with the availability of flood insurance decreases the economic impact of future flood losses to both the particular community and the nation as a whole. This rule in and of itself does not have a significant economic impact. Any economic impact results from the community's decision not to (adopt) (enforce) adequate flood plain management, thus placing itself in noncompliance of the Federal standards required for community participation. In each entry, a complete chronology of effective dates appears for each listed community.

**List of Subjects in 44 CFR Part 64**

Flood insurance, Flood plains.

Section 64.6 is amended by adding in alphabetical sequence new entries to the table.

**§ 64.6 List of Eligible Communities.**

| State and county | Location | Community No. | Effective dates of of sale of flood insurance in community | Special flood hazard area identified | Date [1] |
|---|---|---|---|---|---|
| Region III | | | | | |
| Pennsylvania: | | | | | |
| Bucks | Bedminster, township of | 421049A | Feb. 5, 1976, emergency; Dec. 1, 1983 regular; Dec. 1, 1983, Suspended. | Jan. 1, 1975 | Dec. 1, 1983. |
| Butler | Middlesex, township of | 421229B | Dec. 10, 1974, emergency; Dec. 1, 1983, regular; Dec. 1, 1983. suspended. | July 26, 1974, July 2, 1976 | Do. |
| West Virginia: Mercer | Bramwell, town of | 540125B | June 6, 1975, emergency; Dec. 1, 1983 regular; Dec. 1, 1983, suspended. | May 24, 1974, Mar. 26, 1976 | Do. |
| Region IV | | | | | |
| Florida: Pinellas | Tarpon Springs, city of | 120259 | July 24, 1970, energency; May 14, 1971, regular December 5, 1983, suspended. | June 1, 1983 | Dec. 5, 1983. |
| North Carolina: Haywood. | Clyde, town of | 370122B | May 20, 1974 emergency; Dec. 1, 1983, regular; Dec. 1, 1983, suspended. | June 14, 1974, Oct. 15 1976 | Dec. 1, 1983. |
| Region V | | | | | |
| Illinois: | | | | | |
| Hardin | Cave-In-Rock, village of | 170274B | Aug. 27, 1975, emergency; Dec. 1, 1983, regular; Dec. 1, 1983, suspended. | Jan. 23, 1974, July 30, 1976 | Dec. 1, 1983 |
| McLean | Heyworth, village of | 170497B | Mar. 7, 1983, emergency; Dec. 1, 1983, regular; Dec. 1.1983, suspended. | June 14, 1974, July 14, 1974 | Do. |
| Indiana:: | | | | | |
| Jefferson | Brooksburg, town of | 180105A | Sept. 18, 1975; emergency; Dec. 1, 1983, regular; Dec. 1, 1983, suspended. | Nov. 29, 1974 | Do. |
| Ohio: | | | | | |
| Harrison and Jefferson. | Adena, village of | 390295B | Feb. 18, 1977 emergency; Dec. 1, 1983, regular; Dec. 1.1983, suspended. | July 23, 1976 Oct. 3, 1980 | Do. |
| Jefferson | Amsterdam, village of | 390296B | Mar. 19, 1976, emergency; Dec. 1, 1983, regular; Dec. 1.1983, suspended. | Apr. 12, 1974, May 28, 1976 | Do. |
| Licking | Unincorporated areas | 390328B | Apr. 15, 1977, emergency; Dec. 1, 1983, regular; Dec. 1, 1983, suspended. | Mar. 10, 1978 | Do. |
| Wisconsin: | | | | | |
| Oconto | Suring, village of | 550300C | Jan. 30, 1975, emergency; Dec. 1, 1983, regular; Dec. 1, 1983, suspended. | May 3, 1974, June 4, 1976, and Feb. 12, 1982. | Dec. 1, 1983. |
| Region VI | | | | | |
| Texas: | | | | | |
| Harris | Morgans Point, city of | 480305B | July 7, 1975, emergency; Dec. 1, 1983, regular; Dec. 1.1983, suspended. | June 28, 1974, Sept. 19, 1975 | Dec. 1, 1983 |
| Region VIII | | | | | |
| North Dakota: | | | | | |
| Dunn | Dunn Center, city of | 380028A | Mar. 28, 1975 emergency; Dec. 1, 1983, regular; Dec. 1.1983, suspended. | Nov. 22, 1974 | Do. |
| Do | Halliday, city of | 380029A | June 4, 1975 emergency; Dec. 1, 1983, regular; Dec. 1, 1983, suspended. | ....do | Do. |
| Do | Killdeer, city of | 380030B | May 27, 1975, emergency; Dec. 1, 1983, regular; Dec. 1, 1983, suspended. | June 28, 1974, Jan. 2, 1976 | Do. |
| Region IX | | | | | |
| Nevada: | | | | | |
| Washoe | Sparks, city of | 320021B | July 18, 1975 emergency; Dec. 1, 1983, regular; Dec. 1, 1983, suspended. | Feb. 8, 1974, June 27, 1975 | Do. |
| Region X | | | | | |
| Washington: | | | | | |
| Snohomish | Index, town of | 530166B | Aug. 27, 1975, emergency; Dec. 1, 1983, regular; Dec. 1, 1983, suspended. | Feb. 8, 1974, Dec. 27, 1974 | Do. |
| Do | Monroe, city of | 530169B | Aug. 14, 1974, emergency; Dec. 1, 1983, regular; Dec. 1, 1983, suspended. | Nov. 5, 1976, Jan. 16, 1979 | Do. |
| Mason | Shelton, city of | 530116B | Aug. 27, 1975, emergency; Dec. 1, 1983, regular; Dec. 1, 1983, suspended. | June 14, 1974, Mar. 19, 1976 | Do. |
| Pierce | Tacoma, city of | 530148B | July 2, 1974 emergency; Dec. 1, 1983, regular; Dec. 1, 1983, suspended. | Oct. 18, 1974, Feb. 18, 1977 | Do. |
| Walla Walla | Unincorporated areas | 530194B | Dec 23, 1971 emergency; Dec. 1, 1983, regular; Dec. 1, 1983, suspended. | Dec. 27, 1974, Sept. 13, 1977 | Do. |

[1] Date certain Federal assistance no longer available in Special Flood Hazard Area.

(National Flood Insurance Act of 1968 (title XIII of the Housing and Urban Development Act of 1968); effective Jan. 28, 1969 (33 FR 17804, Nov. 28, 1968), as amended, 42 U.S.C. 4001–4128; Executive Order 12127, 44 FR 19367; and delegation of authority to the Associate Director, State and Local Programs and Support)

Issued: November 21, 1983.

**Dave McLoughlin,**

*Deputy Associate Director, State and Local Programs and Support.*

[FR Doc. 83-31802 Filed 11-28-83; 8:45 am]

BILLING CODE 6718-01-M

## 44 CFR Part 67

## National Flood Insurance Program; Final Flood Elevation Determinations; Florida, et al.

**AGENCY:** Federal Emergency Management Agency.

**ACTION:** Final rule.

**SUMMARY:** Final base (100-year) flood elevations are finalized for the communities listed below.

The base (100-year) flood elevations are the basis for the flood plain management measures that the community is required to either adopt or show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

**EFFECTIVE DATE:** The date of issuance of the Flood Insurance Rate Map (FIRM) showing base (100-year) flood elevations, for the cummunity. This date may be obtained by contacting the office where the maps are available for inspection indicated on the table below:

**ADDRESSES:** See table below:

**FOR FURTHER INFORMATION CONTACT:** Dr. Brian R. Mrazik, Chief, Engineering Branch, Natural Hazards Division, Federal Emergency Management Agency, Washington, D.C. 20472; (202) 287-0230.

**SUPPLEMENTARY INFORMATION:** The Federal Emergency Management Agency gives notice of the final determinations of flood elevations for each community listed. Proposed base flood elevations or proposed modified base flood elevations have been published in the **Federal Register** for each community listed.

This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1968 (Title XIII of the Housing and Urban Development Act of 1968 (Pub. L. 90-448)), 42 U.S.C. 4001-4128, and 44 CFR Part 67. An opportunity for the community or individuals to appeal the proposed determination to or through the community for a period of ninety (90) days has been provided.

The Agency has developed criteria for flood plain management in flood-prone areas in accordance with 44 CFR Part 60.

Pursuant to the provisions of 5 U.S.C. 605(b), the Associate Director, to whom authority has been delegated by the Director, Federal Emergency Management Agency, hereby certifies for reasons set out in the proposed rule that the final flood elevation determinations, if promulgated, will not have a significant economic impact on a substantial number of small entities. Also, this rule is not a major rule under terms of Executive Order 12291, so no regulatory analyses have been proposed. It does not involve any collection of information for purposes of The Paperwork Reduction Act.

### List of Subjects in 44 CFR Part 67

Flood insurance, Flood plains.

Interested lessees and owners of real property are encouraged to review the proof Flood Insurance Study and Flood Insurance Rate Map available at the address cited below for each community.

The modified base flood elevations are finalized in the communities listed below. Elevations at selected locations in each community are shown. No appeal was made during the 90-day period and the proposed base flood elevations have not been changed.

| State | City, town, and county | Source of flooding | location | #Depth in feet above ground. *Elevation in feet (NGVD). Modified |
|---|---|---|---|---|
| Florida | (Unincorporated) Clay County (FEMA-6508) | North Prong Double Branch | At confluence with Double Branch | *32 |
| | | | About 2.0 miles upstream of confluence with Double Branch. | *59 |
| Maps available for inspection at the Clay County Planning, Zoning and Building Department, Clay County Courthouse, P.O. Box 367, Green Cove Springs, Florida. | | | | |
| Florida | Pinellas Park (city of) Pinellas County (FEMA-6547). | Ditch 2a | Intersection of 46th Street North and 88th Avenue North. | *15 |
| | | | Intersection of Lake Drive and Maple Drive | *13 |
| | | Boca Ciega Bay | 700 feet northwest of the intersection of 113th Place and 64th Street. | *11 |
| | | Tampa Bay | 1,100 feet southwest of the intersection of Interstate Highway 275 and Gandy Bridge Boulevard. | *9 |
| Maps are available for review at the Engineering Department, City Hall, Pinellas Park, Florida. | | | | |
| Georgia | (C) Powder Springs, Cobb County (FEMA-6547) | Wildhorse Creek | Just upstream of Macedonia Road | *913 |
| | | Lost Mountain Creek | At mouth at Wildhorse Creek | *902 |
| | | | Just upstream of Forest Hills Road | *920 |
| Maps available for inspection at P.O. Box 46, Powder Springs, Georgia. | | | | |
| Illinois | (C) Alton, Madison County (FEMA-6547) | West Fork Wood River | About 0.5 mile upstream of Burlington Northern Railroad. | *450 |
| | | | About 1.1 miles upstream of Burlington Northern Railroad. | *451 |
| Maps available for inspection at the City Hall, 101 East Third, Street, Alton, Illinois. | | | | |
| Illinois | (C) Crest Hill, Will County (FEMA-6538) | Tributary A Des Plaines River | About 1,300 feet upstream of mouth | *570 |
| | | | Just downstream of Elgin, Joliet and Eastern Railway | *578 |
| | | | About 600 feet upstream of Elgin, Joliet and Eastern Railway. | *585 |
| | | Rock Run | About 525 feet downstream of U.S. Route 30 | *586 |
| | | St. Francis Academy Creek | At confluence with Rock Run Creek | *591 |

| State | City, town, and county | Source of flooding | location | #Depth in feet above ground. *Elevation in feet (NGVD). Modified |
|---|---|---|---|---|
| | | | About 700 feet ustream of the confluence with Rock Run Creek. | *592 |
| | | St. Anne School Tributary | About 100 feet uptream of Theodore Street | *622 |
| | | | At Confluence with Rock Run | *591 |
| | | | About 900 feet upstream of the confluence with Rock Run. | *597 |
| | | | Just upstream of Theodore Street | *627 |
| Maps available for inspection at 1610 Plainfield Road, Crest Hill, Illinois | | | | |
| Illinois | (C) Elgin, Cook, and Kane Counties (FEMA-6547). | Lord's Park Tributary | Just upstream of Vills Street | *724 |
| Maps available for inspection at Engineering Department, 150 Dexter Court, Elgin, Illinois. | | | | |
| Illinois | (V) Melrose Park, Cook County (FEMA-6547) | Backwater effects from Addison Creek. | Intersection of Division Street and 38th Street | *634 |
| Maps available for inspection at 706 North 18th Avenue, Melrose Park, Illinois. | | | | |
| Illinois | (C) Mendota, LaSalle County (FEMA-6538) | Mendota Creek | Approximately 1,000 feet downstream of First Street | *727 |
| | | | The upstream side of the Lakwood Drive Bridge | *755 |
| | | | Approximately 0.7 mile upstream of Lakewood Drive Bridge. | *769 |
| Maps available for inspection at City Hall, 607 8th Street, Mendota, Illinois. | | | | |
| Kansas | (C) Halstead, Harvey County (FEMA-6547) | Little Arkansas River | About 0.64 mile downstream of County Road 576 | *1,389 |
| | | | Just downstream of County Road 801 | *1,396 |
| | | Black Kettle Creek | At confluence with Little Arkansas River | *1,395 |
| | | | Just upstream of Main Street | *1,395 |
| | | Halstead Slough | About 1800 feet downstream of Tenth Street | *1,389 |
| | | | Just downstream of County Road 801 | *1,392 |
| Maps available for inspection at the City Hall, 303 Main Street, Halstead, Kansas | | | | |
| Mississippi | (C) Grenada, Grenada County (FEMA-6547) | Yalobusha River Tributatry 1 | Just downstream of State Highway 8 | *201 |
| | | | About 850 feet upstream of State Highway 8 | *207 |
| | | Yalobusha River Tributary 1B | At mouth at Yalobusha River Tributary 1 | *207 |
| | | | About 800 feet upstream of mouth | *207 |
| Maps available for inspection at City Hall, Grenada, Mississippi. | | | | |
| South Dakota | Spearfish (city of) Lawrence County (FEMA-6547). | Spearfish Creek | Intersection of 3rd Street and Quincy Street | *3597 |
| Maps are available for review at City Hall, 722 Main Street, Spearfish; South Dakota. | | | | |

(National Flood Insurance Act of 1968 (Title XIII of Housing and Urban Development Act of 1968), effective January 28, 1969 (33 FR 17804, November 28, 1968), as amended; (42 U.S.C. 4001-4128); Executive Order 12127, 44 FR 19367; and delegation of authority to the Associate Director)

Issued: November 16, 1983.

**Dave McLoughlin,**

*Deputy Associate Director, State and Local Programs and Support.*

[FR Doc. 83-31801 Filed 11-28-83; 8:45 am]

BILLING CODE 6718-03-M

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

[MM Docket No. 83-466; RM-4365]

### Television Broadcast Station in El Dorado, Arkansas; Changes in Table of Assignments

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** Action taken herein deletes UHF Television Channel 18 and substitutes UHF Television Channel 43 at El Dorado, Arkansas, in response to a petition filed by Great Southern TV Broadcasting, an applicant for UHF Television Channel 33, Bossier City, Louisiana, whose application was short-spaced to Channel 18 at El Dorado. This action also preserves the "cut-off" status of CMM, Inc., the applicant on Channel 18, enabling it to amend its application to reflect operation on Channel 43.

**DATE:** Effective: January 27, 1984.

**ADDRESS:** Federal Communications Commission, Washington, D.C. 20554.

**FOR FURTHER INFORMATION CONTACT:** D. David Weston, Mass Media Bureau, (202) 634-6530.

### List of Subjects in 47 CFR 73

Television broadcasting.

### Report and Order (Proceeding Terminated)

In the matter of Amendment of § 73.606(b), Table of Assignments, Television Broadcast Stations. (El Dorado, Arkansas); MM Docket No. 83-466; RM-4365.

Adopted: October 31, 1983.

Released: November 21, 1983.

By the Chief, Policy and Rules Division.

1. Before the Commission for consideration is the *Notice of Proposed Rule Making*, 48 FR 26462, published June 8, 1983, in response to a petition filed by Great Southern TV Broadcasting ("Southern"), one of seven applicants for Channel. 33 allocated to Shreveport, Louisiana.[1] Southern proposes the deletion of Channel 18, El Dorado, Arkansas, and the substitution of Channel 43 to eliminate a short-spacing of 7.7 miles between Channel 18 and its sending application (BPCT-820909KQ) for Channel 33, Bossier City, Louisiana.[2] CMM, Inc. ("CMM") and Noe Enterprises, Inc. ("Noe"), mutually exclusive applicants for Channel 18, El Dorado, Arkansas [3] have filed

[1] The seven applications were recently designated for hearing in MM Docket Nos. 83-682 through 83-688. See, *Hearing Designation Order*, 48 FR 33052, published July 20, 1983.

[2] Although Channel 33 is allocated to Shreveport, Louisiana, Southern applied for it at Bossier City, Louisiana, in accordance with § 73.607(b) of the Rules. That Section was deleted effective February 17, 1983, but applications on file as of that date are processed under the old rule. See, *Suburban Community Policy*, 53 RR 2d 681, 698 (1983).

[3] CMM, Inc. filed its application for Channel 18 on March 1, 1983 (BPCT-830301KK). Noe Enterprises,

Continued

supporting comments. Comments in opposition were filed by Media South Broadcasting Corp. ("Media South"), a mutually-exclusive applicant with Southern in the Channel 33 proceeding. Southern filed supporting comments for the proposed substitution and reply comments to the opposition.

2. As the *Notice* indicated, the Commission expressed concern that Southern's alleged public interest benefit of greater site flexibility for the proposed channel substitution was no longer valid in view of a pending application for operation on Channel 18 which specified a transmitter site near the reference coordinates for El Dorado. However, the Commission noted that the allegation was made before the filing of the Channel 18 application [4] and determined that in view of the changed circumstances and its actions in *Clarksdale, Mississippi*,[5] the best procedure was to resolve its concern after Southern and other interested parties had the opportunity to comment on the public interest aspects of the proposal. The *Notice* solicited comments specifically on whether applicants for Channel 18 would object to the deletion of that channel and/or operation on Channel 43, or alternatively, whether they would be willing to accept a 7.7 mile site restriction on Channel 18 at El Dorado, Arkansas.

3. Initially, Southern argues that its proposal was "particularly sensible" since no application for full-service operation [6] on Channel 18 in El Dorado had been filed when it filed its petition for rule making and "the short-spacing in the Channel 33 proceeding was to a reference point rather than an actual proposal and therefore was purely hypothetical." Further, the Commission had "no reason to prefer" an operation on Channel 18 over one on Channel 43.[7] Southern concludes that in these circumstances, its proposal would have served the "public interest" by increasing the site alternatives" and by "curing a short-spacing situation in the Channel 33 proceeding." Southern now argues that in addition to curing a potential short-spacing situation, its proposal "will achieve the settled public interest goals of * * * simplifying and expediting two adjudicatory proceedings and enhancing the prospects for competitive service."

4. Southern asserts that in the current situation, the El Dorado and Shreveport application proceedings are intertwined and that "adoption of its proposal will simplify the scope and expedite the resolution of adjudicatory proceedings" in the two markets. Southern has also raised procedural questions on the acceptability of the Channel 18 applications and points out that adoption of its proposal also "eliminates all of these questions in a sound and simple manner." However, as the Commission noted in its *Notice*, it was primarily concerned with the public interest benefits of the rule making proposal, specifically, with respect to prospective applicants' objections to the deletion of Channel 18 and operation on Channel 43, or alternatively, whether they would accept a site restriction on 7.7 miles on Channel 18 at El Dorado, Arkansas. In this respect, Southern, Noe and CMM have all filed comments supporting the proposed substitution of Channel 43 for Channel 18 at El Dorado, Arkansas. Southern points out that Noe and CMM reached an agreement in principle on this proposed substitution. In essence, Noe will withdraw its application and continue its translator operations on Channel 18, and CMM will amend its pending application to specify Channel 43 in lieu of Channel 18 at El Dorado, Arkansas. All point to the public interest benefits to be gained by avoiding a protracted comparative hearing for Channel 18 at El Dorado; the early inauguration of new competitive television service on Channel 43 to El Dorado; the continuing benefits to the community provided by Noe's existing translator service and the elimination of mileage separation problems arising because of short-spacing between the application for Channel 33 in Bossier City and the Channel 18 application in El Dorado. The Commission is, therefore, satisfied that Southern has demonstrated that the proposed substitution has public interest benefits and that the only applicants for that channel, Noe and CMM, have no objection to the deletion of Channel 18 and the substitution on Channel 43 in that community.[8]

5. There remains only the question of Media South's objections to the proposed substitution. Media South is a mutually exclusive applicant with Southern in the Channel 33 proceeding and has alleged numerous procedural defects in the filing and prosecution of Southern's application.[9] Those matters, of course, must be resolved within the context of that application proceeding and need not be commented on during this rule making proceeding. With respect to the rule making under consideration, Media South alleges that Southern offers no "public interest justification" for its proposal since the channel substitution is "not necessary to provide new, additional or enhanced television service to either Shreveport or El Dorado." Media South also points out that the only public interest benefit advanced by Southern for its proposal, that of greater flexibility in site selection is no longer valid. Media South also alleges that Southern "filed its petition for rule making in an attempt to manipulate the Commission's rule making processes." In support, it points out that Southern has avoided "dismissal of its application" in the Channel 33 proceeding because of the pendency of this rule making proceeding. It also alleges that the Commission, by issuing the *Notice*, "appears to be paying excessive deference to the dictates of due process" which is "penalizing and prejudicing others" in the Channel 33 proceeding. In support, it alleges that it is "patently unfair that the six other applicants for Channel 33 * * * should suffer delay in the processing and disposition of their applications * * *" while the Commission treats Southern's "meritless proposal with an excess of regulatory fairness."

6. In reply comments, Southern alleges that Media South is "using this rule making proceeding as a forum for airing its objections" to its application in the Channel 33 proceeding. Accordingly, Southern's response within that context need not be considered in this rule making proceeding. With respect to Media South's objections "that no public interest for the proposed substitution exists," Southern asserts that the "proposed substitution will benefit the

Inc. filed a mutually exclusive application on April 29, 1983 (BPCT-830429KK), the "cut-off" date for filing competing applications for Channel 18, El Dorado, Arkansas.

[4] Southern's petition for rule making was filed on February 1, 1983 and CMM's application for Channel 18, El Dorado, Arkansas, was filed on March 1, 1983. See also fn. 3, *supra*.

[5] See *Clarksdale and Greenville, Mississippi and Birmingham, Alabama*, 43 FR 1502 (1977), wherein the Commission granted a channel substitution in response to a petition filed by a UHF television applicant whose pending application was short-spaced to an unapplied for and unoccupied UHF television allocation.

[6] Noe Enterprises, Inc., currently a mutually-exclusive applicant for Channel 18, has operated a translator station on Channel 18, El Dorado, for the last 13 years. The translator operation, however, poses no short-spacing problem for the application in the Channel 33 proceeding.

[7] See *New Smyrna Beach, Florida*, 50 RR 2d 1714, 1716 (1982).

[8] The agreement assumes preservation of CMM's "cut-off" status for its pending application if the channel substitution is made.

[9] Media South initially filed a petition in November, 1982 seeking dismissal of Southern's application alleging failure to comply with the mileage separation requirements of § 73.698 or to request a waiver of the requirements.

public in El Dorado by allowing the immediate institution of a new competitive service, the preservation of an existing service and elimination of the time consuming delay of a complex hearing proceeding." In response to Media South's allegations relating to Southern's motives in initiating this rule making proceeding, Southern asserts "all applicants in the Channel 33 proceeding, including Media South, have potential technical deficiencies in their proposals" and that by "initiating this proceeding [it] acted earlier than the other applicants and most diligently in seeking a sensible solution to a potential short spacing situation." The Commission is convinced that Southern has demonstrated that Media South's objections to this rule making proceeding are not supported by the facts. The Commission will, therefore, make the requested substitution at El Dorado and delete Channel 18 and substitute Channel 43 in that community.

7. With respect to Media South's views on the Commission's actions in considering Southern's petition and issuing the *Notice* in this proceeding, it is sufficient to point out that Southern's petition has merit as well as substantial public interest benefits that will not only expedite the Channel 33 proceeding but will result in the early inauguration of new competitive service in El Dorado, Arkansas.

8. Finally, the agreement in principle is contingent upon CMM, Inc. retaining its "cut-off" status which enables it to amend its pending application to reflect operation on UHF television Channel 43 without the filing of competing applications for that channel. In cases like this, it has been our policy to afford applicants continued protection from the filing of competing applications if, during the rule making which propose the substitute channel, no other interest is expressed in applying for that proposed assignment. See *Austin A. Harrison*, 3 RR 2d 847 (1964); *Miami, Florida*, 46 RR 2d 1272 (1980). See also *Tucson, Arizona*, Docket No. 20507, 41 FR 26574 (1976), and cases cited therein. In view of the lack of other expressed interest in applying for the El Dorado channel, CMM, Inc. will be permitted to amend its application to specify UHF television Channel 43 in lieu of UHF television Channel 18 without losing its protected "cut-off" status.

**§ 73.606 [Amended]**

9. Accordingly, pursuant to authority contained in Sections 4(i), 5(d)(1), 303(g) and (r) and 307(b) of the Communications Act of 1934, as amended, and §§ 0.204(b) and 0.283 of the Commission's Rules, it is ordered, that effective January 27, 1984, the Television Table of Assignments, § 73.606(b) of the Rules, is amended with respect to the community listed below:

| City | Channel No. |
|---|---|
| El Dorado, Arkansas | 10−, *34+, and 43− |

10. It is further ordered, that the requirements of § 73.3573 are waived on our own motion pursuant to §§ 1.108 and 0.283 of the Rules to permit CMM, Inc. to amend its application (File No. BPCT-830301KK) to substitute UHF Television Channel 43 for UHF Television Channel 18 at El Dorado, Arkansas, and retain its cut-off protection.

11. It is further ordered, that this proceeding is terminated.

12. For further information concerning the above, contact D. David Weston, Mass Media Bureau, (202) 634-6530.

Federal Communications Commission.

**Roderick K. Porter,**

*Chief, Policy and Rules Division, Mass Media Bureau.*

[FR Doc. 83-31842 Filed 11-28-83; 8:45 am]

BILLING CODE 6712-01-M

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## 47 CFR Part 73

**[MM Docket No. 83-354; RM-4290]**

## Television Broadcast Station in San Luis Obispo, California; Changes Made in Table of Assignments

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** Action taken herein assigns UHF television Channel 33 to San Luis Obispo, California, in response to a petition filed by William V. Johnson. The assignment could provide that community with its second local commercial television allocation.

**DATE:** Effective January 23, 1984.

**ADDRESS:** Federal Communications Commission, Washington, D.C. 20554.

**FOR FURTHER INFORMATION CONTACT:** Nancy V. Joyner, Mass Media Bureau, (202) 634-6530.

### List of Subjects in 47 CFR 73

Television broadcasting.

### Report and Order (Proceeding Terminated)

In the matter of amendment of § 73.606(b), Table of Assignments, Television Broadcast Stations. (San Luis Obispo, California) MM Docket No. 83-354, RM-4290.

Adopted: November 2, 1983.

Released: November 16, 1983.

By the Chief, Policy and Rules Division.

1. Before the Commission is the *Notice of Proposed Rule Making*, 48 FR 16087, published April 14, 1983, proposing the assignment of UHF television Channel 33 to San Luis Obispo, California, as that community's second commercial television allocation. The *Notice* was issued in response to a petition filed by William V. Johnson ("petitioner"), who filed comments reiterating his intention to apply for the channel, if assigned. No oppositions to the proposal were received.

2. San Luis Obispo (population 34,252),[1] the seat of San Luis Obispo County (population 155,345), is located approximately 260 kilometers (160 miles) northwest of Los Angeles, California. Commercial television Channel 6, licensed to Station KSBY-TV, and noncommercial educational Channel *15 (vacant and unapplied for), are currently allocated to that community.

3. We believe that the public interest would be served by assigning UHF television Channel 33 to San Luis Obispo. Petitioner has demonstrated the need for a second television allocation to that community. The assignment can be made consistent with the minimum distance separation requirements of the Commission's Rules and other technical criteria.

**§ 73.606 [Amended]**

4. Accordingly, pursuant to the authority contained in Sections 4(i), 5(d)(1), 303 (g) and (r) and 307(b) of the Communications Act of 1934, as amended, and §§ 0.61, 0.204(b) and 0.283 of the Commission's Rules, it is ordered, that effective January 23, 1984, the Television Table of Assignments, § 73.606(b) of the Commission's Rules, is amended with respect to the community listed below as follows:

| City | Channel No. |
|---|---|
| San Luis Obispo, California | 6+, *15+, and 33 |

5. It is further ordered, That this proceeding it terminated.

6. For further information concerning this proceeding, contact Nancy V. Joyner, Mass Media Bureau, (202) 634-6530.

[1] Population figures were extracted from the 1980 U.S. Census, Advance Reports.

Federal Communications Commission.

**Roderick K. Porter,**

*Chief, Policy and Rules Division, Mass Media Bureau.*

[FR Doc. 83-31845 Filed 11-28-83; 8:45 am]

BILLING CODE 6712-01-M

## 47 CFR Part 73

**[MM Docket No. 83-387; RM-4359]**

## FM Broadcast Station in McAlester, Oklahoma; Changes Made in Table of Assignments

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** Action taken herein assigns FM Channel 285A to McAlester, Oklahoma, in response to a request filed by Megacom. The assignment could provide McAlester with its second FM service.

**EFFECTIVE DATE:** January 23, 1984.

**ADDRESS:** Federal Communications Commission, Washington, D.C. 20554.

**FOR FURTHER INFORMATION CONTACT:** Nancy V. Joyner, Mass Media Bureau (202) 634-6530.

**SUPPLEMENTARY INFORMATION:**

### List of Subjects in 47 CFR Part 73

Radio broadcasting.

### Report and Order (Proceeding Terminated)

In the matter of amendment of § 73.202(b), Table of Assignments, FM Broadcast Stations. (McAlester, Oklahoma); MM Docket No. 83-387; RM-4359.

Adopted: October 31, 1983.

Released: November 16, 1983.

By the Chief, Policy and Rules Division.

1. Before the Commission is the Notice of Proposed Rule Making, 48 FR 18853, published April 26, 1983, proposing the assignment of Channel 285A to McAlester, Oklahoma, as that community's second FM service, in response to a petition filed by Megacom ("petitioner"). Petitioner filed supporting comments reiterating its intention to apply for the channel, if assigned. No oppositions to the proposal were received.

2. We believe the public interest would be served by a grant of petitioner's request since it could provide a competitive FM service to McAlester for the expression of diverse viewpoints and programming.

3. As indicated in the Notice, Channel 285A can be assigned to McAlester consistent with the minimum distance separation requirements of Section 73.207 of the Commission's Rules.

4. Accordingly, pursuant to the authority contained in Sections 4(i), 5(d)(1), 303 (g) and (r) and 307(b) of the Communications Act of 1934, as amended, and § 0.61, 0.204(b) and 0.283 of the Commission's Rules, it is ordered, That effective January 23, 1984, the FM Table of Assignments, § 73.202(b) of the Commission's Rules, is amended as follows:

| City | Channel No. |
|---|---|
| McAlester, Oklahoma | 267, 285A |

5. It is further ordered, That this proceeding is terminated.

6. For further information concerning the above, contact Nancy V. Joyner, Mass Media Bureau (202) 634-6530.

Federal Communications Commission.

**Roderick K. Porter,**

*Chief, Policy and Rules Division, Mass Media Bureau.*

[FR Doc. 83-31844 Filed 11-28-83; 8:45 am]

BILLING CODE 6712-01-M

## 47 CFR Part 73

**[BC Docket No. 80-201; RM-3249, RM-3710 et al.]**

## FM Broadcast Stations in North Charleston, Eastover, and Ravenel, South Carolina et al.; Changes in Table of Assignments

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This action grants a petition for reconsideration, filed by Ridge Broadcasting Company and by Clarendon County Broadcasting Company, of the Commission's *Memorandum Opinion and Order* assigning a Class A FM channel to Leesville, South Carolina, and dismisses a motion to stay the effective date of the *Memorandum Opinion and Order* filed by Edgefield-Saluda Radio Company, Inc. This action: (1) Provides for a first local FM service to Johnston, South Carolina, and Saluda, South Carolina; (2) substitutes a Class C channel for a Class A channel at Manning, South Carolina; (3) Substitutes Class A channels for existing Class A channels at Batesburg and Bamberg, South Carolina; and (4) deletes a Class A channel assignment to Leesville, South Carolina, previously granted in this proceeding. This action also modifies the license of the Class A station in Manning to specify operation on a Class C channel and the licenses of Class A stations at Bamberg and Batesburg to specify other Class A channels.

**EFFECTIVE DATE:** January 27, 1984.

**ADDRESS:** Federal Communications Commission, Washington, D.C. 20554.

**FOR FURTHER INFORMATION CONTACT:** Joel Rosenberg, Mass Media Bureau, (202) 634-6530.

**SUPPLEMENTARY INFORMATION:**

### List of Subjects in 47 CFR Part 73

Radio broadcasting.

### Memorandum Opinion and Order (Proceeding Terminated)

In the matter of amendment of § 73.202(b Table of Assignments, FM Broadcast Stations. (North Charleston, Eastover and Ravenel, South Carolina); BC Docket No. 8( 201, RM-3249, RM-3710; Amendment of § 73.202(b), Table of Assignments, FM Broadcast Stations. (Elloree, South Carolin BC Docket No. 80-211, RM-3579; Amendme of § 73.202(b), Table of Assignments, FM Broadcast Stations. (Mount Pleasant, Parri Island, *Manning, Bamberg,* and *Batesburg, South Carolina*); BC Docket No. 80-213, RM 3406, RM-3718, RM-3719; Amendment of § 73.202(b), Table of Assignments, FM Broadcast Stations. (*Johnston, Leesville, Winnsboro Mills, Saluda, Union,* and *Batesburg, South Carolina*); BC Docket No. 81-171, RM-3518, RM-3556, RM-3613, RM-3666, RM-3771.

Adopted November 4, 1983.

Released: November 21, 1983.

By the Chief, Policy and Rules Division.

1. The Commission has before it: (1) petition for reconsideration filed by Ridge Broadcasting Company ("Ridge' and by Clarendon County Broadcastir Company ("CCBC"),[1] and (2) a motion for stay filed by Edgefield-Saluda Rad Company, Inc. ("Edgefield").[2] Ridge ar CCBC seek reconsideration of the acti assigning FM Channel 237A to Leesvil South Carolina, and denying FM channel assignments to various other South Carolina communities. Edgefiel seeks to stay the effective date of the Bureau's action. William K. Durst ("Durst") and The Broadcasting Company of Union ("BCU") filed comments.

*Background*

2. A *Further Notice of Proposed Rul Making and Order to Show Cause,* released March 24, 1981 (46 FR 19737), published March 26, 1981), consolidat three *Notices of Proposed Rule Makin* four counterproposals to the *Notices,* and five additional petitions for rule making not previously docketed

[1] Public Notice of the petition was given on Ma 1983, Report No. 1402.

[2] Edgefield also filed an Application for Revie which was subsequently withdrawn.

concerning related assignment proposals for various South Carolina communities. The *Further Notice* proposed seven separate assignment plans involving these communities. The plans were divided into Set A[3] and Set B. Any of the three proposed plans in Set A could be adopted independently and without conflicting with any of the four proposed plans in Set B. Adoption of any plan would preclude adoption of any other plan in the same set. The following assignment plans were included as Set B:

| | Plan B-I | | Plan B-II | | Plan B-III | | Plan B-IV | |
|---|---|---|---|---|---|---|---|---|
| | Present | Proposed | Present | Proposed | Present | Proposed | Present | Proposed |
| Manning | 221A | 223 | 221A | 223 | 221A | 223 | 221A | 221A |
| Bamberg | 224A | 221A | 224A | 221A | 224A | 221A | 224A | 224A |
| Batesburg | 221A | 237A | 221A | 237A | 221A | 237A | 221A | 221A |
| Johnston | | 224A | | 224A | | 224A | | |
| Winnsboro Mills | | 221A | | | | | | |
| Saluda | | | | | | 221A | | |
| Union | | | | 221A | | | | |
| Leesville | | | | | | | | 237A |

3. The *Report and Order*, 51 R.R. 2d 25 (Broadcast Bureau 1982) denied the requested assignments to all of the Set B communities. Petitions seeking reconsideration of this action were filed by Durst, proponent of the Saluda and Leesville proposals; by CCBC, proponent of the channel substitution at Manning; and by Edgefield, proponent of a Johnston assignment. The *Memorandum Opinion and Order*, 53 R.R. 2d 341 (1983), denied the CCBC and Edgefield petitions but did assign channel 237A to Leesville as requested by Durst.

4. As noted in the *Memorandum Opinion and Order*, Plans B-I, B-II, and B-III, necessitate the substitution of channels at both Bamberg and Batesburg. These substitutions could permit an upgrading of Station WTWE, Manning, from a Class A to a Class C channel, a first FM assignment at Johnston, and a first FM assignment at either Winnsboro Mills (Plan B-I), Union (Plan B-II), or Saluda (Plan B-III). The Batesburg, substitution requires Ridge, licensee of Station WKWQ-FM, Batesburg, to relocate its transmitter to comply with minimum distance requirements, but Ridge has heretofore objected to the proposed substitution and concomitant transmitter relocation. Petitioners now state that they have made an agreement with Ridge to relocate its transmitter. In this regard, petitioners note that they have obtained an option to purchase specified land which is said to be satisfactory as a transmitter site in case the Commission approves the changes proposed in Plans B-I, B-II, or B-III. Petitioners assert that CCBC's proposal to substitute Class C Channel 223 for Channel 221A in Manning (thereby necessitating the substitution of Channel 221A for Channel 224A at Bamberg and the substitution of Channel 237A for Channel 221A at Batesburg) would enable CCBC to provide a first aural nighttime service to some 13,485 people residing in a 370 square mile area and a second FM service to some 61,820 people in a 953 square mile area, most of which does not now receive any AM mighttime service. Combined with the first FM services that could be provided to two communities, petitioners claim that their proposal would provide public benefits "far in excess" of the single first local service resulting from the assignment of Channel 237A to Leesville (Plan B-IV) (as provided in the *Memorandum Opinion and Order*). Petitioners also note that previous negotiations between them concerning relocation of Ridge's WKWQ-FM transmitter were unsuccessful but that, subsequent to release of the *Memorandum Opinion and Order*, further negotiations resulted in the agreement noted. According to petitioners, the success of the negotiations could not have been reported to the Commission earlier, and therefore, this fact was not previously relied on. Petitioners assert that the only reason cited in the *Memorandum Opinion and Order* for denying the proposals in Plans B-I, B-II, and B-III, the unwillingness of Ridge to relocate its transmitter, is no longer valid.

5. Durst states that he is satisfied with the assignment of Channel 237A to Leesville and will apply for that channel.[4] He also requests that, if the assignment of Channel 237A to Leesville is deleted, Channel 221A be assigned to Saluda (Plan B-III), where he will apply to operate a station. Durst asserts that Saluda is an incorporated community and a county seat with no radio station located there or nearby. According to Durst. Saluda merits a first local broadcast service.

6. BCU supports the petition for reconsideration and urges an assignment of Channel 221 to the community of Union (Plan B-II). According to BCU, such an assignment would accord with section 307(b) of the Communications Act of 1934, as amended. BCU claims a "crucial need" for an FM assignment to Union County and its approximately 30,000 people. BCU asserts that service from Union County's only radio station is "severely limited," particularly at night by radio interference. BCE states that Union County is "isolated" and that no other radio station can adequately serve its residents. BCU claims that, among Winnsboro Mills, Saluda, Leesville, and Union, the community of Union has "by far" the largest population,[5] and that those other communities receive adequate local aural services. BCU also states its intention to operate a station on Channel 221A at the community of Union.

*Discussion*

7. As noted in the *Memorandum Opinion and Order*, the Commission will not force a licensee to relocate its transmitter absent a showing that a specific alternative transmitter site is suitable and available for use by the affected station. Since that showing was

[3] Disposition of the Set A proposals has generated an Application for Review which will be treated separately by Commission action.

[4] Durst filed an application for Channel 237A at Leesville on July 11, 1983 (File No. BPH-830711AA).

[5] The 1980 U.S. Census reports a population of 10,523 for Union; 1,890 for Winnsboro Mills; 2,752 for Saluda; and 2,296 for Leesville, South Carolina.

not made, the Commission declined to make the channel substitution at Batesburg, a prerequisite for implementation of Plans B–I, B–II, or B–III. Because Ridge has now agreed to relocate its transmitter site to a specified and apparently suitable location, it is now possible to implement either Plan B–I, B–II, or B–III in lieu of Plan B–IV. That is, Class C Channel 223 could be substituted for Channel 221A at Manning, Channel 224A could be assigned to Johnston and Channel 221A could be made available to either Winnsboro Mills (B–I), Union (B–II), or Saluda (B–III) in lieu of the assignment of Channel 237A to Leesville (B–IV). Accordingly, with the one major obstacle removed, we are now in a position to examine the four plans in Set B.

8. The original FM assignment priorities were set out in the *Further Notice of Proposed Rule Making* in Docket No. 14185, 27 FR 7797, 7798 (published August 7, 1962), and restated in *Anamosa and Iowa City, Iowa* 46 F.C.C. 2d 520 (1974). As noted in the *Report and Order* in this proceeding, these priorities are applicable to the instant situation. The first such priority is to provide each community with a first local aural service. Although all four plans in Set B would provide at least one community with its first FM station, only one plan can provide two communities with a first local aural service. Plan B–III would provide both Saluda and Johnston with their first FM stations. In comparison, the other three plans would satisfy lower priority needs. Plan B–IV would provide only Leesville with its first local aural service. Since Winnsboro Mills (Plan B–I) has a daytime-only AM station (WCKM), and Union (Plan B–II) has a full time AM station (WBCU), either city would obtain a second local aural service. Therefore, compared to both Union and Winnsboro Mills, Saluda merits the assignment of Channel 221A in order that it be provided with its first local aural service. In addition, as in any of these three plans, Manning would receive a Class C channel in lieu of its existing Class A channel, enabling the station at Manning to provide a first nighttime aural service to 13,485 persons and a second FM service to 61,820 persons.

9. As set forth in the *Further Notice*, a substitution of Channel 221A for Channel 224A at Bamberg requires a site restriction of 2.8 miles west-northwest of that community, and a substitution of Channel 237A for Channel 221A at Batesburg requires a site restriction of 3.1 miles southeast of that community. Further, assignments of Channel 224A to Johnston and Channel 221A to Saluda require site restrictions of 4.2 miles south and 3.1 miles northwest, respectively. All of these site restrictions are necessary in order to conform to the minimum spacing requirements provided by the Commission's Rules.

10. Established Commission policy provides for reimbursement for reasonable costs of a change in a station's frequency from the parties benefitting from the new channel assignments. In the instant situation, however, the petitioners have already agreed between themselves that Ridge will relocate its transmitter and change its frequency of operation from Channel 221A to Channel 237A. It appears that the affected parties have already provided for reimbursement amounts for the site and frequency changes of Station WKWQ–FM. The agreement between Ridge and CCBC provides that the cost of securing an option on a new transmitter site, of engineering and legal fees, and of the costs for switching frequency are to be borne by CCBC. This agreement complies with Commission policy on the matter of reimbursement and removes the risks previously associated with Ridge involuntarily moving its transmitter.

11. As for the change in frequency at Bamberg from Channel 224A to Channel 221A, reimbursement is also a prerequisite. The benefitting parties would be Station WTWE, Manning, and the ultimate permittees for the new assignments at Johnston and Saluda. Thus, the substitution of channels at Bamberg is conditioned upon the reimbursement for reasonable expenses being provided by these three parties equally with the known parties initially responsible when the Bamberg station is ready to make the conversion. Currently, only Station WTWE, Manning, is known to be a beneficiary. The other two parties would be determined by the issuance of construction permits at Johnston and Saluda.

12. Other than the interest of CCBC, there were no other parties desirous of applying for newly assigned Class C Channel 223 at Manning in response to the *Further Notice*. Accordingly, Commission policy, as set forth in *Cheyenne, Wyoming*, 62 F.C.C. 2d 63 (1976), would permit modification of CCBC's license to specify operation on that channel in lieu of Channel 221A.

13. Finally, Edgefield's motion for stay has become moot in light of the actions taken herein concerning the petition for reconsideration. Thus, that motion will be dismissed.

13. Accordingly, it is ordered, That effective January 27, 1984, the FM Table of Assignments, § 73.202(b) of the Commission's Rules, is amended as follows with respect to the following communities:

| City | Channel No. |
|---|---|
| Bamberg, South Carolina | 221A |
| Batesburg, South Carolina | 237A |
| Johnston, South Carolina | 224A |
| Leesville, South Carolina | |
| Manning, South Carolina | 223 |
| Saluda, South Carolina | 221A |

14. It is further ordered, That the petition for reconsideration, filed by Ridge Broadcasting Company and by Clarendon County Broadcasting Company, is granted.

15. It is further ordered, pursuant to the authority contained in § 316(a) of th Communications Act of 1934, as amended, That the outstanding license for Station WKWQ–FM, held by Ridge

Broadcasting Company at Batesburg, South Carolina, is modified effective January 27, 1984, to specify operation on Channel 237A in lieu of Channel 221A. The costs of reimbursement have been included in the agreement entered into by Clarendon County Broadcasting Company and Ridge Broadcasting Company, Inc. Station WKWQ-FM may continue to operate on Channel 221A for one year after the effective date of this *Order* or until a license is issued for Channel 223 at Manning, or for Channel 221A at Bamberg, or a permit is issued for Channel 224A at Johnston or for Channel 221A at Saluda, whichever is first. Additionally, the modification of license for Station WKWQ-FM is subject to the following conditions:

(a) The licensee shall file with the Commission a minor change application for a construction permit (Form 301), specifying the new facilities.

(b) Upon grant of the construction permit, program tests may be conducted in accordance with § 73.1620.

(c) Nothing contained herein shall be construed to authorize a major change in transmitter location or to avoid the necessity of filing an environmental impact statement pursuant to § 1.1301 of the Commission's Rules.

16. It is further ordered, pursuant to the authority contained in § 316(a) of the Communications Act of 1934, as amended, That the outstanding license for Station WWBD, held by WWBD Inc., at Bamberg, South Carolina, is modified effective January 27, 1984, to specify operation on Channel 221A in lieu of Channel 224A, with the condition that it will be reimbursed for the reasonable costs incurred in switching frequencies on an equal basis from CCBC and from the ultimate permittees of Channels 224A at Johnston and of Channel 221A at Saluda. Station WWBD may continue to operate on Channel 224A for one year after the effective date of this *Order* or until a permit is issued for Channel 224A at Johnston or a license is issued for Channel 223 at Manning, whichever is first. Additionaly, the modification of license for Station WWBD is subject to the following conditions:

(a) The licensee shall file with the Commission a minor change application for a construction permit (Form 301), specifying the new facilities.

(b) Upon grant of the construction permit, program tests may be conducted in accordance with § 73.1620.

(c) Nothing contained herein shall be construed to authorize a major change in transmitter location or to avoid the necessity of filing an environmental impact statement pursuant to § 1.1301 of the Commission's Rules.

17. It is further ordered, pursuant to authority contained in § 316 of the Communications Act of 1934, as amended, That effective 1983, the outstanding license for Station WTWE, held by Clarendon County Broadcasting Company at Manning, South Carolina, is modified to specify operation on Channel 223. Station WTWE may continue to operate on Channel 221A for one year from the effective date of this action or until a license is issued for Station WKWQ-FM, Batesburg, South Carolina, whichever is earlier. The modification of license for Station WTWE is subject to the following conditions:

(a) The licensee shall file with the Commission a minor change application for a construction permit (Form 301), specifying the new facilities.

(b) Upon grant of the construction permit, program tests may be conducted in accordance with § 73.1620.

(c) Nothing contained herein shall be construed to authorize a major change in transmitter location or to avoid the necessity of filing an environmental impact statement pursuant to § 1.1301 of the Commission's Rules.

18. It is further ordered, That the motion for stay filed by Edgefield-Saluda Broadcasting Company, Inc. is dismissed.

19. It is further ordered, That the Secretary of the Commission shall send a copy of this *Order* by certified mail, return receipt requested, to WWBD, Inc., P.O. Box 3543, Bamberg, South Carolina 29003; to: Ridge Broadcasting Company P.O. Box 410, Batesburg, South Carolina 29000, and to Clarendon County Broadcasting Company, P.O. Box 400, Manning, South Carolina 29102.

20. It is further ordered, That this proceeding is terminated.

21. Authority for the actions taken herein is contained in sections 4(i), 5(c)(1), 303 (g) and (r), and 307(b) of the Communications Act of 1934, as amended, and §§ 0.61, 0.204(b), and 0.281 of the Commission's Rules.

22. For further information concerning this proceeding, contact Joel Rosenberg, Mass Media Bureau, (202) 634-6530.

Federal Communications Commission.

**Roderick K. Porter,**

*Chief, Policy and Rules Division, Mass Media Bureau.*

[FR Doc. 83-31643 Filed 11-28-83; 8:45 am]

BILLING CODE 6712-01-M

## 47 CFR Part 73

**[MM Docket No. 83-267; RM-4308]**

## Television Broadcast in Tampa, Florida; Changes Made in Table of Assignments

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** This action assigns UHF television Channel 50 to Tampa, Florida, as its fourth commercial television service, in response to a request from Harry C. Powell, Jr.

**DATE:** Effective: January 23, 1984.

**ADDRESS:** Federal Communications Commission, Washington, D.C. 20554.

**FOR FURTHER INFORMATION CONTACT:** Nancy V. Joyner, Mass Media Bureau, (202) 634-6530.

### List of Subjects in 47 CFR Part 73

Television broadcasting.

### Report and Order; Proceeding Terminated

In the matter of amendment of § 73.606(b), Table of Assignments, Television Broadcast Stations (Tampa, Florida) (MM Docket No. 83-267, RM-4308).

Adopted: November 2, 1983.

Released: November 16, 1983.

By the Chief, Policy and Rules Division.

1. Before the Commission for consideration is the Notice of Proposed Rule Making, 48 FR 14677, published April 5, 1983, issued in response to a request filed by Harry C. Powell, Jr. ("petitioner"), proposing the assignment of UHF television Channel 50 to Tampa, Florida, as that community's fourth commercial television service. Supporting comments were filed by the petitioner reaffirming his intention to apply for the channel, if assigned. No oppositions to the proposal were received.

2. Tampa (population 271,523) [1], the seat of Hillsborough County (population 646,960), is located on the west coast of Florida, approximately 320 kilometers (200 miles) northwest of Miami. Currently, Tampa is served by commercial television Channels 8 (Station WXFL), 13 (Station WTVT) and 28 (Station WFTS), as well as noncommercial educational Channels *3 (Station WEDU) and *16 (Station WUSF).

3. We believe the public interest would be served by assigning UHF television Channel 50 to Tampa, Florida,

[1] Population figures were extracted from the 1980 U.S. Census, Advance Reports.

since it could provide a fourth commercial television service to that community. As explained in the Notice the assignment herein can be made consistent with the minimum mileage separation requirements of §§ 73.610 and 73.698 of the Commission's Rules.

**§ 73.606 [Amended]**

4. Accordingly, pursuant to the authority contained in Sections 4(i), 5(d)(1), 303 (g) and (r) and 307(b) of the Communications Act of 1934, as amended, and §§ 0.61, 0.204(b) and 0.283 of the Commission's Rules, it is ordered, that effective January 23, 1984, the Television Table of Assignments, § 73.606(b) of the Commission's Rules, is amended for the community below as follows:

| City | Channel No. |
|---|---|
| Tampa, Fla | *3, 8−, 13−, *16, 28, and 50 |

5. It is further ordered, that this proceeding is terminated.

6. For further information concerning this proceeding, contact Nancy V. Joyner, Mass Media Bureau, (202) 634-6530.

Federal Communications Commission.

**Roderick K. Porter,**

*Chief, Policy and Rules Division, Mass Media Bureau.*

[FR Doc. 83-31846 Filed 11-28-83; 8:45 am]

BILLING CODE 6712-01-M

## 47 CFR Part 73

**[MM Docket No. 83-242; RM-4289]**

## Television Broadcast Stations in Minneapolis-St. Paul, Minnesota; Changes Made in Table of Assignments

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** Action taken herein assigns UHF television Channel 45 to Minneapolis-St. Paul, Minnesota, as that community's seventh commercial television service, in response to a petition filed by Millard V. Oakley.

**DATE:** Effective: January 23, 1984.

**ADDRESS:** Federal Communications Commission, Washington, D.C. 20554.

**FOR FURTHER INFORMATION CONTACT:** Nancy V. Joyner, Mass Media Bureau, (202) 634-6530.

### List of Subjects in 47 CFR Part 73

Television broadcasting.

### Report and Order; Proceeding Terminated

In the matter of amendment of § 73.606(b), Table of Assignments, Television Broadcast Stations. (Minneapolis-St. Paul, Minnesota) (MM Docket No. 83-242, RM-4289).

Adopted: October 31, 1983.

Released: November 16, 1983.

By the Chief, Policy and Rules Divisions.

1. Before the Commission is the Notice of Proposed Rule Making, 48 FR 15663, published April 12, 1983, which proposed the assignment of UHF television Channel 45 to Minneapolis, Minnesota, as that community's seventh commercial television service, in response to a petition filed by Millard V. Oakley ("petitioner"). Supporting comments were filed by petitioner reaffirming his intention to apply for the channel, if assigned. No oppositions to the proposal were received.

2. Minneapolis (population 370,951,[1] the seat of Hennepin County (population 941,411), is located in southeastern Minnesota, approximately 560 kilometers (350 miles) northwest of Chicago, Illinois. Currently, commercial Channels 4 (WCCO-TV), 9 (KMSP-TV), 11 (WTCN-TV), 23 (KTMA-TV), and 29 (WFBT-TV), are licensed to the community.[2]

3. The Commission believes that the public interest would be served by assigning UHF television Channel 45 to Minneapolis. An apparent need for the additional television service to the community has been shown, and the assignment can be made consistent with the minimum distance separation requirements of §§ 73.610 and 73.698 of the Commission's Rules and other technical criteria.

4. Since all television channels currently licensed to Minneapolis or St. Paul are assigned on a hyphenated basis, Channel 45 will likewise be allocated thereto to conform with that policy.

5. Canadian concurrence in the proposal has been obtained.

**§ 73.606 [Amended]**

6. Accordingly, pursuant to the authority contained in Sections 4(i), 5(d)(1), 303 (g) and (r) and 307(b) of the Communications Act of 1934, as amended, and §§ 0.61, 0.204(b), and 0.283 of the Commission's Rules, it is ordered, that effective January 23, 1984, the Television Table of Assignments, § 73.606(b) of the Commission's Rules, is amended for the community listed as follows:

[1] Population figures were extracted from the 1980 U.S. Census, Advance Reports.

[2] Additionally, commercial Channel 5, used at St. Paul, is allocated to Minneapolis-St. Paul.

| City | Channel No. |
|---|---|
| Minneapolis-St. Paul, Minn | *2−, 4, 5−, 9+, 11−, *1 23+, 29+, and 45. |

7. It is further ordered, that this proceeding is terminated.

8. For further information concerning the above, contact Nancy V. Joyner, (202) 634-6530.

Federal Communications Commission.

**Roderick K. Porter,**

*Chief, Policy and Rules Division, Mass Medi Bureau.*

[FR Doc. 83-31848 Filed 11-28-83; 8:45 am]

BILLING CODE 6712-01-M

## 47 CFR Part 73

**[MM Docket No. 83-243; RM-4284]**

## Television Broadcast Station in Greenville, North Carolina; Changes Made in Table of Assignments

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** Action taken herein assigns UHF television Channel 38 to Greenville, North Carolina, in response to a petition filed by Millard V. Oakley. The assignment could provide Greenville with its third commercial television service.

**DATE:** Effective: January 23, 1984.

**ADDRESS:** Federal Communications Commission, Washington, D.C. 20554.

**FOR FURTHER INFORMATION CONTACT:** Nancy V. Joyner, Mass Media Bureau, (202) 634-6530.

### List of Subjects in 47 CFR Part 73

Television broadcasting.

### Report and Order; Proceeding Terminated

In the matter of amendment of § 73.606(b), Table of Assignments, Television Broadcast Stations. (Greenville, North Carolina) (MM Docket No. 83-243, RM-4284).

Adopted: October 31, 1983.

Released: November 16, 1983.

By the Chief, Policy and Rules Division.

1. Before the Commission for consideration is the Notice of Proposed Rule Making, 48 FR 14695, published April 5, 1983, issued in response to a petition filed by Millard V. Oakley ("petitioner"), proposing the assignmen of UHF Television Channel 38 to Greenville, North Carolina, as that community's third commercial televisic service. Supporting comments were file by petitioner reiterating his intention tc apply for the channel, if assigned. No

oppositions to the proposal were received.

2. Greenville (population 2,865),[1] the seat of Pitt County (population 83,651), is located in eastern North Carolina, approximately 110 kilometers (70 miles) southeast of Raleigh. Currently, it is assigned commercial television Channels 9 (WNCT-TV) and 14 (construction permit issued), and noncommercial educational Channel *25 (WUNK-TV)

3. We believe the public interest would be served by assigning UHF television Channel 38 to Greenville, North Carolina. Petitioner has demonstrated the need for the additional television broadcast service to that community. Additionally, as indicated in the Notice, the assignment can be made consistent with the minimum distance separation requirements of Sections 73.610 and 73.698 of the Commission's Rules.

**§ 73.606 [Amended]**

4. Accordingly, pursuant to the authority contained in Sections 4(i), 5(d)(1), 303 (g) and (r) and 307(b) of the Communications Act of 1934, as amended, and §§ 0.61, 0.204(b), and 0.283 of the Commission's Rules, it is ordered that effective January 23, 1984, the Television Table of Assignments, § 73.606(b) of the Rules, is amended with regard to the community below as follows:

| City | Channel No. |
|---|---|
| Greenville, N.C. | 9−, 14, *25, and 38+. |

5. It is further ordered, that this proceeding is terminated.

6. For further information concerning the above, contact Nancy V. Joyner, Mass Media Bureau, (202) 634-6530.

Federal Communications Commission.

**Roderick K. Porter,**

*Chief, Policy and Rules Division, Mass Media Bureau.*

[FR Doc. 83-31647 Filed 11-28-83; 8:45 am]

BILLING CODE 6712-01-M

## 47 CFR Part 73

**[MM Docket No. 83-240; RM-4345]**

## TV Broadcast Stations in Morehead, Kentucky and Bryson City, North Carolina; Changes Made in Table of Assignments

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule.

**SUMMARY:** Action taken herein assigns UHF television Channel 67 to Morehead, Kentucky, in response to a request from Stanley G. Emert. The assignment could provide Morehead with its first local commercial television service.

**DATE:** Effective: January 23, 1984.

**ADDRESS:** Federal Communications Commission, Washington, D.C. 20554.

**FOR FURTHER INFORMATION CONTACT:** Nancy V. Joyner, Mass Media Bureau, (202) 634-6530.

**List of Subjects in 47 CFR Part 73:**

Television broadcasting.

**Report and Order; Proceeding Terminated**

In the matter of amendment of § 73.606(b), Table of Assignments, TV Broadcast Stations. (Morehead, Kentucky and Bryson City, North Carolina); MM Docket No. 83-240, RM-4345.

Adopted: November 2, 1983.
Released: November 16, 1983.
By the Chief, Policy and Rules Division.

1. The Commission herein considers the Notice of Proposed Rule Making, 48 FR 14692, published April 15, 1983, issued in response to a request filed by Stanley G. Emert ("petitioner"), proposing the assignment of UHF television Channel 67 to Morehead, Kentucky, as that community's first commercial television allocation. Petitioner filed supporting comments in which he reiterated his intention to apply for the channel, if assigned. No oppositions to the proposal were received.

2. Morehead (population 7,789),[1] the seat of Rowan County (population 19,049), is located in northeastern Kentucky, approximately 145 kilometers (90 miles) southeast of Cincinnati, Ohio. At the present time, it is served by educational Station WKMB (Channel *38).

3. As indicated in the Notice, the proposed assignment of UHF television Channel 67 to Morehead, Kentucky, requires a minus carrier offset as well as a change on the co-channel at Bryson City, North Carolina, from minus to zero, in order to conform to the minimum distance separation requirements of §§ 73.610 and 73.698 of the Commission's Rules. The Bryson City channel is currently unused.

4. In view of the above, and having found no policy objections to the proposal, we believe the public interest would be served by assigning UHF television Channel 67 to Morehead, Kentucky, since it could provide a first commercial television service to the community.

5. Canadian concurrence has been obtained.

**§ 73.606 [Amended]**

6. Accordingly, pursuant to the authority contained in Sections 4(i), 5(d)(1), 303 (g) and (r) and 307(b) of the Communications Act of 1934, as amended, and §§ 0.61, 0.204(b) and 0.283 of the Commission's Rules, it is ordered, That effective January 23, 1983, the Television Table of Assignments, § 73.606(b) of the Commission's Rules, is amended for the communities listed below as follows:

| City | Channel No. |
|---|---|
| Morehead, Ky | *38+, 67− |
| Bryson City, N.C. | *67 |

7. It is further ordered, that this proceeding is terminated.

8. For further information concerning the above, contact Nancy V. Joyner, Mass Media Bureau, (202) 634-6530.

Federal Communications Commission.

**Roderick K. Porter,**

*Chief, Policy and Rules Division, Mass Media Bureau.*

[FR Doc. 83-31649 Filed 11-28-83; 8:45 am]

BILLING CODE 6712-01-M

## DEPARTMENT OF TRANSPORTATION

### Office of the Secretary

### 49 CFR Part 71

**[OST Docket No. 9; Amdt. 71-19a]**

## Standard Time Zone Boundaries in the State of Alaska; Clarification

**AGENCY:** Office of the Secretary, DOT.

**ACTION:** Clarification.

**SUMMARY:** In the Federal Register of September 22, 1983 (48 FR 43276), DOT published a final rule realigning time zones in the State of Alaska; the realignment took effect October 30, 1983. Questions have arisen as to the proper way to depict the new time zone boundary line on navigational charts. This document provides a textual description of the line for this purpose.

**FOR FURTHER INFORMATION CONTACT:** Robert I. Ross, Office of the General Counsel, C-50, Department of Transportation, Washington, D.C. 20590; (202) 426-4723.

**SUPPLEMENTARY INFORMATION:** The final rule which took effect October 30, 1983,

[1] Population figures were extracted from the 1980 U.S. Census, Advance Reports.

[1] Population figures were extracted from the 1980 U.S. Census, Advance Reports.

reduces from four to two the number of time zones in Alaska. Effective on that date, the entire State was moved to the Yukon time zone (9 hours behind Greenwich Mean Time), except that part of the Aleutian Islands that is west of 169 degrees 30 minutes west longitude; that part is in the Alaska-Hawaii time zone, 10 hours behind Greenwich. To facilitate its depiction on navigational charts, the State of Alaska has suggested, and representatives of the Departments of Defense, Commerce, and Transportation have agreed upon, the following description of the boundary between the two zones:

Starting on the international boundary line as established in the United States-Russian Convention of 1967, longitude 169 degrees west as it passes between Big Diomede Island and Little Diomede Island, going southerly and westerly along said convention line to its intersection with longitude 173 degrees west, thence southerly along said longitude to latitude 60 degrees north, thence easterly along said latitude to longitude 171 degrees west, thence southerly along said longitude to latitude 55 degrees north, thence easterly along said latitude to longitude 169 degrees 30 minutes west, thence southerly along said longitude as far as necessary.

All parts of the State of Alaska east of this line are in the Yukon time zone; all parts west of it are in the Alaska-Hawaii time zone. A map of the United States showing this new line in Alaska is available (without charge for small quantities) at the address and telephone number shown above. The map also shows every State and county in the United States, all United States time zones, and the areas of the United States exempt from the observance of daylight saving time.

**Authority:** Act of March 19, 1918, as amended by the Uniform Time Act of 1966 and Pub. L. 97-449, 15 U.S.C. 260-64; 49 CFR 1-59(a).

Issued in Washington, DC, on November 17, 1983.

**James H. Burnley IV,**

*General Counsel.*

[FR Doc. 83-31873 Filed 11-28-83; 8:45 am]

BILLING CODE 4910-62-M

## Research and Special Programs Administration

## 49 CFR Parts 107, 171, 172, 173, 175 and 178

**[Docket No. HM-184A, Amdt. Nos. 107-12, 171-77, 172-87 173-170, 175-30, 178-78]**

## Implementation of the ICAO Technical Instructions

**AGENCY:** Materials Transportation Bureau (MTB), Research and Special Programs Administration, DOT.

**ACTION:** Final rule.

**SUMMARY:** This document amends the Hazardous Materials Regulations (HMR) in order to permit the offering, acceptance and transportation by aircraft, and by motor vehicle incident to transportation by aircraft, of hazardous materials shipments conforming to the most recent edition of the International Civil Aviation Organization (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO Technical Instructions). These amendments are necessary to facilitate the continued shipment of hazardous materials in international commerce by air when the 1984 edition of the ICAO Technical Instructions becomes effective on January 1, 1984, pursuant to decisions taken by the ICAO Council regarding implementation of Annex 18 to the Convention on International Civil Aviation.

**EFFECTIVE DATE:** January 1, 1984.

**FOR FURTHER INFORMATION CONTACT:** Edward A. Altemos, Office of Hazardous Materials Regulation, Materials Transportation Bureau, U.S. Department of Transportation, 400 Seventh Street, SW., Washington, D.C. 20590, (202) 426-0656.

**SUPPLEMENTARY INFORMATION:** On August 4, 1983, the MTB published a notice (Docket HM-184A, Notice No. 83-4) in the **Federal Register** (48 FR 35471) which requested public comment on the need to amend the Hazardous Materials Regulations (HMR) in order to take account of the 1984 edition of the ICAO Technical Instructions.

Seventeen commenters responded to Notice No. 83-4. Following full consideration of the comments received, the proposals contained in the notice are being adopted with certain changes. All comments received generally supported the actions proposed in the Notice of Proposed Rulemaking. Certain commenters made comments or suggestions relative to specific provisions in the proposed amendments. The following is a summary of such comments by section.

*Section 171.7.* No comments.

*Section 171.8.* One commenter noted that the definition of "Competent authority" proposed for inclusion in this section differed slightly from that contained in 49 CFR, Part 107. While there is no substantive difference in these definitions, the MTB believes there is merit in maintaining consistency in the wording of the definitions and is amending the definition of "Competent authority" in § 107.3 to agree with that now being included in § 171.8.

*Section 171.11.* Two commenters supported, in principle, the changes proposed to this section, but felt that the specific reference to Class 6.1, Packing Group III and Class 9 in the proposed paragraph (d)(4)(i) was redundant in view of the inclusion of the words ". . . that is regulated by this subchapter for transportation by highway . . ." in paragraph (d)(4). The MTB does not agree since there are certain materials in ICAO Class 6.1, Packing Group III and ICAO Class 9 which are regulated by highway, but for which no single DOT Hazard Class corresponds to the ICAO Class (e.g., "Drugs *or* Medicines, n.o.s., containing flammable aerosol *and/or* non-flammable aerosol, *and/or* flammable liquid *and/or* toxic substance, in small inner packagings", ICAO Class 9). Therefore, the specific references to ICAO Class 6.1, Packing Group III and ICAO Class 9 have been retained.

*Section 172.406.* In the preamble to the Notice, it was inadvertently stated that a change was being proposed to this section to allow the use of the method of identification of aircraft unit load devices and freight containers prescribed in the ICAO Technical Instructions to be employed as an alternative to the labeling required by this section. One commenter felt that such a provision should be included in this section. However, since §172.406(e)(3) already permits placarding in accordance with § 172.512(b) as an alternative to labeling, and the ICAO method of identification is being included in § 172.512(b), a similar amendment to § 172.406(e)(3) is considered unnecessary.

*Section 172.512.* One commenter requested clarification regarding the responsibility to placard a freight container or aircraft unit load device being offered for transportation by highway subsequent to being transported by air, and which had been identified as containing dangerous goods during air transport in the manner provided in Part 5, Chapter 2, Section 2.7 of the ICAO Technical Instructions. It is the opinion of the MTB that, as provided in § 172.506, it is the responsibility of the person offering the hazardous material to the motor carrier to provide the motor carrier with the placards required for the transportation of the freight container or aircraft unit load device by highway.

*Section 173.6.* No comments.

*Section 173.86.* One commenter made a general comment regarding this section in which he stated that the section should contain the criteria by

which the Associate Director for Hazardous Materials Regulation may approve a new explosive or authorize the transportation of a sample. The MTB believes this is unnecessary since the minimum test criteria are already set forth in Subpart C of 49 CFR or in the supplement of the ICAO Technical Instructions, as appropriate. It must be emphasized that, in making the proposal to amend § 173.86, the MTB did not intend to suggest that there would be a significant departure from existing practice in approving explosives, except as necessary to facilitate the movement of explosives domestically and internationally.

Five comments were received regarding the proposed new § 173.86(f). One commenter opposed the addition on the basis that ". . . all explosives should be tested and approved by the competent authority . . .". Proposed paragraph (f) *does* require approval by the competent authority (i.e., the MTB) and, even under the existing § 173.86, the competent authority (i.e., the MTB) does not actually test explosives, but instead delegates the actual testing to disinterested third parties or Federal agencies. Therefore, the MTB considers that within the context of this comment, the proposed § 173.86(f) is, in principle, no different from the existing § 173.86 and, therefore, no change to the proposed wording is being made as a result of this comment.

Two commenters supported the basic principle of the proposed § 173.86(f), but objected to the proposed wording because it would eliminate the requirement for third party testing of explosives. The MTB shares this concern and has modified the wording of this paragraph to provide that an approval may be issued only on the basis of a report of tests conducted by disinterested third parties, or on the basis of approvals issued by the competent authortiy of a foreign government. In the former case, the approval may only be issued when examination of the explosives by the Bureau of Explosives or Bureau of Mines is impracticable. These commenters also suggested that a limitation of ten pounds be placed on the weight of an explosives sample which the Associate Director may authorize for transportation for the purpose of examination by the Bureau of Explosives or Bureau of Mines. The MTB believes this to be unnecessary since the maximum weight of sample to be transported will be considered by the MTB before issuing an authorization. Therefore, no change has been made in this regard. However, this provision has been expanded to include shipment of the sample to the Bureau of Mines or other government agency.

One commenter suggested that, pursuant to the provisions of § 173.86(f), on the basis of tests conducted solely by a shipper or manufacturer, the Associate Director should be permitted only to authorize the transportation of an explosives sample for examination by the Bureau of Explosives or Bureau of Mines and should not be authorized to issue an approval. The MTB believes that the revised wording of this paragraph, which requires tests to be performed by disinterested third parties, addresses the concerns of this commenter and has made no further changes in this regard.

One commenter supported the proposed § 173.86(f) and felt that the MTB should generally be permitted to issue approvals on the basis of manufacturer's tests and without Bureau of Explosives or Bureau of Mines examination. The MTB believes that such unqualified reliance on manufacturer's tests for the approval of explosives is not in the public interest. As indicated in the MTB's response to previous comments, it is the MTB's intent that Bureau of Explosives or Bureau of Mines examination should be required except when it is impracticable and when the results of tests performed by disinterested third parties can be provided as a substitute for Bureau of Explosives or Bureau of Mines testing.

One comment was received relative to the proposed § 173.86(g). This commenter suggested that this paragraph be modified to permit land mode shipments from Canada to be made under the authority of approvals issued by the Canadian Competent Authority. The MTB is of the opinion that since this question relates specifically to reciprocal arrangements between the United States and Canada, it should more appropriately be dealt with under Docket No. HM-188 and that any decision regarding this suggestion should await final publication of the new Canadian multimodal regulations. Therefore, no change is being made to § 173.86(g) as suggested.

*Sections 175.10–175.630.* No comments.

*Section 178.0–3.* This section has been amended to permit the marking of packagings with the United Nations (UN) symbol and packaging identification code as provided in the ICAO Technical Instructions. Although this amendment was not proposed in the notice, the MTB believes that, due to minor differences between the provisions in the IMDG Code and those in the ICAO Technical Instructions for the marking of packagings with the UN symbol and packaging identification code, it is imperative to authorize the application of these markings in accordance with the ICAO Technical Instructions as well as the IMDG Code. Since the amendment does not impose mandatory additional requirements, notice and procedure thereon are considered unnecessary.

**List of Subjects**

*49 CFR Part 107*

Hazardous materials program procedures.

*49 CFR Part 171*

Hazardous materials transportation, Incorporation by reference.

*49 CFR Part 172*

Hazardous materials transportation, Labeling, Packaging and containers.

*49 CFR Part 173*

Hazardous materials transportation, Packaging and containers.

*49 CFR Part 175*

Hazardous materials transportation, Air carriers.

*49 CFR Part 178*

Hazardous materials, Motor vehicle safety, Packaging and containers.

In consideration of the foregoing, 49 CFR Part 107, 171, 172, 173 and 175 and 178 are amended as follows:

## PART 107—HAZARDOUS MATERIALS PROGRAM PROCEDURES

1. In § 107.3, the definition of "Competent Authority" is revised to read:

**§ 107.3 Definitions.**

* * * * *

"Competent Authority" means a national agency responsible under its national law for the control or regulation of a particular aspect of the transportation of hazardous materials (dangerous goods). The term "Appropriate authority", as used in the ICAO Technical Instructions, has the same meaning as "Competent Authority". The Associate Director for Hazardous Materials Regulation, Materials Transportation Bureau, is the United States Competent Authority for purposes of this part.

* * * * *

## PART 171—GENERAL INFORMATION, REGULATIONS AND DEFINITIONS

2. In § 171.7 paragraph (d)(27) is revised to read:

**§ 171.7 Matter incorporated by reference.**

* * * * *

(d) * * *

(27) International Civil Aviation Organization Technical Instructions for the Safe Transport of Dangerous Goods by Air, DOC 9284–AN/905 (ICAO Technical Instructions), 1984 edition.

* * * * *

3. In § 171.8 a new definition for "Competent authority" is added in appropriate alphabetical order to read:

**§ 171.8 Definitions and abbreviations.**

* * * * *

"Competent authority" means a national agency responsible under its national law for the control or regulation of a particular aspect of the transportation of hazardous materials (dangerous goods). The term "Appropriate authority", as used in the ICAO Technical Instructions, has the same meaning as "Competent Authority". The Associate Director for Hazardous Materials Regulation, Materials Transportation Bureau, is the United States Competent Authority for purposes of this subchapter and 46 CFR Parts 64 and 146.

* * * * *

4. In § 171.11, paragraph (d)(7) is renumbered (d)(8), paragraphs (d)(4)(ii) and (d)(4)(iii) are renumbered (d)(4)(iii) and (d)(4)(iv) respectively, paragraph (d)(4)(i) is revised and new paragraphs (d)(4)(ii) and (d)(7) are added to read:

**§ 171.11 Use of ICAO Technical Instructions.**

* * * * *

(d) * * *

(4) When a hazardous material, that is regulated by this subchapter for transportation by highway, is transported by motor vehicle on a public highway under the provisions of this section, the motor vehicle must be placarded in accordance with Subpart F of Part 172 of this subchapter and the shipping paper must include—

(i) With the exception of hazardous materials in ICAO Class 6.1, Packaging Group III, and in ICAO Class 9, the name of the DOT hazard class most closely corresponding to the ICAO Class in association with the basic description required by the ICAO Technical instructions unless the shipping name contains the key word or words of the hazard class of the material;

(ii) The letters "ORM–E" in association with the basic description for a material in ICAO Class 6.1, Packing Group III or in ICAO Class 9, that is also a hazardous substance;

* * * * *

(7) If a United States variation is indicated in the ICAO Technical Instructions for any provision governing the transport of the hazardous material, the hazardous material is transported in conformance with that variation.

* * * * *

## PART 172—HAZARDOUS MATERIALS TABLES AND HAZARDOUS MATERIALS COMMUNICATIONS REGULATIONS

5. In § 172.512, the section heading and paragraphs (a) and (b) are revised to read:

**§ 172.512 Freight containers and aircraft unit load devices.**

(a) *Capacity of 640 cubic feet or more.* Each person who offers for transportation, and each person who loads and transports, a hazardous material in a freight container or aircraft unit load device having a capacity of 640 cubic feet or more shall affix to the freight container or aircraft unit load device the placards specified for the material in accordance with § 172.504. However,—

(1) The placarding exception provided in § 172.504(c)(1) applies to motor vehicles transporting freight containers and aircraft unit load devices,

(2) The placarding exception provided by paragraphs (c)(1) and (c)(2) of § 172.504 applies to each freight container and aircraft unit load device being transported for delivery to a consignee immediately following air or water shipment, and,

(3) Placarding is not required on a freight container or aircraft unit load device if it is only transported by air and is identified as containing a hazardous material in the manner provided in Part 5, Chapter 2, Section 2.7, of the ICAO Technical Instructions.

(b) *Capacity less than 640 cubic feet.* Each person who offers for transportation by air, and each person who loads and transports by air, a hazardous material in a freight container or aircraft unit load device having a capacity of less than 640 cubic feet shall affix one placard of the type specified by paragraph (a) of section unless the freight container or aircraft unit load device—

(1) Is labeled in accordance with § 172.406(e)(3);

(2) Contains radioactive materials requiring the Radioactive Yellow III label and is placarded with one Radioactive placard and is labeled in accordance with § 172.406(e); or,

(3) Is identified as containing a hazardous material in the manner provided in Part 5, Chapter 2, Section 2.7, of the ICAO Technical Instructions. When hazardous materials are offered for transportation, not involving air transportation, in a freight container having a capacity of less than 640 cubic feet the freight container need not be placarded. However, if not placarded it must be labeled in accordance with Subpart E of this part.

* * * * *

## PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

6. In § 173.6, a new paragraph (d) is added to read:

**§ 173.6 Shipments by air.**

* * * * *

(d) No person may offer for transportation aboard aircraft an overpack containing hazardous materials which require segregation under the provisions of § 175.78 of this subchapter.

7. In § 173.86, paragraph (c)(2) is amended by replacing the words "paragraph (d) or (e)" with the words "paragraph (d), (e), (f), or (g)", paragraph (d) is revised by removing the words "and approval" and new paragraph (f) and (g) are added to read:

**§ 173.86 New explosives definitions; approval and notification.**

* * * * *

(f) Notwithstanding the provisions of paragraph (b) or (d) of this section, the Associate Director for Hazardous Materials Regulation may approve a new explosive on the basis of an approval issued for the explosive by the competent authority of a foreign government, or, when examination of explosives by the Bureau of Explosives or Bureau of Mines is impracticable, on the basis of reports of tests conducted by disinterested third parties, or may approve the transportation of an explosives sample for the purpose of examination by the Bureau of Explosives, or the Bureau of Mines or other government agency.

(g) Notwithstanding the provisions of paragraph (b) of this section, an explosive may be transported under the provisions of §§ 171.11, 171.12 or 176.11 without the approval of the Associate Director for Hazardous Materials Regulation provided that the Associate Director for Hazardous Materials Regulation has acknowledged, in writing, the acceptabilty of an approval issued by the competent authority of a foreign government pursuant to the provisions of the UN Recommendations, the ICAO Technical Instructions, the IMDG Code or other national or

international regulations based on the provisions of the UN Recommendations. In such cases, a copy of the approval of the foreign competent authority, and a copy of the written acknowledgement of its acceptability must accompany each shipment of that explosive.

## PART 175—CARRIAGE BY AIRCRAFT

8. In § 175.10, paragraph (a)(18) is amended and a new paragraph (a)(21) added to read:

**§ 175.10 Exceptions.**

(a)* * *

(18) Carbon dioxide gas cylinders worn by passengers for the operation of mechanical limbs and spare cylinders of a similar size for the same purpose in sufficient quantities to ensure an adequate supply for the duration of the journey.

* * * * *

(21) Catalytic hair curlers containing hydrocarbon gas, not more than one per passenger or crew member, when carried in checked baggage, provided that the safety cover is securely fitted over the heating element. Gas refills for such curlers are not permitted in checked or carry-on baggage.

9. In § 175.33, a new paragraph (a)(6) is added to read:

**§175.33 Notification of pilot-in-command.**

(a)* * *

(6) An indication, when applicable, that a hazardous material is being carried under terms of an exemption.

* * * * *

**§ 175.78 [Amended]**

10. In § 175.78, Note 3 to Table 1 is revised by removing the period at the end of the note and adding the words "except that compatibility groups C, D and E may be stowed together. Explosives of ICAO Division 1.4, Compatibility Group S may be stowed with explosives of all compatability groups with the exception of A and L."

11. In § 175.630, paragraph (a) is revised to read:

**§ 175.630 Special requirements for poisons and etiologic agents.**

(a) Hazardous materials bearing the POISON or ETIOLOGIC AGENT label may not be carried in the same compartment of an aircraft with material which is marked as or known to be foodstuffs, feed, or any other edible material intended for consumption by humans or animals unless either the posions or etiologic agents and the foodstuffs, feed, or other edible materials are loaded in separate unit load devices which, when stowed on the aircraft, are not adjacent to each other, or the poisions or etiologic agents are loaded in one closed unit load device and the foodstuffs, feed or other materials are loaded in another closed unit load device.

* * * * *

## PART 178—SHIPPING CONTAINER SPECIFICATIONS

12. In § 178.0–3, paragraphs (a) and (a)(1) are amended to read:

**§ 178.0–3 United Nations symbol and packaging identification code.**

(a) In addition to the markings required by this subchapter, packagings may be marked with the United Nations symbol and packaging identification code as provided in the ICAO Technical Instructions or in Annex 1 to the IMDG Code provided that the person applying these markings has established that the packaging conforms to the applicable provisions of the ICAO Technical Instructions or Annex 1 to the IMDG Code, respectively.

(1) If an indication of the State in whose territory the specified tests have been carried out or of the State authorizing the allocation of the mark is required, the letters "USA" shall be used.

* * * * *

(49 U.S.C. 1803, 1804, 1808; 49 CFR 1.53 App. A to Part 1)

**Note.**—The Materials Transportation Bureau has determined that this document does not constitute a "major rule" under the terms of Executive Order 12291 or a significant regulation under DOT's regulatory policy and procedures (44 FR 11034) or require an environmental impact statement under the National Environmental Policy Act (49 U.S.C. 4321, et seq.). I certify that this proposal will not have a significant economic impact on a substantial number of small entities because the overall economic impact of this proposal is minimal. A regulatory evaluation and environmental assessment are available for review in the docket.

Issued in Washington, D.C. on November 21, 1983.

**L. D. Santman,**

*Director, Materials Transportation Bureau.*

[FR Doc. 83–31764 Filed 11–28–83; 8:45 am]

BILLING CODE 4910–60–M

# Proposed Rules

Federal Register
Vol. 48, No. 230
Tuesday, November 29, 1983

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.

## NUCLEAR REGULATORY COMMISSION

### 10 CFR Parts 30, 40 and 150

### Tritium and Source Material Reports

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Proposed rule.

**SUMMARY:** The Nuclear Regulatory Commission proposes amending the reporting requirements applicable to NRC and Agreement State licensees who transfer source material. The proposed rule would lower the reportable quantity of source material transfers from 1,000 kilograms to 1 kilogram. This action is necessary to satisfy existing international commitments. The NRC is also proposing the removal of the requirement that NRC and Agreement State licensees report tritium inventories. The NRC has determined that the existing reporting requirement for tritium is not necessary for conduct of its regulatory programs.

**DATE:** Comment period expires January 30, 1984. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except as to comments received on or before this date.

**ADDRESSES:** Mail written comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch. Deliver comments to Room 1121, 1717 H Street, NW, Washington, DC between 8:15 am and 5:00 pm weekdays.

Copies of the regulatory analyses, the OMB supporting statement, and any comments received on the proposed rule may be examined at the NRC Public Document Room at 1717 H Street, NW, Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** June Robertson, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: (301) 427-4004.

**SUPPLEMENTARY INFORMATION:**

#### Background

In early 1982, the NRC Safeguards staff conducted a study to reexamine several assumptions underlying the proposed development of an Integrated Safeguards Information System. One of the issues examined was the need for the current safeguards reporting requirements placed on licensees. The staff concluded that all material transfer and inventory data that licensees are currently required to report to NRC are necessary to satisfy existing international commitments and domestic safeguards needs, with the exception of the requirement to report tritium inventories. The examination also indicated that requirements applicable to source material transfer reports should be changed to reflect existing international commitments. This amendment would eliminate the tritium reporting requirements and change the source material transfer report requirements as suggested by the examination.

The proposed rule also suggests changes for clarity. They include deleting specific addresses from the regulation and stating that requirements of these parts are not applicable to general licensees.

#### Tritium Reporting Requirements

The NRC is proposing the deletion of the requirement to report tritium inventories placed on NRC and Agreement State Licensees. Currently, each licensee who is authorized to possess at any one time and location more than 10,000 curies of tritium is required to submit a semi-annual statement of the licensee's tritium inventory. This requirement, effected by the U.S. Atomic Energy Commission prior to the establishment of the NRC, was designed to assist the federal government in the overall management of tritium inventories in the United States. In proposing the current action, the NRC has determined that such a requirement is unnecessary for the conduct of its safety and safeguards regulatory programs.

#### Source Material Reports

The proposed rule would require reports from NRC and Agreement State licensees who transfer 1 kilogram or more of source material. Although current instructions and practices by most large industrial licensees set the reporting level at 1 kilogram, the current regulations establish the reporting level at 1,000 kilograms. The regulations are being changed to assure that existing international commitments will continue to be satisfied, and to correct an inconsistency between the regulations and reporting instructions. The lowered reporting requirement is necessary to allow the NRC to fulfill the obligations of the US/IAEA Agreement, the US/Canadian and the US/Australian Bilateral Agreements and the requirements for reporting imports and exports of nuclear material as recommended by the IAEA Consultants Group. These Agreements require information on transfers of 1 kilogram or more of source material. The US/IAEA Agreement became effective December 9, 1980. Entry into the Agreement allows the IAEA to apply its safeguards requirements to all U.S. peaceful nuclear activities. The Bilateral Agreements require the U.S. to track Australian and Canadian origin nuclear material in order to identify the location, use, and enrichment of foreign material in the U.S. Therefore, the reportable level of source material must be lowered to make NRC requirements compatible with these agreements.

The exemption of natural or depleted uranium metal used as permanently installed shielding was added because the IAEA does not require transfer reporting of nonnuclear end use material.

The change to lower the reportable quantity affects approximately 300 NRC and Agreement State licensees of which approximately 200 are small independent industrial manufacturers with an estimated annual gross income of less than $1 million and payrolls of fewer than 500 people. The small industrial licensee will each file an estimated two reports annually as a result of this change. The 100 large industrial licensees are currently reporting at the proposed level. Each large industrial licensee currently files approximately 60 additional reports over what is presently required by regulation.

**No Environmental Impact**

This proposed rule is non-substantive and insignificant from the standpoint of environmental impact. As a result, an environmental impact statement or negative declaration and environmental impact appraisal need not be prepared for the proposed change to Parts 30 and 40. The Commission's rules, at 10 CFR 51.5(d)(2), provide that an environmental impact statement or negative declaration and environmental appraisal need not be prepared for the proposed change to Part 150.

**Paperwork Reduction Act Statement**

This proposed rule amends information collection requirements that are subject to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.). This rule has been submitted to the Office of Management and Budget for review and approval of the paperwork requirements.

**Regulatory Analysis**

The NRC has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the NRC. The draft analysis is available for inspection in the NRC Public Document Room, 1717 H Street, NW, Washington, DC. Single copies of the draft analysis may be obtained from June Robertson, Office of Nuclear Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: (301) 427-4004.

The NRC requests public comment on the draft regulatory analysis. Comments on the draft analysis may be submitted as indicated under the **ADDRESSES** heading.

**Regulatory Flexibility Certification**

Based upon the information available at this stage of the rulemaking proceeding and in accordance with the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission hereby certifies that, if promulgated, this rule will not have a significant economic impact upon a substantial number of small entities due to the small number of reports involved. The proposed rule affects about 300 specific source material licensees. Approximately 100 of these licensees are large industrial manufacturers who submit approximately 60 reports each per year that are not required by the current rule. The large businesses are currently reporting at the proposed level as specified in the current reporting instructions because of compatibility with their in-house recordkeeping. However, approximately 200 of the affected licensees are small independent industrial manufacturers with an average annual gross income of less than $1 million who are not presently reporting at the proposed level.

The total time required by a licensee to complete each transfer report is estimated at approximately 1 hour. This is time needed to complete the report. No research or compilation is necessary as all information is transcribed from bills of lading, in-house records kept for other purposes, sales agreements, etc. The small industrial licensee will submit an average of two reports per year. Multiplying the time per small licensee, the result yields an annual burden of about 2 hours per small industrial licensee and approximately 60 hours per large industrial licensee to perform the proposed reporting for a total combined annual burden of approximately 6400 hours.

The average small independent industrial licensee has an annual gross income of less than $1 million and employs fewer than 500 people. The costs for complying with the proposed source material reporting requirement will not pose a significant economic impact. The additional annual cost for each of the small licensees will be approximately $120. The annual cost for each large licensee will be approximately $3,600.

During calendar year 1981, one licensee submitted one tritium inventory report. An estimated 1 hour is required to complete one inventory report. Consequently, it is estimated that the present reporting burden would be reduced by 1 hour per year.

Any small entity subject to this regulation which determines that, because of its size, it is likely to bear a disproportionate adverse economic impact should notify the Commission of this in a comment that indicates:

(a) The licensee's size in terms of annual income, revenue, or number of employees;

(b) How the proposed regulation would result in a significant economic burden upon the licensee as compared to that placed upon a larger licensee; and

(c) How the proposed regulations could be modified to take into account the licensee's differing needs or capabilities.

**List of Subjects**

*40 CFR Part 30*

Byproduct material, Government contracts, Intergovernmental relations, Isotopes, Nuclear materials, Penalty, Radiation protection, Reporting and recordkeeping requirements.

*40 CFR Part 40*

Government contracts, Hazardous materials—transportation, Nuclear materials, Penalty, Reporting and recordkeeping requirements, Source material, Uranium.

*40 CFR Part 150*

Hazardous materials—transportation, Intergovernmental relations, Nuclear materials, Penalty, Reporting and recordkeeping requirements, Security measures, Source material, special nuclear material.

For the reasons set out in the preamble and under the authority of the Atomic Energy of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and 5 U.S.C. 553, the NRC is proposing to adopt the following amendments to 10 CFR Parts 30, 40, and 150.

## PART 30—RULES OF GENERAL APPLICABILITY TO DOMESTIC LICENSING OF BYPRODUCT MATERIAL

1. The authority citation for Part 30 continues to read as follows:

**Authority:** Secs. 81, 82, 161, 182, 183, 186, 68 Stat. 935, 948, 953, 954, 955, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2111, 2112, 2201, 2232, 2236, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 30.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 30.34(b) also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 30.61 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 30.3, 30.34 (b) and (c), 30.41 (a) and (c) and 30.53 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 30.36, 30.51, 30.52 and 30.55 are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

**§ 30.55 [Amended]**

2. In § 30.55, paragraphs (b) and (e) are removed and reserved.

## PART 40—DOMESTIC LICENSING OF SOURCE MATERIAL

3. The authority citation for Part 40 continues to read as follows:

**Authority:** Secs. 62, 63, 64, 65, 81, 161, 182, 183, 186, 68 Stat. 932, 933, 935, 948, 953, 954, 955, as amended, secs. 11e(2), 83, 84, Pub. L. 95-604, 92 Stat. 3033, as amended, 3039, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2014(e)(2), 2092, 2093, 2094, 2095, 2111, 2113, 2114, 2201, 2232, 2233, 2236, 2282); sec. 274, Pub. L. 86-373, 73 Stat. 688 (42 U.S.C. 2021); secs. 201, as amended, 202, 206, 88 Stat. 1242,

as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 40.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 40.31(g) also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 40.46 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Section 40.71 also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 40.3, 40.25(d)(1)-(3), 40.35 (a)-(d), 40.41 (b) and (c), 40.46, 40.51 (a) and (c) and 40.63 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); and §§ 40.25 (c) and (d) (3) and (4), 40.26(c)(2), 40.35(e), 40.42, 40.61, 40.62, 40.64, and 40.65 are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

4. In § 40.64, paragraphs (a), (b) and (d) are revised to read as follows:

**§ 40.64 Reports.**

(a) Except as specified in paragraphs (d) and (e) of this section, each specific licensee who transfers, receives, or adjusts the inventory in any manner at any time by 1 kilogram or more of uranium or thorium, or any combination of uranium or thorium shall complete and distribute a Nuclear Material Transaction Report on Form DOE/NRC 741 in accordance with the printed instructions (NUREG/BR-0006) for completing the form. Copies of the form and instructions may be obtained by writing to U.S. Nuclear Regulatory Commission, Division of Safeguards, Washington, DC 20555. Each licensee who transfers the material shall submit a completed copy of Form DOE/NRC 741 to the Commission and three copies to the receiver of the material no later than the close of business the next working day. Each licensee who receives the material shall submit a completed copy of Form DOE/NRC 741 to the Commission and to the shipper of the material within ten (10) days after the material is received. The Commission's copies of the reports must be submitted to the address specified in the printed instructions.

(b) Except as specified in paragraphs (d) and (e) of this section, each licensee who is authorized to possess at any one time and location more than 1,000 kilograms of uranium or thorium or any combination of uranium or thorium shall submit to the Commission within 30 days after September 30 of each year a statement of the licensee's source material inventory. The reports must be submitted to the address specified in the Reporting instructions (NUREG/BR-0007), and include the reporting Identification Symbol (RIS) assigned by the Commission to the licensee. Copies of the reporting instructions may be obtained by writing U.S. Nuclear Regulatory Commission, Division of Safeguards, Washington, DC 20555.

* * * * *

(d) The reports described in paragraphs (a), (b), and (c) of this section are not required for—

(1) Processed ores containing less than five (5) percent of uranium or thorium, or any combination of uranium or thorium, by dry weight;

(2) Thorium contained in magnesium-thorium and tungsten-thorium alloys, if the thorium content in the alloys does not exceed 4 percent by weight;

(3) Chemical catalysts containing uranium depleted in the U-235 isotope to 0.4 percent or less, if the uranium content of the catalyst does not exceed 15 percent by weight; or

(4) Any natural or depleted uranium metal used as permanently installed shielding, including but not limited to shielding in shipping containers or teletherapy, radiography, x-ray, or accelerator devices.

* * * * *

## PART 150—EXEMPTIONS AND CONTINUED REGULATORY AUTHORITY IN AGREEMENT STATES AND IN OFFSHORE WATERS UNDER SECTION 274

5. The authority citation for Part 150 is revised to read as follows:

**Authority:** Sec. 161, 68 Stat. 948, as amended, sec. 274, 73 Stat. 688 (42 U.S.C. 2201, 2021); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).

Sections 150.3, 150.15, 150.15a, 150.31, 150.32 also issued under secs. 11e(2), 81, 68 Stat. 923, 935, as amended, secs. 83, 84, 92 Stat. 3033, 3039 (42 U.S.C. 2014e(2), 2111, 2113, 2114). Section 150.14 also issued under sec. 53, 68 Stat. 930, as amended (42 U.S.C. 2073). Section 150.17a also issued under sec. 122, 68 Stat. 939 (42 U.S.C. 2152). Section 150.30 also issued under sec. 234, 83 Stat. 444 (42 U.S.C. 2282).

For the purposes of sec. 223, 68 Stat. 958, as amended (42 U.S.C. 2273); §§ 150.20(b)(2)-(4) and 150.21 are issued under sec. 161b, 68 Stat. 948, as amended (42 U.S.C. 2201(b)); § 150.14 is issued under sec. 161i, 68 Stat. 949, as amended (42 U.S.C. 2201(i)); and §§ 150.16-150.19 and 150.20(b)(1) are issued under sec. 161o, 68 Stat. 950, as amended (42 U.S.C. 2201(o)).

**§§ 150.3, 150.14, 150.15, 150.15a, 150.30, 150.31, 150.32 [Amended]**

6. Remove the authority citations following §§ 150.3, 150.14, 150.15, 150.15a, 150.30, 150.31, and 150.32.

6. Remove the authority citations following §§ 150.3, 150.14, 150.15, 150.15a, 150.30, 150.31, and 150.32.

7. In § 150.17, paragraphs (a), (b) and (d) are revised to read as follows:

**§ 150.17 Submission to the Commissior source material transfer reports.**

(a) Except as specified in paragraph (d) of this section, each person who, under an Agreement State License, transfers or receives at any one time 1 kilogram or more of uranium or thoriu or any combination of uranium or thorium, shall complete and distribute Nuclear Material Transaction Report DOE/NRC Form 741 in accordance wi the printed instructions for completing the form (NUREG/BR-006). Copies of forms and instructions may be obtain by writing to U.S. Nuclear Regulatory Commission, Division of Safeguards, Washington, DC 20555. Each person w transfers the material shall submit a completed copy of DOE/NRC Form 74 to the address specified in the printed instructions and three (3) copies to th receiver of the material no later than t close of business the next working da Each person who receives the materia shall submit a completed copy of DOE NRC Form 741 to the address specifie in the printed instructions and to the shipper of the material within ten (10) days after the material is received.

(b) Except as specified in paragraph (d) of this section, each person who is authorized to possess at any one time and location under an Agreement Stat license, more than 1,000 kilograms of uranium or thorium, or any combinati of uranium or thorium, shall submit to the Commission within 30 days after September 30 of each year, a statemer of the licensee's source material inventory. These reports must be submitted to the address specified in t printed instructions (NUREG/BR-000 and include the Reporting Identificati Symbol (RIS) assigned by the Commission to the licensee. Copies of the reporting instructions may be obtained by writing to U.S. Nuclear Regulatory Commission, Division of Safeguards, Washington, DC 20555.

* * * * *

(d) The reports described in paragraphs (a), (b), and (c) of this section are not required for:

(1) Processed ores containing less than five (5) percent or uranium or thorium, or any combination of uraniu and thorium, by dry weight;

(2) Thorium contained in magnesiun thorium and tungsten-thorium alloys, i the thorium content in the alloys does not exceed 4 percent by weight;

(3) Chemical catalysts containing uranium depleted in the U-235 isotope to 0.4 percent or less, if the uranium content of the catalyst does not excee 15 percent by weight; or

(4) Any natural or depleted uranium metal used as permanently installed

shielding, including but not limited to shielding in shipping containers or teletherapy, radiography, x-ray, or accelerator devices.

**§ 150.19 [Amended]**

8. In § 150.19, paragraph (b) is removed and reserved.

Dated at Bethesda, Maryland, this 14th day of November 1983.

For the Nuclear Regulatory Commission.

**William J. Dircks,**

*Executive Director for Operations.*

[FR Doc. 83-31874 Filed 11-28-83; 8:45 am]

BILLING CODE 7590-01-M

## CIVIL AERONAUTICS BOARD

### 14 CFR Ch. II

**[EDR-466A; Docket 41686]**

### Computer Reservations Systems; Extension of Reply Comment Period

Dated: November 23, 1983.

**AGENCY:** Civil Aeronautics Board.

**ACTION:** Extension of Reply Comment Period.

**SUMMARY:** The CAB is extending for two weeks the reply comment period for its advanced notice of proposed rulemaking on carrier-owned computer reservation systems used by travel agents. This action is taken at the request of several parties.

**DATES:** Reply Comments by December 16, 1983.

Comments and other relevant information received after this date will be considered by the Board only to the extent practicable.

**ADDRESSES:** Twenty copies of reply comments should be sent to Docket 41686, Civil Aeronautics Board, 1825 Connecticut Avenue, NW., Washington, D.C. 20428. Individuals may submit their views as consumers without filing multiple copies. Comments may be examined in Room 711, Civil Aeronautics Board, 1825 Connecticut Avenue, NW., Washington, D.C., as soon as they are received.

**FOR FURTHER INFORMATION CONTACT:** Barry L. Molar, Office of General Counsel, or Paul S. Smith, Bureau of Domestic Aviation, Civil Aeronautics Board, 1825 Connecticut Ave. NW., Washington, D.C. 20428; 202-673-5205, 202-673-5822.

**SUPPLEMENTARY INFORMATION:** In EDR-466, 48 FR 41811, the Board requested comments on the need for Board rules governing the marketing to travel agents of computer reservation systems owned by air carriers, including rules on access to systems by other carriers. The Board also asked for comments on a variety of specific proposals for rules in this area. By EDR 466A, 48 FR 47003, October 17, 1983, the Board established November 17, 1983 as the due date for comments, and December 2, 1983 as the due date for reply comments.

Telephonic requests for extension of the period for reply comments have been received from United Air Lines, American Airlines, and Tymshare. The comments that we have received are complex and voluminous. The Department of Justice has filed over 1000 pages of comments and evidence. On the basis of our examination, we now conclude that the 2 weeks originally provided for reply comments may not be sufficient to allow parties an opportunity to throughly analyze and respond.

On the basis of these considerations, we have decided that parties should be allowed an additional 2 weeks for the filing of reply comments. The additional time will allow them to more thoroughly analyze the issues and arguments raised in the comments, and will in the long run improve the quality of the record in this proceeding.

Accordingly, under authority delegated in 14 CFR 385.20(d), the reply comment period for Docket 41686 is hereby extended until December 16, 1983.

By the Civil Aeronautics Board.

**Richard B. Dyson,**

*Associate General Counsel, Rules and Legislation.*

[FR Doc. 83-31872 Filed 11-28-83; 8:45 am]

BILLING CODE 6320-01-M

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### 14 CFR Part 71

**[Airspace Docket No. 82-AWP-21]**

### Alteration of VOR Federal Airway; Ca.

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Withdrawal of notice of proposed rulemaking.

**SUMMARY:** This action withdraws **Federal Register** Document 83-9746 published in the **Federal Register** on April 14, 1983 (48 FR 16066) to amend Part 71 of the Federal Aviation Regulations (14 CFR Part 71). The proposed amendment would have realigned VOR Federal Airway V-460 between Poggi, CA, to Julian, CA, via an east dogleg. After analysis of additional information the FAA has determined the amendment does not satisfy current operational requirements.

**DATE:** The proposed rule is withdrawn effective November 28, 1983.

**FOR FURTHER INFORMATION CONTACT:** Lewis W. Still, Airspace and Air Traffic Rules Branch (AAT-230), Airspace-Rules and Aeronautical Information Division, Air Traffic Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, D.C. 20591; telephone: (202) 426-8626.

#### Withdrawal of the Proposal

Pursuant to the authority delegated to me, effective November 28, 1983, **Federal Register** Document 83-9746 (Airspace Docket No. 82-AWP-21) published in the **Federal Register** on April 14, 1983 (48 FR 16066), is hereby withdrawn.

Issued in Washington, D.C., on November 18, 1983.

**B. Keith Potts,**

*Manager, Airspace-Rules and Aeronautical Information Division.*

[FR Doc. 83-31799 Filed 11-28-83; 8:45 am]

BILLING CODE 4910-13-M

### 14 CFR Parts 91, 107, 108, 109, 121, and 135

**[Docket No. 23847; NPRM 83-18]**

### Airport, Airspace, Aviation Security, and Flight Operations Requirements, 1984 Summer Olympics, Los Angeles, California; Correction

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Notice of proposed rulemaking (NPRM); correction.

**SUMMARY:** On Friday, November 25, 1983, the Federal Aviation Administration published a Notice of Proposed Rulemaking (NPRM) (48 FR 53374) to establish airport, airspace, aviation security, and flight operation requirements for the XXIII Olympic Games to be held primarily in the vicinity of Los Angeles, Calif., in the summer of 1984. This document is issued to correct a date that was set out in the preamble.

**FOR FURTHER INFORMATION CONTACT:** Gene Falsetti, Air Traffic Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, D.C. 20591; telephone (202) 426-8783.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 83-31667 beginning on page 53374 in the issue published on November 25, 1983, third column, third line from the

top "November 25, 1983" should read "December 9, 1983."

Issued in Washington, D.C., on November 25, 1983.

**Edward P. Faberman,**

*Deputy Chief Counsel.*

[FR Doc. 83-32039 Filed 11-25-83; 4:03 pm]

BILLING CODE 4910-13-M

## CIVIL AERONAUTICS BOARD

### 14 CFR Part 252

**[Economic Regulations Docket 41431; EDR-461C]**

### Smoking Aboard Aircraft; Extension of Comment Period

Dated: November 23, 1983.

**AGENCY:** Civil Aeronautics Board.

**ACTION:** Supplemental notice of proposed rulemaking.

**SUMMARY:** The CAB is extending the reply comment period in its rulemaking to amend its smoking rule. The Air Transport Association of America requested this extension.

**DATE:** Reply comments by: December 27, 1983.

**ADDRESSES:** Twenty copies of comments should be sent to Docket 41431, Civil Aeronautics Board, 1825 Connecticut Avenue, N.W., Washington, D.C. 20428. Individuals may submit their views as consumers without ruling multiple copies. Comments may be examined in Room 711, Civil Aeronautics Board, 1825 Connecticut Avenue, N.W., Washington, D.C. as soon as they are received.

**FOR FURTHER INFORMATION CONTACT:** David Schaffer, Office of General Counsel, Civil Aeronautics Board, 1825 Connecticut Avenue, N.W., Washington, D.C. 20428; 202-673-5442.

**SUPPLEMENTARY INFORMATION:** By EDR-461, 48 FR 24918, June 3, 1983, the Board proposed to revise and strengthen is rule controlling smoking aboard aircraft. It proposed to require airlines to ban smoking on their small aircraft, ban cigar and pipe smoking on all aircraft, ban smoking when the aircraft ventilation system is not producing adequate ventilation, and provide special seating for passengers who are especially sensitive to smoke. Ninety days were allowed for public comment and 30 days for reply comments. These comment deadlines were suspended by EDR-461A, 48 FR 36273, August 10, 1983, however, so that the Board could consider including additional issues in this rulemaking proceeding.

By EDR-461B, 48 FR 43341, September 23, 1983, the Board issued additional proposals. It proposed to ban smoking on short flights and to require airlines to provide additional special protections for passengers who are especially sensitive to smoke. Forty-five days were allowed for comments on all these proposals, and 20 days were allowed for replies. The initial round of comments was due on November 7. The Board received more than two dozen formal comments and thousands of letters. Replies to these comments are due November 28.

The Air Transport Association of America (ATA) has asked that the Board extend the reply comment deadline beyond November 28. It noted that some of the initial comments had been served after the November 7th deadline, and that many of the comments, both timely and late-filed, were voluminous. It also stated that these comments raised important and complicated questions concerning passenger health and aircraft ventilation that could not be adequately addressed in the short time provided. For these reasons, ATA asked that the due date for reply comments be extended to January 5, 1984.

The request for an extension of time to file reply comments is granted in part, and the new reply comment deadline is December 27, 1983. This rulemaking on smoking has generated an unusual amount of public interest, so it is particularly important that the Board give the airlines and others sufficient time to submit available information and arguments. It does not appear that an extension of the reply comment period will prejudice any other person or delay a final decision. It will not be possible to hold the oral argument (the next stage in this proceeding) until after the new year. Extending the reply comment period beyond December 27, however, would not give the Board and its staff sufficient time to review and digest the comments prior to the oral argument.

Accordingly, under authority delegated by the Board in 14 CFR 385.20(d), the time for filing comments in this proceeding is extended to December 27, 1983.

**List of Subjects in 14 CFR Part 252**

Air carriers, Consumer protection, Smoking.

(Secs. 204, 404, 407, and 416 of Pub. L. 85-726, as amended, 72 Stat. 743, 760, 766, 771; 49 U.S.C. 1324, 1374, 1377, 1386))

By Civil Aeronautics Board.

**Richard B. Dyson,**

*Associate General Counsel, Rules and Legislation Division.*

[FR Doc. 83-31766 Filed 11-28-83; 8:45 am]

BILLING CODE 6320-01-M

## SECURITIES AND EXCHANGE COMMISSION

### 17 CFR Parts 240 and 249

**[Release No. 34-20410; File No. S7-709, S7-959]**

### SECO Program; Minimum Qualification Requirements and Initial Form and Fees for Registered Nonmember Brokers and Dealers

**AGENCY:** Securities and Exchange Commission.

**ACTION:** Withdrawal of proposed rules.

**SUMMARY:** The Commission announces the withdrawal of a proposed amendment to Rule 15b7-1 concerning minimum qualification requirements for registered nonmember brokers and dealers and their associated persons and also the withdrawal of proposed amendments to Rule 15b9-1 concerning initial information form and fees for registered nonmember brokers and dealers. The withdrawals are made in light of amendments to the Securities Exchange Act of 1934 which eliminate the Commission's SECO Program.

**EFFECTIVE DATE:** November 29, 1983.

**FOR FURTHER INFORMATION CONTACT:** Katherine A. England, Esq., (202) 272-2411, Room 5204, Division of Market Regulation, Securities and Exchange Commission, Washington, D.C. 20549.

**SUPPLEMENTARY INFORMATION:** The Securities and Exchange Commission ("Commission") announces the withdrawal of proposed Rule 15b7-1 under the Securities Exchange Act of 1934 ("Act") which had been published for comment in 1982 [1] and proposed amendments to Rule 15b9-1 under the Act which were published for a comment in 1983.[2]

In a companion release today,[3] the Commission announced the rescission of 15 rules and the amendment of six rules under the Act that relate to the SECO Program. These actions were necessitated by amendments to the Act [4] which eliminate direct regulation

[1] Securities Exchange Act Release No. 18710 (May 4, 1982), 47 FR 20783 (May 14, 1982).

[2] Securities Exchange Act Release No. 19478 (February 1, 1983), 48 FR 6130 (February 10, 1983).

[3] Securities Exchange Act Release No. 20409 (November 22, 1983).

[4] Public Law No. 98-38, 97 Stat. 205.

of certain broker-dealers by the Commission through the SECO Program and require any broker-dealer engaged in an over-the-counter ("OTC") securities business to join a registered national securities association.

Proposed Rule 15b7-1 would have established minimum qualification requirements for nonmember broker-dealers and their associated persons. Proposed amendments to Rule 15b9-1 would have clarified that broker-dealers must either join a registered national securities association or register as SECO before transacting any OTC business. Legislation amending the Act to require all broker-dealers conducting an OTC securities business to join a registered national securities association and eliminate the SECO Program has obviated the need for both the proposed amendment to Rule 15b9-1 and proposed Rule 15b7-1.

Accordingly, the Commission is hereby withdrawing Proposed Rule 15b7-1 (§ 240.1567-1 and § 249.511) and the proposed amendments to Rule 15b9-1 (§ 240.15b9-1).

Dated: November 22, 1983.
By the Commission.

**George A. Fitzsimmons,**
*Secretary.*

[FR Doc. 83-31911 Filed 11-28-83; 8:45 am]
BILLING CODE 8010-01-M

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### 18 CFR Part 141

[Docket No. RM83-11-000]

### Revision of Monthly Report of Cost and Quality of Fuel for Electric Plants: Form No. 423; Extension of Comment Period

November 23, 1983.

**AGENCY:** Federal Energy Regulatory Commission, DOE.

**ACTION:** Notice of proposed rulemaking; extension of comment period.

**SUMMARY:** On September 26, 1983, the Commission issued a Notice of Proposed Rulemaking involving the revision of Form No. 423, "Monthly Report of Cost and Quality of Fuel for Electric Plants" (48 FR 44845, September 30, 1983). The comment period is being extended at the request of the Edison Electric Institute, the Association of American Railroads and the American Electric Power Service Corporation.

**DATE:** Comments must be submitted on or before December 27, 1983.

**ADDRESS:** Submit comments to: Office of the Secretary, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426.

**FOR FURTHER INFORMATION CONTACT:** Kenneth F. Plumb, Secretary, (202) 357-8400.

On November 9, 15 and 18, 1983, Edison Electric Institute (EEI), the Association of American Railroads (AAR) and American Electric Power Service Corporation (AEP) filed respective motions for an extension of time to file comments in response to the Commission's Notice of Proposed Rulemaking issued September 26, 1983, in the above-docketed proceeding. EEI's motion states that it requires additional time to resolve the complex issues of law which are raised in the proposed rule and also to determine what impact the proposal will have on EEI's member companies. AAR's motion states that the association requires additional time to consult with its membership and to determine the appropriate manner of addressing the issues which are presented in the proposed rulemaking. In support of its request, AEP's motion states that because of certain logistical problems related to the relocation of its corporate offices, the company requires additional time to coordinate the preparation of its response with various departments within the AEP System.

Upon consideration, notice is hereby given that an extension of time for the filing of comments is granted to and including December 27, 1983.

[FR Doc. 83-31895 Filed 11-28-83; 8:45 am]
BILLING CODE 6717-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 351

[Docket No. 82N-0291]

### Vaginal Drug Products for Over-the-Counter Human Use; Establishment of a Monograph

*Correction*

In FR Doc. 83-27596 beginning on page 46694 in the issue of Thursday, October 13, 1983, make the following corrections:

1. On page 46694, column one, in the **DATES** paragraph, lines two and three, "March 19, 1984" should read "February 10, 1984".

2. On page 46729, column three, in the paragraph following § 351.180(c), line fifteen, "March 19, 1984" should read "February 10, 1984".

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### 26 CFR Part 1

[LR-680]

### Personal Holding Companies; Withdrawal of Notice of Proposed Rulemaking

**AGENCY:** Internal Revenue Service, Treasury.

**ACTION:** Withdrawal of notice of proposed rulemaking.

**SUMMARY:** This document withdraws the notice of proposed rulemaking relating to personal holding companies that was published in the **Federal Register** for September 5, 1968 (33 FR 12553).

Because of the extreme age of these proposed amendments to the regulations and because of the passage of legislation affecting these sections of the Code in the years intervening since the publication of these proposed amendments to the regulations, it was determined that these proposed amendments should be withdrawn.

**FOR FURTHER INFORMATION CONTACT:** Susan Thompson Baker of the Legislation and Regulations Division, Office of the Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, N.W., Washington, D.C. 20224 (Attention: CC:LR:T) (202-566-3459).

**SUPPLEMENTARY INFORMATION:**

#### Background

This document withdraws the notice of proposed rulemaking that was published in the **Federal Register** for September 5, 1968 (33 FR 12553). That notice proposed regulations under sections 541 through 544, 551 through 554, 856, 1016, 1022, 1023, 1244, and 1361 of the Internal Revenue Code of 1954 to conform the Income Tax Regulations to section 225 of the Revenue Act of 1964 (78 Stat. 79) and to section 3 of the Act of August 22, 1964 (Pub. L. 88-484, 78 Stat. 598).

#### Drafting Information

The principal author of this document is Susan Thompson Baker of the Legislation and Regulations Division, Office of the Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service participated in developing this document, both in matters of substance and style.

*Withdrawal of Proposed Amendments to the Regulations*

The proposed amendments to 26 CFR Part 1 relating to personal holding companies published in the **Federal Register** for September 5, 1968 (33 FR 12553), are hereby withdrawn.

**Roscoe L. Egger, Jr.,**

*Commissioner of Internal Revenue.*

[FR Doc. 83-31921 Filed 11-28-83; 8:45 am]

BILLING CODE 4830-01-M

## POSTAL SERVICE

### 39 CFR Part 10

### Proposed International Express Mail Service to Egypt

**AGENCY:** Postal Service.

**ACTION:** Proposed rule.

**SUMMARY:** Pursuant to an agreement with the postal administration of Egypt, the Postal Service proposes to begin International Express Mail Service with Egypt at postage rates indicated in the table below. The proposed service is scheduled to begin on February 1, 1984.

**DATE:** Comments must be received on or before December 29, 1983.

**ADDRESS:** Written comments should be directed to the General Manager, Rate Development Division, Office of Rates, Rates and Classification Department, U.S. Postal Service, Washington, D.C. 20260-5350. Copies of all written comments will be available for public inspection and photocopying between 9 a.m. and 4 p.m., Monday through Friday, in Room 8620, 475 L'Enfant Plaza West, SW., Washington, D.C. 20260-5350.

**FOR FURTHER INFORMATION CONTACT:** Leon W. Perlinn, (202) 245-4414.

**SUPPLEMENTARY INFORMATION:** The International Mail Manual is incorporated by reference in the **Federal Register**, 39 CFR 10.1. Additions to the manual concerning the proposed new service, including the rate table reproduced below, will be made in due course. Accordingly, although 39 U.S.C. 407 does not require advance notice and the opportunity for submission of comments on international service, and the provisions of the Administrative Procedure Act regarding proposed rulemaking (5 U.S.C. 553) do not apply (39 U.S.C. 410 [a]), the Postal Service invites interested persons to submit written data, views or arguments concerning the proposed International Express Mail Service to Egypt at the rates indicated in the table below.

**List of Subjects in 39 CFR Part 10**

Postal Service, Foreign relations.

EGYPT.—INTERNATIONAL EXPRESS MAIL

| Custom designed service [1] [2] | | On demand service [2] | |
|---|---|---|---|
| Weight not over | | Weight not over | |
| Pounds | Rate | Pounds | Rate |
| 1 | $28.00 | 1 | $20.00 |
| 2 | 31.70 | 2 | 23.70 |
| 3 | 35.40 | 3 | 27.40 |
| 4 | 39.10 | 4 | 31.10 |
| 5 | 42.80 | 5 | 34.80 |
| 6 | 46.50 | 6 | 38.50 |
| 7 | 50.20 | 7 | 42.20 |
| 8 | 53.90 | 8 | 45.90 |
| 9 | 57.60 | 9 | 49.60 |
| 10 | 61.30 | 10 | 53.30 |
| 11 | 65.00 | 11 | 57.00 |
| 12 | 68.70 | 12 | 60.70 |
| 13 | 72.40 | 13 | 64.40 |
| 14 | 76.10 | 14 | 68.10 |
| 15 | 79.80 | 15 | 71.80 |
| 16 | 83.50 | 16 | 75.50 |
| 17 | 87.20 | 17 | 79.20 |
| 18 | 90.90 | 18 | 82.90 |
| 19 | 94.60 | 19 | 86.60 |
| 20 | 98.30 | 20 | 90.30 |
| 21 | 102.00 | 21 | 94.00 |
| 22 | 105.70 | 22 | 97.70 |

[1] Rates in this table are applicable to each piece of International Custom Designed Express Mail shipped under a Service Agreement providing for tender by the customer at a designated Post Office.

[2] Pickup is available under a Service Agreement for an added charge of $5.60 for each pickup stop, regardless of the number of pieces picked up. Domestic and International Express Mail picked up together under the same Service Agreement incurs only one pickup charge.

An appropriate amendment to 39 CFR 10.3 to reflect these changes will be published when the final rule is adopted.

(39 U.S.C. 401, 404, 407)

**W. Allen Sanders,**

*Associate General Counsel, Office of General Law and Administration.*

[FR Doc. 83-31839 Filed 11-28-83; 8:45 am]

BILLING CODE 7710-12-M

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[AD-FRL 2478-3]

### Approval and Promulgation of State Implementation Plans; Intent To Promulgate Federal Implementation Plans

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of Intent to Promulgate Federal Implementation Plans.

**SUMMARY:** This notice announces the Environmental Protection Agency's intent to promulgate Federal Implementation Plans (FIP's) for lead for certain States under the Clean Air Act. EPA is required to publish this notice under the terms of a recent consent order issued by the United States District Court for the District of Columbia in Clean Air Act litigation concerning lead implementation plans.

**FOR FURTHER INFORMATION CONTACT:** John J. Silvasi, Office of Air Quality Planning and Standards, Control Programs Development Division (MD-15), U.S. EPA, Research Triangle Park, N.C. 27711 (telephone 919-541-5665).

**SUPPLEMENTARY INFORMATION:** On July 26, 1983, the U.S. District Court for the District of Columbia entered an order approving a Settlement Agreement between the U.S. Environmental Protection Agency (EPA) and the Natural Resources Defense Council, Inc. (NRDC) in settlement of litigation filed by NRDC against EPA for failure to perform nondiscretionary duties concerning the adoption and implementation of State plans for control of airborne lead emissions, *NRDC* v. *Ruckelshaus*, No. 82-2137 (D.D.C.). The NRDC argued that under Section 110 of the Clean Air Act (the Act), 42 U.S.C. 7410, final lead implementation plans for all the States were to have been promulgated no later than January 1980 and that at the time they filed their suit in July 1982, over half the States were without final lead implementation plans. The Settlement Agreement established specific deadlines for the completion of State Implementation Plans (SIP's) for lead for States lacking such plans at the time the Settlement Agreement was signed on July 26, 1983. If the States do not submit their own lead SIP's to EPA for review and approval, EPA must develop and promulgate the necessary plans pursuant to Section 110(c) of the Act, 42 U.S.C. 7410(c). For a discussion of the Settlement Agreement, see the notice published in the August 10, 1983 **Federal Register**, 48 FR 36250-51.

Under the Settlement Agreement, the States were divided into three categories. The Agreement established a trigger date of August 1, 1983, for submission of lead SIP's for States with (a) major stationary sources of lead emissions; or (b) recorded violations of the national ambient air quality standard (NAAQS) for lead since 1980; or (c) both (a) and (b). These States, referred to in the Agreement as Appendix II States, are:

Alaska, California (Fresno and Los Angeles areas), Florida, Idaho, Illinois (Granite City area), Indiana, Minnesota, Mississippi, Montana, Nebraska (Omaha area), New Jersey, New York, Pennsylvania (Philadelphia and the areas around three secondary lead smelters in Berks and Carbon Counties), Tennessee (outside Davidson and Hamilton Counties), Texas (Dallas and El Paso areas), Washington.

The EPA is supposed to propose action (approval and disapproval) on the submitted Appendix II SIP's by January 3, 1984. Based on the Settlement

Agreement, Connecticut and the Anapra area of New Mexico are also subject to the schedule applicable to Appendix II States.

If an Appendix II State does not submit a lead SIP to EPA in time for EPA to propose action on it by January 3, 1984, EPA must publish a proposed FIP for that State by April 1, 1984. To date the following sixteen Appendix II States plus Connecticut and New Mexico (Anapra area) have submitted draft or final lead SIP's to EPA:

Alaska, California (Fresno and Los Angeles), Florida, Idaho (except Shoshone County), Illinois, Indiana (Granite City), Minnesota, Mississippi, Montana, Nebraska (Omaha area), New Jersey, New York, Pennsylvania (Philadelphia only submitted), Tennessee (outside Davidson and Hamilton Counties), Texas (Dallas and El Paso areas), Washington, Connecticut, New Mexico (Anapra area).

The following two Appendix II States have not submitted lead SIP's to EPA:

Idaho (Shoshone County), Pennsylvania (the areas around three secondary lead smelters in Berks and Carbon Counties).

In accordance with the terms of the Settlement Agreement, which requires EPA to publish a notice of intent to promulgate lead FIP's for nonsubmitting Appendix II States pursuant to Section 110(c) of the Act, 42 U.S.C. 7410(c), EPA announces its intention to promulgate lead FIP's by April 1, 1984, for the two States listed above that have not submitted lead SIP's to EPA. If, however, EPA receives a lead SIP from either of these States in time for EPA to propose action on that SIP by January 3, 1984, EPA will not be required to propose a lead FIP for that State. EPA has been providing technical assistance to both of these States to expedite the preparation and submission of lead SIP's.

Through EPA's "parallel processing" procedures, EPA will propose rulemaking on draft lead SIP's to obtain public comment concurrently with a State's public comment period. For a description of the parallel processing procedure, see the **Federal Register** of June 23, 1982 (47 FR 27073). Therefore, although EPA would prefer to receive a final lead SIP from each of the Appendix II States in time to propose rulemaking by January 3, 1984, EPA will proceed with proposed rulemaking on draft SIP's when they are received.

Dated: November 16, 1983.

**Joseph A. Cannon,**

*Acting Assistant Administrator for Air, Noise, and Radiation.*

[FR Doc. 83-31834 Filed 11-28-83; 8:45 am]

BILLING CODE 6560-50-M

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## 40 CFR Part 81

**[A-10-FRL 2461-6]**

## Notice of Proposed Rulemaking—State of Idaho

*Correction*

In FR Doc. 83-29577, beginning on page 50361, in the issue of Tuesday, November 1, 1983, make the following corrections:

1. On page 50361, in the third column, in the **SUMMARY** paragraph, in the eleventh line "date" should read "data".

2. On page 50362, in the second column, in the fourth indented paragraph, in the eleventh line "3300" should read "330".

BILLING CODE 1505-01-M

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## FEDERAL COMMUNICATIONS COMMISSION

## 47 CFR Part 73

**[MM Docket No. 83-1236; RM-4370]**

## TV Broadcast Stations in Ventura, California; Proposed Changes in Table of Assignments

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** Action taken herein proposes to assign UHF television Channel 41 to Ventura, California, as that community's second commercial television broadcast service, in response to a petition filed by Stanley J. Mewhort.

**DATES:** Comments must be filed on or before January 9, 1984, and reply comments on or before January 24, 1984.

**ADDRESS:** Federal Communications Commission, Washington, D.C. 20554.

**FOR FURTHER INFORMATION CONTACT:** Nancy V. Joyner, Mass Media Bureau (202) 634-6530.

### List of Subjects in 47 CFR Part 73

Television broadcasting.

### Notice of Proposed Rule Making

In the matter of amendment of § 73.606(b), Table of Assignments, TV Broadcast Stations. (Ventura, California) (MM Docket No. 83-1236, RM-4370).

Adopted: November 2, 1983.

Released: November 17, 1983.

By the Chief, Policy and Rules Division.

1. Before the Commission for consideration is a petition for rule making filed by Stephen J. Mewhort ("petitioner"), proposing the assignment of UHF television Channel 41 to Ventura, California, as that community's second commercial television service. Petitioner indicated his intention to apply for the channel, if assigned as proposed.

2. Ventura (population unlisted in the 1980 U.S. Census) in Ventura County (population 529,174), [1] is located in southern California, approximately 90 kilometers (55 miles) northwest of Los Angeles. UHF television Channel 16 (applications pending), is currently assigned to Ventura.

3. Channel 41 can be assigned to Ventura in harmony with the minimum distance separation requirements of §§ 73.610 and 73.698 of the Commission's Rules, and other technical criteria. However, since the proposal is within 400 kilometers (250 miles) of the common U.S.-Mexican border, the Commission must obtain the concurrence of the Mexican government in the proposal.

**§ 73.606 [Amended]**

4. On the basis of the foregoing, we believe the proposal merits consideration since it could provide a second commercial television broadcast service to Ventura. Accordingly, the Commission proposes to amend the Television Table of Assignments, § 73.606(b) of the Commissions Rules, as follows:

| Channel No. | City | |
|---|---|---|
| | Present | Proposed |
| Ventura, Calif | 16+ | 16+, 41+ |

5. The Commission's authority to institute rulemaking proceedings, showings required, cut-off procedures, and filing requirements are contained in the attached Appendix and are incorporated by reference herein. Note: A showing of continuing interest is required by paragraph 2 of the Appendix before a channel will be assigned.

6. Interested parties may file comments on or before January 9, 1984, and reply comments on or before January 24, 1984, and are advised to read the Appendix for the proper procedures. Additionally, a copy of such comments should be served on the petitioners, or their counsel or consultant, as follows:

[1] Population figure was extracted from the 1980 U.S. Census.

Stephen J. Mewhort, P.O. Box 843, Clovis, CA 93612, (Petitioner)

and

Edward M. Johnson, One Regency Square, Suite 450, Knoxville, TN 37515, (Consultant to Petitioner)

7. The Commission has determined that the relevant provisions of the Regulatory Flexibility Act of 1980 do not apply to rulemaking proceedings to amend the TV Table of Assignments, § 73.606(b) of the Commission's Rules. See, *Certification that Sections 603 and 604 of the Regulatory Flexibility Act Do Not Apply to Rule Making to Amend §§ 73.202(b), 73.504 and 73.606(b) of the Commission's Rules*, 46 FR 11549, published February 9, 1981.

8. For further information concerning this proceeding, contact Nancy V. Joyner, Mass Media Bureau, (202) 634-6530. However, members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel assignments. An *ex parte* contact is a message (spoken or written) concerning the merits of a pending rulemaking, other than comments officially filed at the Commission, or oral presentation required by the Commission. Any comment which has not been served on the petitioner constitutes an *ex parte* presentation and shall not be considered in the proceeding. Any reply comment which has not been served on the person(s) who filed the comment, to which the reply is directed, constitutes an *ex parte* presentation and shall not be considered in the proceeding.

Federal Communications Commission.

**Roderick K. Porter,**

*Chief, Policy and Rules Division, Mass Media Bureau.*

## Appendix

1. Pursuant to authority found in Sections 4(i), 5(d)(1), 303 (g) and (r), and 307(b) of the Communications Act of 1934, as amended, and §§ 0.61, 0.204(b) and 0.283 of the Commission's Rules, it is proposed to amend the TV Table of Assignments, § 73.606(b) of the Commission's Rules and Regulations, as set forth in the Notice of Proposed Rule Making to which this Appendix is attached.

2. *Showings Required.* Comments are invited on the proposal(s) discussed in the Notice of Proposed Rule Making to which this Appendix is attached. Proponent(s) will be expected to answer whatever questions are presented in initial comments. The proponent of a proposed assignment is also expected to file comments even if it only resubmits or incorporates by reference its former pleadings. It should also restate its present intention to apply for the channel if it is assigned, and, if authorized, to build a station promptly. Failure to file may lead to denial of the request.

3. *Cut-Off Procedures.* The following procedures will govern the consideration of filings in this proceeding.

(a) Counterproposals advanced in this proceeding itself will be considered, if advanced in initial comments, so that parties may comment on them in reply comments. They will not be considered if advanced in reply comments. (See § 1.420(d) of the Commission's Rules.)

(b) With respect to petitions for rulemaking which conflict with the proposal(s) in this *Notice*, they will be considered as comments in the proceeding, and Public Notice to this effect will be given as long as they are filed before the date for filing initial comments herein. If they are filed later than that, they will not be considered in connection with the decision in this docket.

(c) The filing of a counterproposal may lead the Commission to assign a different channel than was requested for any of the communities involved.

4. *Comments and Reply Comments; Service.* Pursuant to applicable procedures set out in §§ 1.415 and 1.420 of the Commission's Rules and Regulations, interested parties may file comments and reply comments on or before the dates set forth in the Notice of Proposed Rule Making to which this Appendix is attached. All submissions by parties to this proceeding or persons acting on behalf of such parties must be made in written comments, reply comments, or other appropriate pleadings. Comments shall be served on the petitioner by the person filing the comments. Reply comments shall be served on the person(s) who filed comments to which the reply is directed. Such comments and reply comments shall be accompanied by a certificate of service. (See § 1.420 (a), (b) and (c) of the Commission's Rules.)

5. *Number of Copies.* In accordance with the provisions of § 1.420 of the Commission's Rules and Regulations, an original and four copies of all comments, reply comments, pleadings, briefs, or other documents shall be furnished the Commission.

6. *Public Inspection of Filings.* All filings made in this proceeding will be available for examination by interested parties during regular business hours in the Commission's Public Reference Room at its headquarters, 1919 M Street NW., Washington, D.C.

[FR Doc. 83-31857 Filed 11-28-83; 8:45 am]

BILLING CODE 6712-01-M

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**47 CFR Part 73**

**[MM Docket No. 83-1232; RM-4569]**

## FM Broadcast Stations in Grass Valley and Chester, California; Proposed Changes in Table of Assignments

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** Action taken herein proposes the assignment of Class B FM Channel 256 to Grass Valley, California, as that community's second FM service, in response to a petition filed by Eric R. Hilding. Additionally, Channel 280A is proposed as a substitute for Class C Channel 255 at Chester, California, to accommodate the Grass Valley proposal.

**DATES:** Comments must be filed on or before January 9, 1984, and reply comments must be filed on or before January 24, 1984.

**ADDRESS:** Federal Communications Commission, Washington, D.C. 20554.

**FOR FURTHER INFORMATION CONTACT:** Nancy V. Joyner, Mass Media Bureau, (202) 634-6530

**List of Subjects in 47 CFR Part 73**

Radio broadcasting.

**Notice of Proposed Rule Making**

In the matter of amendment of § 73.202(b), Table of Assignments, FM Broadcast Stations. (Grass Valley and Chester, California); MM Docket No. 83-1232, RM-4569.

Adopted: November 2, 1983.

Released: November 17, 1983.

By the Chief, Policy and Rules Division.

1. Before the Commission for consideration is a petition for rule making filed by Eric R. Hilding ("petitioner"), requesting the assignment of Class B FM Channel 256 to Grass Valley, California, as that community's second FM assignment. Petitioner states that he will apply for the channel, if assigned.

2. In order to assign Class B Channel 256 to Grass Valley consistent with the minimum distance separation requirements, petitioner states it will require a substitution for Class C Channel 255 at Chester, California. Petitioner notes that even though the assignment of Channel 255 to Chester

occurred over eighteen months ago,[1] thus providing that community with its first local FM allocation, the channel has been unapplied for since then. As a result of a lack of interest in the Class C channel at Chester, petitioner requests that Channel 280A and/or Channel 285A be substituted for Channel 255 to accommodate his proposal.

3. Since Grass Valley and Chester are 76 miles apart, whereas a separation of 135 miles is required between a Class B channel and a first adjacement Class C allocation, we will propose the substitution of channels at Chester to accommodate the petitioner's proposal. Since Chester is a small isolated community, and no interest was shown in the Class C allocation, it is questionable whether a Class A channel, much less two, would be more or less likely to elicit interest. In any event, in order to maintain the provision of a first local FM service to Chester, we shall propose the substitution of Channel 280A for Class C Channel 255 at that community.

4. Each of the assignments proposed herein complies with the minimum distance separation requirements of Section 73.207 of the Commission's Rules.

**§ 73.202**

**[Amended]**

5. In view of the above, the Commission believes it is appropriate to solicit comments on the proposal to amend the FM Table of Assignments, § 73.202(b) of the Commission's Rules, as follows:

| City | Channel No. | |
|---|---|---|
| | Present | Proposed |
| Chester, Calif | 255 | 280A. |
| Grass Valley, Calif | 232A | 232A, 256. |

6. The Commission's authority to institute rule making proceedings, showings required, cut-off procedures, and filing requirements are contained in the attached Appendix and are incorporated by reference herein.

**Note.**—A showing of continuing interest is required by paragraph 2 of the Appendix before a channel will be assigned.

7. Interested parties may file comments on or before January 9, 1984, and reply comments on or before January 24, 1984, and are advised to read the Appendix for the proper procedures. A copy of such comments should be served on the petitioner, as follows: Eric R. Hilding, P.O. Box 1300, Freedom, CA 95019.

8. The Commission has determined that the relevant provisions of the Regulatory Flexibility Act of 1980 do not apply to rule making proceedings to amend the FM Table of Assignments, § 73.202(b) of the Commission's Rules. See, *Certification that Sections 603 and 604 of the Regulatory Flexibility Act Do Not Apply to Rule Making to Amend §§ 73.202(b), 73.504 and 73.606(b) of the Commission's Rules,* 46 FR 11549, published February 9, 1981.

9. For further information concerning this proceeding, contact Nancy V. Joyner, Mass Media Bureau, (202) 634-6530. However, members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel assignments. An *ex parte* contact is a message (spoken or written) concerning the merits of a pending rule making other than commens officially filed at the Commission or oral presentation required by the Commission. Any comment which has not been served on the petitioner constitutes an *ex parte* presentation and shall not be considered in the proceeding. Any reply comment which has not been served on the person(s) who filed the comment, to which the reply is directed, constitutes an *ex parte* presentation and shall not be considered in the proceeding.

Federal Communications Commission.

**Roderick K. Porter,**

*Chief, Policy and Rules Division Mass Media Bureau.*

## Appendix

1. Pursuant to authority found in Sections 4(i), 5(d)(1), 303 (g) and (r), and 307(b) of the Communications Act of 1934, as amended, and §§ 0.61, 0.204(b) and 0.283 of the Commission's Rules, it is proposed to amend the FM Table of Assignments, § 73.202(b) of the Commission's Rules and Regulations, as set forth in the Notice of Proposed Rule Making to which this Appendix is attached.

2. *Showings Required.* Comments are invited on the proposal(s) discussed in the Notice of Proposed Rule Making to which this Appendix is attached. Proponent(s) will be expected to answer whatever questions are presented in initial comments. The proponent of a proposed assignment is also expected to file comments even if it only resubmits or incorporates by reference its former pleadings. It should also restate its present intention to apply for the channel if it is assigned, and, if authorized, to build a station promptly. Failure to file may lead to denial of the request.

3. *Cut-off Procedures.* The following procedures will govern the consideration of filings in this proceeding.

(a) Counterproposals advanced in this proceeding itself will be considered, if advanced in initial comments, so that parties may comment on them in reply comments. They will not be considered if advanced in reply comments. (See § 1.420(d) of the Commission's Rules.)

(b) With respect to petitions for rule making which conflict with the proposal(s) in this Notice, they will be considered as comments in the proceeding, and Public Notice to this effect will be given as long as they are filed before the date for filing initial comments herein. If they are filed later than that, they will not be considered in connection with the decision in this docket.

(c) The filing of a conterproposal may lead the Commission to assign a different channel than was requested for any of the communities involved.

4. *Comments and Reply Comments; Service.* Pursuant to applicable procedures set out in §§ 1.415 and 1.420 of the Commission's Rules and Regulations, interested parties may file comments and reply comments on or before the dates set forth in the Notice of Proposed Rule Making to which this Appendix is attached. All submissions by parties to this proceeding or persons acting on behalf of such parties must be made in written comments, reply comments, or other appropriate pleadings. Comments shall be served on the petitioner by the person filing the comments. Reply comments shall be served on the person(s) who filed comments to which the reply is directed. Such comments and reply comments shall be accompanied by a certificate of service. (See § 1.420 (a), (b) and (c) of the Commission's Rules.)

5. *Number of Copies.* In accordance with the provisions of Section 1.420 of the Commission's Rules and Regulations, an original and four copies of all comments, reply comments, pleadings, briefs, or other documents shall be furnished the Commission.

6. *Public Inspection of Filings.* All filings made in this proceeding will be available for examination by interested parties during regular business hours in the Commission's Public Reference

[1] See, BC Docket No. 82-149, 47 FR 32541 (1982), published July 28, 1982.

Room at its headquarters, 1919 M Street, N.W., Washington, D.C.

[FR Doc. 31851 Filed 11-28-83; 8:45 am]
BILLING CODE 6712-01-M

## 47 CFR Part 73

**[MM Docket No. 83-1235; RM-4543]**

## Television Broadcast Station in Fort Walton, Florida; Proposed Changes in Table of Assignments

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** This action proposes the assignment of UHF television Channel 17 to Fort Walton Beach, Florida, as that community's third television service, in response to a petition filed by Fort Walton Beach Television, Inc.

**DATES:** Comments must be filed on or before January 9, 1984, and reply comments must be filed on or before January 24, 1984.

**ADDRESS:** Federal Communications Commission, Washington, D.C. 20554.

**FOR FURTHER INFORMATION CONTACT:** Mark N. Lipp, Mass Media Bureau, (202) 634-6530.

### List of Subjects in 47 CFR Part 73

Television broadcasting.

### Notice of Proposed Rule Making

In the matter of Amendment of § 73.606(b), Table of Assignments, Television Broadcast Stations. (Fort Walton Beach, Florida); MM Docket No. 83-1235, RM-4543.

Adopted: November 2, 1983.

Released: November 17, 1983.

By the Chief, Policy and Rules Division.

1. The Commission has under consideration a petition for rule making filed by Fort Walton Beach Television, Inc. ("petitioner"), proposing the assignment of UHF television Channel 17 to Fort Walton Beach, Florida, as that community's third television facility. Petitioner submitted information in support of the proposal and expressed its interest in applying for the channel, if assigned. The channel can be assigned in compliance with the minimum distance separation requirements and other criteria.

2. Fort Walton Beach (population 20,829),[1] in Okaloosa County (population 109,920), is located in the southwestern part of the Florida panhandle, approximately 210 kilometers (130 miles) south of Montgomery, Alabama.

[1] Population figures are taken from the 1980 U.S. Census, Advance Report.

**§ 73.606 [Amended]**

3. Based on the information provided by the petitioner, we believe that an adequate showing has been made to propose a third local television broadcast service to Fort Walton Beach, Florida. Comments are invited on the proposal to amend the Television Table of Assignments (Section 73.606(b) of the Rules) with regard to the following community:

| City | Channel No. | |
|---|---|---|
| | Present | Proposed |
| Fort Walton Beach, Fla | 35, 53 | 17-, 35, and 53. |

4. The Commission's authority to institute rule making proceedings, showings required, cut-off procedures, and filing requirements are contained in the attached Appendix and are incorporated by reference herein.

**Note.**—A showing of continuing interest is required by paragraph 2 of the Appendix before a channel will be assigned.

5. Interested parties may file comments on or before January 9, 1984, and reply comments on or before January 24, 1984, and are advised to read the Appendix for the proper procedures. Additionally, a copy of such comments should be served on the petitioners, or their counsel, or consultant, as follows:

Walton Beach Television, Inc., P.O. Box 777, Marianna, FL 32446, (Petitioner)

and

Edward M. Johnson & Associates, Inc., One Regency Square, Suite 450, Knoxville, TN 37915, (Consultant to Petitioner)

6. The Commission has determined that the relevant provisions of the Regulatory Flexibility Act of 1980 do not apply to rule making proceedings to amend the TV Table of Assignments, § 73.606(b) of the Commission's Rules. See, *Certification that Sections 603 and 604 of the Regulatory Flexibility Act Do Not Apply to Rule Making To Amend §§ 73.202(b), 73.504 and 73.606(b) of the Commission's Rules,* 46 FR 11549, published February 9, 1981.

7. For further information concerning this proceeding, contact Mark N. Lipp, Mass Media Bureau, (202) 634-6530. However, members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel assignments. An *ex parte* contact is a message (spoken or written) concerning the merits of a pending rule making other than comments officially filed at the Commission or oral presentation required by the Commission. Any comment which has not been served on the petitioner constitutes an *ex parte* presentation and shall not be considered in the proceeding. Any reply comment which has not been served on the person(s) who filed the comment, to which the reply is directed, constitutes an *ex parte* presentation and shall not be considered in the proceeding.

Federal Communications Commission.

**Roderick K. Porter,**

*Chief, Policy and Rules Division, Mass Media Bureau.*

### Appendix

1. Pursuant to authority found in Sections 4(i), 5(d)(1), 303 (g) and (r), and 307(b) of the Communications Act of 1934, as amended, and §§ 0.61, 0.204(b) and 0.283 of the Commission's Rules, it is proposed to amend the TV Table of Assignments, § 73.606(b) of the Commission's Rules and Regulations, as set forth in the Notice of Proposed Rule Making to which this Appendix is attached.

2. *Showings Required.* Comments are invited on the proposal(s) discussed in the Notice of Proposed Rule Making to which this Appendix is attached. Proponent(s) will be expected to answer whatever questions are presented in initial comments. The proponent of a proposed assignment is also expected to file comments even if it only resubmits or incorporates by reference its former pleadings. It should also restate its present intention to apply for the channel if it is assigned, and, if authorized, to build a station promptly. Failure to file may lead to denial of the request.

3. *Cut-off Procedures.* The following procedures will govern the consideration of filings in this proceeding.

(a) Counterproposals advanced in this proceeding itself will be considered, if advanced in initial comments, so that parties may comment on them in reply comments. They will not be considered if advanced in reply comments. (See Section 1.420(d) of the Commission's Rules.)

(b) With respect to petitions for rule making which conflict with the proposal(s) in this Notice, they will be considered as comments in the proceeding, and Public Notice to this effect will be given as long as they are filed before the date for filing initial comments herein. If they are filed later

than that, they will not be considered in connection with the decision in this docket.

(c) The filing of a counterproposal may lead the Commission to assign a different channel than was requested for any of the communities involved.

4. *Comments and Reply Comments; Service.* Pursuant to applicable procedures set out in §§ 1.415 and 1.420 of the Commission's Rules and Regulations, interested parties may file comments and reply comments on or before the dates set forth in the Notice of Proposed Rule Making to which this Apendix is attached. All submissions by parties to this proceeding or persons acting on behalf of such parties must be made in written comments, reply comments, or other appropriate pleadings. Comments shall be served on the petitioner by the person filing the comments. Reply comments shall be served on the person(s) who filed comments to which the reply is directed. Such comments and reply comments shall be accompanied by a certificate of service. (See Section 1.420 (a), (b) and (c) of the Commission's Rules.)

5. *Number of Copies.* In accordance with the provisions of Section 1.420 of the Commission's Rules and Regulations, an original and four copies of all comments, reply comments, pleadings, briefs, or other documents shall be furnished the Commission.

6. *Public Inspection of Filings.* All filings made in this proceeding will be available for examination by interested parties during regular business hours in the Commission's Public Reference Room at its headquarters, 1919 M Street, NW., Washington, D.C.

[FR Doc. 83-31854 Filed 11-28-83; 8:45 am]

BILLING CODE 6712-01-M

## 47 CFR Part 73

**[MM Docket No. 83-1233; RM-4542]**

## FM Broadcast Station in Bloomfield, New Mexico; Proposed Changes in Table of Assignments

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** Action taken herein proposes the assignment of Class C FM Channel 283 to Bloomfield, New Mexico, as that community's first FM assignment, in response to a petition filed by KBRY, Inc.

**DATES:** Comments must be filed on or before January 9, 1984, and reply comments must be filed on or before January 24, 1984.

**ADDRESS:** Federal Communications Commission, Washington, D.C. 20554.

**FOR FURTHER INFORMATION CONTACT:** Mark N. Lipp, Mass Media Bureau, (202) 634-6530.

### List of Subjects in 47 CFR Part 73

Radio broadcasting.

### Notice of Proposed Rule Making

In the matter of amendment of § 73.202(b), Table of Assignments, FM Broadcast Stations (Bloomfield, N. Mex.); MM Docket No. 83-1233, RM-4542.

Adopted: November 2, 1983.
Released: November 17, 1983.

By the Chief, Policy and Rules Division.

1. The Commission has under consideration a petition for rule making filed by KBRY, Inc. ("petitioner"), proposing the assignment of Class C Channel 283 to Bloomfield, N. Mex., as that community's first FM service. Petitioner submitted information in support of the proposal and expressed its interest in filing for the channel, if assigned. The channel can be assigned in compliance with the minimum distance separation requirements.

**§ 73.202 [Amended]**

2. In view of the fact that this assignment could provide a first service to Bloomfield, N. Mex., the Commission believes it is appropriate to invite comments on the proposal to amend the FM Table of Assignments (Section 73.202(b) of the Commission's Rules) with respect to the following community:

| City | Channel No. | |
|---|---|---|
| | Present | Proposed |
| Bloomfield, N. Mex. | | 283 |

3. The Commission's authority to institute rule making proceedings, showings required, cut-off procedures, and filing requirements are contained in the attached Appendix and are incorporated by reference herein.

Note.—A showing of continuing interest is required by paragraph 2 of the Appendix before a channel will be assigned.

4. Interested parties may file comments on or before January 9, 1984, and reply comments on or before January 24, 1984, and are advised to read the Appendix for the proper procedures. A copy of such comments should be served on the petitioner's counsel, as follows: Vincent J. Curtis, Jr., Esq., Fletcher, Heald and Hildreth, 1225 Connecticut Avenue, N.W., Suite 400, Washington, D.C. 20036.

5. The Commission has determined that the relevant provisions of the Regulatory Flexibility Act of 1980 do not apply to rule making proceedings to amend the FM Table of Assignments, § 73.202(b) of the Commission's Rules. See, *Certification that Sections 603 and 604 of the Regulatory Flexibility Act Do No Apply to Rule Making to Amend §§ 73.202(b), 73.504 and 73.606(b) of the Commission's Rules,* 46 FR 11549, published February 9, 1981.

6. For further information concerning this proceeding, contact Mark N. Lipp, Mass Media Bureau, (202) 634-6530. However, members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel assignments. An *ex parte* contact is a message (spoken or written) concerning the merits of a pending rule making other than comments officially filed at the Commission or oral presentation required by the Commission. Any comment which has not been served on the petitioner constitutes an *ex parte* presentation and shall not be considered in the proceeding. Any reply comment which has not been served on the person(s) who filed the comment, to which the reply is directed, constitutes an *ex parte* presentation and shall not be considered in the proceeding.

Federal Communications Commission.

**Roderick K. Porter,**

*Chief, Policy and Rules Division, Mass Media Bureau.*

### Appendix

1. Pursuant to authority found in Sections 4(i), 5(d)(1), 303 (g) and (r), and 307(b) of the Communications Act of 1934, as amended, and §§ 0.61, 0.204(b) and 0.283 of the Commission's Rules, it is proposed to amend the FM Table of Assignments, § 73.202(b) of the Commission's Rules and Regulations, as set forth in the Notice of Proposed Rule Making to which this Appendix is attached.

2. *Showings Required.* Comments are invited on the proposal(s) discussed in the Notice of Proposed Rule Making to which this Appendix is attached. Proponent(s) will be expected to answer whatever questions are presented in initial comments. The proponent of a proposed assignment is also expected to file comments even if it only resubmits or incorporates by reference its former pleadings. It should also restate its present intention to apply for the channel if it is assigned, and, if authorized, to build a station promptly.

Failure to file may lead to denial of the request.

3. *Cut-Off Procedures.* The following procedures will govern the consideration of filings in this proceeding.

(a) Counterproposals advanced in this proceeding itself will be considered, if advanced in initial comments, so that parties may comment on them in reply comments. They will not be considered if advanced in reply comments. (See Section 1.420(d) of the Commission's Rules.)

(b) With respect to petitions for rulemaking which conflict with the proposal(s) in this Notice, they will be considered as comments in the proceeding, and Public Notice to this effect will be given as long as they are filed before the date for filing initial comments herein. If they are filed later than that, they will not be considered in connection with the decision in this docket.

(c) The filing of a counterproposal may lead the Commission to assign a different channel than was requested for any of the communities involved.

4. *Comments and Reply Comments; Service.* Pursuant to applicable procedures set out in §§ 1.415 and 1.420 of the Commission's Rules and Regulations, interested parties may file comments and reply comments on or before the dates set forth in the Notice of Proposed Rule Making to which this Appendix is attached. All submissions by parties to this proceeding or persons acting on behalf of such parties must be made in written comments, reply comments, or other appropriate pleadings. Comments shall be served on the petitioner by the person filing the comments. Reply comments shall be served on the person(s) who filed comments to which the reply is directed. Such comments and reply comments shall be accompanied by a certificate of service. (See § 1.420 (a), (b) and (c) of the Commission's Rules.)

5. *Number of Copies.* In accordance with the provisions of § 1.420 of the Commission's Rules and Regulations, an original and four copies of all comments, reply comments, pleadings, briefs, or other documents shall be furnished the Commission.

6. *Public Inspection of Filings.* All filings made in this proceeding will be available for examination by interested parties during regular business hours in the Commission's Public Reference Room at its headquarters, 1919 M Street NW., Washington, D.C.

[FR Doc. 83-31852 Filed 11-28-83; 8:45 am]
BILLING CODE 6712-01-M

**47 CFR Part 73**

**[MM Docket No. 83-1234; RM-4533]**

## Television Broadcast in Chippewa Falls, Wisconsin; Proposed Changes in Table of Assignments

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** Action taken herein proposes the assignment of UHF television Channel 48 to Chippewa Falls, Wisconsin, as that community's first television facility, in response to a petition filed by Bushland Radio Specialties.

**DATES:** Comments must be filed on or before January 9, 1984, and reply comments must be filed on or before January 24, 1984.

**ADDRESS:** Federal Communications Commission, Washington, D.C. 20554.

**FOR FURTHER INFORMATION CONTACT:** Mark N. Lipp, Mass Media Bureau (202) 634-6530.

### List of Subjects in 47 CFR Part 73

Television broadcasting.

### Notice of Proposed Rule Making

In the matter of Amendment of § 73.606(b), Table of Assignments, Television Broadcast Stations. (Chippewa Falls, Wisconsin); MM Docket No. 83-1234, RM-4533.

Adopted: November 2, 1983.
Released: November 17, 1983.
By the Chief, Policy and Rules Division.

1. The Commission herein considers a petition for rule making filed by Bushland Radio Specialties ("petitioner") proposing the assignment of UHF televison Channel 48 to Chippewa Falls, Wisconsin, as that community's first television facility. The petitioner submitted information in support of the proposal and expressed its interest in applying for the channel, if assigned.

2. Chippewa Falls (population 11,845),[1] seat of Chippewa County (population 51,702), is located in west central Wisconsin, approximately 135 kilometers (85 miles) east of Minneapolis, Minnesota.

3. Since the proposed assignment of UHF televison Channel 48 to Chippewa Falls, Wisconsin, is within 400 kilometers (250 miles) of the U.S.-Canadian border, Canadian concurrence must be obtained .

**§ 73.606 [Amended]**

4. Based on the information submitted by petitioner, we believe that an adequate showing has been made to propose a first local television broadcast service to Chippewa Falls. Comments are invited on the proposal to amend the Television Table of Assignments (Section 73.606(b) of the Commission's Rules) with respect to the following city:

| City | Channel No. | |
|---|---|---|
| | Present | Proposed |
| Chippewa Falls, Wis. | | 48 |

5. The Commission's authority to institute rule making proceedings, showings required, cut-off procedures, and filing requirements are contained in the attached Appendix and are incorporated by reference herein.

**Note.**—A showing of continuing interest is required by paragraph 2 of the Appendix before a channel will be assigned.

6. Interested parties may file comments on or before January 9, 1984, and reply comments on or before January 24, 1984, and are advised to read the Appendix for the proper procedures. Additionally, a copy of such comments should be served on the petitioners, or their counsel, or consultant, as follows: Edward M. Johnson and Associates, One Regency Square, #450, Knoxville, TN 37915, (Consultant to Bushland Radio Specialties).

7. The Commission has determined that the relevant provisions of the Regulatory Flexibility Act of 1980 do not apply to rule making proceedings to amend the TV Table of Assignments, § 73.606(b) of the Commission's Rules. See, *Certification that Sections 603 and 604 of the Regulatory Flexibility Act Do Not Apply to Rule Making to Amend §§ 73.202(b), and 73.504 and 73.606(b) of the Commission's Rules,* 46 FR 11549, published February 9, 1981.

8. For further information concerning this proceeding, contact Mark N. Lipp, Mass Media Bureau, (202) 634-6530. However, members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration, or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel assignments. An *ex parte* contact is a message (spoken or written) concerning the merits of a pending rule making, other than comments officially filed at the Commission, or oral presentation required by the Commission. Any comment which has not been served on the petitioner constitutes an *ex parte* presentation and shall not be considered

[1] Population figures are taken from the 1980 U.S. Census, Advance Reports.

in the proceeding. Any reply comment which has not been served on the person(s) who filed the comment, to which the reply is directed, constitutes an *ex parte* presentation and shall not be considered in the proceeding.

Federal Communications Commission.

**Roderick K. Porter,**

*Chief, Policy and Rules Division, Mass Media Bureau.*

## Appendix

1. Pursuant to authority found in Sections 4(i), 5(d)(1), 303 (g) and (r), and 307(b) of the Communications Act of 1934, as amended, and §§ 0.61, 0.204(b) and 0.283 of the Commission's Rules, it is proposed to amend the TV Table of Assignments, § 73.606(b) of the Commission's Rules and Regulations, as set forth in the Notice of Proposed Rule Making to which this Appendix is attached.

2. *Showings Required.* Comments are invited on the proposal(s) discussed in the Notice of Proposed Rule Making to which this Appendix is attached. Proponent(s) will be expected to answer whatever questions are presented in initial comments. The proponent of a proposed assignment is also expected to file comments even if it only resubmits or incorporates by reference its former pleadings. It should also restate its present intention to apply for the channel if it is assigned, and, if authorized, to build a station promptly. Failure to file may lead to denial of the request.

3. *Cut-off Procedures.* The following procedures will govern the consideration of filings in this proceeding.

(a) Counterproposals advanced in this proceeding itself will be considered, if advanced in initial comments, so that parties may comment on them in reply comments. They will not be considered if advanced in reply comments. (See § 1.420(d) of the Commission's Rules.)

(b) With respect to petitions for rule making which conflict with the proposal(s) in this Notice, they will be considered as comments in the proceeding, and Public Notice to this effect will be given as long as they are filed before the date for filing initial comments herein. If they are filed later than that, they will not be considered in connection with the decision in this docket.

(c) The filing of a counterproposal may lead the Commission to assign a different channel than was requested for any of the communities involved.

4. *Comments and Reply Comments; Service.* Pursuant to applicable procedures set out in §§ 1.415 and 1.420 of the Commission's Rules and Regulations, interested parties may file comments and reply comments on or before the dates set forth in the Notice of Proposed Rule Making to which this Appendix is attached. All submissions by parties to this proceeding or persons acting on behalf of such parties must be made in written comments, reply comments, or other appropriate pleadings. Comments shall be served on the petitioner by the person filing the comments. Reply comments shall be served on the person(s) who filed comments to which the reply is directed. Such comments and reply comments shall be accompanied by a certificate of service. (See § 1.420 (a), (b) and (c) of the Commission's Rules.)

5. *Number of Copies.* In accordance with the provisions of § 1.420 of the Commission's Rules and Regulations, an original and four copies of all comments, reply comments, pleadings, briefs, or other documents shall be furnished the Commission.

6. *Public Inspection of Filings.* All filings made in this proceeding will be available for examination by interested parties during regular business hours in the Commission's Public Reference Room at its headquarters, 1919 M Street, NW., Washington, D.C.

[FR Doc. 83-31853 Filed 11-28-83; 8:45 am]

BILLING CODE 6712-01-M

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**47 CFR Part 73**

**[MM Docket No. 83-1237; RM-4544]**

## Television Broadcast Station in Newton, Iowa; Proposed Changes in Table of Assignments

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** This action proposes the assignment of UHF television Channel 39 to Newton, Iowa, as that community's first television facility in response to a petition filed by IPBC, Inc.

**DATES:** Comments must be filed on or before January 9, 1984, and reply comments must be filed on or before January 24, 1984.

**ADDRESS:** Federal Communications Commission, Washington, D.C. 20554.

**FOR FURTHER INFORMATION CONTACT:** Mark N. Lipp, Mass Media Bureau, (202) 634-6530.

### List of Subjects in 47 CFR Part 73

Television broadcasting.

### Notice of Proposed Rulemaking

In the matter of amendment of § 73.606(b), Table of Assignments, Television Broadcast Stations. (Newton, Iowa) (MM Docket No. 83-1237, Rm-4544).

Adopted: November 2, 1983.

Released: November 17, 1983.

By the Chief, Policy and Rules Division.

1. The Commission has under consideration a petition for rule making filed by IPBC, Inc. ("petitioner"), proposing the assignment of UHF television Channel 39 to Newton, Iowa, as that community's first television facility. Petitioner submitted information in support of the proposal and expressed its interest in applying for the channel, if assigned. The channel can be assigned in compliance with the minimum distance separation requirements and other criteria.

2. Newton (population 15,292),[1] seat of Jasper County (population 36,425), is located in central Iowa, approximately 50 kilometers (30 miles) east of Des Moines, Iowa.

**§ 76.606 [Amended]**

3. Based on the information submitted by petitioner, we believe that an adequate showing has been made to support proposing the assignment of a first local television broadcast service to Newton, Iowa. Comments are invited on the proposal to amend the Television Table of Assignments (Section 73.606(b) of the Commission's Rules) with respect to the following community:

| City | Channel No. | |
|---|---|---|
| | Present | Proposed |
| Newton, Iowa | | 39+ |

4. The Commission's authority to institute rule making proceedings, showings required, cut-off procedures, and filing requirements are contained in the attached Appendix and are incorporated by reference herein.

**Note.**—A showing of continuing interest is required by paragraph 2 of the Appendix before a channel will be assigned.

5. Interested parties may file comments on or before January 9, 1984, and reply comments on or before January 24, 1984, and are advised to read the Appendix for the proper procedures. Additionally, a copy of such comments should be served on the petitioners, or their counsel, or consultant, as follows: Dominic Monahan, Esq., Dow, Lohnes and Albertson, 1225 Connecticut Ave., N.W.,

[1] Population figures are taken from the 1980 U.S. Census, Advance Report.

Suite 500, Washington, D.C. 20036 (Counsel for petitioner).

6. The Commission has determined that the relevant provisions of the Regulatory Flexibility Act of 1980 do not apply to rule making proceedings to amend the TV Table of Assignments, § 73.606(b) of the Commission's Rules. See, *Certification that Sections 603 and 604 of the Regulatory Flexibility Act Do Not Apply to Rule Making to Amend Sections 73.202(b), 73.504 and 73.606(b) of the Commission's Rules,* 46 Fed. Reg. 11549, published February 9, 1984.

7. For further information concerning this proceeding, contact Mark N. Lipp, Mass Media Bureau, (202) 634–6530. However, members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel assignments. An *ex parte* contact is a message (spoken or written) concerning the merits of a pending rule making other than comments officially filed at the Commission or oral presentation required by the Commission. Any comment which has not been served on the petitioner constitutes an *ex parte* presentation and shall not be considered in the proceeding. Any reply comment which has not been served on the person(s) who filed the comment, to which the reply is directed, constitutes an *ex parte* presentation and shall not be considered in the proceeding.

Federal Communications Commission.

**Roderick K. Porter,**

*Chief, Policy and Rules Division, Mass Media Bureau.*

## Appendix

1. Pursuant to authority found in Sections 4(i), 5(d)(1), 303(g) and (r), and 307(b) of the Communications Act of 1934, as amended, and §§ 0.61, 0.204(b) and 0.283 of the Commission's Rules, it is proposed to amend the TV Table of Assignments, § 73.606(b) of the Commission's Rules and Regulations, as set forth in the Notice of Proposed Rule Making to which this Appendix is attached.

2. *Showings Required.* Comments are invited on the proposal(s) discussed in the Notice of Proposed Rule Making to which this Appendix is attached. Proponent(s) will be expected to answer whatever questions are presented in initial comments. The proponent of a proposed assignment is also expected to file comments even if it only resubmits or incorporates by reference its former pleadings. It should also restate its present intention to apply for the channel if it is assigned, and, if authorized, to build a sation promptly. Failure to file may lead to denial of the request.

3. *Cut-off Procedures.* The following procedures will govern the consideration of filings in this proceeding.

(a) Counterproposals advanced in this proceeding itself will be considered, if advanced in initial comments, so that parties may comment on them in reply comments. They will not be considered if advanced in reply comments. (See Section 1.420(d) of the Commission's Rules.)

(b) With respect to petitions for rule making which conflict with the proposal(s) in this *Notice*, they will be considered as comments in the proceeding, and Public Notice to this effect will be given as long as they are filed before the date for filing initial comments herein. If they are filed later than that, they will not be considered in connection with the decision in this docket.

(c) The filing of a counterproposal may lead the Commission to assign a different channel than was requested for any of the communities involved.

4. *Comments and Reply Comments; Service.* Pursuant to applicable producres set our in §§ 1.415 and 1.420 of the Commission's Rules and Regulations, interested parties may file comments and reply comments on or before the dates set forth in the Notice of Proposed Rule Making to which this Appendix is attached. All submissions by parties to this proceeding or persons acting on behalf of such parties must be made in written comments, reply comments, or other appropriate pleadings. Comments shall be served on the petitioner by the person filing the comments. Reply comments shall be served on the person(s) who filed comments to which the reply is directed. Such comments and reply comments shall be accompanied by a certificate of service. (See § 1.420 (a), (b) and (c) of the Commission's Rules.)

5. *Number of Copies.* In accordance with the provisions of Section 1.420 of the Commission's Rules and Regulations, an original and four copies of all comments, reply comments, pleadings, briefs, or other documents shall be furnished the Commission.

6. *Public Inspection of Filings.* All filings made in this proceeding will be available for examination by interested parties during regular business hours in the Commission's Public Reference Room at its headquarters, 1919 M Street, N.W., Washington, D.C.

[FR Doc. 83–31835 Filed 11–28–83; 8:45 am]

BILLING CODE 6712–01–M

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**47 CFR Part 73**

**[MM Docket No. 83–1231; RM–4541]**

## FM Broadcast Station in Camden, Arkansas; Proposed Changes in Table of Assignments

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** This action proposes to assign Channel 237A to Camden, Arkansas as its second FM service in response to a petition filed by Gary D. Terrell.

**DATES:** Comments must be filed on or before January 9, 1984, and reply comments must be filed on or before January 24, 1984.

**ADDRESS:** Federal Communications Commission, Washington, D.C. 20554.

**FOR FURTHER INFORMATION CONTACT:** Mark N. Lipp, Mass Media Bureau, (202) 634–6530.

**List of Subjects in 47 CFR Part 73**

Radio broadcasting.

**Notice of Proposed Rulemaking**

In the matter of amendment of § 73.202(b), Table of Assignments, FM Broadcast Stations, (Camden, Arkansas) (MM Docket No. 83–1231; RM–4541).

Adopted: October 31, 1983.

Released: November 17, 1983.

By the Chief, Policy and Rules Division.

1. The Commission has before it a petition for rulemaking filed June 28, 1983, by Gary D. Terrell ("petitioner"), proposing the assignment of Channel 237A to Camden, Arkansas, as that community's second FM service. Petitioner submitted information in support of the proposal and expressed his interest in applying for the channel, if assigned. A site restriction of 5.7 miles south of Camden is required to avoid short-spacing to FM Station KJKK (Channel 237A), Murfreesboro, Arkansas, and Station KADL–FM (Channel 235), Pine Bluff, Arkansas.

**§ 73.202 [Amended]**

2. In view of the fact that the proposed assignment could provide a second local FM broadcast service to Camden, Arkansas, the Commission believes it is appropriate to propose amending the FM Table of Assignments (Section 73.202(b) of the Commission's Rules) with respect to the following community:

| City | Channel No. | |
|---|---|---|
| | Present | Proposed |
| Camden, Arkansas | 246 | 237A, and 246. |

3. The Commission's authority to institute rulemaking proceedings, showings required, cut-off procedures, and filing requirements are contained in the attached Appendix and are incorporated by reference herein.

Note.—A showing of continuing interest is required by paragraph 2 of the Appendix before a channel will be assigned.

4. Interested parties may file comments on or before January 9, 1984, and reply comments on or before January 24, 1984, and are advised to read the Appendix for the proper procedures. Additionally, a copy of such comments should be served on the petitioner, through his consultant, as follows: Edward M. Johnson and Associates, Inc., One Regency Square, Suite 450, Knoxville, TN 37915.

5. The Commission has determined that the relevant provisons of the Regulatory Flexibility Act of 1980 do not apply to rule making proceedings to amend the FM Table of Assignments, § 73.202(b) of the Commission's Rules. See, *Certification that Sections 603 and 604 of the Regulatory Flexibility Act Do Not Apply to Rule Making to Amend §§ 73.202(b), 73.504 and 73.606(b) of the Commission's Rules,* 46 FR 11549, published February 9, 1981.

6. For further information concerning this proceeding contact Mark N. Lipp, Mass Media Bureau, (202) 634–6530. However, members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration of court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel assignments. An *ex parte* contact is a message (spoken or written) concerning the merits of a pending rule making other than comments officially filed at the Commisssion or oral presentation required by the Commission. Any comment which has not been served on the petitioner constitutes and *ex parte* presentation and shall not be considered in the proceeding. Any reply comment which has not been served on the person(s) who filed the comment, to which the reply is directed, constitutes and *ex parte* presentation and shall not be considered in the proceeding.

Federal Communications Commission.

**Roderick K. Porter,**

*Chief, Policy and Rules Division, Mass Media Bureau.*

## Appendix

1. Pursuant to authority found in sections 4(i), 5(d)(l), 303(g) and (r), and 307(b) of the Communications Act of 1934, as amended, and §§ 0.61, 0.024(b) and 0.283 of the Commission's rules, it is proposed to amend the FM Table of Assignments, § 73.202(b) of the Commission's Rules and Regulations, as set forth in the *Notice of Proposed Rule Making* to which this Appendix is attached.

2. *Showings Required.* Comments are invited on the proposal(s) discussed in the *Notice of Proposed Rule Making* to which this Appendix is attached. Proponent(s) will be expected to answer whatever questions are presented in initial comments. The proponent of a proposed assignment is also expected to file comments even if it only resubmits or incorporates by reference its former pleadings. It should also restate its present intention to apply for the channel if it is assigned, and, if authorized, to build a station promptly. Failure to file may lead to denial of the request.

3. *Cut-off Procedures.* The following procedures will govern the consideration of filings in this proceeding.

(a) Counterproposals advanced in this proceeding itself will be considered, if advanced in initial comments, so that parties may comment on them in reply comments. They will not be considered if advanced in reply comments. (See Section 1.420(d) of the Commission's Rules.)

(b) With respect to petitions for rule making which conflict with the proposal(s) in this *Notice,* they will be considered as comments in the proceeding, and Public Notice to this effect will be given as long as they are filed before the date for filing initial comments herein. If they are filed later than that, they will not be considered in connection with the decision in this docket.

(c) The filing of a counterproposal may led the Commission to assign a different channel than was requested for any of the communities involved.

4. *Comments and Reply Comments; Service.* Pursuant to applicable procedures set out in §§ 1.415 and 1.420 of the Commission's rules and regulations, interested parties may file comments and reply comments or before the dates set foth in the *Notice of Proposed Rule Making* to which this Appendix is attached. All submissions by parties to this proceeding or persons acting on behalf of such parties must be made in written comments, reply comments, or other appropriate pleadings. Comments shall be served on the petitioner by the person filing the comments. Reply comments shall be served on the person(s) who filed comments to which the reply is directed. Such comments and reply comments shall be accompanied by a certificate of service. (See § 1.420 (a), (b) and (c) of the Commission's Rules.)

5. *Number of Copies.* In accordance with the provisions of § 1.420 of the Commission's Rules and Regulations, an original and for copies of all comments, reply comments, pleadings, briefs, or other documents shall be furnished the Commission.

6. *Public Inspection of Filings.* All filings made in this proceeding will be available for examination by interested parties during regular business hours in the Commission's Pubic Reference Room at its headquarters, 1919 M Street, N.W., Washington, D.C.

[FR Doc. 83–31855 Filed 11–28–83; 8:45 am]

BILLING CODE 6712–01–M

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

### 50 CFR Part 17

### Proposed Endangered Status for Seven Birds and Two Mammals From the Mariana Islands

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Proposed rule.

**SUMMARY:** The Service proposed to determine seven birds, *Halcyon cinnamomina cinnamomina* (Micronesian kingfisher), *Myiagra freycineti* (Guam broadbill or *chuguanguang*), *Zosterops conspicillata conspicillata* (bridled white-eye or *nossa*), *Gallinula chloropus guami* (Mariana gallinule or *pulattat*), *Aerodramus vanikorensis bartschi* (Vanikoro swiftlet or *yayahuak*), *Rallus owstoni* (Guam rail or *koko*), *Corvus kubaryi* (Mariana crow or *aga*), and two mammals, the Guam population of *Pteropus mariannus mariannus* (Mariana fruit bat or *fanihi*) and *Pteropus tokudae* (little Mariana fruit bat), to be Endangered species under the authority contained in the Endangered Species Act of 1973, as amended. Two political entitles are involved: the Territory of Guam and the Commonwealth of the Northern Mariane Islands. A determination that these nine

Mariana Island taxa are Endangered would implement the protection provided by the Endangered Species Act of 1973, as amended. The Service seeks data and comments from the public on this proposal.

**DATES:** Comments from the public must be received on or before February 27, 1984. Public hearing requests must be received by January 13, 1984.

**ADDRESSES:** Interested persons or organizations are requested to submit comments or materials to the Regional Director, U.S. Fish and Wildlife Service, 500 N.E. Multnomah Street, Portland, Oregon 97232. Comments and material relating to this proposal are available for public inspection by appointment during normal business hours at the Service's Office of Environmental Services, 300 Ala Moana Boulevard., Room 6307, Honolulu, Hawaii 96850.

**FOR FURTHER INFORMATION CONTACT:** Mr. Sanford Wilbur, Chief, Division of Endangered Species, U.S. Fish and Wildlife Service, 500 N.E. Multnomah Street, Portland, Oregon 97232 (503/231-6131).

**SUPPLEMENTARY INFORMATION:**

## Background

The Service has received two petitions from the Government of Guam to list certain species from that island as Endangered species. The first of these petitions was sent on August 28, 1978, by the Honorable Ricardo J. Bordallo, Governor of Guam, requesting that the Service list the following species: Mariana fruit dove (*Ptilinopus roseicapillus*), Mariana gallinule (*Gallinula chloropus guami*), Guam rail (*Rallus owstoni*), Vanikoro Swiftlet (*Aerodramus vanikorensis bartschi*), Mariana fruit bat (*Pteropus mariannus mariannus*), and the little Mariana fruit bat (*Pteropus tokudae*). The second petition was sent by the Honorable Joseph E. Ada, then Acting Governor of Guam, on February 27, 1979. It petitioned the Service to list the Micronesian kingfisher (*Halcyon cinnamomina cinnamomina*); Micronesian broadbill (*Myiagra oceanica freycineti*), now known as Guam broadbill (*Myiagra freycineti*); White-throated ground dove (*Gallicolumba xanthonura xanthonura*); Cardinal honey-eater (*Myzomela cardinalis saffordi*); Mariana crow (*Corvus kubaryi*); and Bridled white-eye (*Zosterops conspicillata conspicillata*).

Subsequently, on May 18, 1979, the Service published a Notice of Review of Status in the **Federal Register** (44 FR 29128-30) requesting information on any of the 12 species under consideration concerning their status, distribution, population trends, critical habitat, or other pertinent data. The Service now has sufficient information to warrant proposing seven birds as endangered throughout their entire range: the Micronesian kingfisher, the Guam rail, Mariana crow, bridled white-eye, Vanikoro swiftlet, Mariana gallinule and the Guam broadbill. The little Mariana fruit bat and the Guam population of the Mariana fruit bat also are being proposed as Endangered. Additional information will be required before the status of the Mariana fruit bat can be assessed as Endangered or Threatened throughout its entire range.

## Summary of Status of Each Species

Guam broadbill (*Myiagra freycineti*). This species is endemic to Guam, the southern-most island of the Mariana group. It formerly occurred over all forested areas of Guam. Although it was probably never abundant, it has suffered a severe decline in recent years. By the early 1970's it was entirely absent from the southern two thirds of the island. It presently has an extremely restricted range and small population. The 1983 census data indicate the population numbers less than 100 birds. This population is apparently restricted to an area of about 150 acres in the Pajon Basin at Ritidian Point, at the north end of the island.

Micronesian kingfisher (*Halcyon cinnamomina cinnamomina*). This subspecies is endemic to Guam. It formerly occurred in forest and forest edge throughout the island. It was considered common as recently as 1945, but subsequently declined drastically as much of its native limestone forest was destroyed. As many as 3,000 individuals may still survive, but the subspecies is restricted to only a fourth of its original range, and the latest surveys indicate that the decline is continuing.

Bridled white-eye (*Zosterops conspicillata conspicillata*). This subspecies is endemic to Guam. It was formerly distributed island-wide. Few were known from the southern end of the island by the 1940's and by 1961 white-eyes were believed extirpated from both south and central Guam. The population has continued this decline and recent surveys indicate an accelerate drop in numbers. Recent observations (January 1983 indicate this bird is now confined to the Pajon Basin (about 150 hectares), represented by less than 50 individuals.

Mariana gallinule (*Gallinula chloropus guami*). This subspecies of the common gallinule was historically distributed in the wetlands of Guam, Saipan, Tinian, and Pagan of the Mariana Islands. Historical populations were more numerous and widely distributed than what exists today. significant loss of suitable freshwater wetlands has reduced populations on Guam to between about 100 and 200 birds. Populations on Tinian, Saipan, and Pagan are apparently stable but very restricted. Avian disease and environmental contaminants may also be playing a role in these observed declines.

Vanikoro Swiftlet (*Aerodramus vanikorensis bartschi*). This subspecies was historically found on Guam, Rota, Agiguan, Tinian, and Saipan of the southern Mariana Islands. It is currently known to occur on Guam, Agiguan, and Saipan. It is one of Guam's most Endangered birds. As few as 50 individuals are thought to remain on Guam. The Rota and Tinian populations have apparently disappeared in the last few years. A small and declining number of birds are found on Saipan and a small population on Agiguan appears to be stable.

Guam rail (*Rallus Owstoni*). The Guam rail is endemic to Guam. It was formerly distributed over all of Guam in grasslands and forest habitats. It is now distributed in several small discontinuous populations in extreme northern Guam. It has apparently undergone a significant decline in numbers and range in recent years. Recent estimates (1983) suggest there are fewer than 100 birds remaining.

Mariana crow (*Corvus kubaryi*). This species is endemic to Guam and Rota of the extreme southern end of the Mariana Islands. It was historically distributed island-wide on Guam and Rota. The crow disappeared from southern Guam in the mid 1960's and from central Guam in the early 1970's. Its population on Guam is now estimated to number 150 to 200 birds, confined to the northern part of the island. On Rota, the crow is uncommon though it apparently has not suffered a population decline as on Guam. Preliminary results from 1982 Fish and Wildlife Service surveys indicate a population of 1,300 birds on Rota.

Mariana fruit bat (*Pteropus mariannus mariannus*). This subspecies is historically known from Guam, Rota, Agiguan, Tinian, and Saipan. Fruit bats recorded from north of Saipan are thought to be the subspecies *paganensis*. It still occurs on all islands of its historical range but, it is now restricted on Guam to mainly the northern cliff line forests. The population on Guam has declined significantly and apparently now numbers between 850 and 1,000. The populations on the other islands, are not well known. There are

insufficient data to assess population levels or trends on these islands. Systematic surveys are planned for these areas. The population on Guam is being proposed because of its significant vulnerability to illegal take. The remaining colonies are distinct units or groups of animals that are subject to recurring disturbances. The individuals remaining on Guam are in need of immediate protection.

Little Mariana fruit bat (*Pteropus tokudae*). This species is endemic to Guam. It apprently has always been less common than *Pteropus mariannus mariannus*, and is subject to the same problems. *P. tokudae* is the smaller of the two bats, but distinction in the field is difficult. Of over 100 fruit bats collected and scientifically examined on the island in the 1960's only one represented *P. tokudae*. This individual was a female and was nursing a young, which escaped capture. No specimens of *P. tokudae* have been taken since then.

The other taxa included in the two petitions submitted by the Governor of Guam are not included in this proposal for the following reasons:

1. Mariana fruit dove (*Ptilinopus roseicapillus*). This species is distributed on other islands north of Guam. It is still considered common on one or more of these islands.

2. White-throated ground dove (*Gallicolumba xanthonura xanthonura*). This subspecies is found in the Mariana Islands and Yap. It is found deep in the forest and is still considered common on one or more of the islands north of Guam and possibly also on Yap.

3. Cardinal honey-eater (*Myzomela cardinalis saffordi*). This subspecies is considered common on one or more of the islands north of Guam.

As additional information is gathered on these taxa the Service will further consider the need to list them.

**Summary of Factors Affecting the Species**

Subsection 4(a)(1) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*) and regulations promulgated to implement the listing provisions of the Act (codified at 50 CFR Part 424; under revision to accommodate 1982 amendments) set forth the procedures for adding species to the Federal lists. The Secretary of the Interior shall determine whether any species is an Endangered species or a Threatened species due to one or more of five factors described in subsection 4(a)(1) of the Act. These factors and their application to the seven Mariana Islands birds and the two fruit bats are as follows:

A. *Present or threatened destruction, modification, or curtailment of its habitat or range.* Large portions of native habitat on Guam have been destroyed as a result of human activities. The reduction in bird numbers probably can be attributed, in part, to this loss. However, the recent, rapid decline in bird populations appears to be unrelated to habitat destruction, as there are remnants of good habitat throughout Guam that are completely devoid of bird or bat life. Although degradation or destruction of native habitat undoubtedly has contributed in the past, and is still contributing, to the endangered status of these members of the native fauna, it appears not to be a main factor.

B. *Overutilization for commercial, recreational, scientific, or educational purposes.* The major factor relating to decrease in the population of the fruit bats is poaching. The fruit bats are delicacies prized by some Guamanians and presently command high prices.

The fruit bats are protected on Guam and may not be hunted legally. It is also illegal to import these bats without a permit or from areas where they are protected. Local educational efforts may be responsible for discouraging some of the demand.

In spite of these deterrents there still remains a considerable demand for these animals. Although imports have declined in recent years there were still almost 11,000 fruit bats imported to Guam under permit in fiscal year 1982. A continued demand coupled with a decline in supply will undoubtedly put increasing pressure on the remaining, depleted local population. Accounts continue to be reported of harassment and attempts to poach local colonies.

None of the seven birds have been subjects of overutilization for any purpose.

C. *Disease or predation* (including grazing). No single factor has yet been implicated in the recent decline of Guam birds, but the cause presently being investigated is the spread of avian diseases. To date, no such disease has been identified in these wild birds. Using Pittman-Robertson and Endangered Species grant funding, the Guam Aquatic and Wildlife Resources Division has initiated studies to determine the presence and extent of avian diseases.

There are some similarities between the pattern of disappearance of birds on Guam and the patterns in other areas in which diseases were thought to play a major role such a Hawaii, where avian malaria and avian pox have been implicated.

Predation by a variety of exotic animals is also suspected as a contributing cause of the observed declines. The introduced brown tree snake (*Boiga irregularis*) (also known as the Philippine rat snake) is now widespread on Guam.

It is primarily an arboreal snake that comes into contact with eggs and hatchlings in nests, and roosting young and adult birds. The introduced monitor lizard (*Varanus indicus*) is also common on the island and a potential predator of birds. Cats, dogs and rats, all introduced to Guam, are additional potential predators.

The impact these exotic predators have on the entire assemblage of native forest-dwelling birds is unknown. This set of effective predators in a small island environment (naturally devoid of predatory mammals and reptiles) creates potentially significant problems for native birds, particularly as the numbers of predators increase and the numbers of native birds decrease.

D. *The inadequacy of existing regulatory mechanisms.* The nine organisms included in this proposed rulemaking were placed on the Guam Endangered Species List on September 24, 1981, and are thereby protected by The Endangered Species Act of Guam (Pub. L. 15–36). Listing as Endangered by the Federal Government under the Endangered Species Act of 1973, as amended, will provide additional protection through Section 7 (interagency cooperation), which will require all Federal agencies to consider the impacts of their actions on these species. Section 9 (prohibitions) requirements will also enhance protection provisions (interstate commerce, export-import, take, possession) for the fruit bats. Such action will also facilitate cooperative efforts by the Service to provide funding and technical assistance to ongoing efforts of the Guam Division of Aquatic and Wildlife Resources.

E. *Other natural or manmade factors affecting its continued existence.* Heavy use of DDT and other chlorinated hydrocarbons during World War II and widespread use of agricultural insecticides since that time may have impacted forest birds, especially insectivorous species. Preliminary results of a 1981 pesticide study indicates that pesticides are not currently a problem for Guam bird life, although they may have been in the past.

Road kills by automobiles are an addiitonal source of mortality for the guam rail.

**Critical Habitat**

The Act requires that, to the maximum extent prudent and determinable, the Secretary designate any habitat of a species that is considered Critical Habitat at the time the species is determined to be Endangered or Threatened. The Service finds that designation of Critical Habitat is neither prudent nor determinable at this time.

The Act defines "Critical Habitat" as "(i) the specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the provisions of Section 4 of this Act, on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protection; and (ii) specific areas outside the geographic area occupied by the species at the time it is listed in accordance with the provisions of Section 4 of this Act, upon a determination by the Secretary that such areas are essential for the conservation of the species."

Critical Habitat for the seven avian and two mammalian taxa from Guam is not being proposed at this time because sufficient data are lacking to make such a proposed determination. Details are lacking on the extent of habitat needed for an expanded population and on potential economic impacts. It is also questionable from a standpoint of prudence, whether Critical Habitat designation will benefit these taxa, and it may, in fact, be detrimental to the fruit bats. Further review of available information is necessary.

Critical Habitat may subsequently be proposed for these seven species in accordance with the 1982 amendments to the Act, if it is determined that such a determination is in fact prudent.

**Available Conservation Measures**

If these nine species of Guam wildlife are determined to be Endangered, all would be subject to the protection of the Endangered Species Act of 1973, as amended.

With respect to these nine species, the effects of this proposal, if published as a final rule, would include, but not necessarily be limited to, those mentioned below:

All prohibitions of Section 9(a)(1) of the Act, as implemented at 50 CFR 17.21, will apply. These prohibitions, in part, would make it illegal for any person subject to the jurisdiction of the United States to take, import or export, ship in interstate or foreign commerce in the course of a commercial activity, or sell or offer to sell those species in interstate or foreign commerce. It would also be illegal to possess, sell, deliver, carry, transport, or ship any such wildlife that was illegally taken, imported or exported. Certain exceptions would apply to agents of the Service and Territorial and Commonwealth conservation agencies for limited purposes.

Regulations at §§ 17.22 and 17.23 provide for the issuance of permits to carry out otherwise prohibited activities involving Endangered species under certain circumstances. Such permits are available for scientific purposes or to enhance the propagation or survival of the species. In some instances, permits may be issued during a specified period of time to relieve undue economic hardship that would be suffered if such relief were not available.

Subsection 7(a)(4) of the Act, as amended, requires Federal agencies to evaluate their actions with respect to any species that is proposed for listing as Endangered, and any proposed Critical Habitat. Provisions for Interagency Cooperation implementing this section are codified at 50 CFR Part 402. New regulations to accommodate amendments to the Act have been proposed at 48 FR 29990. The Act requires Federal agencies to evaluate their actions with respect to any species proposed for listing and to confer with the Service on any of their actions that are likely to jeopardize these proposed species. If this proposal is published as a final rule, Federal agencies would be required to insure that actions they authorize, fund or carry out are not likely to jeopardize the continued existence of these species.

If these animals are listed as Endangered species, certain conservation authorities would become available and protective measures may be undertaken for them. These could include increased management of the species and their habitat, the provision of three-fourths Federal (and one-fourth Territorial or Commonwealth) funds for the species conservation through a cooperative agreement under Section 6(c)(2) of the Act, and the development of a recovery plan for the species as specified in Subsection 4(g).

**National Environmental Policy Act**

In accordance with a recommendation from the Council on Environmental Quality (CEQ), the Service has not prepared any NEPA documentation for this proposed rule. The recommendation from CEQ was based, in part, upon a decision in the Sixth Circuit Court of Appeals which held that the preparation of NEPA documentation was not required as a matter of law for listings under the Endangered Species Act. *PLF v. Andrus* 657 F.2d. 829 (6th Cir. 1981).

**Public Comments Solicited**

The Director intends that the rules finally adopted will be as accurate and effective as possible in the conservation of each Endangered species. Therefore, any comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, private interests, or any other interested party concerning any aspect of this proposed rule are hereby solicited. Comments particularly are sought concerning:

(1) Biological or other relevant data concerning any threat (or lack thereof) to the species included in this proposal:

(2) The location of any population of these species and the reasons why any habitat of these species should or should not be designated as Critical Habitat;

(3) Additional information concerning the range and distribution of these species;

Final promulgation of a rule on these species will take into consideration any comments and additional information received by the Service, and such communications may lead to adoption of a final rule that differs from this proposal.

The Endangered Species Act provides for a public hearing on this proposal, if requested. Requests must be filed within 45 days of the date of the proposal. Such requests should be made in writing and addressed to the Regional Director, U.S. Fish and Wildlife Service, Lloyd 500 Building, Suite 1692, 500 N.E. Multnomah Street, Portland, Oregon 97232.

**Primary Authors**

The primary authors of the proposed rule are Derral Herbst and Peter Stine, Office of Environmental Services, U.S. Fish and Wildlife Service, Box 50167, Honolulu, Hawaii 96850 (808/546-7530).

**References**

Engbring, J. 1983. Forest birds of Guam in critical danger. Endgr. Spp. Tech. Bull. 8(1):6-8.

Engbring, J., and F. Ramsey. In Press. Distribution and abundance of the forest birds of Guam; results of a 1981 survey. Biological Services Program Bulletin.

Guam Aquatic and Wildlife Resources Division. 1979. Annual report. p. 301-325.

Guam Aquatic and Wildlife Resources Division. 1981. The current status and distribution and natural history of the Marianas fruit bat on Guam. Aquatic and Wildlife Resources Div. Tech. Report No. 1. p. 160-172.

**List of Subjects in 50 CFR Part 17**

Endangered and threatened species, Fish, Marine mammals, Plants (agriculture).

**Proposed Regulation Promulgation**

**PART 17—[AMENDED]**

Accordingly, it is hereby proposed to amend Part 17, Subchapter B of Chapter I, Title 50 of the Code of Federal Regulations, as set forth below:

1. The authority citation for Part 17 reads as follows:

**Authority:** Pub. L. 93–205, 87 Stat. 884; Pub. L. 95–632, 92 Stat. 3751; Pub. L. 96–159, 93 Stat. 1225; and Pub. L. 97–304, 96 Stat. 1411 (16 U.S.C. 1531 *et seq.*).

2. Amend the table at § 17.11(h) by adding in alphabetical order under Mammals (2) and Birds (7) the following 9 entries:

**§ 17.11 Endangered and threatened wildlife.**

* * * * *

(h) * * *

| Species | | Historic range | Population where endangered or threatened | Status | When listed | Critical habitat | Special rules |
|---|---|---|---|---|---|---|---|
| Common name | Scientific name | | | | | | |
| Mammals | | | | | | | |
| Bat, Little Mariana fruit | *Pteropus tokudae* | Western Pacific Ocean: Guam. | Entire range | E | | NA | NA. |
| Bat, Mariana fruit | *Pteropus mariannus mariannus* | Western Pacific Ocean: Guam, Tinian, Rota, Saipan, Agiguan. | Guam | E | | NA | NA. |
| Birds | | | | | | | |
| Broadbill, Guam | *Myiagra freycineti* | Western Pacific Ocean: Guam. | Entire range | E | | NA | NA. |
| Crow, Mariana | *Corvus kubaryi* | Western Pacific Ocean: Guam, Rota. | do | E | | NA | NA. |
| Gallinule, Mariana | *Gallinula chloropus guami* | Western Pacific Ocean: Guam, Tinian, Saipan, Pagan. | do | E | | NA | NA. |
| Kingfisher, Micronesian | *Halcyon cinnamomina cinnamomina* | Western Pacific Ocean: Guam. | do | E | | NA | NA. |
| Rail, Guam | *Rallus owstoni* | Western Pacific Ocean: Guam. | do | E | | NA | NA. |
| Swiftlet, Vanikoro | *Aerodramus (=Collocalia) vanikorensis bartschi.* | Western Pacific Ocean: Guam, Tinian, Rota, Saipan, Agiguan. | do | E | | NA | NA. |
| White-eye, bridled | *Zosterops conspicillata conspicillata* | Western Pacific Ocean: Guam. | do | E | | NA | NA. |

Dated: October 26, 1983.

**G. Ray Arnett,**

*Assistant Secretary for Fish and Wildlife and Parks.*

[FR Doc. 83–31860 Filed 11–28–83; 8:45 am]

BILLING CODE 4310–55–M

# Notices

Federal Register
Vol. 48, No. 230
Tuesday, November 29, 1983

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

### Foreign Agricultural Service

### Import Limitation; Country of Origin Quota Adjustment

**AGENCY:** Foreign Agricultural Service, USDA.

**ACTION:** Notice of country of origin adjustment for certain condensed milk from Denmark.

**SUMMARY:** Presidential Proclamation 4708, issued December 11, 1979, amended Headnote 3(a) of Part 3 of the Appendix to the Tariff Schedules of the United States to permit the Secretary of Agriculture to make country of origin adjustments for unlicensed quotas that will not be filled by the country of origin listed opposite the quota. This notice implements such an adjustment with respect to the quota quantity assigned to Denmark for condensed milk in airtight containers.

**EFFECTIVE DATE:** December 2, 1983.

**FOR FURTHER INFORMATION CONTACT:** Phillip J. Christie, Head, Import Licensing Group, Dairy, Livestock and Poultry Division, Foreign Agricultural Service, Room 6616 South Building, Department of Agriculture, Washington, D.C. 20250 or telephone at (202) 447-5270.

**SUPPLEMENTARY INFORMATION:** This action has been reviewed under Executive Order 12291 and Secretary's Memorandum 1512-1 and has been determined to be "nonmajor" since it will not have any of the significant effects specified in those documents. Furthermore, to the extent, if any, that the provisions of the Regulatory Flexibility Act (5 U.S.C. 601) apply to this notice, the Administrator, Foreign Agricultural Service, hereby certifies that this notice will not have a significant economic impact on a substantial number of small entities. The adjustment of the country of origin from which the quota item specified herein may be entered does not affect the ability of importers to import this quota item, but only expands the number of countries from which the item may be imported. Also, since this action is being taken in recognition of changes in the market which have already occurred, this action will not cause any new economic impact.

An assessment of the impact of this notice on the environment was made and, based on this evaluation, this action is not a major federal action and will have no foreseeable significant effects on the quality of the human environment. Consequently, no environmental impact statement is necessary for this notice.

Part 3 of the Appendix to the Tariff Schedules of the United States (TSUS) sets forth import limitations imposed on certain dairy products, including certain condensed milk. Headnote 3(a)(iii) of that Appendix allows for reallocating the quota amount of a dairy article listed in that Appendix among the countries of origin specified for a given article if it is determined that the quota amount assigned to a particular country is not likely to be entered from that country within a given calendar year. I hereby determine that it is not likely that the amount of condensed milk specified in TSUS Item 949.90 for Denmark will be entered from that country during calendar year 1983.

Notice is hereby given that the 1983 unused quota quantity for condensed milk specified in TSUS Item 949.90 for Denmark may be imported from Canada, Denmark, the Netherlands and Australia for the remainder of the 1983 quota year.

The quota quantity for TSUS Item 949.90 will revert to the original supplying country on January 1, 1984.

Issued at Washington, D.C., this 23rd day of November 1983.

**Leo V. Mayer,**

*Acting Administrator.*

[FR Doc. 83-31875 Filed 11-23-83; 3:56 pm]

BILLING CODE 3410-10-M

## Human Nutrition Information Service

### Dietary Guidelines Advisory Committee; 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: Dietary Guidelines Advisory Committee.

Date: December 13 and 14, 1983.

Place: Auditorium, Hubert H. Humphery Building, U.S. Department of Health and Human Services, 200 Independence Avenue, SW., Washington, D.C. 20201.

Time: December 13, 10 a.m. to 5 p.m.; and December 14, 9 a.m. to 3 p.m.

Purpose: To review comments received on "Nutrition and Your Health: Dietary Guidelines for Americans," Home and Garden Bulletin Number 232, and make any recommendations the committee seems appropriate.

Agenda: The agenda will include the following items: Review of the progress of the Dietary Guidelines subcommittees since the July 1983 meeting, review of written comments received since July 1983, discussion of any proposals related to the Dietary Guidelines, and plans for future work of the Committee

The meeting is open to public. There is a limited amount of space available for public attendance.

Dated: November 22, 1983.

Done at Washington, D.C. this 22 day of November, 1983.

**Isabel D. Wolf,**

*Administrator, Human Nutrition Information Service.*

[FR Doc. 83-31812 Filed 11-28-83; 8:45 am]

BILLING CODE 3410-KE-M

## CIVIL AERONAUTICS BOARD

### Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits

Permits Filed under Subpart Q of the Board's Procedural Regulations; Week Ended November 18, 1983.

### Subpart Q Applications

The due date for answers, conforming application, or motions to modify scope are set forth below for each application. Following the answer period the Board may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

| Date filed | Docket No. | Description |
|---|---|---|
| Nov. 14, 1993 | 41817 | Lusair International, Inc., c/o Roy Nerenberg, Nerenberg, Nassau & Courtot, 1025 Vermont Avenue, N.W., Suite 605, Washington, D.C. 20005.<br>Application of Lusair International, Inc. pursuant to Section 401 of the Act and Subpart Q of the Board's Procedural Regulations requests authority to engage in interstate and overseas charter air transportation (including inclusive tour charters) of persons, property (except all-cargo service is as defined in the Act), and mail, as follows:<br>Between any point in any State of the United States or the District of Columbia or any territory or possession of the United States, and any other point in any State of the United States or the District of Columbia or any territory or possession of the United States (except between points within the State of Alaska);<br>Conforming Applications, Motions to Modify Scope and Answers may be filed by December 13, 1983. |
| Nov. 14, 1993 | 41818 | Lusair International, Inc., c/o Roy Nerenberg, Nerenberg, Nassau & Courtot, 1025 Vermont Avenue, N.W., Suite 605, Washington, D.C. 20005.<br>Application of Lusair International, Inc. pursuant to Section 401 of the Act and Subpart Q of the Board's Procedural Regulations requests authority to engage in foreign charter air transportation (including inclusive tour charters of persons, property and mail, as follows:<br>Between any point in any State of the United States or the District of Columbia or any territory or possession of the United States, and<br>1. Any point in Canada;<br>2. Any point in Mexico;<br>3. Any point in Jamaica, the Bahama Islands Bermuda, Haiti, the Dominican Republic, Trinidad, Aruba, and Leeward and Windward Islands and any other foreign Place in the Gulf of Mexico or the Caribbean Sea;<br>4. Any point in Central or South America; and<br>5. Any point in Greenland, Iceland, the Azores and Europe.<br>Conforming Applications, Motions to Modify Scope and Answers may be filed by December 12, 1983. |
| Nov. 14, 1983 | 41715<br>41716 | Silvas Air Lines Inc. d/b/a Silvas *** Express, c/o Louis C. F. Silvas II, 701-Northdale Cove, Columbus, Mississippi 39701.<br>Evidence Request of Silvas Air Lines, Inc. pursuant to Order 83-10-51.<br>Answers may be filed by December 12, 1983. |
| Nov. 14, 1983 | 41741<br>41742 | Airmark Corporation, c/o Aidan D. Jones, Finley, Kumble, Wagner, Heine, Underaberg, Manley & Casey, 1120 Connecticut Ave., N.W. Washington, D.C. 20036.<br>Amendment to the Application of Airmark Corporation pursuant to Order 83-10-94.<br>Answers may be filed by December 12, 1983. |
| Nov. 15, 1983 | 40966 | Bidzy Ta Hot' Aana, Inc. d/b/a Tanana Air Service, c/o John B. Patterson, Strachan, Kelly & Patterson, 880 H Street, Suite 201, Achorage, Alaska 99501.<br>Response of Bidzy Ta Hot' Aana, Inc. d/b/a Tanana Air Service to Order Requesting Further Evidence.<br>Answers may be filed by December 13, 1983. |

**Phyllis T. Kaylor,**
*Secretary.*

[FR Doc. 83-31889 Filed 11-28-83; 8:45 am]

BILLING CODE 6320-01-M

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**[Order 83-11-89]**

## Fitness Determination of Provo Air, Inc.; Order To Show Cause

**AGENCY:** Civil Aeronautics Board.

**ACTION:** Notice of commuter air carrier fitness determination—Order 83-11-89, order to show cause.

**SUMMARY:** The Board is proposing to find that Provo Air, Inc. is fit, willing, and able to provide commuter air carrier service under section 419(c)(2) of the Federal Aviation Act, as amended, and that the aircraft used in this service conform to applicable safety standards. The complete text of this order is available, as noted below.

**DATES:** Responses: All interested persons wishing to respond to the Board's tentative fitness determination shall serve their responses on all persons listed below no later than December 13, 1983, together with a summary of the testimony statistical data, and other material relied upon to support the allegations.

**ADDRESSES:** Responses or additional data should be filed with the Special Authorities Division, Room 915, Civil Aeronautics Board, Washington, D.C. 20428, and with all persons listed in Attachment A to the order.

**FOR FURTHER INFORMATION CONTACT:** Timothy E. Carmody, Bureau of Domestic Aviation, Civil Aeronautics Board, 1825 Connecticut Avenue, NW., Washington, D.C. 20428, (202) 673-5121.

**SUPPLEMENTARY INFORMATION:** The complete text of Order 83-11-89 is available from the Distribution Section, Room 100, 1825 Connecticut Avenue, NW., Washington, D.C. 20428. Persons outside the metropolitan area may send a postcard request for Order 83-11-89 to that address.

By the Civil Aeronautics Board, November 23, 1983.

**Phyllis T. Kaylor,**
*Secretary.*

[FR Doc. 83-31891 Filed 11-28-83; 8:45 am]

BILLING CODE 6320-01-M

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**[Order 83-11-84; Docket 41841]**

## Ryan Aviation Corp. Fitness Investigation

**AGENCY:** Civil Aeronautics Board.

**ACTION:** Notice of Order Instituting the *Ryan Aviation Corporation Fitness Investigation:* Order 83-11-84, Docket 41841.

**SUMMARY:** The Board is instituting the *Ryan Aviation Corporation Fitness Investigation* to consider the issues of (1) whether Ryan is a citizen of the United States as defined by section 101(16) of the Federal Aviation Act; (2)

whether Ryan is fit, willing and able to perform the air service described in its application and to comply with the Act and the Board's rules, regulations and requirements; and (3) whether we should approve, exempt or disclaim jurisdiction over any control or interlocking relationships under sections 408 and 409 which may exist.

**DATES:** Petitions for reconsideration and for leave to intervene and requests for additional evidence shall be filed by December 1, 1983.

**ADDRESSES:** All pleadings should be filed in the Docket Section, Civil Aeronautics Board, Washington, D.C. 20428 in Docket 41841.

**FOR FURTHER INFORMATION CONTACT:** Don Hainbach, Bureau of International Aviation, Civil Aeronautics Board, 1825 Connecticut Avenue, NW., Washington, D.C. 20428, (202) 673-5035.

**SUPPLEMENTARY INFORMATION:** The complete text of Order 83-11-84 is available from our Distribution Section, Room 100, 1825 Connecticut Avenue, NW., Washington, D.C. 20428. Persons outside the metropolitan area may send a postcard request for Order 83-11-89 to that address.

By the Civil Aeronautics Board, November 22, 1983.

**Phyllis T. Kaylor,**

*Secretary.*

[FR Doc. 83-31890 Filed 11-28-83; 8:45 am]

BILLING CODE 6320-01-M

## CIVIL AERONAUTICS BOARD

### Uniform System of Accounts and Reports for Certificated Air Carriers; Report of Financial and Operating Statistics for Certificated Air Carriers

**AGENCY:** Civil Aeronautics Board.

**ACTION:** Notice of Proposed Collection of Information under the Provisions of the Paperwork Reduction Act (44 U.S.C. 35).

**SUMMARY:** The Civil Aeronautics Board is requesting the Office of Management and Budget's approval of the extension of CAB Form 41, "Report of Financial and Operating Statistics for Certificated Air Carriers," filed pursuant to section 22 of Part 241 of the Board's Economic Regulations. OMB approval is required under the Paperwork Reduction Act of 1980.

**DATED:** November 18, 1983.

**FOR FURTHER INFORMATION CONTACT:** Linda K. Koman, Data Requirements Section, Information Management Division, Office of Comptroller, Civil Aeronautics Board, 1825 Connecticut Avenue, NW., Washington, D.C. 20428, (202) 673-6042.

**SUPPLEMENTARY INFORMATION:**

Agency Clearance Officer from Whom a Copy of the Collection of Information and Supporting Documents is Available: Robin A. Caldwell (202) 673-5922

How Often the Collection of Information Must Be Filed: Monthly, Quarterly, Semiannually and Annually

Who is Asked or Required to Report: U.S. Certificated Air Carriers Estimate of Number of Annual Responses: 10,147

Estimate of Number of Annual Hours Needed to Complete the Collection of Information: 43,632

**Phyllis T. Kaylor,**

*Secretary.*

[FR Doc. 83-31888 Filed 11-28-83; 8:45 am]

BILLING CODE 6320-01-M

### Uniform System of Accounts and Reports for Certificated Air Carriers; Service Segment Data

**AGENCY:** Civil Aeronautics Board.

**ACTION:** Notice of Proposed Collection of Information under the Provisions of the Paperwork Reduction Act (44 U.S.C. 35).

**SUMMARY:** The Civil Aeronautics Board is requesting the Office of Management and Budget's approval of extension of the submission of Service Segment Data by certificated air carriers pursuant to the reporting requirements contained in Section 19-3 of Part 241 of the Board's Economic Regulations.

**DATED:** November 22, 1983.

**FOR FURTHER INFORMATION CONTACT:**

Bernard Davis, Data Requirments Section, Information Management Division, Office of Comptroller, Civil Aeronautics Board, 1825 Connecticut Avenue, NW., Washington, D.C. 20428, (202) 673-6042.

**SUPPLEMENTARY INFORMATION:**

Agency Clearance Officer from Whom a Copy of the Collection of Information and Supporting Documents is Available: Robin A. Caldwell, (202) 673-5922

How Often the Collection of Information Must Be Filed: Monthly Who is Asked or Required to Report: U.S. Certificated Air Carriers

Estimate of Number of Annual Responses: 420

Estimate of Number of Annual Hours Needed to Complete the Collection of Information: 21,200

**Phyllis T. Kaylor,**

*Secretary.*

[FR Doc. 83-31887 Filed 11-28-83; 8:45 am]

BILLING CODE 6320-01-M

## DEPARTMENT OF COMMERCE

### Office of the Secretary

### President's Private Sector Survey on Cost Control

**AGENCY:** Office of the Secretary, Commerce.

**ACTION:** Notice of Open Meeting of the Subcommittee of the President's Private Sector Survey on Cost Control (PPSSCC).

**SUMMARY:** The Subcommittee was established by the Executive Committee of the PPSSCC to review the reports prepared by the Survey's Task Forces and formulate the recommendations to the President. Some of the Task Forces looked at specific agencies,such as the Department of Commerce, and others looked at cross-cutting topics, such as personnel.

#### Time and Place

December 8, 1983 at 11 a.m. The meeting will be held at the U.S. Department of Commerce Auditorium, First Floor, Herbert C. Hoover Building, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230.

#### Agenda

The following draft reports will be discussed by Subcommittee members:

1. Research and Development;
2. Financial Management in the Federal Government;
3. Wage Setting Laws: Impact of the Federal Government; and
4. Anomalies in the Federal Work Environment.

Copies of the draft reports are available at the Department's Central Reference and Records Inspection Facility, Room 6628 Hoover Building, 14th Street and Constitution Avenue, NW., Washington, D.C. 20230. Please call Ms. Phyllis D. Lambry or Ms. Geraldine P. LeBoo on (202) 377-3271 for information concerning fees and procedures for obtaining copies by mail.

**SUPPLEMENTARY INFORMATION:** The Subcommittee will hold at least one more meeting. The exact date will be noticed in the **Federal Register.** Copies of the draft reports discussed at this meeting will be available approximately two weeks prior to the meeting at the Department's Central Reference and Records Inspection Facility, address above.

#### Public Participation

The December 8 meeting will be open to the public. Seating will be on a first-come, first-served basis, up to the safe

capacity of the meeting room. Media representatives are encouraged to call Mr. Malcolm Barr, Director, News Relations, Department of Commerce, 377-4901 to arrange for coverage at the meeting.

The public may file written statements for consideration by the Subcommittee any time before, at, or after the meeting. It is strongly recommended that statements be filed after the draft reports are made public, but before the Subcommittee meeting is hold to ensure that the comments are considered by the Subcommittee before adoption of a report. The comments should be filed at the Department of Commerce's Central Reference and Records Inspection Facility, address and phone number as above. Because of the lengthy number of recommendations in the four reports to be discussed, the meeting agenda will not include time for oral statements from public attendees. Statements the public wishes to make in response to the open meeting are welcome, and will be handled in the same manner as comments on the draft reports. All public statements received will be available for public review.

**FOR FURTHER INFORMATION CONTACT:** Ms. Janet Colson, Committee Control Officer for the Executive Committee of the President's Private Sector Survey on Cost Control, telephone (202) 466-5170.

Dated: November 25, 1983.

**Marilyn S. McLennan,**

*Chief, Information Management Division, Office of the Secretary.*

[FR Doc. 83-31979 Filed 11-28-83; 8:45 am]

BILLING CODE 3510-CW-M

## Foreign-Trade Zones Board

**[Order No. 235]**

## Resolution and Order Approving the Application of the City of Laredo, Texas, for a Foreign-Trade Zone in Webb County, Adjacent to the Laredo Customs Port of Entry; Resolution and Order

Pursuant to the authority granted in the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a-81u), the Foreign-Trade Zones Board has adopted the following Resolution and Order:

The Board, having considered the matter, hereby orders:

After consideration of the application of the City of Laredo, Texas, filed with the Foreign-Trade Zones Board (the Board) on July 25, 1983, requesting a grant of authority for establishing, operating, and maintaining a general-purpose foreign-trade zone in Webb County, Texas, adjacent to the Laredo Customs port of entry, the Board, finding that the requirements of the Foreigns Trade Zones Act, as amended, and the Board's regulations are satisfied, and that the proposal is in the public interest, approves the application.

As the proposal involves open space on which buildings may be constructed by parties other than the grantee, this approval includes authority to the grantee to permit the erection of such buildings, pursuant to Section 400.815 of the Board's regulations, as are necessary to carry out the zone proposal, providing that prior to its granting such permission it shall have the concurrences of the local District Director of Customs, the U.S. Army District Engineer, when appropriate, and the Board's Executive Secretary. Further, the grantee shall notify the Board's Executive Secretary for approval prior to the commencement of any manufacturing operation within the zone. The Secretary of Commerce, as Chairman and Executive Officer of the Board, is hereby authorized to issue a grant of authority and appropriate Board Order.

### Grant To Establish, Operate, and Maintain a Foreign-Trade Zone in Webb County, Texas, Adjacent to the Laredo Customs Port of Entry

Whereas, by an Act of Congress approved June 18, 1934, an Act "To provide for the establishment, operation, and maintenance of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes," as amended (19 U.S.C. 81a-81u) (the Act), the Foreign-Trade Zones Board (the Board) is authorized and empowered to grant to corporations the privilege of establishing, operating, and maintaining foreign-trade zones in or adjacent to ports of entry under the jurisdiction of the United States;

Whereas, the City of Laredo, Texas, (the Grantee) has made application (filed July 25, 1983, Docket No. 23-83, 48 FR 36302) in due and proper form to the Board, requesting the establishment, operation, and maintenance of a foreign-trade zone consisting of 3 sites in Webb County, Texas, adjacent to the Laredo Customs port of entry;

Whereas, notice of said application has been given and published, and full opportunity has been afforded all interested parties to be heard; and,

Whereas, the Board has found that the requirements of the Act and the Board's regulations (15 CFR Part 400) are satisfied;

Now, therefore, the Board hereby grants to the Grantee the privilege of establishing, operating, and maintaining a foreign-trade zone, designated on the records of the Board as Zone No. 94 at the locations mentioned above and more particularly described on the maps and drawings accompanying the application in Exhibits IX and X, subject to the provisions, conditions, and restrictions of the Act and the regulations issued thereunder, to the same extent as though the same were fully set forth herein, and also to the following express conditions and limitations:

Activation of the foreign-trade zone shall be commenced by the Grantee within a reasonable time from the date of issuance of the grant, and prior thereto the Grantee shall obtain all necessary permits from Federal, State, and municipal authorities.

The Grantee shall allow officers and employees of the United States free and unrestricted access to and throughout the foreign-trade zone in the performance of their official duties.

The Grantee shall notify the Executive Secretary of the Board for approval prior to the commencement of any manufacturing operations within the zone.

The grant shall not be construed to relieve the Grantee from liability for injury or damage to the person or property of others occasioned by the construction, operation, or maintenance of said zone, and in no event shall the United States be liable therefor.

The grant is further subject to settlement locally by the District Director of Customs and the Army District Engineer with the Grantee regarding compliance with their respective requirements for the protection of the revenue of the United States and the installation of suitable facilities.

In witness whereof, the Foreign-Trade Zones Board has caused its name to be signed and its seal to be affixed hereto by its Chairman and Executive Officer at Washington, D.C. this 22nd day of November 1983, pursuant to Order of the Board.

Foreign-Trade Zones Board.

**Malcolm Baldrige,**

*Chairman and Executive Officer.*

Attest:

**John J. DaPonte,**

*Executive Secretary.*

[FR Doc. 83-31925 Filed 11-28-83; 8:45 am]

BILLING CODE 3510-DS-M

[Order No. 236]

## Resolution and Order Approving the Application of the Starr County Industrial Foundation, for a Foreign-Trade Zone in Starr County, Texas, Adjacent to the Rio Grande City and Roma Customs Ports of Entry; Resolution and Order

Pursuant to the authority granted in the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board has adopted the following Resolution and Order:

The Board, having considered the matter, hereby orders:

After consideration of the application of the Starr County Industrial Foundation, a Texas nonprofit development corporation, filed with the Foreign-Trade Zones Board (the Board) on July 25, 1983, requesting a grant of authority for establishing, operating, and maintaining a general-purpose foreign-trade zone in Starr County, Texas, adjacent to the Rio Grande City and Roma Customs ports of entry, the Board, finding that the requirements of the Foreign-Trade Zones Act, as amended, and the Board's regulations are satisfied, and that the proposal is in the public interest, approves the application.

As the proposal involves open space on which buildings may be constructed by parties other than the grantee, this approval includes authority to the grantee to permit the erection of such buildings, pursuant to Section 400.815 of the Board's regulations, as are necessary to carry out the zone proposal, providing that prior to its granting such permission it shall have the concurrence of the local District Director of Customs, the U.S. Army District Engineer, when appropriate, and the Board's Executive Secretary. Further, the grantee shall notify the Board's Executive Secretary for approval prior to the commencement of any manufacturing operation within the zone. The Secretary of Commerce, as Chairman and Executive Officer of the Board, is hereby authorized to issue a grant of authority and appropriate Board Order.

### Grant to Establish, Operate, and Maintain a Foreign-Trade Zone in Starr County, Texas, Adjacent to the Rio Grande City and Roma Customs Ports of Entry

Whereas, by an Act of Congress approved June 18, 1934, an Act "To provide for the establishment, operation, and maintenance of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes," as amended (19 U.S.C. 81a–81u) (the Act), the Foreign-Trade Zones Board (the Board) is authorized and empowered to grant to corporations the privilege of establishing, operating, and maintaining foreign-trade zones in or adjacent to ports of entry under the jurisdiction of the United States;

Whereas, the Starr County Industrial Foundation, a Texas non-profit development corporation, (the Grantee) has made application (filed July 25, 1983, Docket No. 24–83, 48 FR 36301) in due and proper form to the Board, requesting the establishment, operation, and maintenance of a foreign-trade zone consisting of 3 sites in Starr County, Texas, adjacent to the Rio Grande City and Roma Customs ports of entry;

Whereas, notice of said application has been given and published, and full opportunity has been afforded all interested parties to be heard; and,

Whereas, the Board has found that the requirements of the Act and the Board's regulations (15 CFR Part 400) are satisfied;

Now, therefore, the Board hereby grants to the Grantee the privilege of establishing, operating, and maintaining a foreign-trade zone, designated on the records of the Board as Zone No. 95 at the location mentioned above and more particularly described on the maps and drawings accompanying the application in Exhibits IX and X, subject to the provisions, conditions, and restrictions of the Act and the regulations issued thereunder, to the same extent as though the same were fully set forth herein, and also to the following express conditions and limitations:

Activation of the foreign-trade zone shall be commenced by the Grantee within a reasonable time from the date of issuance of the grant, and prior thereto the Grantee shall obtain all necessary permits from Federal, State, and municipal authorities.

The Grantee shall allow officers and employees of the United States free and unrestricted access to and throughout the foreign-trade zone in the performance of their official duties.

The Grantee shall notify the Executive Secretary of the Board for approval prior to the commencement of any manufacturing operations within the zone.

The grant shall not be construed to relieve the Grantee from liability for injury or damage to the person or property of others occasioned by the construction, operation, or maintenance of said zone, and in no event shall the United States be liable therefor.

The grant is further subject to settlement locally by the District Director of Customs and the Army District Engineer with the Grantee regarding compliance with their respective requirements for the protection of the revenue of the United States and the installation of suitable facilities.

In witness whereof, the Foreign-Trade Zones Board has caused its name to be signed and its seal to be affixed hereto by its Chairman and Executive Officer at Washington, D.C. this 22nd day of November 1983, pursuant to Order of the Board.

Foreign-Trade Zones Board.

**Malcolm Baldrige,**

*Chairman and Executive Officer.*

Attest:

**John J. DaPonte,**

*Executive Secretary.*

[FR Doc. 83-31926 Filed 11-28-83 8:45 am]

BILLING CODE 3510-DS-M

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[Order No. 237]

## Resolution and Order Approving the Application of the City of Eagle Pass, Texas, for a Foreign-Trade Zone in Maverick County, Adjacent to the Eagle Pass Customs Port of Entry; Resolution and Order

Pursuant to the authority granted in the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81a), the Foreign-Trade Zones Board has adopted the following Resolution and Order:

The Board, having considered the matter, hereby orders:

After consideration of the application of the City of Eagle Pass, Texas, filed with the Foreign-Trade Zones Board (the Board) on July 25, 1983, requesting a grant of authority for establishing, operating, and maintaining a general-purpose foreign-trade zone in Maverick County, Texas, adjacent to the Eagle Pass Customs port of entry, the Board, finding that the requirements of the Foreign-Trade Zones Act, as amended, and the Board's regulations are satisfied with respect to Sites 1, 2, 4, and portions of Site 3, and that the proposal is in the public interest, approves the application with the exception of Site 5 and subject to the condition that any activation of approved zone space at Site 3 beyond 200 acres requires further Board approval.

As the proposal involves open space on which buildings may be constructed by parties other than the grantee, this approval includes authority to the grantee to permit the erection of such buildings, pursuant to Section 400.815 of the Board's regulations, as are necessary to carry out the zone proposal, providing

that prior to its granting such permission it shall have the concurrences of the local District Director of Customs, the U.S. Army District Engineer, when appropriate, and the Board's Executive Secretary. Further, the grantee shall notify the Board's Executive Secretary for approval prior to the commencement of any manufacturing operation within the zone. The Secretary of Commerce, as Chairman and Executive Officer of the Board, is hereby authorized to issue a grant of authority and appropriate Board Order.

**Grant to Establish, Operate, and Maintain a Foreign-Trade Zone in Maverick County, Texas, Adjacent to the Eagle Pass Customs Port of Entry**

Whereas, by an Act of Congress approved June 18, 1934, an Act "To provide for the establishment, operation, and maintenance of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes," as amended (19 U.S.C. 81a–81u) (the Act), the Foreign-Trade Zones Board (the Board) is authorized and empowered to grant to corporations the privilege of establishing, operating, and maintaining foreign-trade zones in or adjacent to ports of entry under the jurisdiction of the United States;

Whereas, the City of Eagle Pass, Texas, (the Grantee) has made application (filed July 25, 1983, Docket No. 25–83, 48 FR 36301) in due and proper form to the Board, requesting the establishment, operation, and maintenance of a foreign-trade zone consisting of 5 sites in Maverick County, Texas, adjacent to the Eagle Pass Customs port of entry;

Whereas, notice of said application has been given and published, and full opportunity has been afforded all interested parties to be heard; and,

Whereas, the Board has found that the requirements of the Act and the Board's regulations (15 CFR Part 400) would be satisfied subject to certain restrictions;

Now, therefore, the Board hereby grants to the Grantee the privilege of establishing, operating, and maintaining a foreign-trade zone, designated on the records of the Board as Zone No. 96 at Sites 1, 2, 3, and 4 mentioned in the application and more particularly described on the maps and drawings accompanying the application in Exhibits IX and X, subject to the provisions, conditions, and restrictions of the Act and the regulations issued thereunder, to the same extent as though the same were fully set forth herein, and also to the following express conditions and limitations:

Approval is denied as to Site 5 and any activation of approved zone space at Site 3 beyond 200 acres requires further Board approval. Activation of the foreign-trade zone shall be commenced by the Grantee within a reasonable time from the date of issuance of the grant, and prior thereto the Grantee shall obtain all necessary permits from Federal, State, and municipal authorities.

The Grantee shall allow officers and employees of the United States free and unrestricted access to and throughout the foreign-trade zone in the performance of their official duties.

The Grantee shall notify the Executive Secretary of the Board for approval prior to the commencement of any manufacturing operations within the zone.

The grant shall not be construed to relieve the Grantee from liability for injury or damage to the person or property of others occasioned by the construction, operation, or maintenance of said zone, and in no event shall the United States, be liable therefor.

The grant is further subject to settlement locally by the District Director of Customs and the Army District Engineer with the Grantee regarding compliance with their respective requirements for the protection of the revenue of the United States and the installation of suitable facilities.

In witness whereof, the Foreign-trade Zones Board has caused its name to be signed and its seal to be affixed hereto by its Chairman and Executive Officer at Washington, D.C. this 22nd day of November 1983, pursuant to Order of the Board.

Foreign-Trade Zones Board.

**Malcolm Baldrige,**

*Chairman and Executive Officer.*

Attest:

**John J. DaPonte,**

*Executive Secretary.*

[FR Doc. 83-31927 Filed 11-28-83; 8:45 am]

BILLING CODE 3510-DS-M

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**[Order No. 238]**

**Resolution and Order Approving the Application of the City of Del Rio, Texas, for a Foreign-Trade Zone in Val Verde County, Adjacent to the Del Rio Customs Port of Entry; Resolution and Order**

Pursuant to the authority granted in the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a–81u), the Foreign-Trade Zones Board has adopted the following Resolution and Order:

The Board, having considered the matter, hereby orders:

After consideration of the application of the City of Del Rio, Texas, filed with the Foreign-Trade Zones Board (the Board) on July 25, 1983, requesting a grant of authority for establishing, operating, and maintaining a general-purpose foreign-trade zone in Val Verde County, Texas, adjacent to the Del Rio Customs port of entry, the Board, finding that the requirements of the Foreign-Trade Zones Act, as amended, and the Board's regulations are satisfied, and that the proposal is in the public interest, approves the application.

As the proposal involves open space on which buildings may be constructed by parties other than the grantee, this approval includes authority to the grantee to permit the erection of such buildings, pursuant to Section 400.815 of the Board's regulations, as are necessary to carry out the zone proposal, providing that prior to its granting such permission it shall have the concurrences of the local District Director of Customs, the U.S. Army District Engineer, when appropriate, and the Board's Executive Secretary. Further, the grantee shall notify the Board's Executive Secretary for approval prior to the commencement of any manufacturing operation within the zone. The Secretary of Commerce, as Chairman and Executive Officer of the Board, is hereby authorized to issue a grant of authority and appropriate Board Order.

**Grant To Establish, Operate, and Maintain a Foreign-Trade Zone in Val Verde County, Texas, Adjacent to the Del Rio Customs Port of Entry**

Whereas, by an Act of Congress approved June 18, 1934, an Act "To provide for the establishment, operation, and maintenance of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes," as amended (19 U.S.C. 81a–81u) (the Act), the Foreign-Trade Zones Board (the Board) is authorized and empowered to grant to corporations the privilege of establishing, operating, and maintaining foreign-trade zones in or adjacent to ports of entry under the jurisdiction of the United States;

Whereas, the City of Del Rio, Texas (the Grantee), has made application (filed July 25, 1983, Docket No. 26–83, 48 FR 36101) in due and proper form to the Board, requesting the establishment, operation, and maintenance of a foreign-trade zone consisting of 4 sites in Val Verde County, Texas, adjacent to the Del Rio Customs port of entry;

Whereas, notice of said application has been given and published, and full opportunity has been afforded all interested parties to be heard; and,

Whereas, the Board has found that the requirements of the Act and the Board's regulations (15 CFR Part 400) are satisfied;

Now, therefore, the Board hereby grants to the Grantee the privilege of establishing, operating, and maintaining a foreign-trade zone, designated on the records of the Board as Zone No. 97 at the locations mentioned above and more particularly described on the maps and drawings accompanying the application in Exhibits IX and X, subject to the provisions, conditions, and restrictions of the Act and the regulations issued thereunder, to the same extent as though the same were fully set forth herein, and also to the following express conditions and limitations:

Activation of the foreign-trade zone shall be commenced by the Grantee within a reasonable time from the date of issuance of the grant, and prior thereto the Grantee shall obtain all necessary permits from Federal, State, and municipal authorities.

The Grantee shall allow officers and employees of the United States free and unrestricted access to and throughout the foreign-trade zone in the performance of their official duties.

The Grantee shall notify the Executive Secretary of the Board for approval prior to the commencement of any manufacturing operations within the zone.

The grant shall not be construed to relieve the Grantee from liability for injury or damage to the person or property of others occasioned by the construction, operation, or maintenance of said zone, and in no event shall the United States be liable therefor.

The grant is further subject to settlement locally by the District Director of Customs and the Army District Engineer with the Grantee regarding compliance with their respective requirements for the protection of the revenue of the United States and the installation of suitable facilities.

In witness whereof, the Foreign-Trade Zones Board has caused its name to be signed and its seal to be affixed hereto by its Chairman and Executive Officer at Washington, D.C. this 22nd day of November 1983, pursuant to Order of the Board.

Foreign-Trade Zones Board.

**Malcolm Baldrige,**

*Chairman and Executive Officer.*

Attest:

**John J. DaPonte,**

*Executive Secretary.*

[FR Doc. 83-31928 Filed 11-28-83; 8:45 am]

BILLING CODE 3510-DS-M

## International Trade Administration

**[A-580-007]**

## Tubes for Tires, Other Than for Bicycle Tires, From the Republic of Korea; Postponement of Preliminary Antidumping Determination

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

**ACTION:** Notice.

**SUMMARY:** The preliminary antidumping determination involving tubes for tires, other than for bicycle tires (inner tubes), from the Republic of Korea (Korea) is being postponed until not later than February 6, 1984.

**EFFECTIVE DATE:** November 29, 1983.

**FOR FURTHER INFORMATION CONTACT:** Steven Lim or Gary Taverman, Office of Investigations, Import Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, N.W., Washington, D.C. 20230, telephone (202) 377-1776/0161.

**SUPPLEMENTARY INFORMATION:** On August 12, 1983, we announced the initiation of an antidumping investigation to determine whether inner tubes from Korea are being, or are likely to be, sold in the United States at less than fair value (48 FR 36637). The notice stated that we would issue a preliminary determination by December 19, 1983.

As detailed in that notice, the petition alleges that imports from Korea of inner tubes are being, or are likely to be, sold in the United States at less than fair value. On November 18, 1983, counsel for the petitioners, Carlisle Tire & Rubber Company, *et al.*, requested that the Department extend the period for the preliminary determination until 210 days after the date of receipt of the petition in accordance with section 733(c)(1)(A) of the Tariff Act of 1930, as amended (the Act). Accordingly, the period for determination in the case is hereby extended. We intend to issue a preliminary determination not later than February 6, 1984.

This notice is published pursuant to section 733(c)(2) of the Act.

Dated: November 22, 1983.

**Alan F. Holmer,**

*Deputy Assistant Secretary for Import Administration.*

[FR Doc. 83-31929 Filed 11-28-83; 8:45 am]

BILLING CODE 3510-DS-M

## National Oceanic and Atmospheric Administration

## Marine Mammal Permits; Bolt Beranek and Newman, Inc.; Modification No. 2 to Permit No. 400

Notice is hereby given that pursuant to the provisions of §§ 216.33 (d) and (e) of the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR Part 216), and § 222.25 of the Regulations Governing Endangered Species Permits (50 CFR Part 222), Scientific Research Permit No. 400 issued to Bolt Beranek and Newman, Inc., 10 Moulton Street, Cambridge, Massachusetts 02238, on December 29, 1982 (48 FR 1827), as modified on March 8, 1983 (48 FR 15940), is further modified to extend the period of authorized taking for one year.

Accordingly, Section B-5 is deleted and replaced by:

"5. This permit is valid with respect to the taking authorized herein until December 31, 1984."

This modification becomes effective upon publication in the **Federal Register.**

The Permit as modified and documentation pertaining to the modification are available for review in the following offices:

Assistant Administrator for Fisheries, National Marine Fisheries Service, 3300 Whitehaven Street, NW., Washington, D.C.; and

Regional Director, National Marine Fisheries Service, Southwest Region, 300 South Ferry Street, Terminal Island, California 90731.

Dated: November 22, 1983.

**William G. Gordon,**

*Assistant Administrator for Fisheries, National Marine Fisheries Service.*

[FR Doc. 83-31828 Filed 11-28-83; 8:45 am]

BILLING CODE 3510-22-M

## Marine Mammal Permits; S.A., Costa d'en Blanes; Issuance of Permit

On September 19, 1983, Notice was published in the **Federal Register** (48 FR 91803), that an application had been filed with the National Marine Fisheries Service by Marineland, S.A., Costa d'en Blanes, Palma Nova, Mallorca, Spain, for a permit to take two (2) Atlantic bottlenose dolphin (*Tursiops truncatus*) for the purpose of public display.

Notice is hereby given that on November 17, 1983, and as authorized by the provisions of the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361–1407), the National Marine Fisheries Service issued a Public Display Permit for the above taking to Marineland, S.A., subject to certain conditions set forth therein.

The Permit is available for review in the following offices:

Assistant Administrator for Fisheries, National Marine Fisheries Service, 3300 Whitehaven Street, NW., Washington, D.C.; and

Regional Director, National Marine Fisheries Service, Southeast Region, 9450 Koger Boulevard, St. Petersburg, Florida 33702.

Dated: November 21, 1983.

**William G. Gordon,**

*Assistant Administrator for Fisheries, National Marine Fisheries Service.*

[FR Doc. 83-31827 Filed 11-28-83; 8:45 am]

BILLING CODE 3510-22-M

## Marine Mammal Permits; Manomet Bird Observatory; Modification No. 1 to Permit No. 365

Notice is hereby given that pursuant to § 216.33 (d) and (e) of the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR Part 216), Scientific Research Permit No. 365 issued to Manomet Bird Observatory, Manomet, Massachusetts 02345, on January 22, 1982, is modified to extend the period of authorized taking for two years and to increase the number of animals authorized to five animals per year.

Accordingly, the following changes are made:

Section A–1 is deleted and replaced by:

"1. Five (5) rehabilitated beached/stranded harbor seals (*Phoca vitulina concolor*) per year may be taken."

Section B–6 is deleted and replaced by:

"6. This permit is valid with respect to the takng authorized herein until December 31, 1985."

This modification becomes effective upon publication in the **Federal Register.**

The Permit is modified and documentation pertaining to the modification are available for review in the following offices:

Assistant Administrator for Fisheries, National Marine Fisheries Service 3300 Whitehaven Street, NW., Washington, D.C.; and

Regional Director, National Marine Fisheries Service, Northeast Region, Federal Building, 14 Elm Street, Gloucester, Massachusetts 01930.

Dated: November 22, 1983.

**William G. Gordon,**

*Assistant Administrator for Fisheries, National Marine Fisheries Service.*

[FR Doc. 83-31829 Filed 11-28-83; 8:45 am]

BILLING CODE 3510-22-M

## Mid-Atlantic Fishery Management Council; Public Comments on Foreign Fishing Applications

**AGENCY:** National Marine Fisheries Service, NOAA; Commerce.

**ACTION:** Opportunity for public comments on foreign fishing applications received by the Mid-Atlantic Fishery Management Council.

**SUMMARY:** The Mid-Atlantic Fishery Management Council was established by Section 302 of the Magnuson Fishery Conservation and Management Act (Pub. L. 94–265, as amended). As required by the Act, Section 204(b)(5), the Council announces that the public may comment on any and all foreign fishing applications received by the Council by December 5, 1983. The council's staff will be available between 9 a.m. and noon on December 5, 1983, to receive comments, which may be made in person at the Council's Headquarters Office, Federal Building, Room 2115, 300 South New Street, Dover, Delaware, between the above-stated hours. In addition, written comments must be mailed in time to be received and reviewed by the Council, by December 5, 1983.

**FOR FURTHER INFORMATION CONTACT:** Mid-atlantic Fishery Management Council, Room 2115 Federal Building, 300 South New Street, Dover, Delaware 19901, Telephone: (302) 674–2331.

Dated: November 22, 1983.

**Carmen J. Blondin,**

*Deputy Assistant Administrator for Fisheries Resource Management, National Marine Fisheries Service.*

[FR Doc. 83-31871 Filed 11-28-83; 8:45 am]

BILLING CODE 3510-22-M

## New England Fishery Management Council; Meeting and Public Hearing

**AGENCY:** National Marine Fisheries Service, NOAA, Commerce.

**ACTION:** Notice of public meeting and public hearing.

**SUMMARY:** The New England Fishery Management Council, established by Section 302 of the Magnuson Fishery Conservation and Management Act [Pub. L. 94–265, as amended], will hold a public meeting and a public hearing on the following topics:

*Public Meeting:* Discuss reports of the groundfish, scallops, lobster, surf clam/ocean quahog, and foreign fishing oversight committees as well as other fishery management and administrative matters.

**PUBLIC HEARING:** Discuss the Regional Director's recommendation regarding regulatory adjustments to the Sea Scallop FMP.

**DATES:**

*Public Meeting:* The meeting will convene on Tuesday, December 13, 1983, at approximately 10:00 a.m. and adjourn on Wednesday, December 14, 1983, at approximately 5:00 p.m. The meeting may be lengthened or shortened depending upon progress on the agenda, or agenda items may be rearranged.

*Public Hearing:* The pub hearing will convene on Wednesday, December 14, 1983, at approximately 9:00 a.m. and will adjourn at approximately 10:30 a.m. on the same day.

**ADDRESS:** The meeting will take place at the King's Grant Inn, Danvers, Massachusetts.

**FOR FURTHER INFORMATION CONTACT:** Douglas G. Marshall, Executive Director, New England Fishery Management Council, Suntaug Office Park, 5 Broadway (Route 1), Saugus, Massachusetts 01906, Telephone: 617–231–0422.

**SUPPLEMENTARY INFORMATION:** For information on seating arrangements, changes to the agenda, and/or written comments, contact the Executive Director.

Dated: November 22, 1983.

**Carmen J. Blondin,**

*Deputy Assistant Administrator for Fisheries Resource Management, National Marine Fisheries Service.*

[FR Doc. 83-31870 Filed 11-28-83; 8:45 am]

BILLING CODE 3510-22-M

# DEPARTMENT OF DEFENSE

## Department of the Navy

## Performance of Commercial Activities; Announcement of Program Cost Studies

Department of the Navy intends to conduct OMB Circular A–76 (48 FR 37110, August 16, 1983) cost studies of various functions at listed activities commencing 3 January 1984. Cost study process is rigorous, time-consuming procedure and, depending upon size of functions involved, can take several months to several years to complete.

Since studies not yet begun, specifications not yet prepared. When bids/proposals desired, appropriate advertisements will be placed.

*Naval Station, Long Beach, CA*
Recreational Library Service
*Fleet Numerical Oceanography Center, Monterey, CA*
Administrative Support
*Nuclear Weapons Training Group Pacific, North Island, San Diego, CA*
Audiovisual Services
*Commander, Training Command, U.S. Pacific Fleet, San Diego, CA*
Audiovisual Services
*Naval Training Center, San Diego, CA*
Furniture Repair/Salvage
Engineering Services and Technical Services
Administrative Support
*Fleet Combat Training Center, San Diego, CA*
Word Processing Center
Reference Libraries/Messenger Service
*Fleet Training Center, San Diego, CA*
Administrative Support
Data Processing Services
*Naval Education & Training Support Center, Pacific*
Test Measurement Equipment
Administrative Support
*Fleet Combat Systems Training Unit, Pacific, San Diego, CA*
Training Development and Support
*Personnel and Administration Assistance Team, Pacific, San Diego, CA*
Other Training
*Submarine Training Facility, San Diego, CA*
Administrative Support Services
*Naval Personnel Research & Development Center, San Diego, CA*
Data Processing Services
*Naval Submarine Support Facility, New London, Groton, CT*
Word Processing Center
Messenger Service
*Naval Air Station, Cecil Field, FL*
Operation of Bulk Liquid Storage
Recreational Library Services
Other ADP Operations and Support and System Design, Development and Programming Services
Administrative Support Services
*Naval Supply Center, Jacksonville, FL*
Physical Inventory
*Naval Station, Mayport, FL*
Recreation Library Services
*Naval Training Center, Orlando, FL*
Communications Center
*Naval Diving and Salvage Training Center, Panama City, FL*
Administrative Support
Storage and Warehousing
*Naval Air Station, Pensacola, FL*
Office Equipment
Air Transportation
Communications Center
*Naval Education and Training Program Development Center, Pensacola, FL*
Recreation Library Services
Communications Centers
*Naval Air Station, Atlanta, GA*
Data Processing Services
*Naval Electronics Engineering Activity, Pacific, Pearl Harbor, HI*
Engineering and Technical Services
Other Engineering and Technical Services
Systems Engineering/Installation of Communication Systems
*Naval Supply Center, Pearl Harbor, HI*
Crane and Rigging Operations
Preservation and Packaging
Administrative Support Services
*Naval Administrative Unit, Idaho Falls, ID*
Other Social Services
*Naval Air Station, New Orleans, LA*
Fueling Services (Aircraft)
*Enlisted Personnel Management Center, New Orleans, LA*
Audiovisual Services
Data Processing Services
System Design, Development and Programming Services
Technical Support Services
Other Automatic Data Processing
Administrative Support Services
*Naval Ordnance Station, Indian Head, MD*
Storage and Warehousing
*Naval Air Station, Meridian, MS*
Air Transportation
*Naval Home, Gulfport, MS*
Installation Bus Service
Motor Vehicle Operation
Other Installation Services
Buildings and Structures (Other than Family Housing)
Grounds and Surfaced Areas
*Naval Supply Center, Charleston, SC*
Preservation and Packaging
*Naval Station, Charleston, SC*
Library
*Polaris Missile Facility Atlantic, Charleston, SC*
Container Maintenance and Repair
Storage and Warehousing
Audiovisual—Still Photography
Administrative Support Services
Data Processing Services
Systems Design, Development and Programming Services
*Naval Air Maintenance Training Group, Memphis, TN*
Other Nonmanufacturing Operations
Other Repair and Maintenance
Administrative Support
Training Development and Support
*Naval Air Station, Chase Field, Beeville, TX*
Communications Center
*Naval Air Station, Corpus Christi, TX*
Recreational Library Services
Air Transportation Services
Communications Center
*Naval Air Station, Kingsville, TX*
Communications Center
*Naval Auxiliary Landing Field Detachment, Orange Grove, TX*
Other Installation Services
Fueling Services
*Naval Civilian Personnel Command, Arlington, VA*
Administrative Support Services
*Naval Amphibious Base, Little Creek, VA*
Other Installation Services
*Naval Safety Center, Norfolk, VA*
Printing and Reproducing
Custodial Services
Application and Software System Analysis and Programming
Aviation Mishap/Hazard Coding
Ship, Sub, Medical Mishap Coding
Microfilm Library
Computer Operations
Data Entry
Library and Technical Information Specialist
Administrative Support Services
Administrative and ADP Technical Guidance
Safety Publications
*Naval Air Station, Oceana, VA*
Other Non-Manufacturing Operations
*Strategic Weapons Facility, Bremerton, WA*
Other Repair, Maintenance, Modification, Alteration, and Rebuild of Equipment
Storage and Warehousing
Administrative Support Services
Data Processing Services
Systems Design, Development, and Programming Services

Dated: November 10, 1983.

**B. W. Cook,**

*Captain, U.S. Navy Head, Commercial Retail/Activities Branch.*

[FR Doc. 83-31315 Filed 11-28-83; 8:45 am]
BILLING CODE 3810-AE-M

## DEPARTMENT OF EDUCATION

### Office of Postsecondary Education

### National Resource Centers Program ans Foreign Language and Area Studies Fellowships Program—Extension of Application Date for Non-Competing Continuation Awards, Increase in Fellowship Stipends and Higher Program Funding Levels for Fiscal Year 1984

*Date Extension:* The closing date for non-competing continuation awards for the National Resource Centers Program and the Foreign Language and Area

Studies Fellowships Program, announced as December 5, 1983 in the **Federal Register** of October 19, 1983, has been extended to December 19, 1983.

*Reason for Extension:* The Department of Education Appropriation Act, 1984, Public Law 98-139, increased the amount of funds available to the Centers and Fellowships programs in fiscal year 1984 over the amount which was available in fiscal year 1983. The previous closing date notice indicated that the amount of funds available for Centers and Fellowships was equal to the amount available in fiscal year 1983.

The closing date extension is being made in order to give eligible institutions time to modify their applications to reflect the increase.

*Increase in Fellowship Stipends:* In view of the additional funds that are available in fiscal year 1984 and the financial need of fellows, the Secretary of Education has determined that the maintenance stipend portion of fellowships shall be increased from $4000 to $5000 for academic year fellowships and from $1000 to $1250 for summer fellowships. In addition, travel will be included as an allowable fellowship cost where the fellow will be studying at another campus; e.g., to a central institute in the summer. The maximum travel cost may not exceed $500.

*Available Funds:* The October 14, 1983 announcement indicated that $10,600,000 would be available for Centers and $6,000,000 for Fellowships. The Department of Education Appropriation Act, 1984, appropriated additional funds for International Education Programs, which resulted in a $1.5 million increase in the allocation for Centers, bringing the total available to $12.1 million, and a $1.2 million increase for Fellowships, bringing the total available to $7.2 million.

*Supplementary Instructions:* Supplementary instructions and materials are being sent to eligible applicants by the Department of Education. If you do not receive the information within five (5) days of this publication, contact the Department at once.

*For Further Information Contact:* Mr. Joseph F. Belmonte, Chief of Centers and Fellowships Branch, International Education Programs, U.S. Department of Education (Room 3923, Regional Office Building 3), 400 Maryland Avenue, SW., Washington, D.C. 20202. Telephone: (202) 245-2356 (20 U.S.C. 1122).

(Catalog of Federal Domestic Assistance No. 84.015—National Resource Centers and Foreign Language and Area Studies Fellowships Programs)

Dated: November 25, 1983.

**Edward M. Elmendorf,**

*Assistant Secretary for Postsecondary Education.*

[FR Doc. 83-31954 Filed 11-28-83; 8:45 am]

BILLING CODE 4000-01-M

## DEPARTMENT OF ENERGY

### Voluntary Agreement and Plan of Action To Implement the International Energy Program; Meeting

In accordance with section 252(c)(1)(A)(i) of the Energy Policy and Conservation Act (42 U.S.C. 6272 (c)(1)(A)(i)), the following meeting notice is provided:

A joint meeting of Subcommittees A and C of the Industry Advisory Board to the International Energy Agency will be held on December 7 and 8, 1983, at the offices of Exxon Corporation, 1251 Avenue of the Americas, New York, New York, beginning at 9:00 a.m. on December 7. The agenda for the meeting is as follows:

1. Opening remarks.
2. U.S. legislation and Plan of Action.
3. Application for legal clearance under the European Economic Community Treaty.
4. Future work program.

As provided in section 252(c)(1)(A)(ii) of the Energy Policy and Conservation Act, this meeting will not be open to the public.

Issued in Washington, D.C., November 17, 1983.

**Craig S. Bamberger,**

*Assistant General Counsel, International Trade and Emergency Preparedness.*

[FR Doc. 83-31795 Filed 11-28-83; 8:45 am]

BILLING CODE 6450-01-M

## Federal Energy Regulatory Commission

**[Docket No. ER80-592, et al. ER80-678-000 and ER80-320-003]**

### Allegheny Power System, et al.; Refund Report

November 23, 1983.

Take notice that on November 11, 1983, Iowa Southern Utilities Company ("Iowa") submitted for filing its Refund Report. Iowa states that no transactions of any kind occurred which would require refunds as a result of the rate levels set by the approved settlement in conjunction with Order 84.

Any person desiring to be heard or to protest this filing should file comments with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, on or before November 30, 1983. Comments will be considered by the Commission in determining the appropriate action to be taken. Copies of this filing are on file with the Commission and are available for public inspection.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 83-31896 Filed 11-28-83; 8:45 am]

BILLING CODE 6717-01-M

**[Docket No. ER80-84-000]**

### Arizona Public Service Co.; Filing

November 23, 1983.

The filing Company submits the following:

Take notice that on November 10, 1983, Arizona Public Service Company (Arizona) tendered for filing Amendment No. 1 to the Arizona-Edison Cholla No. 4 Layoff Agreement between Arizona Public Service Company (Arizona), and Southern California Edison Company (Edison), executed October 27, 1983.

Arizona states that the proposed changes would correct errors existing in the original Agreement, increase Edison's entitlement share of Cholla No. 4 generating capacity and associated energy, and extend the term of the Agreement from June 1, 1989 to May 31, 1990.

Copies of the filing have been served upon the Arizona Corporation Commission and Southern California Edison Company.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426 in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before December 9, 1983. 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 motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 83-31897 Filed 11-28-83; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER84-86-000]

## Arizona Public Service Co.; Filing

November 23, 1983.

The filing Company submits the following:

Take notice that on November 10, 1983, Arizona Public Service Company (Arizona) tendered for filing as a tariff change an Amendment to the Interruptible Transmission Service Agreement between Arizona Electric Power Cooperative, Inc. (AEPCO) and Arizona executed October 19, 1983.

Arizona states that the Amendment updates the rate to current levels.

Arizona requests an effective date of November 1, 1983, and therefore requests waiver of the Commission's notice requirements.

A copy of the filing have been served upon the Arizona Corporation Commission.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 3895.214). All such motions or protests should be filed on or before December 7, 1983. 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 motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 83-31898 Filed 11-28-83; 8:45 am]

BILLING CODE 6717-01-M

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[Docket No. ER84-87-000]

## Arizona Public Service Co.; Filing

November 23, 1983.

The filing Company submits the following:

Take notice that on November 10, 1983, Arizona Public Service Company (Arizona) tendered for filing as a tariff change an Amendment to the Interruptible Transmission Service Agreement between San Diego Gas & Electric Company (SDG&E) and Arizona executed October 19, 1983. This Amendment updates the rate to current levels.

Arizona requests an effective date of November 1, 1983, and therefore requests waiver of the Commission's notice requirements.

A copy of this filing has been served upon the Arizona Corporation Commission.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 or 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before December 7, 1983. 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 proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 83-31899 Filed 11-28-83; 8:45 am]

BILLING CODE 6717-01-M

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[Docket No. ER84-85-000]

## Arizona Public Service Co.; Filing

November 23, 1983.

The filing Company submits the following:

Take notice that on November 10, 1983, Arizona Public Service Company (Arizona) tendered for filing Amendment 2 to the executed Agreement for transmission service to be initiated January 1984 between Plains Electric Generation and Transmission Cooperative, Inc., and Arizona Public Service Company.

Arizona requests an effective date of January 1, 1984, and therefore requests waiver of the Commission's notice requirements.

A copy of this filing has been served upon the Arizona Corporation Commission.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before December 7, 1983. 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 motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 83-31900 Filed 11-28-83; 8:45 am]

BILLING CODE 6717-01-M

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[Docket No. ER84-91-000]

## Delmarva Power & Light Co.; Filing

November 23, 1983.

The filing Company submits the following:

Take notice that on November 14, 1983, Delmarva Power & Light Company (Delmarva) tendered for filing proposed changes to Supplement No. 5 to Rate Schedule FPC No. 11 (Schedule 1.01 to Supplement Agreement between Delmarva and the Easton Utilities Comission and the Town of Easton (Easton)). The proposed changes are expected to increase revenues from jurisdictional services.

Delmarva states that the proposed changes to Supplement No. 5, to be implemented in two phases, are intended to permit Delmarva to recover foregone savings as a result of bulk power transactions undertaken for Easton under Schedule 1.01 and to permit Delmarva to recover foregone revenues resulting from the power used to reallocate transmission line transfer capability in providing such services.

Copies of this filing has been served upon Easton and the Maryland Public Service Commission.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should by filed on or before December 9, 1983. Protest 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 motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 83-31901 Filed 11-28-83; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. ER84-93-000]

## Delmarva Power & Light Co.; Filing

November 23, 1983.

The filing Company submits the following:

Take notice that on November 14, 1983, Delmarva Power & Light Company (Delmarva) tendered for filing Third Revised Leave No. 38, to Delmarva's FERC Electric Transmission Service Rate Schedules 56, 58, 59, 60, 64 and 65.

Delmarva requests an effective date of January 1, 1984, and therefore requests waiver of the Commission's notice requirements.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before December 9, 1983. 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 motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 83-31902 Filed 11-28-83; 8:45 am]

BILLING CODE 6717-01-M

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[Docket ER84-83-000]

## Idaho Power Co.; Filing

November 23, 1983.

The filing Company submits the following:

Take notice that on November 10, 1983, Idaho Power Company (Idaho) tendered for filing in compliance with the Federal Energy Regulatory Commission's Order of October 7, 1978, a summary of sales made under the Company's 1st Revised FERC Electric Tariff, Volume No. 1 (Supersedes Original Volume No. 1) during September 1983, along with cost justification for the rate charged. This filing includes the following supplements:

Utah Power & Light Company, Supplement 23; Montana Power Company, Supplement 21; Sierra Pacific Power Company, Supplement 21; Portland General Electric Company, Supplement 16; Washington Water Power Company, Supplement 12; City of Burbank, Supplement 13; City of Pasadena, Supplement 13; City of Glendale, Supplement 13; Los Angeles Dept of Water & Power, Supplement 13; Southern California Edison Company, Supplement 14; San Diego Gas & Electric Company, Supplement 11.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before December 7, 1983. 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 motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 83-31903 Filed 11-28-83; 8:45 am]

BILLING CODE 6717-01-M

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[Docket No. ER84-90-000]

## Ohio Edison Co.; Filing

November 23, 1983.

The filing Company submits the following:

Take notice that on November 14, 1983, Ohio Edison Company (OE) tendered for filing proposed changes in its FPC Electric Service Tariff, No. 44. The proposed changes would extend the existing manual back-up provision between OE's Sammis Unit 6 and The Cleveland Electric Illuminating Company's Avon Lake Unit 9.

OE states that the change has been proposed because the mutual back-up provision incorporated into the Agreement dated February 23, 1963 was to terminate October 15, 1983. OE and Cleveland Electric Illuminating Company desire to continue the mutual back-up provision.

OE requests an effective date of October 15, 1983, and therefore requests waiver of the notice requirements.

Copies of this filing have been served upon the Public Utilities Commission of Ohio.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with Rule 211 or 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before December 9, 1983. 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 proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 83-31904 Filed 11-28-83; 8:45 am]

BILLING CODE 6717-01-M

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[Docket No. ER84-92-000]

## Pennsylvania Power & Light Co.; Notice of Filing

November 23, 1983.

The filing Company submits the following:

Take notice that Pennsylvania Power & Light Company (PP&L), on November 14, 1983, tendered for filing proposed changes in its Rate Schedule FERC Nos. 28, 32, 45, 50, 51, 54, 56, 57, 58, 63, 65, 69, 70, 71, 79 and 61, applicable to the Boroughs of Watsontown, Duncannon, Blakely, Weatherly, Schuylkill Haven, Perkasie, St. Clair, Catawissa, Ephrata, Lehighton, Olyphant, Hatfield, Mifflinburg, Quackertown, Kutztown and to Citizens' Electric Company of Lewisburg, respectively. The proposed changes would increase revenues from jurisdictional sales and service by $4,169,105 or 20.0%, based on the 12-month period ending June 30, 1984.

PP&L states that the proposed increase is required by the increase in the cost of providing service to said jurisdictional customers which PP&L has experienced since the base rates of these customers became effective on July 4, 1982.

PP&L requests an effective date of January 14, 1984.

Copies of this filing were served upon PP&L's jurisdictional customers named above and upon the Pennsylvania Public Utility Commission.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before December 9, 1983. 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 motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 83-31905 Filed 11-28-83; 8:45 am]

BILLING CODE 6717-01-M

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**[Docket No. ER84-88-000]**

## San Diego Gas & Electric Co.; Filing

November 23, 1983.

The filing Company submits the following:

Take notice that on November 10, 1983, San Diego Gas & Electric Company (SDG&E) tendered for filing two agreements entitled "Short Term Firm Agreements" which have been executed by SDG&E and Southern California Edison Company (Edison).

SDG&E states that under the terms and conditions of the agreements, SDG&E will make available to Edison short term firm and interruptible transmission service between San Onofre and the United States-Mexico border near Tijuana.

SDG&E requests an effective date of December 9, 1983, and therefore requests waiver of the Commission's notice requirements.

Copies of this filing have been served upon the Public Utilities Commission of the State of California and Edison.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before December 9, 1983. 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 motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 83-31906 Filed 11-28-83; 8:45 am]

BILLING CODE 6717-01-M

**[Docket No. ER84-89-000]**

## Southern California Edison Co.; Filing

November 23, 1983.

The filing Company submits the following:

Take notice that on November 14, 1983, Southern California Edison Company (Edison) tendered for filing a notice of change of rates for transmission service as embodied in Amendment No. 1 of the Edison-Vernon Integration and Interruptible Transmission Service Agreement (Amendment) between Edison and the City of Vernon, California (Rate Schedule FERC No. 149).

Edison requests an effective date of January 1, 1984, and therefore requests waiver of the Commission's notice requirements.

Copies of this filing have been served upon the Public Utilities Commission of the State of California and the City of Vernon, California.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before December 9, 1983. 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 motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 83-31907 Filed 11-28-83; 8:45 am]

BILLING CODE 6717-01-M

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**[Docket No. ER84-94-000]**

## Southern California Edison Co.; Notice of Filing

November 23, 1983.

The filing Company submits the following:

Take notice that on November 14, 1983, Southern California Edison Company (Edison) tendered for filing a notice of change of rates for transmission service as embodied in Edison's agreements with the following entities:

| | Rate schedules FERC No. |
|---|---|
| City of Los Angeles | 102, 118, 140, and 141. |
| Pacific Gas and Electric Company | 117 and 147. |
| Western Area Power Administration | 120. |
| Arizona Power Pooling Association | 93. |
| Arizona Electric Power Cooperative | 132. |
| California Department of Water Resources | 38, 112, and 113. |

Edison requests an effective date of January 1, 1984, and therefore requests waiver of the Commission's notice requirements.

Copies of this filing were served upon the Public Utilities Commission of the State and all interested parties.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). All such motions or protests should be filed on or before December 9, 1983. 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 motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 83-31908 Filed 11-28-83; 8:45 am]

BILLING CODE 6717-01-M

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# ENVIRONMENTAL PROTECTION AGENCY

**[SWH-FRL-2478-6]**

## Availability of Draft Report on Investigation of Stablex®

## Material Emplaced at West Thurrock Facility, England

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of availability of draft report on investigation of Stablex® material emplaced at West Thurrock Facility, England and request for comments.

**SUMMARY:** This notice announces the availability of, and requests public comment on, a draft report prepared by the U.S. Army Corps of Engineers for EPA on the SEALOSAFE® solidification process which is proposed for use by the

Stablex Corporation at two sites in the United States.

**DATE:** Comments on the draft report must be submitted no later than February 27, 1984.

**ADDRESSES:** A copy of the draft report may be obtained, free of charge, by calling the RCRA/Superfund Hotline at (800) 424-9346 (Toll-free) or in Washington, D.C. at (202) 382-3000 or the RCRA Docket at (202) 382-4672. Comments on the draft report should be sent to the Docket Clerk, Office of Solid Waste (WH-562), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460. Communications should identify the docket as Stablex Report."

**FOR FURTHER INFORMATION CONTACT:** Eileen Claussen, Office of Solid Waste (WH-562), U.S. Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460, (202) 382-4637.

**SUPPLEMENTARY INFORMATION:** Over the past several years, EPA has received several exclusion petitions from the Stablex Corporation to temporarily exclude from hazardous waste regulation the treatment residue to be generated from Stablex's proposed facilities in Groveland, Michigan and Hooksett, New Hampshire. Based on their petitions, EPA granted conditional temporary exclusions for the SEALOSAFE® treated waste to be generated at these proposed facilities. In addition, Stablex also allowed EPA to visit the Stablex Limited facility in England (a licensee of the Stablex process). Thus, in the Spring of 1981, EPA and the U.S. Army Engineers Waterways Experiment Station (WES) undertook a field and laboratory study to characterize the treated residue generated at Stablex Limited's facility in Essex County, England. This study was undertaken in part to determine whether the data submitted as part of the Stablex Corporation's petitions could be verified in a full scale facility operating under field conditions.

Thirteen cores of the solidified SEALOSAFE® treated waste were collected by the U.S. Army Corps of Engineers from the Aveley Clay Pit and Thurrock Chalk Quarry disposal areas at Stablex Limited's Thurrock site in England to determine if, under routine waste management conditions, these wastes would degrade with time and leach significant concentrations of toxic heavy metals and cyanide and contaminate the surrounding environment. In addition, samples of surface water, ground water, uncured SEALOSAFE® treated waste, and subwaste rock and soil were also collected to characterize the effectiveness of the treatment process used at the West Thurrock facility.

The draft report describes the methods used in collecting these samples, the procedures used and results obtained in testing and analyzing them, and a discussion of the analytical results.

EPA believes that the additional data/information in this report should be considered before reaching a decision on the final delisting of the wastes proposed to be treated via the SEALOSAFE® process at Stablex Corporation's proposed facilities in the United States. Accordingly, EPA is requesting public comment on this draft report.

Dated: November 21, 1983.

**Lee M. Thomas,**

*Assistant Administrator.*

[FR Doc. 83-31720 Filed 11-28-83; 8:45 am]

BILLING CODE 6560-50-M

## EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

### Privacy Act of 1974; Amendments to Systems of Records

**AGENCY:** Equal Employment Opportunity Commission.

**ACTION:** Final Notice.

**SUMMARY:** Amendment of two Privacy Act Systems of Records maintained by the Equal Employment Opportunity Commission to be in compliance with Section 2 of the Debt Collection Act of 1982 (Pub. L. 97-365).

**DATES:** These amendments are effective November 29, 1983.

**FOR FURTHER INFORMATION CONTACT:** R. William Mason, Legal Services, Office of Legal Counsel, EEOC, 2401 E Street, NW., Washington, D.C. 20507, Telephone number (202) 634-6592.

**SUPPLEMENTARY INFORMATION:** The original text of the Privacy Act contained 11 provisions under which agencies could disclose personal information from systems of records without securing the subject's consent. 5 U.S.C 552a(b). The Debt Collection Act of 1982 amended the Privacy Act to create a new general disclosure authority as subsection (b)(12). This subsection permits agencies to disclose information from their systems of records, without obtaining the consent of the record subject, "to a consumer reporting agency in accordance with section 3(d) of the Federal Claims Collection Act of 1966, 31 U.S.C. 3711(f)." Debt Collection Act of 1982, section 2, 96 Stat. 1749. In order to insure against indiscriminate disclosures, the Debt Collection Act places stringent limitations on the disclosure process affecting both the timing and content of the disclosure pursuant to subsection (b)(12). The Act also places restrictions on who can receive the information pursuant to subsection (b)(12) and what that recipient can do with the information received. *See* 31 U.S.C. 3711(f). The term "consumer reporting agency" is defined under the Debt Collection Act of 1982 as either:

1. "Any person which, for monetary fees, dues, or on a cooperative nonprofit basis, regularly engages in whole or in part in the practice of assembling or evaluating consumer credit information or other information on consumers for the purpose of furnishing consumer reports to third parties, and which uses any means or facility of interstate commerce for the purpose of preparing or furnishing consumer reports * * *." 15 U.S.C. 1681a(f); or

2. "Any person who, for monetary fees, dues, or on a cooperative nonprofit basis, regularly engages in whole or in part in the practice of (I) obtaining credit or other information on consumers for the purpose of furnishing such information to consumer reporting agencies (as defined in 15 U.S.C. 1681a(f) above), or (II) serving as a marketing agent under arrangements enabling third parties to obtain such information from such reporting agencies * * *." 31 U.S.C. 3711(d)(4).

The Privacy Act of 1974, as amended, 5 U.S.C. 552a(e)(4), requires agencies to publish, upon establishment or revision, a notice of the existence and character of their systems of records. The Equal Employment Opportunity Commission last published the full text of its systems of records at 47 FR 18654 (April 30, 1982). This notice amends the Systems of Records for EEOC-7, Employee Pay and Leave Records, and EEOC-8, Employee Travel and Reimbursement Records, as published in 47 FR 18654 to permit the disclosure of information as authorized by section 2 of the Debt Collection Act of 1982. This notice constitutes a final rule since it implements a legislative requirement for which no published comment period is necessary. There is no regulatory impact under Executive Order 12291. Under section 605(b) of the Regulatory Flexibility Act, the EEOC further certifies that this rule will not have a significant impact on a substantial number of small entities.

Signed at Washington, D.C., this 22nd day of November 1983.

For the Commission.

**Clarence Thomas,**

*Chairman, Equal Employment Opportunity Commission.*

Systems of Records EEOC-7, Employee Pay and Leave Records, and EEOC-8, Employee Travel and Reimbursement Records, found at 47 FR 18660-18661 (April 30, 1982), are amended to read as follows:

## EEOC-7

**SYSTEM NAME:**

Employee Pay and Leave Records—EEOC.

**SYSTEM LOCATION:**

All locations listed in Appendix A.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Current and former employees of EEOC.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Time and attendance cards and forms; leave records (employee name, branch or office, pay period ending, leave and overtime used during the pay period); requests for leave (earned or advance) or leave of absence; requests for an authorization of overtime; annual attendance record (indicates name, social security number, service computation date, hours and dates worked and taken as leave, pay plan, salary and occupation code, grade, leave earned and used); bond issuance and bond balance.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

5 U.S.C. 301; 44 U.S.C. 396(a).

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

May be used by authorized EEOC personnel to keep a daily record of leave and overtime acquired and used; as a basis for maintaining an employee's official time card; and as a counseling aid for employees and to assist in evaluating an employee's performance.

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

Routine uses of records maintained in this system include providing a copy of an employee's Department of the Treasury Form W-2, Wage and Tax Statement, to the State, city, or other local jurisdiction which is authorized to tax the employee's compensation. The record will be provided in accordance with a withholding agreement between the State, city,or other local jurisdiction and the Department of Treasury pursuant to 5 U.S.C. 5516, 5517, or 5520, or in the absence thereof, in response to a written request from an appropriate official of the taxing jurisdiction to the Chairman. The request must include a copy of the applicable statute or ordinance authorizing the taxation of compensation and should indicate whether the authority of the jurisdiction to tax the employee is based on place of residence, place of employment, or both.

Pursuant to a withholding agreement between a city and the Department of the Treasury (5 U.S.C. 5520), copies of executed city tax withholding certificates shall be furnished the city in response to a written request from an appropriate city official to the Chairman.

In the absence of a withholding agreement, the social security number will be furnished only to a taxing jurisdiction which has furnished this agency with evidence of its independent authority to compel disclosure of the social security number, in accordance with Section 7 of the Privacy Act, 5 U.S.C. 552a, Pub. L. 93-579.

Records maintained in this system may be disclosed, as necessary, to employees of the Educational Systems Corporation for research purposes only to study the effects of providing day-care services on the job productivity and worker satisfaction of Commission employees.

In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a "routine use," to the appropriate agency, whether Federal, State, local or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto.

A record from this system of records may be disclosed as a "routine use" to a Federal, State or local agency maintaining civil, criminal or other relevant enforcement information or other pertinent information such as current licenses, if necessary, to obtain information relevant to an agency decision concerning the hiring or retention of any employee, the issuance of a security clearance, the letting of a contract or the issuance of a license, grant or other benefit.

A record from this system of records may be disclosed to a Federal agency, in response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation or the issuance of a license, grant or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision in the matter.

A record from this system of records may be disclosed to an authorized appeal grievance examiner, formal complaints examiner, equal employment opportunity investigator, arbitrator or other duly authorized official engaged in investigation or settlement of a grievance, complaint, or appeal filed by an employee. A record from this system of records may be disclosed to the Office of Personnel Management in accordance with the agency's responsibility for evaluation and oversight of Federal personnel management.

A record from this system of records may be disclosed to officers and employees of the General Services Administration in connection with administrative services provided to this agency under agreement with GSA.

**DISCLOSURE TO CONSUMER REPORTING AGENCIES:**

*Disclosures pursuant to 5 U.S.C. 552a(b)(12):* Disclosures may be made from this system to "consumer reporting agencies" as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) or the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)).

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OR RECORDS IN THE SYSTEM:**

**STORAGE:**

Stored on magnetic tape.

**RETRIEVABILITY:**

Indexed by an assigned employee code.

**SAFEGUARDS:**

Access to any information maintained therein is limited to employees whose official duties require such access.

**RETENTION AND DISPOSAL:**

The records are maintained for three (3) years. Thereafter, they are manually destroyed.

**SYSTEM MANAGER(S) AND ADDRESS:**

Chief, Finance Branch, EEOC, 2401 E Street NW., Washington, D.C. 20506.

**NOTIFICATION PROCEDURE:**

Inquires concerning this system of records should be addressed to the

System manager, It is necessary to furnish the following information (1) name (2) social security number (3) mailing address to which the response is to be sent.

**RECORD ACCESS PROCEDURES:**

Same as above.

**CONTESTING RECORD PROCEDURES:**

Same as above.

**RECORD SOURCE CATEGORIES:**

Bills, receipts, and claims presented by employees and original data generated by the Commission.

**RECORD SOURCE CATEGORIES:**

Official personnel folder, data submitted by employees, and data submitted by the offices where the individuals are or were employed.

**EEOC-8**

**SYSTEM NAME:**

Employee Travel and Reimbursement Records:

**SYSTEM LOCATION:**

EEOC Headquarters, 2401 E Street NW., Washington, D.C. 20506.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Current and former EEOC employees.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Includes travel orders, records of travel advances, amounts owed the agency by employees for travel and other purposes, amounts payable to the employee for travel and other purposes, payments made to the employees for travel and other reimburasable transactions and a record of the difference between the cost of official travel as estimated in the travel order and the amount actually expended by the employee.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

31 U.S.C. 66a. 44 U.S.C. 3101.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Used by authorized personnel in the Finance Branch at headquarters as a record of planned and completed travel expenses; as a justification of government travel disbursements; and to record accounts receivable from and payable to the government for accounts advanced to the employee or owed to the employee for official travel and other purposes.

In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred as a "routine use," to the appropriate agency, whether Federal, State, local or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto.

A record from this system of records may be disclosed as a "routine use" to a Federal, State or local agency maintaining civil, criminal or other relevant enforcement information or other pertinent information such as current licenses, if necessary to obtain information relevant to an agency decision concerning the hiring or retention of any employee, the issuance of a security clearance, the letting of a contract or the issuance of license, grant or other benefit.

A record from this system of records may be disclosed to a Federal agency, in response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation or the issuance of a license, grant or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision in the matter.

A record from this system of records may be disclosed to an authorized appeal grievance examiner, formal complaints examiner, equal employment opportunity investigator, arbitrator or other duly authorized official engaged in investigation or settlement of a grievance, complaint, or appeal filed by an employee. A record from this system of records may be disclosed to the Office of Personnel Management in accordance with the agency's responsibility for evaluation and oversight of Federal personnel management.

A record form this system of records may be disclosed to officers and employees of the General Services Administration in conection with administrative services provided to this agency under agreement with GSA.

**DISCLOSURES TO CONSUMER REPORTING AGENCIES:**

*Disclosures pursuant to 5 U.S.C. 552a(b)(12):* Disclosures may be made from this system to "consumer reporting agencies" as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) of the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)).

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Stored on prepared forms and on punched and unpunched cards.

**RETRIEVABILITY:**

Indexed alphabetically by name, social security number, and/or chronologically by event and name.

**SAFEGUARDS:**

Access to and use of these records are limited to those persons whose official duties require such access. Personnel screening is employed to prevent unauthorized disclosure. Files are stored in standard cabinets, safes and secured rooms.

**RETENTION AND DISPOSAL:**

Maintained for varying periods of time in accordance with GSA General Records Schedule 2. They are then manually destroyed.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director of each Commission Office or Division at headquarters; District and Area Directors (see Appendix A.).

**NOTIFICATION PROCEDURE:**

Employees of the Commission wishing to know whether information about them is maintained in this system of records should address inquiries to the Director of the Office or Division where employed or to the District or Area Director if employed at a field installation (see Appendix A.). Former employees separated from the Commission and no longer in the federal service should address all inquiries to the National Personnel Records Center, General Services Administration, 111 Winnebago Street, St. Louis, Missouri 03118. The individual should provide his or her full name, date of birth, social security number and mailing address.

**RECORD ACCESS PROCEDURE:**

Same as the above.

**CONTESTING RECORD PROCEDURES:**

Same as the above.

[FR Doc. 83-31799 Filed 11-28-83; 8:45 am]
BILLING CODE 6570-06-M

## FEDERAL COMMUNICATIONS COMMISSION

### FCC Rules Pamphlets Now Available

November 14, 1983.

FCC Rules Pamphlets listed on the attachment are now available from the Government Printing Office (GPO). The listing provides the price and stock number of, and the rule parts included in, each pamphlet. In conjunction with the listing, an order form is provided for your use.

Several rule parts that were originally contained in various volumes are now available as separate pamphlets. Further, rule parts previously contained in Volumes X and XI have been regrouped by subject matter into separate pamphlets. These changes have been instituted to allow those interested in one specific part to purchase only the segment needed.

Like the FCC Rules Volumes, the pamphlets are revised as of September 30, 1982, and produced using an automated system. The Commission anticipates reprinting each pamphlet each year or whenever the need arises. These pamphlets are not sold on a subscription basis but, rather, as separate publications.

Rules in these pamphlets are identical to the corresponding portions of Title 47 of the Code of Federal Regulations. It is not necessary to purchase both. In addition, it is possible that an updated set of pamphlets will be printed early in 1984, depending on the success of further refinements to the automated process.

Questions and comments may be directed to Callie Holder at 1919 M Street, NW., Room 224, Washington, D.C. 20554, or by phone at (202) 632-4178.

**William J. Tricarico,**

*Secretary, Federal Communications Commission.*

Part 13—Commercial Radio Operators (Formerly in Volume I), S/N 004-000-00415-9, $2.25.

Part 17—Construction, Marking, and Lighting of Antenna Structures (Formerly in Volume I), S/N 004-000-00416-7, $2.75.

Part 41—Telegraph and Telephone Franks; Part 51—Occupational Classification and Compensation of Employees of Telephone Companies; Part 52—Classification of Wire-Telegraph Employees; Part 66—Applications Relating to Consolidation, Acquisition, or Control of Companies (Parts listed above were formerly in Volume X), S/N 004-000-00417-5, $2.75.

Part 42—Preservation of Records of Communication Common Carriers; Part 43—Reports of Communication Common Carriers and Certain Affiliates; Part 63—Extension of Lines and Discontinuance of Service by Carriers; Part 64—Miscellaneous Rules Relating to Common Carriers (Parts listed above were formerly in Volume X), S/N 004-000-00418-3, $4.00.

Part 61—Tariffs; Part 62—Applications to Hold Interlocking Directorates; Part 67—Jurisdictional Separations (Parts listed above were formerly in Volume X), S/N 004-000-00419-1, $3.00.

Part 68—Connection of Terminal Equipment to the Telephone Network (Formerly in Volume X), S/N 004-000-00420-5, $4.50.

Part 76—Cable Television Service; Part 78—Cable Television Relay Service (Parts listed above were in Volume XI), S/N 004-000-00421-1, $3.75.

Part 95—Subpart E (Technical Regulations) (Formerly in Volume VI), S/N 004-000-00414-1, $2.00.

Part 95—Subpart C (Radio Control) (Formerly in Volume VI), S/N 004-000-00426-4, $2.25.

Part 97—Amateur Radio Service (Formerly in Volume VI), S/N 004-000-00424-8, $375.

Part 99—Disaster Communications Service (Formerly in Volume VI), S/N 004-000-00422-1, $2.25.

Part 100—Direct Broadcast Satellite Service, S/N 004-000-00423-0, $2.00.

[FR Doc. 83-31863 Filed 11-28-83; 8:45 am]
BILLING CODE 6712-01-M

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[CC Docket No. 80-286]

### Federal-State Joint Board Meeting

November 22, 1983.

The Federal-State Joint Board in this proceeding will meet on Wednesday, November 30, 1983 at 1:00 p.m. in Room 856, the Commission Meeting Room, at 1919 M Street, N.W., Washington, D.C. The Joint Board will discuss issues related to the separation of local exchange telephone costs, including, among other things: (1) Protection for high costs areas; (2) possible activities designed to monitor implementation of access charges and separations changes; and (3) effects of access charges on Centrex/CO lines.

For further information contact Claudia Pabo of the Policy and Program Planning Division, Common Carrier Bureau at (202) 632-9342.

**William J. Tricarico,**

*Secretary, Federal Communications Commission.*

[FR Doc. 83-31867 Filed 11-28-83; 8:45 am]
BILLING CODE 6712-01-M

### National Industry Advisory Committee, Common Carrier Communications Subcommittee; Meeting

November 18, 1983.

Pursuant to the provisions of Pub. L. 92-463, announcement is made of a public meeting of the Common Carrier Communications Subcommittee of the National Industry Advisory Committee (NIAC) to be held Thursday, December 8, 1983. The meeting will consist of two parts, as follows:

At 9:30 A.M. the Common Carrier Communications Subcommittee will join the Emergency Broadcast Subcommittee at the Board Room of the National Association of Broadcasters, 1771 N Street, N.W., Washington, D.C. This joint meeting will be briefed by Commission staff on emergency communications functions.

At 2:00 P.M. the Common Carrier Communications Subcommittee will convene at AT&T Long Lines, 1120-20th Street, N.W. Washington, D.C. in Conference Room A/B on the 10th Floor. The purpose and agenda of this afternoon session are as follows:

Purpose: To consider emergency communications matters.

Agenda:

1. Opening remarks by Chairman.
2. Review of morning joint meeting and determination of recommendations to be presented to Long Range Planning Committee.
3. Report by the National Communications System (NCS) concerning a study of potential revision of the restoration priority (RP) system for private line services.
4. Determination of a Subcommittee position concerning RP systems for private line services.
5. Other business.
6. Adjournment.

Any member of the public may atend or file a written statement with the subcommittee either before or after the meeting. Anyone wishing to make an oral statement must consult with the Subcommittee prior to the meeting. Those desiring more specific information about the meeting may telephone the NIAC Executive Secretary in the FCC Emergency Communications Division at (202) 634-1549.

**William J. Tricarico,**

*Secretary, Federal Communications Commission.*

[FR Doc. 83-31868 Filed 11-28-83; 8:45 am]
BILLING CODE 6712-01-M

## Public Information Collection Requirement Submitted to Office of Management and Budget for Review

November 18, 1983.

The Federal Communications Commission has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1980, Pub. L. 96-511.

Copy of the submission are available from Richard D. Goodfriend, Agency Clearance Officer, (202) 632-7513. Persons wishing to comment on this information collection should contact David Reed, Office of Management and Budget, Room 3235 NEOB, Washington, D.C. 20503, (202) 395-7231.

Title: No Offer on Solicitation.

Form No.: FCC 205.

Action: Existing collection in use without OMB control number.

Respondents: Business (including small business).

Estimated Annual Burden: 60 Responses; 5 hours.

The form is attached to all Invitations for Bid and Requests for Proposals. Prospective bidders deciding against submission of bid or proposal complete and return form noting reason(s).

**William J. Tricarico,**

*Secretary, Federal Communications Commission.*

[FR Doc. 83-31866 Filed 11-28-83; 8:45 am]

BILLING CODE 6712-01-M

## Technical Subgroup of Radio Advisory Committee Resumes Meeting December 12, 1983

The Technical Subgroup of the Advisory Committee on Radio Broadcasting resumes its continuing meeting Monday, December 12, 1983 at 2 p.m. in the 5th Floor Conference Room of the National Association of Broadcasters, 1771 N Street NW., Washington, D.C.

The Subgroup will continue its consideration of matters pertinent to the development and implementation of a new bilateral AM agreement between the United States and Canada which is expected to replace the North American Regional Broadcasting Agreement (NARBA).

The Subgroup will also discuss similar bilateral discussions which are being conducted with Mexico, looking toward post-Rio revision of the U.S.-Mexican AM Agreement.

The meeting, a continuing one, will be resumed after the December 12, 1983, session at such time and place as is decided at that session. It is open for participation by all interested persons.

For further information, please call the Subgroup Chairman, Mr. Wallace E. Johnson, at (703) 841-0500.

**William J. Tricarico,**

*Secretary, Federal Communications Commission.*

[FR Doc. 83-31882 Filed 11-28-83; 8:45 am]

BILLING CODE 6712-01-M

## Telecommmunications Industry Advisory Group; Definitions and Rules Subcommittee Meeting

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is given of a meeting of the Telecommunications Industry Advisory Group's (TIAG) Definitions and Rules Subcommittee scheduled to meet on Monday, December 12, 1983. The meeting will begin at 9:30 am in the offices of AT&T, 1120 20th Street NW., Washington, DC, will be open to the public. The agenda is as follows:

I. General Administrative Matters
II. Review of Minutes of Previous Meeting
III. Rewrite of USOA Other Balance Sheet Accounts
IV. Other Business
V. Presentation of Oral Statements
VI. Adjournment

With prior approval of Subcommittee Chairman John Utzinger, oral statements, while not favored or encouraged, may be allowed if time permits and if the Chairman determines that an oral presentation is conducive to the effective attainment of Subcommittee objectives. Anyone not a member of the Subcommittee and wishing to make an oral presentation should contact Mr. Utzinger ((203) 965-2830) at least five days prior to the meeting date.

**William J. Tricarico,**

*Secretary, Federal Communications Commission.*

[FR Doc. 83-31885 Filed 11-28-83; 8:45 am]

BILLING CODE 6712-01-M

# FEDERAL EMERGENCY MANAGEMENT AGENCY

**[FEMA-694-DR]**

## Major Disaster and Related Determinations; Idaho

**AGENCY:** Federal Emergency Management Agency.

**ACTION:** Notice.

**SUMMARY:** This is a notice of the Presidential declaration of a major disaster for the State of Idaho (FEMA-694-DR), dated November 18, 1983, and related determinations.

**DATED:** November 18, 1983.

**FOR FURTHER INFORMATION CONTACT:** Sewall H.E. Johnson, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, D.C. 20472 (202) 287-0501.

Notice: Notice is hereby given that, in a letter of November 18, 1983, the President declared a major disaster under the authority of the Disaster Relief Act of 1974, as amended, (42 U.S.C. 5121 *et seq.*, Pub. L. 93-288) as follows:

I have determined that the damage in certain areas of the State of Idaho, resulting from an earthquake which began on October 28, 1983, is of sufficient severity and magnitude to warrant a major-disaster declaration under Pub. L. 93-288. I therefore declare that such a major disaster exists in the State of Idaho.

In order to provide Federal assistance, you are hereby authorized to allocate, from funds available for these purposes, such amounts as you find necessary for Federal disaster assistance and administrative expenses. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under Pub. L. 93-288 for Public Assistance will be limited to 75 percent of total eligible costs in the designated area.

The time period prescribed for the implementation of Section 313(a), priority to certain applications for public facility and public housing assistance, shall be for a period not to exceed six months after the date of this declaration.

Notice is hereby given that pursuant to the authority vested in the Director of the Federal Emergency Management Agency under Executive Order 12148, and redelegated to me, I hereby appoint Ms. Joan F. Hodgins of the Federal Emergency Management Agency to act as the Federal Coordinating Officer for this declared disaster.

I do hereby determine the following areas of the State of Idaho to have been affected adversely by this declared major disaster:

**Custer County for Individual Assistance and Public Assistance.**

Butte and Gooding Counties are designated eligible for Federal assistance to disaster-damaged public schools under Pub. L. 81-815 and Pub. L. 81-874, as appropriate.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance. Billing Code 6718-02.)

**Dave McLoughlin,**

*Deputy Associate Director, State and Local Programs and Support, Federal Emergency Management Agency.*

[FR Doc. 83-31800 Filed 11-28-83; 8:45 am]

BILLING CODE 6718-01-M

## FEDERAL HOME LOAN BANK BOARD

[No. AC-303]

### Liberty Federal Savings and Loan Association, Macon, Georgia; Final Action Approval of Conversion Application

Dated: November 8, 1983.

Notice is hereby given that on October 19, 1983, the Office of General Counsel of the Federal Home Loan Bank Board, acting pursuant to the authority delegated to the General Counsel or his designee, approved the application of Liberty Federal Savings and Loan Association, Macon, Georgia, for permission to convert to the stock form of organization. Copies of the application are available for inspection at the Secretariat of said Corporation, 1700 G Street, NW., Washington, D.C. 20552 and at the Office of the Supervisory Agent of said Corporation at the Federal Home Loan Bank of Atlanta, P.O. 56527, Peachtree Center Station, Atlanta, Georgia 30343.

By the Federal Home Loan Bank Board.

J. J. Finn,

*Secretary.*

[FR Doc. 83-31821 Filed 11-28-83; 8:45 am]

BILLING CODE 6720-01-M

[No. AC-304]

### Great Lakes Federal Savings and Loan Association, Ann Arbor, Michigan; Final Action Approval of Conversion Application

Dated: November 8, 1983.

Notice is hereby given that on October 14, 1983, the Office of General Counsel of the Federal Home Loan Bank Board, acting pursuant to the authority delegated to the General Counsel or his designee, approved the application of Great Lakes Federal Savings and Loan Association, Ann Arbor, Michigan, for permission to convert to the stock form of organization. Copies of the application are available for inspection at the Secretariat of said Corporation, 1700 G Street, NW., Washington, D.C. 20552 and at the Office of the Supervisory Agent of said Corporation at the Federal Home Loan Bank of Indianapolis, P.O. Box 60, Indianapolis, Indiana 46206.

By the Federal Home Loan Bank Board.

J. J. Finn,

*Secretary.*

[FR Doc. 83-31822 Filed 11-28-83; 8:45 am]

BILLING CODE 6720-01-M

[No. AC-306]

### Northwestern Savings and Loan Association, Traverse City, Michigan; Final Action Approval of Post-Approval Amendment to Mutual-to-Stock Conversion Application

Dated: November 8, 1983.

Notice is hereby given that on October 17, 1983, the General Counsel of the Federal Home Loan Bank ("Board"), acting pursuant to authority delegated to him by the Board, approved post-approval amendments to the Plan of Conversion of Northwestern Savings and Loan Association, Traverse City, Michigan. The Application for Conversion has been approved by the Board by Resolution No. 81-683, dated November 16, 1981. Copies of the Application and all amendments thereto are available for inspection at the Secretariat of the Board, 1700 G Street, NW., Washington, D.C. 20552 and at the Office of the Supervisory Agent, Federal Home Loan Bank of Indianapolis, P.O. Box 60, Indianapolis, Indiana 46204.

By the Federal Home Loan Bank Board.

J. J. Finn

*Secretary*

[FR Doc. 83-31824 Filed 11-28-83; 8:45 am]

BILLING CODE 6720-01-M

[No. AC-300]

### Home Federal Savings and Loan Association of High Point, High Point, North Carolina; Final Action Approval of Post-Approval Amendments to Mutual-to-Stock Conversion Application

Dated: November 8, 1983.

Notice is hereby given that on October 21, 1983, the General Counsel of the Federal Home Loan Bank Board ("Board"), acting pursuant to authority delegated to him by the Board, approved Post-Approval Amendment No. 1 to the mutual-to-stock conversion application of First Federal Savings and Loan Association of High Point, High Point, North Carolina ("Association"). The application had been approved by the Board by Resolution No. 80-543, dated August 21, 1980. Copies of the application and all amendments thereto are available for inspection at the Secretariat of the Board, 1700 G Street, NW., Washington, D.C. 20552, and at the Office of the Supervisory Agent, Federal Home Loan Bank of Atlanta, P.O. Box 56427, Peachtree Center Station, Atlanta, Georgia 30343.

By the Federal Home Loan Bank Board.

J. J. Finn,

*Secretary.*

[FR Doc. 83-31818 Filed 11-28-83; 8:45 am]

BILLING CODE 6720-01-M

[No. AC-299]

### Home Federal Savings and Loan Association, Statesville, North Carolina; Final Action Approval of Post-Approval Amendments to Mutual-to-Stock Conversion Application

Dated: November 8, 1983.

Notice is hereby given that on October 21, 1983, the General Counsel of the Federal Home Loan Bank Board ("Board"), acting pursuant to authority delegated to him by the Board, approved Post-Approval Amendment No. 1 to the mutual-to-stock conversion application of Home Federal Savings and Loan Association, Statesville, North Carolina ("Association"). The application had been approved by the Board by Resolution No. 80-574, dated September 3, 1980. Copies of the application and all amendments thereto are available for inspection at the Secretariat of the Board, 1700 G Street, NW., Washington, D.C. 20552, and at the Office of the Supervisory Agent, Federal Home Loan Bank of Atlanta, P.O. Box 56527, Peachtree Center Station, Atlanta, Georgia 30343.

By the Federal Home Loan Bank Board.

J. J. Finn,

*Secretary.*

[FR Doc. 83-31817 Filed 11-28-83; 8:45 am]

BILLING CODE 6720-01-M

[No. AC-297]

### Security Savings Bank, FSB, Carlsbad, New Mexico; Final Action Approval of Post-Approval Amendments to Mutual-to-Stock Conversion Application

Dated: November 8, 1983.

Notice is hereby given that on October 17, 1983, the General Counsel of the Federal Home Loan Bank Board ("Board"), acting pursuant to authority delegated to him by the Board, approved Post-Approval Amendment No. 1 to the mutual-to-stock conversion application of Security Savings Bank, FSB, Carlsbad, New Mexico ("Association"). The application had been approved by the Board by Resolution No. 81-3, dated January 5, 1981. Copies of the application and all amendments thereto are available for inspection at the Secretariat of the Board, 1700 G Street, NW., Washington, D.C. 20552, and at the

Office of the Supervisory Agent, Federal Home Loan Bank of Dallas, 500 East John Carpenter Freeway, P.O. Box 619026, Dallas/Fort Worth, Texas 75261-9026.

By the Federal Home Loan Bank Board.

J. J. Finn,

*Secretary.*

[FR Doc. 83-31815 Filed 11-28-83; 8:45 am]

BILLING CODE 6720-01-M

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[No. AC-298]

## Capitol Federal Savings and Loan Association, Oklahoma City, Oklahoma; Final Action Approval of Post-Approval Amendments to Mutual-to-Stock Conversion Application

Dated: November 8, 1983.

Notice is hereby given that on October 21, 1983, the General Counsel of the Federal Home Loan Bank Board ("Board"), acting pursuant to authority delegated to him by the Board, approved Post-Approval Amendment No. 3 to the mutual-to-stock conversion application of Capitol Federal Savings and Loan Association, Oklahoma City, Oklahoma ("Association"). The application had been approved by the Board by Resolution No. 81-684, dated November 16, 1981. Copies of the application and all amendments thereto are available for inspection at the Secretariat of the Board, 1700 G Street, NW., Washington, D.C. 20552, and at the Office of the Supervisory Agent, Federal Home Loan Bank of Topeka, P.O. Box 176, Topeka, Kansas 66601.

By the Federal Home Loan Bank Board.

J. J. Finn,

*Secretary.*

[FR Doc. 83-31816 Filed 11-28-83; 8:45 am]

BILLING CODE 6720-01-M

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[No. AC-302]

## Vermont Federal Bank, FSB, Burlington, Vermont; Final Action Approval of Conversion Application

Dated: November 8, 1983.

Notice is hereby given that on October 19, 1983, the Office of General Counsel of the Federal Home Loan Bank Board, acting pursuant to the authority delegated to the General Counsel or his designee, approved the application of Vermont Federal Bank, FSB, Burlington, Vermont, for permission to convert to the stock form of organization. Copies of the application are available for inspection at the Secretariat of said Corporation, 1700 G Street, NW., Washington, D.C. 20552, and at the Office of the Supervisory Agent of said Corporation at the Federal Home Loan Bank of Boston, One Federal Street, Boston, Massachusetts 02110.

By the Federal Home Loan Bank Board.

J. J. Finn,

*Secretary.*

[FR Doc. 83-31820 Filed 11-28-83; 8:45 am]

BILLING CODE 6720-01-M

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[No. AC-301]

## Great Western Federal Savings Bank, Bellevue, Washington; Final Action Approval of Conversion Application

Dated: November 8, 1983.

Notice is hereby given that on October 14, 1983, the Office of General Counsel of the Federal Home Loan Bank Board acting pursuant to the authority delegated to the General Counsel or his designee, approved the application of Great Western Federal Savings Bank, Bellevue, for permission to convert to the stock form of organization. Copies of the application are available for inspection at the Secretariat of said Corporation, 1700 G Street, NW., Washington, D.C. 20552, and at the Office of the Supervisory Agent of said Corporation at Federal Home Loan Bank of Seattle, 600 Stewart Street, Seattle, Washington 98101.

By the Federal Home Loan Bank Board.

J. J. Finn,

*Secretary.*

[FR Doc. 83-31819 Filed 11-28-83; 8:45 am]

BILLING CODE 6720-01-M

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[No. AC-305]

## First Northern Savings and Loan Association, Green Bay, Wisconsin; Final Action Approval of Conversion Application

Dated: November 8, 1983.

Notice is hereby given that on October 18, 1983, the Office of General Counsel of the Federal Home Loan Bank Board, acting pursuant to the authority delegated to the General Counsel or his designee, approved the application of First Northern Savings and Loan Association, Green Bay, Wisconsin, for permission to convert to the stock form of organization. Copies of the application are available for inspection at the Secretariat of said Corporation, 1700 G Street, NW., Washington, D.C. 20552 and at the Office of the Supervisory Agent of said Corporation at the Federal Home Loan Bank of Chicago, 111 East Wacker Drive, Suite 800, Chicago, Illinois 60601.

By the Federal Home Loan Bank Board.

J. J. Finn,

*Secretary.*

[FR Doc. 83-31823 Filed 11-28-83; 8:45 am]

BILLING CODE 6720-01-M

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# FEDERAL RESERVE SYSTEM

## Centurion Bancorp, Inc., et al.; Acquisition of Bank Shares by Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3(a)(3) of the Bank Holding Company Act (12 U.S.C. 1842(a)(3)) to acquire voting shares or assets of a bank. 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 may be inspected at the offices of the Board of Governors, or at the Federal Reserve Bank indicated for that application. With respect to each application, interested persons may express their views in writing to the address indicated for that application. 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.

A. **Federal Reserve Bank of Richmond** (Lloyd W. Bostian, Jr., Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. *Centurion Bancorp, Inc.*, Charleston, West Virginia; to acquire 100 percent of the voting shares or assets of Cardinal State Bank, Beckley, West Virginia. Comments on this application must be received not later than December 22, 1983.

B. **Federal Reserve Bank of Dallas** (Anthony J. Montelaro, Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. *Northshore Bancshares, Inc.*, Houston, Texas; to acquire 76.17 percent of the voting shares or assets of La Marque United Bank, La Marque, Texas. Comments on this application must be received not later than December 21, 1983.

C. **Board of Governors of the Federal Reserve Bank System** (William W. Wiles, Secretary) Washington, D.C. 20551:

1. *Allied Bancshares, Inc.*, Houston, Texas; to acquire 100 percent of the voting shares or assets of Collin Creek Bank, N.A., Plano, Texas. This application may be inspected at the

offices of the Board of Governors or the Federal Reserve Bank of Dallas. Comments on this application must be received not later than December 22, 1983.

2. *Firstar Corporation,* Appleton, Wisconsin; to acquire 100 percent of the voting shares or assets of State Bank of Green Valley, Green Valley, Wisconsin. This application may be inspected at the offices of the Board of Governors or the Federal Reserve Bank of Chicago. Comments on this application must be received not later than December 22, 1983.

Board of Governors of the Federal Reserve System, November 22, 1983.

**James McAfee,**

*Associate Secretary of the Board.*

[FR Doc. 83-31796 Filed 11-28-83; 8:45 am]

BILLING CODE 6210-01-M

## NW Services Corporation, et al.; Formation of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become bank holding companies by acquiring voting shares or assets of a bank. 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 may be inspected at the offices of the Board of Governors, or at the Federal Reserve Bank indicated for that application. With respect to each application, interested persons may express their views in writing to the address indicated for that application. 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.

A. **Federal Reserve Bank of Atlanta** (Robert E. Heck, Vice President) 104 Marietta Street, NW., Atlanta, Georgia 30303:

1. *NW Services Corporation,* Ringgold, Georgia; to become a bank holding company by acquiring up to 100 percent of the voting shares of Northwest Georgia Bank, Ringgold, Georgia. Comments on this application must be received not later than December 21, 1983.

B. **Federal Reserve Bank of St. Louis** (Delmer P. Weisz, Vice President) 411 Locust Street, St. Louis, Missouri 63166:

1. *The Farmers and Merchants Bankshares, Inc.,* Stuttgart, Arkansas; to become a bank holding company by acquiring 100 percent of the voting shares of The Farmers and Merchants Bank, Stuttgart, Arkansas. Comments on this application must be received not later than December 20, 1983.

C. **Federal Reserve Bank of Dallas** (Anthony J. Montelaro, Vice President) 400 South Akard Street, Dallas, Texas 75222:

1. *Alvin Bancshares, Inc.,* Alvin, Texas; to become a bank holding company by acquiring 100 percent of the voting shares of Alvin State Bank, Alvin, Texas. Comments on this application must be received not later than December 22, 1983.

Board of Governors of the Federal Reserve System, November 22, 1983.

**James McAfee,**

*Associate Secretary of the Board.*

[FR Doc. 83-31797 Filed 11-28-83; 8:45 am]

BILLING CODE 6210-01-M

## Moore Financial Group Inc.; Proposed de Novo Nonbank Activities by Bank Holding Company

The organization identified in this notice has applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.4(b)(1) of the Board's Regulation Y (12 CFR 225.4(b)(1)), for permission to engage in *de novo* (or continue to engage in an activity earlier commenced *de novo*), directly or indirectly, solely in the activities indicated, which have been determined by the Board of Governors to be closely related to banking.

With respect to this application, interested persons may express their views 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 comment that requests a hearing must include 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, summarzing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of that proposal.

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank indicated. Comments and requests for hearing should identify clearly the specific application to which they relate, and should be submitted in writing and received by the appropriate Federal Reserve Bank not later than the date indicated.

A. **Federal Reserve Bank of San Francisco** (Harry W. Green, Vice President) 101 Market Street, San Francisco, California 94105:

1. *Moore Financial Group Incorporated,* Boise, Idaho (lending, loan servicing and leasing activities; Idaho, Oregon and Utah): To engage, through its subsidiary, Moore Corporate Financial Services, Inc., in making or acquiring loans and other extensions of credit such as would be made by a commercial or non-commercial finance company or mortgage company, including loans secured by a borrower's inventory, accounts receivable, real property, or other assets; servicing such loans for others; and the making of leases for real or personal property in accordance with the Board's Regulation Y. These activities would be conducted from offices located in Boise, Idaho; Salt Lake City, Utah; and Beaverton, Oregon, serving the States of Idaho, Utah and Oregon, respectively. Comments on this application must be received not later than December 21, 1983.

Board of Governors of the Federal Reserve System, November 22, 1983.

**James McAfee,**

*Associate Secretary of the Board.*

[FR Doc. 83-31798 Filed 11-28-83; 8:45 am]

BILLING CODE 6210-01-M

# DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

**[Docket No. 83N-0154]**

## International Drug Scheduling; Convention on Psychotropic Substances; Benzodiazepines; Notice of Public Meeting

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is requesting interested persons to submit written comments concerning proposals by the World Health Organization (WHO) that the Commission on Narcotic Drugs (CND) of the United Nations impose international manufacturing and distribution restrictions, pursuant to international treaty, on certain "benzodiazepine" drugs (drugs that produce sedative-hypnotic, anti-anxiety, and anti-convulsant effects). FDA also is

announcing that an informal public meeting will be held on December 9, 1983, on the WHO proposals. The comments received in response to this notice and the public meeting will be considered in preparing the United States' position on these proposals for a meeting of CND in Vienna, Austria, in February 1984. This notice requesting written comments is required by the Controlled Substances Act (CSA).

**DATES:** The public meeting will be held on December 9, 1983, starting at 1 p.m. Comments by December 15, 1983.

**ADDRESSES:** The public meeting will be held in Conference Rm. G, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD. Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. Written notice of intent to participate should be sent to the contact person listed below.

**FOR FURTHER INFORMATION CONTACT:** Halyna P. Breslawec, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

**SUPPLEMENTARY INFORMATION:** This notice offers interested persons an opportunity to comment on international drug control measures that will be proposed by WHO under the 1971 Convention on Psychotropic Substances (Psychotropic Convention). The Department of Health and Human Services (HHS) is advised that WHO has recommended that 33 individual benzodiazepine drugs be subject to international controls under Schedule IV of the Psychotropic Convention.

## Background on 1981 and 1982 Cycles

In 1981, WHO recommended that CND control the following 12 benzodiazepine drugs under Schedule IV of the Psychotropic Convention: chlordiazepoxide, clonazepam, clorazepate, diazepam, flurazepam, lorazepam, medazepam, nitrazepan, oxazepam, oxazolam, prazepam, and temazepam.

CND, at its meeting in February 1982, did not act on the WHO recommendation. The 1981 WHO assessment, information submitted in response to a request for information published in the **Federal Register** of April 10, 1981 (46 FR 21447), information submitted in response to a notice requesting comments on the WHO recommendation published in the **Federal Register** of December 18, 1981 (46 FR 61374), and the public record on which FDA's position on the 1981 WHO assessment was based are on file in FDA's Dockets Management Branch (address above) under Docket No. 81N-0121.

In 1982, WHO recommended that CND control an additional 14 benzodiazepine drugs under Schedule IV of the Psychotropic Convention: alprazolam, bromazepam, camazepam, clobazam, cloxazolam, estazolam, fluidiazepam, flunitrazepam, ketazolam, minetazepam, nordiazepam, pinazepam, tetrazepam, and triazolam.

CND, at its meeting in February 1983, acted on the WHO recommendations of 1981 and 1982 to schedule 26 benzodiazepine drugs in Schedule IV of the Psychotropic Convention. CND first voted on each drug individually; none of the 26 drugs received the necessary number of affirmative votes required to schedule. In a subsequent action, CND took a single vote on scheduling all 26 drugs as a group. The vote did not receive the necessary affirmative votes required to schedule all 26 benzodiazepine drugs.

CND requested that WHO review and assess all benzodiazepines marketed at the end of February 1983 and make recommendations for scheduling the benzodiazepines on a drug-by-drug basis.

The 1982 WHO assessment, information submitted in response to a request for information published in the **Federal Register** of May 7, 1982 (47 FR 19793), information submitted in response to a notice requesting comments on the WHO recommendation published in the **Federal Register** of December 3, 1982 (47 FR 54548), and the public record on which FDA's position on the 1982 WHO assessment was based are on file in FDA's Dockets Management Branch under Docket No. 82N-0145.

## 1983 Cycle

Earlier this year, FDA learned that WHO intended to make recommendations to CND concerning the scheduling under the Psychotropic Convention of the following 39 benzodiazepine drugs: alprazolam, bromazepam, camazepam, chlordiazepoxide, clobazam, clonazepam, clorazepate, clotiazepam, cloxazolam, delorazepam, diazepam, estazolam, ethyl loflazepate, etifoxine, fludiazepam, flunitrazepam, flurazepam, halazepam, haloxazolam, ketazolam, loprazolam, lorazepam, lormetazepam, medazepam, nimetazepam, nitrazepam, nordiazepam, oxazepam, oxazolam, pinazepam, pirenzepine, prazepam, propizepine, temazepam, tetrazepam, tibezonium, tofisopam, triazolam, and zopiclone.

The 39 drugs reviewed include the 12 drugs reviewed and recommended for control by WHO in 1981, the 15 drugs reviewed by WHO in 1982 of which 14 were recommended for control, and 12 drugs not previously considered for control by WHO.

In the **Federal Register** of May 18, 1983 (48 FR 21661), FDA, on behalf of HHS, requested that information on the abuse potential, actual abuse, and medical usefulness of the 12 benzodiazepine drugs not previously reviewed be submitted. FDA noted that information submitted in response to earlier requests for information on 27 drugs previously considered for control by WHO had been retained by FDA. FDA requested that any new information on these 27 drugs, i.e., information generated since those notices were published or information not previously submitted, be submitted.

Information submitted in response to this request was transmitted to WHO by the Secretary of HHS for consideration of placing international restrictions on these drugs. Information submitted in response to this request and a copy of the United States Government's submission are on file on FDA's Dockets Management Branch.

HHS has received official notification, through the Department of State, from WHO that it has recommended that CND control 33 benzodiazepines in Schedule IV of the Psychotropic Convention. The information HHS received from the Department of State is on file in FDA's Dockets Management Branch (address above). This information, and certain documents utilized by WHO, may be seen in that office between 9 a.m. and 4 p. m., Monday through Friday.

None of the 33 drugs that HHS is advised that WHO has recommended for control is currently scheduled internationally. Placing these drugs in Schedule IV of the Psychotropic Convention would require each of the member countries (including the United States) to impose controls regarding licensing, prescriptions, importing and exporting, recordkeeping and reporting, and government inspections. Because of existing domestic controls now in force for alprazolam, chlordiazepoxide, clonazepam, clorazepate, diazepam, flurazepam, halazepam, lorazepam, oxazepam, prazepam, temazepam, and triazolam (each currently controlled domestically in Schedule IV of the CSA), the proposed CND action, if adopted, would not obligate the United States to reschedule them domestically. However, the proposed action, if adopted, would require additional manufacturer reporting requirements for each substance controlled internationally.

See section 307(e) of the CSA (21 U.S.C. 827(e)) as amended by the Psychotropic Substances Act of 1978 (Pub. L. 95–633).

The remaining 21 benzodiazepines that HHS is advised WHO has recommended for control are not currently marketed or controlled in the United States. These drugs, if controlled under the Psychotropic Convention, would have to be placed into a schedule under the CSA sufficient to meet treaty obligations.

**Summary of WHO Recommendations**

HHS is advised that WHO has reviewed information pertaining to 39 benzodiazepine-type drugs marketed throughout the would for clinicall use. One of these 39 drugs—zopiclone—was excluded from consideration by WHO because it was not marketed at the end of February 1983. After an individual review of the remaining 38 drugs, WHO recommended that CND control 33 drugs (i.e., each of the benzodiazepines listed above, except for etifoxine, pirenzepine, propizepine, tibezonium, tofisopam) under Schedule IV of the Psychotropic Convention.

HHS is also advised that WHO's decision to recommend international control of these drugs was based on data relevant to the scheduling criteria provided for by the 1971 Psychotropic Convention: (i) Chemical structure, receptor binding characteristics, sedative-hypnotic, anti-convulsant, and anxiolytic profile of central nervous system effects; (ii) animal data on psychological and physical dependence potential; (iii) human experimental data on both dependence and abuse potential; (iv) clinical data on dependence and public health problems; (v) epidemiological data on public health and social problems; (vi) extent of abuse or likelihood of abuse and seriousness of public health and social problems resulting from such abuse; and (vii) utilization and usefulness in therapy.

HHS is advised that the WHO review group found that for a number of the drugs no data were available other than on points (i) and (vii) listed above. The WHO group reviewed existing data and determined that if a drug under review possessed characteristics fulfilling point (i) above, the drug had the capacity to produce a state of dependence and the likelihood of abuse constituted a public health and social problem warranting the placing of the drug under international control.

Therefore, as required by section 201(d)(2)(B) of the CSA (21 U.S.C. 811(d)(2)(B)), FDA, at the direction of the Assistant Secretary for Health, HHS, invites interested persons to submit comments about these proposed CND actions. The comments received will be considered by FDA (in consultation with the National Institute on Drug Abuse) on behalf of HHS in its evaluation of the WHO recommendations. HHS will then recommend to the Secretary of State the position which the United States should take when voting on the scheduling proposals at the CND meeting in February 1984.

**Open Public Meeting**

FDA, on behalf of HHS, has concluded that it is in the public interest to hold an open public meeting for the purpose of allowing interested persons to present their views on the proposed CND actions discussed above (see 21 CFR 10.65).

The meeting will be informal and is intended only for the presentation of views on the proposed actions. Thus, although the FDA official(s) conducting the meeting may direct questions to those presenting views for purposes of clarification, no participant may interrupt the presentation of another participant for any reason. Any interested person may attend and present his or her views provided that FDA receives written notice of intent to participate at least 3 days before the meeting. The open public meeting will be held on December 9, 1983, starting at 1 p.m., in Conference Rm. G, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857. Written notice of intent to participate should be sent to Halyna Breslawec, Rm. 11–46 (address above).

Interested persons may, on or before December 15, 1983, submit to the Dockets Management Branch (address above) written comments regarding this notice. This short comment period is necessary to assure that HHS may, in timely fashion, make its required evaluations and recommendations. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 23, 1983.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 83–31958 Filed 11–28–83; 8:45 am]

BILLING CODE 4160–01–M

## Health Resources and Services Administration

### Steering Subcommittee of the National Council on Health Planning and Development; Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of December 1983:

Name: Steering Subcommittee of the National Council on Health Planning and Development.

Date and Time: December 15, 1983; 2:30 p.m.–4:30 p.m.

Place: Conference Room B, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857 (Meeting by Conference Call). Due to the limited nature of the meeting, a conference call will be substituted for the regular scheduled meeting.

Open for entire meeting.

Purpose: The objectives of the Steering Subcommittee are to: (1) Assist the Chairperson in planning the order and timing of agenda topics for full Council consideration and action to assure that the Secretary will receive advice and/or recommendations on each of its three areas of functional responsibilities under section 1503(a) in an appropriate time and manner; (2) coordinate information about and among subcommittee activities and plans; and (3) provide preliminarey review of proposed changes in Council operations.

Agenda: (1) Report by the Interim Executive Secretary; (2) Status reports on the Office of Health Planning and the Office of Health Facilities; (3) Discussion of Agenda for the first Council meeting in 1984; and (4) other Council business.

Anyone requiring information regarding the subject Subcommittee should contact Mrs. Dorothy L. Trower, Staff, National Council on Health Planning and Development, Room 9A18, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Telephone (301) 443–6377.

Agenda items are subject to change as priorities dictate.

Date: November 18, 1983.

**Jackie E. Baum,**

*Advisory Committee Management Officer, HRSA.*

[FR Doc. 83–31825 Filed 11–28–83; 8:45 am]

BILLING CODE 4160–16–M

## National Institutes of Health

### Biotechnology Resources Review Committee; Meeting

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the Biotechnology Resources Review Committee, Division of Research Resources (DRR), December 8, 1983, Conference Room 9, National Institutes

of Health, Bethesda, Maryland 20205. Meeting notice is being published later than usual because of uncertainty of availability of consultants pertinent to the adequate review of applications to be considered.

This meeting will be open to the public December 8 from 8:30 a.m. to approximately 11:00 a.m. during which time there will be comments by the Director, DRR, an update on the Biotechnology Resources Program, a report on electron microscopy activities, and discussion of possible training activities in resources. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in Sections 552b(c)(4) and 552b(c)(6), Title 5, United States Code and Section 10(d) of Pub. L. 92-463, the meeting will be closed to the public from approximately 11:00 a.m. to approximately 5:00 p.m. on December 8 for the review, discussion, and evaluation of individual research grant applications. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Mr. James Augustine, Information Officer, Division of Research Resources, Bldg. 31, Rm. 5B-10, National Institutes of Health, Bethesda, MD 20205, telephone area code 301 496-5545, will provide summaries of meetings and rosters of committee members.

Dr. Charles L. Coulter, Executive Secretary, Biotechnology Resources Review Committee, Division of Research Resources, Bldg. 31, Rm. 5B-41, National Institutes of Health, Bethesda, MD 20205, telephone area code 301 496-5411, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program No. 13.371, Biotechnology Research, National Institutes of Health)

Dated: November 17, 1983.

**Betty J. Beveridge,**

*NIH Committee Management Officer.*

[FR Doc. 83-31831 Filed 11-28-83; 8:45 am]

BILLING CODE 4140-01-M

## Environmental Health Sciences Review Committee; Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Environmental Health Sciences Review Committee on December 5-6, 1983, in Building 101 Conference Room, Research Triangle Park, North Carolina. This meeting will be open to the public from 9:00 a.m. to approximately 10:30 a.m. on December 5, for general discussions. Attendance by the public is limited to space available.

In accordance with provisions set forth in section 552b(c)(4) and 552b(c)(6), Title 5, United States Code and Section 10(d) of Pub. L. 92-463, the meeting will be closed to the public from 10:30 a.m., December 5, to adjournment on December 6, for the review, discussion and evaluation of individual grant applications and contract proposals. These applications and proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications and proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Dr. Carol Shreffler, Executive Secretary, Environmental Health Sciences Review Committee, National Institute of Environmental Health Sciences, National Institutes of Health, P.O. Box 12233, Research Triangle Park, North Carolina 27709 (telephone 919-541-7826), will provide summaries of meeting, rosters of committee members, and substantive program information.

(Catalog of Federal Domestic Assistance Program Nos. 13.112, Characterization of Environmental Health Hazards; 13.113, Biological Response to Environmental Health Hazards; 13.114, Applied Toxicological Research and Testing; 13.115, Biometry and Risk Estimation; 13.894, Resource and Manpower Development, National Institutes of Health)

Dated: November 17, 1983.

**Betty J. Beveridge,**

*Committee Management Officer, NIH.*

[FR Doc. 83-31830 Filed 11-28-83; 8:45 am]

BILLING CODE 4140-01-M

# DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

## Office of the Assistant Secretary for Fair Housing and Equal Opportunity

**[Docket No. N-83-1308; FR-1840]**

## Availability of Funding Under the Fair Housing Assistance Program; Competitive Solicitation

**AGENCY:** Office of the Assistant Secretary for Fair Housing and Equal Opportunity, HUD.

**ACTION:** Notice of Fund Availability.

**SUMMARY:** HUD is issuing a Notice to solicit applications from eligible State and local fair housing agencies for funding under the Fair Housing Assistance Program (FHAP). Agencies must meet specific eligibility criteria as set forth in this Notice and 24 CFR Part 111 in order to qualify for consideration under this program. This Notice pertains to Type-II Competitive Funding applications only.

**FOR FURTHER INFORMATION CONTACT:** Steven J. Sacks, Director, Federal, State and Local Programs Division, Office of Fair Housing Enforcement and Section 3 Compliance, Office of Fair Housing and Equal Opportunity, Room 5214, 451 Seventh Street, SW., Washington, D.C. 20410. Telephone: (202) 426-3500. (This is not a toll-free number.) Application kits are available upon written or telephone request. To ensure a prompt response, it is suggested that requests for application kits be made by telephone.

**DATE:** An application for Type-II competitive FHAP funding must be submitted between November 29, 1983 and February 13, 1984, unless it qualifies for a late application exception as specified in the application kit and is received before funds are awarded.

**SUPPLEMENTARY INFORMATION:** The FHAP was authorized by Congress to provide HUD with the resources to enhance the fair housing capabilities of State and local civil rights agencies. The FHAP has two types of funding: Type I-Non-Competitive Funding and Type II-Competitive Funding. Type I-Non-Competitive Funding includes capacity building, training, complaint monitoring and reporting systems, and contributions. Type II-Competitive Funding includes specialized project proposals developed by State and local agencies to enhance fair housing programs.

On June 1, 1983, the Department published in the **Federal Register** (48 FR 24362) an interim rule amending Part 111. The amendment provides for expanded training under the Type-I component of the Program. The Type-II funds of the Program are unaffected by the rule change. Notice of availability of Type-I Non-Competitive Funding will be published at a later date.

### Program Background

Title VIII of the Civil Rights Act of 1968, 42 U.S.C. 3601-19 (the Federal Fair Housing Law), prohibits discrimination in the sale, rental or financing of housing and in the provision of brokerage services. Section 810(c) of that Title provides that wherever a State or local fair housing law provides rights and remedies substantially equivalent to those in the Federal Fair Housing Law,

the Secretary is required to notify the appropriate State or local agency of any complaint filed with HUD that appears to constitute a violation of State or local law. Section 816 provides that the Secretary may cooperate with State and local agencies charged with the administration of State and local fair housing laws and, with the consent of the agencies, may use their services and their employees, and may reimburse the agencies for services rendered in carrying out the Federal Fair Housing Law.

**Other Matters**

This program is described in the Catalog of Federal Domestic Assistance at 14.401, Fair Housing Assistance Program.

Executive Order 12372: Applicants are advised that they must follow Department procedures established to implement Executive Order 12372, "Intergovernmental Review of Federal Programs." On June 24, 1983, HUD published regulations in the **Federal Register** (48 FR 29206) to implement E.O. 12372. These procedures replace the intergovernmental consultation system developed under OMB Circular A-95, which expired on September 30, 1983. The Executive Order authorizes States to establish their own process for review and comment on proposed Federal financial assistance programs. To comply with the Executive Order, all applicants for FHAP funding must provide an opportunity for review and comment to State and local elected officials (1) if the applicant's State has established a State process and (2) the FHAP has been specifically identified for review. If the Order applies, the applicant should submit its proposal to HUD and to the State process simultaneously.

Applicants must provide HUD with a written assurance certifying the date on which a copy of the proposal was furnished to the State process. The 60-day comment period will begin five days from the date identified in the certification.

The single point of contact and other commenting parties must mail their comments to Steven J. Sacks, Director, Federal, State and Local Programs, Office of Fair Housing and Equal Opportunity, Room 5214, 451 Seventh Street, S.W., Washington, D.C. 20410.

*I. Eligibility*

To be eligible to apply for funds under the Program, an agency must meet the criteria prescribed in 24 CFR 111.104. Specifically, an agency: (1) Must be certified as a substantially equivalent agency under 24 CFR Part 115; and (2) must have executed a written Memorandum of Understanding with HUD that describes the working relationship to be in effect between the agency and the appropriate Regional Office of Fair Housing and Equal Opportunity.

If an agency has applied to the Department for recognition as a substantially equivalent agency, and has been found by the Department to have both statutory authority equivalent to Title VIII and an operational capability equivalent to that of the Department, the fact that the agency has not yet been certified will not prevent the agency from submitting funding proposals under the FHAP. At a minimum, evidence of such a Departmental finding will consist of the Secretary's approval to add the agency to the list of recognized jurisdictions published in the **Federal Register**. Under these circumstances, an agency may enter into negotiations with the regional Office of Fair Housing and Equal Opportunity to develop a Memorandum of Understanding and may, at the same time, submit funding proposals. No funds will be committed to any agency until it has been formally recognized as substantially equivalent.

All proposals for Type-II funding must have ultimate relevance to matters pertaining to housing discrimination based on an individual's race, color, religion, sex or national origin.

*II. Method of Competition*

A. Scope: Applications are solicited for specialized project proposals as described in 24 CFR 111.103. A total of $1.7 million is available under this Notice.

B. Classes of Funding: Past experience in competitive funding under the Program indicates that larger agencies, particularly those State agencies in the more populous States, have a decided advantage over smaller State and local agencies in an open competition for Type-II funds. Accordingly, two classes of funding have been established.

1. Class A: Large Jurisdictions—All agencies that serve jurisdictions with populations of three million or more *or* that receive an annual housing discrimination complaint workload of 100 or more will be treated as Class A agencies. For purposes of this determination, the complaint workload is evidenced either by the total number of cases dual-filed with the agency and HUD during the period of July 1, 1982 through June 30, 1983 *or* by the total number of cases received by HUD from the geographical area within the agency's jurisdiction during the same period, whichever is greater. All Class A agencies must compete within Class A.

2. Class B: Small Jurisdictions—All Agencies that serve jurisdictions with populations below 3 million *and* that receive an annual housing discrimination complaint workload fewer than 100 as described above will be treated as Class B agencies. Class B agencies may elect to compete in either Class A or Class B, but not both.

3. Multiple Agency Proposals: Eligible agencies may wish to join together in submitting a proposal in Class A or Class B. Multiple agency proposals are acceptable subject to the following conditions:

(a) One agency must be designated as the applicant, submitting on behalf of itself with all others as proposed subcontractors. In the event of an award the applicant will be treated as the recipient.

(b) Agencies electing to participate in a multiple agency proposal, whether as an applicant or as a subcontractor, may not submit individual proposals.

(c) The Class of the agency submitting the multiple agency proposal as the applicant will determine the Class in which the proposal competes.

C. Program Totals and Agency Maximums: A total of $1 million is available for award to Class A applicants, with a maximum of $150,000 per applicant for single agency proposals and $200,000 for multiple agency proposals. A total of $700,000 is available for award to Class B applicants, with a maximum of $75,000 per agency for single agency proposals and $100,000 for multiple agency proposals.

D. Applications: An agency may submit only one Type-II proposal. Applicants must submit all information required in the Type-II application kit, and must include sufficient information to establish that the proposal meets the criteria set forth in 24 CFR 111.106. Proposals must include a clear narrative description of the project and a timetable delineating the points at which the various components of the project will be initiated and completed.

Projects should be no longer than two years in duration. Applicants should note that any research activities must serve to enhance the agency's fair housing programs. Projects that appear to be aimed solely or primarily at research or data gathering unrelated to existing or planned fair housing enforcement or outreach programs will not be approved.

E. Award Procedures: Applications for Type-II funding will be evaluated competitively, by Class, and awarded points based on the Factors for Award identified below. The weight of each

factor is indicated by the assigned number of points.

**Factors for Award**

1. Substantive Factors (65 points).

a. Degree to which project proposal identifies and addresses significant fair housing problems and issues within the jurisdiction (20 points).

b. Degree to which the project can be expected to impact successfully upon the problems or issues that the proposal addresses, including the degree to which the project is of continuing use to the agency in dealing with housing discrimination (20 points).

c. Usefulness of the concept, methodology or information resulting from the project to other fair housing agencies (10 points).

d. Clarity and thoroughness of project description (15 points).

2. Planning and Management Factors (35 points).

a. Experience and qualifications of existing personnel identified for key project positions or a description of the process and qualifications to be used for selection of key personnel, including subcontractors/consultants. (Where project-related duties will not be the sole responsibility of key personnel, applicant should include percentage of time persons will spend on project) (15 points).

b. Reasonableness of estimated timetable for implementation and completion of project (10 points).

c. Adequacy and clarity of proposed procedures to be used by the agency for monitoring progress of project and ensuring timely completion (10 points).

3. Cost Factors—An applicant's proposed costs will be considered together with the factors in 1. and 2. above in determining the proposals most advantageous to the Government.

The Assistant Secretary reserves the right to make discretionary awards to applicants for proposals submitted in response to this Notice that have been determined to be responsive, to ensure a more equitable geographic distribution or to achieve program objectives that would not otherwise be met under the above award factors. The total funds available for discretionary awards will not exceed $300,000.

*III. Applicant Notification and Award Procedures*

A. Notification: No information will be available to applicants during the period of HUD evaluation except for notification in writing to those applicants that are determined ineligible. Awards for Type-II projects are expected to be announced by HUD within three months of the closing date.

B. Negotiations: After HUD has ranked the applications and identified qualified candidates (but before the award), HUD may require that applicants participate in negotiations and submit application revisions resulting from those negotiations.

C. Funding Instrument: It is HUD's normal practice to fund successful applicants under cost-reimbursable Cooperative Agreements. HUD reserves the right to employ the form of agreement determined to be most appropriate after negotiation with the applicant.

Authority: Title VIII, Civil Rights Act of 1968 (42 U.S.C. 3601); Section 7(d), Department of Housing and Urban Development Act (42 U.S.C. 3535(d)).

Dated: November 21, 1983.

**Antonio Monroig,**

*Assistant Secretary for Fair Housing and Equal Opportunity.*

[FR Doc. 83-31803 Filed 11-28-83; 8:45 am]

BILLING CODE 4210-28-M

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

[INT FEIS-83-58]

### Proposed New Mexico Generating Station and Other Possible End Uses of the Ute Mountain Land Exchange

**AGENCY:** Bureau of Land Management (BLM), Interior.

**ACTION:** Notice of availability of the final environmental impact statement (FEIS).

**SUMMARY:** Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969, the BLM has prepared a FEIS on the Proposed New Mexico Generating Station (NMGS) and Other Possible End Uses of the Ute Mountain Land Exchange. The NMGS is a 2000-MW coal-fired-electric generating plant proposed by the Public Service Company of New Nexico (PNM) on land within the Ute Mountain Land Exchange. NMGS would be constructed approximately 35 miles south of Farmington, New Mexico in San Juan County. The proposed action includes two 40-mile water pipelines and two 100-mile 500 kV transmission lines. Four 500-MW units are proposed with the first unit planned by 1990. Two alternate pipeline and transmission line routes were analyzed along with other alternatives. The Ute Mountain Land Exchange would transfer lands along the Rio Grande River in Taos County to BLM in exchange for lands in the Sam Juan Basin in San Juan County to PNM for the plant site and related facilities. The No Action and Delay of Action Alternatives were also analyzed.

**FOR FURTHER INFORMATION CONTACT:** John Kenny, New Mexico State Office, Bureau of Land Management, P.O. Box 1449, Santa Fe, NM 87501, (505) 988-6565.

**SUPPLEMENTARY INFORMATION:** Copies of the FEIS will be available for inspection at the following locations:

Bureau of Land Management, Public Affairs, Interior Building, 18th and C Streets, NW., Washington, D.C. 20240, (202) 343-6011

Albuquerque District Office, Western Bank Building, Room 819, 505 Marquette, NW., Albuquerque, NM 87105

Bureau of Land Management, Public Assistance, New Mexico State Office, Montoya Federal Building, South Federal Place, Santa Fe, New Mexico 87501, (505) 988-6283

Farmington Resource Area, 900 La Plata Highway, Farmington, New Mexico 87401

A limited number of single copies of the FEIS can be obtained from the New Mexico State Office and the Albuquerque District at the addresses listed above.

**Norman P. Duquette,**

*Acting State Director.*

[FR Doc. 83-31826 Filed 11-28-83; 8:45 am]

BILLING CODE 4310-84-M

[M-1169]

### Partial Termination of Proposed Withdrawal and Reservation of Lands; Montana

November 21, 1983.

In **Federal Register** Document No. 82-8741 published in Vol. 47, No. 63 of Thursday, April 1, 1982, the following land description was omitted:

T. 19 N., R. 30 W.,

Sec. 27, That portion of the SE¼NW¼SE¼ lying south and east of Big Creek Road No. 386.

The area described contains approximately 7 acres in Mineral County, Montana.

The above lands will be relieved of their segregative effect at 9 a.m. on December 1, 1983.

**John A. Kwiatkowski,**

*Deputy State Director, Division of Lands and Renewable Resources.*

[FR Doc. 83-31832 Filed 11-28-83; 8:45 am]

BILLING CODE 4310-84-M

## Revocation of the Poncha Known Geothermal Resources Area, Chaffee County, Colorado

**SUMMARY:** Pursuant to the authority vested in the Secretary of the Interior by Section. 21(a) of the Geothermal Steam Act of 1970 (84 Stat. 1566, 1572; 30 U.S.C. 1020), and delegations of authority in 220 Departmental Manual 4. 1H, and Secretarial Orders 3071 and 3087, the following described lands are hereby revoked as the Poncha Geothermal Resources Area, effective November 7, 1983.

(6) Colorado—Poncha Known Geothermal Resources Area (Revoked)

**New Mexico Principal Meridian, Colorado**

T. 49 N., R. 8 E.,
Secs. 13 to 15, inclusive;
Secs. 23 and 24.

The deleted area described aggregates 3,200 acres, more or less.

Dated: November 10, 1983.

**Wright Sheldon.**

*District Manager.*

[FR Doc. 83-31597 Filed 11-28-83; 8:45 am]

BILLING CODE 4310-84-M

## Revocation of the Valley View Known Geothermal Resources Area, Saguache County, Colorado

**SUMMARY:** Pursuant to the authority vested in the Secretary of the Interior by Section 21(a) of the Geothermal Steam Act of 1970 (84 State 1566, 1572; 30 U.S.C. 1020), and delegations of authority in 220 Departmental Manual 4.1H, and Secretarial Orders 3071 and 3087, the following described lands are hereby revoked as the Valley View Geothermal Resources Area, effective November 7, 1983.

(6) Colorado—Valley View Known Geothermal Resources Area (Revoked)

**New Mexico Principal Meridian, Colorado**

T. 45 N., R. 10 E.,
Secs. 10, 11, and 15.
Secs. 1 to 4, inclusive;
T. 46 N., R. 10 E.,
Sec. 35.

The deleted area described aggregates 5,099 acres, more or less.

Dated: November 10, 1983.

**Wright Sheldon,**

*District Manager.*

[FR Doc. 83-31596 Filed 11-28-83 8:45am]

BILLING CODE 4310-84-M

## Revocation of the Mineral Hot Springs Known Geothermal Resources Area, Saguache County, Colorado

**SUMMARY:** Pursuant to the authority vested in the Secretary of the Interior by Section 21(a) of the Geothermal Steam Act of 1970 (84 Stat. 1566, 1572; 30 U.S.C. 1020), and delegations of authority in 220 Departmental Manual 4.1H, and Secretarial Orders 3071 and 3087, the following described lands are hereby revoked as the Mineral Hot Springs Geothermal Resources Area, effective November 7, 1983.

(6) Colorado—Mineral Hot Springs Geothermal Resources Area (Revoked)

**New Mexico Principal Meridian, Colorado**

T. 45 N., R. 9 E.,
Secs. 1 to 3, inclusive;
Secs. 10 to 12, inclusive.
T. 46 N., R. 9 E.,
Secs. 22, 25, and 34.

The deleted area described aggregates 5,765 acres, more or less.

Dated: November 10, 1983.

**Wright Sheldon,**

*District Manager.*

[FR Doc. 83-31598 Filed 11-28-83; 8:45 am]

BILLING CODE 4310-84-M

# National Park Service

## National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before November 18, 1983. Pursuant to § 60.13 of 36 CFR Part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, National Park Service, U.S. Department of the Interior, Washington, DC 20243. Written comments should be submitted by December 14, 1983.

**Carol D. Shull,**

*Chief of Registration, National Register.*

**CALIFORNIA**

*Los Angeles County*

Los Angeles, *Hacienda Arms Apartments,* 8439 Sunset Blvd.

**CONNECTICUT**

*Fairfield County,* Ridgefield, *Ridgefield Center Historic District,* Roughly bounded by Pound St., Fairview Ave., Prospect, Ridge, and Whipstick Rds.

*New Haven County*

New Haven, *Lighthouse Point Carousel,* Lighthouse Point Park, Lighthouse Ave.

**DELAWARE**

*New Castle County*

Delaware City, *Delaware City Historic District,* Roughly bounded by the Delaware River, Dragon Creek, DE 9, and the Delaware and Chesapeke Canals

Wilmington, *Cool Spring Park Historic District* Bounded by Park Pl., Jackson, Van Buren, and 10th Sts.

*Sussex County*

Greenwood vicinity, *Richards Historic District,* County Rd. 34

**IDAHO**

*Shoshone County*

Avery vicinity, *Mallard Peal Lookout,* SE of Avery

**ILLINOIS**

*Cook County*

Wilmette, *Linden Avenue Terminal,* 330 Linden Ave.

**MAINE**

*Knox County*

*Allen's Island*

*Penobscot County*

*Maine Archeological Survey Site*

*Sagadahoc County*

*Hunter Site, Old Stone Bridge Site*

**MARYLAND**

*Baltimore (Independent City)*

*Charles Village-Abell Historic District,* Roughly bounded by University Pkwy., Guilford Ave., and 25th, Mace, Charles, and Barclay Sts.

**MICHIGAN**

*Iron County*

Alpha, *Alpha Public Buildings Historic Complex (Iron County MRA),* Main St.

Alpha, *First National Band Building (Iron County MRA),* 303 Main St.

Amasa, *Amasa Hiatoric Business District (Iron County MRA),* 100, 200, and 300, block of Pine St.

Amasa, *Bowers, Joseph, House (Iron County MRA),* 3,8 Hemlock Ave.

Amasa, *Jacobson, Jacob, House* (Iron County MRA), 327 Maple Ave.

Amasa, *Pork City Historic District (Iron County MRA),* Park City and DNR Rds.

Caspian, *Caspian Community Center (Iron County MRA),* 404 Brady Ave.

Caspian, *Caspian Mine Headframe (Iron County MRA),* N of Caspin Rd.

Caspian, *Dober Mining Company House (Iron County MRA),* 1 19th St.

Caspin, *Italian Society Duke of Abruzzi Hall (Iron County MRA),* E of McGillis Ave. between Morgan and Sawyer Sts.

Crystal Falls, *Cole, Frank W., House (Iron County MRA),* 121 3rd St.

Crystal Falls, *Crystal Falls Dam and Power Plant (Iron County MRA),* Pine St.

Crystal Falls, *Crystal Inn (Iron County MRA),* 400 Superior Ave.

Crystal Falls, *Diele, Ernest, House (Iron County MRA),* 213 Marquette Ave.

Crystal Falls, *Falls Location Historic District (Iron County MRA)*, at Paint River
Crystal Falls, *Finnish and Swedish Mercantile Association Building (Iron County MRA)*, 336 Superior Ave.
Crystal Falls, *H.W. Harte Block-Crystal Falls Village Hall (Iron County MRA)*, 414–418 Superior Ave.
Crystal Falls, *Hasselstrom, John, House (Iron County MRA)*, 400 Crystal Ave.
Crystal Falls, *Huse, Frank C., House (Iron County MRA)*, 408 5th ST.
Crystal Falls, *John H. Parks Company-Wills Hardware Building (Iron County MRA)*,319 Superior Ave.
Crystal Falls, *Murphy, Timothy, House (Iron County MRA)*, 17 N. 4th St.
Crystal Falls, *Rau, Herman, House (Iron County MRA)*, 309 Marquette Ave.
Crystal Falls, *Ross, David M., House (Iron County MRA)*, 120 S. 4th St.
Crystal Falls, *Royce, Steven, House (Iron County MRA)*, 920 Forest Pkwy.
Crystal Falls, *Russell, William, House (Iron County MRA)*, 209 Michigan Ave.
Crystal Falls, *Soderman, John, Farmhouse (Iron County MRA)*, North 6th St.
Iron River, *Beechwood Store (Iron County MRA)*, 215 Beechwood Rd.
Iron River, *Bethany Lutheran Church (Iron County MRA)*, 184 Beechwood Rd.
Iron River, *Byers, Isaac W., House (Iron County MRA)*, 5 N. 8th Ave.
Iron River, *Camp Gibbs Historic District (Iron County MRA)*, 129 W. Camp Gibbs Rd.
Iron River, *Central School (Iron County MRA)*, 200 Cayuga St.
Iron River, *Cloverland Hotel (Iron County MRA)*,423 3rd St.
Iron River, Ericson, Rudolf, House (Iron County MRA), 626 W. Boyington St. Iron River, Frailing, Henry House (Iron County MRA), 19 W. Cuyuga St.
Iron River, *Haggerty, Dennis J., House (Iron County MRA)*,7 N. 7th Ave.
Iron River, *Hane, Gottfried, House (Iron County MRA)*,703 W. Cayuga St.
Iron River, *Iron County Fair Exhibition Hall (Iron County MRA)*,Franklin St.
Iron River, *Iron River Creamery (Iron County MRA)*,5 W. Cayuga St.
Iron River, *Iron River Town Hall (Iron County MRA)*,106 W. Genesee St.
Iron River, *Joseph, Joseph, House (Iron County MRA)*,105 N. 8th Ave.
Iron River, *Lincoln School (Iron County MRA)*,NW of Madison St. and 2nd Ave.
Iron River, *MacKinnon, Alexander, House (Iron County MRA), 134* Cayuga St.
Iron River, *MacKinnon, Donald C., House (Iron County MRA)*, 411 N. 9th St.
Iron River, *Moss, William, House (Iron County MRA)*, 528 W. Genesee St.
Iron River, *Murno-M.A. Hanna Mining Company Office Building (Iron County MRA)*, 702 N. 4th St.
Iron River, *Nelson E. Fisher House-High Banks (Iron County MRA)*, US 2
Iron River, *Scalcucci's Grocery (Iron County MRA)*, 2102 River Ave.
Iron River, *St. Mary's Assumption Catholic Church (Iron County MRA)*, 105 5th Ave.
Iron River, *Sturgeon, Robert H., House (Iron County MRA)*, 112 Cayuga St.
Iron River, *Tully, William J., House (Iron County MRA)*, 419 W. Cayuga St.
Iron River, *Van Ornum's Addition Historic District (Iron County MRA)*, 927, 937, 941, 947, and 953 4th Ave.
Iron River, *Van Wagner, Harvey, House (Iron County MRA)*, 103 N. 7th Ave.
Iron River, *Wall-Seppanen House (Iron County MRA)*, 21 N. 7th Ave.
Iron River, *Windsor, Joseph, House (Iron County MRA)*, 629 W. Genesee St.
Mansfield, Mansfield *Mine Location Historic District (Iron County MRA)*, Stream Rd.
Mineral Hills, *James Mine Historic District (Iron County MRA)*, Mineral Ave. and Mower St.
Mineral Hills, *Spies Boardinghouse (Iron County MRA)*, 700 Grant St.
Stambaugh, *Cooks Run Trout Feeding Station (Iron County MRA)*, 180 Cooks Run Rd.
Stambaugh, *Hamilton, George, House (Iron County MRA)*, 504 Selden Rd.
Stambaugh, *Hanson, John W., House (Iron County MRA)*, 601 Roosevelt ave.
Stambaugh, *Harris, Joseph House (Iron County MRA)*, 615 Washington Ave.
Stambaugh, *Hiawatha Mine Number One Complex, (Iron County MRA)*, W of selden Rd.
Stambaugh, *Holmes, Nels A., Farmstead (Iron County MRA)*, Off MI 189
Stambaugh, *House at 902 Selden Road (Iron County MRA)*, 902 Seldne Rd.
Stambaugh, *Levine, Louis, House (Iron County MRA)*, 502 Selden Rd.
Stambaugh, *M.A. Hanna Company Michigan District Superintendent's House (Iron County MRA)*, 506 Selden Rd.
Stambaugh, *McLean, John S., House (Iron County MRA)*, 230 4th St.
Stambaugh, *McQuown, Lafayette, House (Iron County MRA)*, 411 Adams St.
Stambaugh, *Pentoga Park Office and Bathouse (Iron County MRA)*, , 1630 County Rd.
Stambaugh, *Stolberg, Charles, House (Iron County MRA)*, 411 3rd St.
Stambaugh, *Swanson, John, House (Iron County MRA)*, , 226 4th St.
Stambaugh, *Van Platen-Fox Lumber Camp Historic Complex, (Iron County MRA)*, 281 University Rd.

**NEBRASKA**

*Antelope County*

Neligh, *Neligh Mill Elevators (Boundary Increase)*, 111 W. Second

**Clay County**

Sutton, *Clark, Isaac Newton, House*, 468 Cedar St.

*Douglas County*

Omaha, *Monmouth Park School*, 4508 N. 33rd St.

*Fillmore County*

Fairmont, *Fairmont Creamery Company Building*, SE of 6th Ave. and F St.

*Greeley County*

Spalding, *St. Michael's Catholic Church Complex*, NE of Greeley Ctr.

**NEW MEXICO**

*Santa Fe County*

*La Bajada Mesa Agricultural Site*,

**TENNESSEE**

*Maury County*

Ashwood vicinity, *Pine Hill*, Old Zion Lane
Columbia, *Maquire, Patrick, House*, 105 N. Campbell Blvd.

*Washington County*

Johnson City, *Range, Peter, Stone House*, 307 Twin Falls Dr.

**TEXAS**

*Bexar County*

Leon Springs vicinity, *Plehwe Complex*, W. of Leon Springs on Boerne Stage Rd.

*Guadalupe County*

Seguin, *Seguin Commercial Historic District*, Roughly bounded by Camp, Myrtle, Washington, and Crockett Sts.

**VERMONT**

*Caledonia County*

Danville, *Grouselands (Waterman Farm)*, Town Hwy #26

**WISCONSIN**

*Door County*

Sturgeon Bay, *South Seventh avenue Historic District*, Roughly bounded by Nebraska and Michigan Sts., 7th and 8th Aves.

[FR Doc. 83-31869 Filed 11-28-83; 8:45 am]
BILLING CODE 4310-70-M

## DEPARTMENT OF LABOR

### Office of the Secretary

### Agency Forms Under Review by the Office of Management and Budget (OMB)

#### Background

The Department of Labor, in carrying out its responsibility under the Paperwork Reduction Act (44 U.S.C. Chapter 35), considers comments on the proposed forms and recordkeeping requirements that will affect the public.

#### List of Forms Under Review

On each Tuesday and/or Friday, as necessary, the Department of Labor will publish a list of the Agency forms under review by the Office of Management and Budget (OMB) since the last list was published. The list will have all entries grouped into new collections, revisions, extensions, or reinstatements. The Departmental Clearance Officer will, upon request, be able to advise members of the public of the nature of any particular revision they are interested in.

Each entry will contain the following information:

The Agency of the Department issuing this form.

The title of the form.

The OMB and Agency form numbers, if applicable.

How often the form must be filled out.

Who will be required to or asked to report.

Whether small businesses or organizations are affected.

An estimate of the number of responses.

An estimate of the total number of hours needed to fill out the form.

The number of forms in the request for approval.

An abstract describing the need for and uses of the information collection

**Comments and Questions**

Copies of the proposed forms and supporting documents may be obtained by calling the Departmental Clearance Officer, Paul E. Larson, Telephone 202-523-6331. Comments and questions about the items on this list should be directed to Mr. Larson, Office of Information Management, U.S. Department of Labor, 200 Constitution Avenue, NW., Room S-5526, Washington, D.C. 20210. Comments should also be sent to the OMB reviewer, Arnold Strasser, Telephone 202-395-6880, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 3208, NEOB, Washington, D.C. 20503.

Any member of the public who wants to comment on a form which has been submitted to OMB should advise Mr. Larson of this intent at the earliest possible date.

**Extension**

Mine Safety and Health Administration

Fire Extinguishing and Abandonment Plans for Refuse Piles and Impoundments

1219-0074; MSHA 215

On occasion

Businesses and other for profit; small businesses or organizationa

75 respondents; 1 or 2 hours

Requires coal mine operators to submit to MSHA for approval fire extinguishing plans and abandonment plans for refuse piles and impoundments. Fire extinguishing plans are required to provide reasonable assurance that the fires will be extinguished in a safe and effective manner. Abandonment plans are required to show prudent engineering practices to preclude the probability of future impoundment of water, sediment or slurry and provide for major slope stability.

Signed at Washington, D.C. this 22nd day of November, 1983.

**Paul E. Larson,**

*Departmental Clearance Officer.*

[FR Doc. 83-31788 Filed 11-28-83; 8:45 am]

BILLING CODE 4510-43-M

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## Employment and Training Administration

## Determinations Regarding Eligibility to Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents summaries of determinations regarding eligibility to apply for adjustment assistance issued during the period November 14, 1983-November 18, 1983.

In order for an affirmative determination to be made and a certification of eligibility to apply for adjustment assistance to be issued, each of the group eligibility requirements of Section 222 of the Act must be met.

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated,

(2) That sales or production, or both, of the firm or subdivision have decreased absolutely, and

(3) That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

**Negative Determinations**

In each of the following cases the investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

*TA-W-14,488; Authlan Manganese Corp., Theodore, AL*

*TA-W-14,447; Erik Anders, Div. of U.S. Industries, Inc., Salisbury, NC*

*TA-W-13,919; Prutton Machine Co., Cleveland, OH*

*TA-W-14,637; Eaton Corp., Axle Div., Cleveland, OH*

*TA-W-14,451; Special Metals Corp., New Hartford & Dunkirk, NY*

*TA-W-14,434; TRW, Inc., TRW Greenfield Tap & Die Div., Greenfield, MA*

*TA-W-14,190; Ingersoll-Rand Co., South Deerfield, MA*

In the following case the investigation revealed that criterion (3) has not been met. Increased imports did not contribute importantly to workers separations at the firm.

*TA-W-14,436; Branford Manufacturing Co., Newark, NJ*

In the following case the investigation revealed that criterion (3) has not been met for the reasons specified.

*TA-W-14,702; Satralloy Inc., Steubenville, OH*

Aggregate U.S. imports of ferrochrome did not increase as required for certification.

**Affirmative Determinations**

*TA-W-14,230; Tuscaloosa Energy Corp., Republic Mine, Elkhorn City, KY*

A certification was issued covering all workers separated on or after July 1, 1982 and before March 1, 1983.

*TA-W-14,367; Kitt Energy Corp., Republic Mine, Elkhorn City, KY*

A certification was issued covering all workers separated on or after July 1, 1982 and before March 1, 1983.

*TA-W-14,611; Vesta Mining Co., McMurray, PA*

A certification was issued covering all workers separated on or after April 19, 1982 and before June 1, 1982.

*TA-W-14,563; Four Star Corp., South Haven, MI*

A certification was issued covering all workers separated on or after June 27, 1982 and before November 15, 1983.

*TA-W-14,617; Teledyne-Pittsburgh Tool Steel Co., Monaca, PA*

A certification was issued covering all workers separated on or after April 26, 1982 and before June 30, 1983.

*TA-W-14,604; Currier Piano Co., Marion, NC*

A certification was issued covering all workers separated on or after April 15, 1982 and before December 31, 1982.

*TA-W-14,549; Krauss Rainwear, Inc., New York, NY*

A certification was issued covering all workers separated on or after March 21, 1982 and before November 1, 1982.

*TA-W-14,583; Guterl Special Steel Corp., Simonds Steel Div., Lockport, NY*

A certification was issued covering all workers engaged in the production of tool steel separated on or after March 14, 1982 and before October 31, 1983.

*TA-W-14,449; L & S Bearing Co., Oklahoma City, OK*

A certification was issued covering all workers in the Punch Press, the Screw Machine and the Heat Treat Departments separated on or after February 17, 1982.

I hereby certify that the aforementioned determinations were issued during the period November 14, 1983–November 18, 1983. Copies of these determinations are available for inspection in Room 9120, U.S. Department of Labor, 601 D Street, NW., Washington, D.C. 20213 during normal business hours or will be mailed to persons who write to the above address.

Dated: November 22, 1983.

**Marvin M. Fooks,**

*Director, Office of Trade Adjustment Assistance.*

[FR Doc. 83-31786 Filed 11-28-83; 8:45 am]

BILLING CODE 4510-30-M

## 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 December 9, 1983.

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 December 9, 1983.

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, 601 D Street, NW., Washington, D.C. 20213.

Signed at Washington, D.C. this 21st day of November 1983.

**Marvin M. Fooks,**

*Director, Office of Trade Adjustment Assistance.*

APPENDIX

| Petitioner: Union/workers or former workers of— | Location | Date received | Date of petition | Petition No. | Articles produced |
|---|---|---|---|---|---|
| Aliquippa & Southern Railroad Co. (USWA) | Aliquippa, PA | 11/17/83 | 11/16/83 | TA-W-15,105 | Transports steel and steel products for J & L Aliquippa Works. |
| Bennett Industries, Farmington Shoe Division. (workers) | Farmington, ME | 11/8/83 | 11/2/83 | TA-W-15,106 | Novelty and jogging shoes. |
| Cooper Industries, Inc., Crescent/Xcelite Div. (IAMAW) | Jamestown, NY | 11/7/83 | 11/2/83 | TA-W-15,107 | Hand tools, adjustable wrenches, pliers. |
| Isley Knitting Mills, Inc. (Co.) | Graham, NC | 11/8/83 | 11/4/83 | TA-W-15,108 | Men's sweaters. |
| Jackson County Iron Co. (company) | Black River Falls, WI | 11/15/83 | 11/8/83 | TA-W-15,109 | Iron ore pellets. |
| Mahoning Valley Railway Co. (USWA) | Youngstown, OH | 11/17/83 | 11/16/83 | TA-W-15,110 | Transports steel and steel products for J & L Campbell Works. |
| Monongahela Connecting Railroad (USWA) | Pittsburgh, PA | 11/17/83 | 11/16/83 | TA-W-15,111 | Transports steel and steel products for J & L Pittsburgh Works. |
| National Steel Service Center, Inc. (USWA) | New Castle, PA | 11/16/83 | 11/14/83 | TA-W-15,112 | Cold rolled sheet steel. |
| Prime Split Corp. (Leatherworkers International Union) | Newburyport, MA | 11/7/83 | 10/28/83 | TA-W-15,113 | Split leather for garments. |
| Selmer Co. (UAW) | Elkhart, IN | 11/15/83 | 11/8/83 | TA-W-15,114 | Clarinets, flutes. |
| Winer Manufacturing Co., Inc., (United Garment Workers of America). | Hammond, IN | 11/17/83 | 11/14/83 | TA-W-15,115 | Men's outerwear jackets & outercoats. |

[FR Doc. 83-31787 Filed 11-28-83; 8:45 am]

BILLING CODE 4510-30-M

# LEGAL SERVICES CORPORATION

## Attorney Involvement by Recipients of Funding

**AGENCY:** Legal Services Corporation.

**ACTION:** Instruction on Private Attorney Involvement 83-6.

**EFFECTIVE DATE:** This Instruction is Effective January 1, 1984.

**FOR FURTHER INFORMATION CONTACT:** Joshua Brooks, Deputy Director Office of Field Services, Legal Services Corporation, 733 15th Street, NW.; Washington, D.C. 20005 (202) 272-4080.

### Instruction

*I. Purpose*

The purpose of this Instruction is to provide direction to recipients of Legal Services Corporation funding on allocating a substantial amount of the recipient's financial support from the Legal Services Corporation to provide the opportunity for the involvement of private attorneys in the delivery of legal assistance to eligible clients. The term, "substantial amount" shall be defined as at least twelve and one-half percent of the recipient's LSC annualized basic field award. Funds received from the Corporation as one-time special grants and state support funds are not utilized in determining the private bar involvement requirement.

Recipients of Native American or migrant funding shall provide the opportunity for involvement in the delivery of services by the private bar in a manner which is generally open to board participation in those activities undertaken with those funds; or shall demonstrate to the satisfaction of the Corporation that such involvement is not feasible.

*II. General Policy*

This Instruction implements and extends a policy and statement of principles on private attorney involvement that was adopted by the Board of Directors of the Corporation on October 2, 1981. That policy requires that a substantial amount of funds be made available to provide the opportunity for the involvement of private attorneys in the delivery of legal assistance to eligible clients. The Corporation encourages the implementation through both pro bono and compensated mechanisms.

The policy builds on local program experience as well as formal research and experimentation undertaken by the

Corporation, that has provided comprehensive information about the delivery of legal services to the poor. This information demonstrates that there are a variety of effective and economical mechanisms to involve private attorneys in either a voluntary or partially-compensated basis in the delivery of legal services to the poor; and there are many private attorneys willing and able to provide high quality legal assistance. There is substantial evidence that mixed delivery systems within each project will provide for the most economical and effective delivery service.

The Corporation's policies are designed to enhance the participation of private attorneys, through local programs. To achieve that goal the Corporation directed each recipient to develop and implement a plan to allocate a substantial amount of its LSC support to activities consistent with an Instruction published on December 14, 1981 and effective on January 14, 1982.

In the case of joint efforts involving two or more recipients, the minimum expenditure requirement shall be applied to the aggregate of the pertinent LSC support for each of the recipients. Each recipient in any such effort shall be a bona fide participant in the activities undertaken by the joint venture.

Recipients of national and state support grant awards, while not subject to the percentage requirement, shall investigate the feasibility, and as is appropriate, implement mechanisms of involving private attorneys pursuant to such grants.

Private attorney involvement shall be an integral part of a total local program undertaken within the established priorities of that program in a manner that furthers the statutory requirement of high quality, economical and effective client-centered legal assistance to the poor. Decisions about how to meet the substantial involvement requirement rest with the recipient through its governing body subject to review and evaluation by the Corporation. The Corporation requires, however, that the recipient develop and maintain its plan in consultation with its clients, staff, the organized bar, including minority and women's bar groups, and private attorneys in it service area. Experience has indicated that effective private attorney involvement occurs in those communities where the legal services program and relevant bar organizations have been able to work together in design and implementation of a plan to achieve that involvement. The funds required to be expended under this part should not be transferred, or sub-granted to other organizations.

*III. Range of Activities*

Private attorneys can be effectively involved in delivery of legal assistance to eligible clients in a variety of ways and in a response to a variety of priority legal needs of clients. At a minimum the following considerations will apply and define a range of activities permitted in meeting the requirements of this Instruction:

(1) The primary consideration in undertaking any such activities will be the provision of high quality civil legal services to eligible clients in an effective and economical manner; and

(2) Activities undertaken by the recipient to meet the requirements of this Instruction might include, but are not necessarily limited to:

(a) Direct delivery of legal assistance to eligible clients through organized pro bono or reduced fee plans utilizing volunteer attorneys, judicare panels, private attorney contracts, and/or organized referral systems; except that "revolving litigation funds" systems shall not be used nor funded under this part nor funded with any LSC support.

(b) Support provided by private attorneys to the recipient in its delivery of legal assistance to eligible clients on either a reduced fee or pro bono basis through the provision of community legal education; training; technical assistance; research; advice and counsel; co-counseling arrangements; or, the use of private law firm facilities, libraries, computer-assisted legal research systems or other resources; and,

(c) Support provided by the recipient in furtherance of activities undertaken pursuant to (a) above including the provision of training; technical assistance; research; advice and counsel; or the use of recipient facilities, libraries, computer assisted legal research systems or other resources.

(3) The specific methods to be undertaken by a recipient to involve private attorneys in the provision of legal assistance to eligible clients will be determined by the recipient taking into account the following factors:

(a) The priority legal needs of eligible clients in the service area;

(b) Effective and economical delivery or legal assistance to eligible clients;

(c) Linguistic and cultural barriers to effective advocacy;

(d) Actual or potential conflicts of interest between specific participating attorneys and individual eligible clients; and,

(e) The substantive and practice expertise, skills, and willingness to undertake new or unique areas of the law of participating attorneys.

(4) Systems designed to provide direct services to clients by private attorneys on either a pro bono or reduced fee basis, shall include at a minimum, the following components:

(a) Intake and case acceptance procedures which are consistent with the recipients established priorities in meeting the legal needs of eligible clients;

(b) Case assignment which insures the referral of cases according to the nature of the legal problem or problems involved and the skills, expertise, and substantive experience of the participating attorney;

(c) Case oversight and follow-up procedures which insure the timely disposition of cases in a manner and in a form calculated to achieve, in so far as possible, the result desired by the client and the efficient utilization of recipient resources; and,

(d) Support and technical assistance procedures which are appropriate and, to the extent feasible, provide access for participating attorneys to materials, training opportunities, and back-up on substantive law and practice considerations.

(5) The recipient shall utilize financial systems and procedures to account for costs allowable in meeting this Instruction which will:

(a) Meet the requirements of the Corporation's *Audit and Accounting Gudie for Recipients and Auditors;*

(b) Accurately identify and account:

- For the recipient's administrative, overhead, staff, and support costs related to private attorney involvement activities;
- For payments to private attorneys for support or direct client services rendered;
- For contractual payments to individuals or organizations which will undertake administrative, supportive, and/or direct services to eligible clients on behalf of the recipient consistent with the provisions of this Instruction; and,
- For other such actual costs as may be incurred by the recipient in this regard.

(c) Income and expenses relating to the PAI effort must be reported separately in the year-end audit. This may be done by establishing a separate fund or by providing a separate supplemental schedule of income and expenses related to the PAI effort as a part of the audit.

(d) Auditors will be required to perform sufficient audit tests to enable them to render an opinion on the recipient's compliance with the requirements of this Instruction.

(e) Programs must maintain the internal records necessary to demonstrate that funds have been utilized for private attorney involvement consistent with this Instruction. Internal records should include contracts on file which set forth payment systems, hourly rates, maximum allowable fees, etc.; bills/invoices which are submitted before payments are made; job descriptions that reflect the assignment of specific responsibilities for PAI activities to specific program staff; and staff time records. Any direct or indirect staff time which is to be allocated as a cost to private attorney involvement must be documented by detailed timesheets in addition to regular attendance reports.

• Personnel costs must be documented by time records certified by the employee or a supervisor who is in a position to know what tasks the employee is performing 100 percent of the time.

• The time record is to be related to pay periods and prepared in intervals not longer than one month.

• 100 percent of an individual's time must be accounted for; it would be insufficient for an employer to record only time spent on PAI activities.

(f) Direct payments to private attorneys should be supported by invoices and internal procedures performed by the program to insure that the services billed have actually been delivered.

(g) Non-personnel costs should be allocated on the basis of reasonable operating data. All allocation methods should be clearly documented.

(h) Contracts with other organizations involving a transfer of funds for PAI activity should indicate that LSC funds will be accounted for in accordance with LSC guidelines. The organization receiving funds will be considered a sub-recipient or sub-grantee and will be bound by all accounting and audit requirements of the Audit Guide and 45 CFR Part 1627. These grants shall be accounted for on a cost-reimburseable basis so that the primary recipient will retain accountability for unspent funds. This part does not pertain to contracts with individual lawyers or law firms who provide legal services directly to eligible clients.

(i) Each recipient which utilizes a compensated private bar mechanism whether judicare, contract, or some other form, must develop a system which includes; a schedule for uniform assignment of encumbrances to similar types of cases, interim billing, a procedure to determine net encumbrances, a mechanism to relate specific encumbrances to specific cases, and the ability to statistically determine the appropriateness of the encumbering system.

(j) Net encumbrances shall not be included in the calculation of whether a program has met the requirements of this Instruction. Nor should they be recorded as an expense for audit purposes. In other words, only actual expenditures or those amounts shown as accounts payable at the end of the fiscal period may be utilized to determine whether or not the program has met the requirements of this Instruction. Services must have been rendered and billed to satisfy expenditure requirements.

(k) In private attorney models, attorneys may be reimbursed for actual costs and expenses, but attorney fees may not be paid at a rate which exceeds 50 percent of the local prevailing market's rate for that type of service.

*IV. Procedure*

The recipient shall develop a plan and budget to meet the requirements of this Instruction which shall be a part of the refunding application or initial grant application. The budget shall be modified as necessary to fulfill this Instruction. That plan shall take into consideration the:

(1) Legal needs of eligible clients in the geographic area served by the recipient and the relative importance of those needs consistent with the priorities established pursuant to Section 1007(a)(2)(C) of the Legal Services Corporation Act (42 USC 2996 F(a)(2) and part 1620 of the Regulations (45 CFR 1620) adopted pursusnt thereto; and

(2) Delivery mechanisms potentially available to provide the opportunity for private attorneys to meet the established priority legal needs of clients in an economical and effective manner.

(3) The results of the consultation as required.

The recipient shall consult with significant segments of the client community, private attorneys, and bar associations including minority and women's bar associations, in the recipient's service area in the development of its annual plan to provide for the involvement of private attorneys in the provision of legal assistance to eligible clients.

Annually, each recipient, pursuant to action taken by the governing body of the recipient, must certify to the Corporation that it is spending such sums as are necessary to comply with this Instruction.

Recipients who choose to spend a portion of the money required under this Instruction to develop *pro bono* activities must assure that the value of the *pro bono* services substantially exceeds the direct and indirect costs being allocated to meet the requirements of this Instruction.

**Note.**— Prohibited Revolving Litigation Funds Systems—A revolving litigation fund is a mechanism which is created to advance funds to private attorneys for the costs, expenses, and/or attorney fees related to litigation in cases where there is an expectation of recovering attorneys fees. The principle and administration of such funds is simple. Monies are held in a fund and its availability is publicized within the legal community to encourage participation by private attorneys. Criteria established for reviewing funding requests and applications are reviewed by staff which administer the fund. When an application is approved, monies are advanced to the private attorney for specified purposes with the understanding that if the case is won, the loan will be repaid with interest or a percent of attorneys fees collected in the case which will be turned over to the fund in repayment of the loan. If the case is lost, the loan is forgiven.

This approach has been used for a number of years by public interest law firms and national legal organizations to encourage private bar involvement in public interest litigation. Previously (1982). the Legal Service, Corporation funded a project of the Migrant Legal Action Program which makes such a fund available to private attorneys who handle cases on behalf of migrant farmworkers. In addition, TRLA has established such a fund in Texas.

The Office of Field Services will not endorse or approve such mechanisms. The potential for abuse is great. Such a mechanism is clearly counter to the restrictions in the Act which are meant to deter Legal Services Corporation funds and recipients involvement in fee-generating cases.

This prohibition does prevent reimbursement or payment of costs and expenses incurred by private attorneys in normal situations where litigation may result in attorney fees.

Dated: November 23, 1983.

**Gregg L. Hartley,**

*Director, Office of Field Services.*

[FR Doc. 83-31919 Filed 11-28-83; 8:45 am]

BILLING CODE 6820-35-M

## General Conditions for 1984 Basic Field, Native American, and Migrant Grant Awards; LSC Instruction 83-7

**AGENCY:** Legal Services Corporation.

**ACTION:** Adoption of LSC Instruction 83-7.

**SUMMARY:** The Legal Services Corporation requires that its recipients of Basic Field, Native American and

Migrant funding agree to certain grant conditions as to their use of such funds. This Instruction sets forth the language contained in the general conditions.

**EFFECTIVE DATE:** January 1, 1984.

**FOR FURTHER INFORMATION CONTACT:** Gail Frances, Manager, Grants and Budget Unit, Office of Field Services, Legal Services Corporation, 733 Fifteenth Street, N.W., Washington, D.C. 20005, (202) 272-4080.

**Authority:** Section 1008(e) of the Legal Services Corporation Act, of 1974, as amended; 42 U.S.C. 2996g(e).

### I. Purpose

The purpose of this Instruction is to provide notice and direction to recipients of Legal Services Corporation funding regarding grant conditions. The Corporation requires all recipients of Basic Field, Native American, and Migrant funding to certify that they shall comply with certain general conditions. Other special conditions may also be attached to grants for classes of recipients or individual recipients.

The recipient program will affirm its agreement to the conditions of each grant award by signature confirmation of the appropriate contracting parties. These documents must be returned to the Corporation within a reasonable period of time after receipt of the grant award letter in order that funds may be released by the Office of the Comptroller.

Under certain circumstances, the Corporation may specifically waive one or more general conditions.

A listing of these general conditions is provided herein and shall be made a part of each grant award.

### II. General Conditions

Each recipient of Corporation Basic Field, Native American, or Migrant funds shall certify that:

1. In addition to its agreement contained in Grant Assurance numbered 1, the recipient specifically agrees that it will comply with any measures adopted by the Congress of the United States whether as Amendments to the Legal Services Corporation Act of 1974, as amended, or for purposes of appropriating funds for the Legal Services Corporation; and that it will comply with all rules, regulations, policies, guidelines, instructions and other directives issued by the Corporation, including those which may be adopted after the effective date of this grant.

2. Consistent with the Instruction on Recipient Fund Balances 83-4 published by the Corporation, unexpended funds, in excess of ten percent (10%) (or such other amounts specifically approved by the Corporation) of the recipient's 1983 support from the Legal Services Corporation, carried forward as a fund balance at the close of the recipient's 1983 fiscal year, shall be set off against this grant award.

Dated: November 23, 1983.

**Gregg L. Hartley,**

*Director, Office of Field Services.*

[FR Doc. 83-31918 Filed 11-28-83; 8:45 am]

BILLING CODE 6820-35-M

## Standard Operating Procedure for Questioned Costs; LSC Instruction 83-8

**AGENCY:** Legal Services Corporation.

**ACTION:** Adoption of LSC Instruction 83-8.

**SUMMARY:** This Instruction outlines the process Legal Services Corporation will undertake to resolve questioned costs arising from the expenditure of recipient programs grant funds.

**FOR FURTHER INFORMATION CONTACT:** Gail Francis, Manager, Grants and Budget Unit, Office of Field Services, Legal Services Corporation, 733 Fifteenth Street, NW., Washington, D.C. 20005, (202) 272-4080.

**SUPPLEMENTARY INFORMATION:**

**Authority:** Section 1008(e) of the Legal Services Corporation Act, of 1974, as amended; 42 U.S.C. 2996g(e).

### I. Summary of Procedures

1. Questioned costs are in infrequent occurrence which typically are identified in connection with recipient programs annual audits. The monitoring office should also advise the Audit Division of any questioned costs which may arise in the conduct of a monitoring visit, correspondence or other contact with the program, and/or from other sources. The monitoring office director is responsible for investigating, documenting, and recommending the appropriate Corporation response to such costs in accordance with applicable guidelines, rules, and regulations. This Standard Operating Procedure (SOP) was developed to assist the monitoring office in discharging this responsibility. The monitoring office will additionally serve as the primary liaison among the program director, the chair of the programs's board of directors (if the circumstances warant), the Audit Division, and the OFS Grants and Budget Unit involving these issues.

At the conclusion of its investigation, the monitoring office will submit a recommendation for the resolve of the questioned costs to the OFS Grants and Budget Unit. Final approval of the disposition of questioned costs by the Manager of the OFS Grants and Budget Unit is necessary prior to notification to the affected recipient program of the questioned costs allowance or disallowance and the resulting recoupment and/or determination of uncollectibility. This decision should be reached within six (6) months from the first posting of a questioned cost on the Audit Division "Status of Unresolved Questioned Costs List." The monitoring office will maintain documentation supporting the disposition of such costs.

2. The monitoring office is responding to costs which are questioned as to their eligibility for LSC funding basically for three reasons:

The cost contravenes specific LSC guidelines; and/or

The cost appears unnecessary or unreasonable in the circumstances; and/or

The cost does not meet normal requirements for adequate documentation.

3. Interim reporting of identified questioned costs wil be reflected on the Audit Division "Status of Unresolved Questioned Cost List" until the matter has been closed. The monitoring office must advise the program director within two (2) weeks of a questioned costs posting to the list. If the costs -singly or collectively- exceed $1,000.00, the chair of the program's board of directors must also be contacted in writing by the monitoring office within the same two (2) week period. The monitoring office must review each "Status of Unresolved Questioned Costs List" and advise the Director of the Audit Division within 45 days of its issuance of any changes.

### II. Investigation Instructions

1. The monitoring office should contact the program director (and chair of the program's board of directors if the circumstances warrant) within two(2) weeks of the posting of a questioned cost to the Audit Division "Status of Unresolved Questioned Costs List." Notification to the program will include a request for a written response from the program addressing the status of the questioned costs and any procedures undertaken for its resolve and to prohibit any recurrence. The program's response should be received at the monitoring office within thirty (30) days after receipt of the notice.

2. Monitoring office representatives may contact any parties it deems necessary during the course of its investigation. Professional courtesy and discretion should be exercised at all times. The person who need to be

contacted may include, but should not be limited to, current and separated employees, current and former members of the board of directors, auditors, vendors, contractors, or other persons having knowledge about the matter.

3. The following general factors should be considered by the monitoring office during the course of its investigation of all questioned costs:

a. The expenditure was a legitimate use of LSC funds which is lacking the required prior LSC approval or which is excessive:

b. The amount is material compared to the program's annualized funding level;

c. The contravention is part of a pattern of financial noncompliance;

d. The practice leading to the occurrence of the questioned cost has been subsequently corrected to avoid recurrence;

e. The program was on prior notice of disallowance of such expenditures;

f. The noncompliance was negligent or willful;

g. Unusual circumstances existed mitigating the contravention;

h. The magnitude of the disruption to client services if the costs are disallowed and must be repaid;

i. The loss of LSC's reversionary interest in the assets purchased;

j. The program has a previous history of other questioned costs; and,

k. Sufficient competent evidential matter which would normally support varous categories of expenditure is not contained in the program's files and cannot be obtained from independent third parties such as vendors.

4. The monitoring Office can accept affidavits of third parties who are in a position to verify the nature and amount of the costs in question. Affidavits from those individuals incurring the expense of responsible for the disbursement are by themselves insufficient. The acceptability of affidavits shall be determined by the monitoring office, with final approval by the Manager of the OFS Grants and Budget Unit. Evidence need not be more substantive than would have been originally required.

**III. Resolution Process**

1. Recommendations from the monitoring office on allowance or disallowance of questioned costs should be sent to the Manager of the OFS Grants and Budget Unit within five months after the first posting of a questioned cost to the "Status of Unresolved Questioned Costs List" unless an extension is granted. Recommendations are to address the relevant factors as outlined in this SOP or other factors considered. Narrative should also be provided which outlines the monitoring office's investigation procedures and efforts to resolve the matter. The five-month timeframe may be extended for good cause upon petition by the monitoring office to the Manager of the OFS Grants and Budget Unit. Good cause includes, but is not limited to, delays due to difficulty in obtaining information from a non-recipient, and pending related litigation or claims.

2. The recommendations open to the monitoring office director are to:

Allow the costs to be charged to LSC's grant, or

Disallow the costs, and,

a. Require the recipient program to obtain repayment from the responsible employee, bonding company, or other third party, to reimburse the LSC fund; or

b. Where the questioned cost was not part of a pattern of financial non-compliance or there existed circumstances mitigating the contravention (including a recent change in management) the costs may be charged to a non-LSC fund to reimburse the LSC fund, or, if no alternative funds are available for reimbursement of the LSC fund and the cumulative amount of the questioned costs do not exceed $25,000.00, the costs may be charged to the LSC fund upon obtaining the commitment of the recipient program's board of directors to address the reasons for the program's failure to comply and to develop and implement a plan to remedy the problem, in which case a special grant condition may be necessary; or

c. Where warranted for breach of fiduciary duty for decisions made or ratified by the program's board of directors LSC may seek reimbursement from the program's board of directors; or

d. Where the questioned costs arose from the expenditures of an entity other than the recipient program, reimbursement of costs may be sought from it, its employees and board of directors; if the Corporation is unable to collect the amount in question, the unrecovered costs may be collected from the recipient program under the procedures described in (b) above; or

e. Where the questioned cost is part of a pattern of deficient financial management and significant mitigating circumstances are lacking, the amount of the questioned costs may be reimbursed by a cash payment from the program to LSC or will be withheld from the grant for the subsequent grant year(s). When the amount to be withheld exceeds 10% of the monthly grant check, recoupment may be made in installments; or

f. Where the questioned cost amounts to substantial failure by a recipient program warranting curtailment of funds under 45 CFR Part 1623, funds may be withheld from grant checks in the current year; or

g. Where warranted for serious and uncorrected poor financial management, termination or denial of refunding under 45 CFR 1606 may be initiated.

3. The Manager of the OFS Grants and Budget Unit may:

Approve the recommendation of the monitoring office; or

Direct the Monitoring office to obtain further information, and grant an extension of time for the resolve of the questioned costs; or

Disapprove the monitoring office's recommendation and provide an alternate decision including reasons therefor.

4. The Manager of the OFS Grants and Budget Unit is to render a written decision on the allowance of disallowance or a questioned cost within thirty (30) days of the date of receipt of recommendations, except where circumstances warrant otherwise, and to notify the monitoring office and Audit Divison of the decision.

5. The monitoring office is to communicate the decision to the program director and chair of the board of directors within two (2) weeks of the decision.

6. Within thirty (30) days of a decision to disallow, the monitoring office shall send a recommendation of a recoupment method or a recommendation to write-off the disallowed costs to the OFS Grants and Budget Unit for approval. The OFS Grants and Budget Unit will confer with the Audit Division, the Office of the Comptroller and, where appropriate, the Office of the General Counsel. Within thirty (30) days after the receipt of the recommendation, the OFS Grants and Budget Unit will notify the recipient program of its decision and will send a copy of the notice to the monitoring office.

**IV. Instructions When Resources are Diverted Through Fraud or Resources are Used for Personal Benefit**

1. The monitoring offices should ensure that the Audit Division and the OFS Grants and Budget Unit are kept fully informed about any fraud or defalcation of funds by recipient programs. The occurrence of fraud or defalcation should be communicated immediately and followed-up with a memorandum detailing: all the facts about the incident, the amount involved,

steps taken by the program to recover the funds, changes made in the program's internal control system to prevent a recurrence and any other pertinent information. The monitoring office is to make monthly progress reports until the matter is resolved.

2. The monitoring office is responsible for ensuring that, depending on the type of fraud or defalcation, the program has taken all necessary steps to seek resolution of the incident. The following guidelines should be aplied:

a. The overriding priority is to recoup the lost resources.

b. The program's board of directors is charged with taking all administrative and legal actions necessary to recover the loss and prevent a recurrence.

c. Within thirty (30) day of its resolve, the program's board of directors is required to submit a report on the disposition of the matter to the monitoring office.

3. The monitoring office should make a recommendation commenting on the disposition of the issue discussed in the board of director's report. The recommendation and a copy of the report should be forwarded to the OFS Grants and Budget Unit within thirty (30) days after its receipt.

5. The OFS Grants and Budget Unit will make the final determination on the resolve of these matters and will coordinate its efforts with the Audit Division, the Office of the Comptroller, and of the Office of the General Counsel. The Grants and Budget Unit will communicate the decision to the program.

Dated: November 23, 1983.

**Gregg L. Hartley,**

*Director, Office of Field Services.*

[FR Doc. 83-31917 Filed 11-28-83; 8:45 am]

BILLING CODE 6820-35-M

## NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

### Humanities Panel; Meetings

**AGENCY:** National Endowment for the Humanities.

**ACTION:** Notice of meetings.

**SUMMARY:** Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 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, D.C. 20506:

1. Date: December 13, 1983.
Time: 8:30 a.m. to 5:00 p.m.
Room: 315.
Program: This meeting will review Summer Stipends applications in English Literature to the 18th Century, submitted to the Division of Fellowships and Seminars, for projects beginning after May 1, 1984.

2. Date: December 13, 1983.
Time: 8:30 a.m. to 5:00 p.m.
Room: 415.
Program: This meeting will review Summer Stipends applications in Music and Dance, submitted to the Division of Fellowships and Seminars, for projects beginning after May 1, 1984.

3. Date: December 14, 1983.
Time: 8:30 a.m. to 5:30 p.m.
Room: 415.
Program: This meeting will review Summer Stipends applications in Psychology, Education, Speech and Communication, submitted to the Division of Fellowships and Seminars, for projects beginning after May 1, 1984.

4. Date: December 15, 1983.
Time: 8:30 a.m. to 5:00 p.m.
Room: 315.
Program: This meeting will review Summer Stipends Applications in Comparative Literature, Literary Theory, and Criticism, submitted to the Division of Fellowships and Seminars, for projects beginning after May 1, 1984.

Date: December 15, 1983.
Time: 8:30 a.m. to 5:00 p.m.
Room: 415.
Program: This meeting will review Summer Stipends applications in American History III, submitted to the Division of Fellowships and Seminars, for projects beginning after May 1, 1984.

6. Date: December 22, 1983.
Time: 9:00 a.m. to 5:00 p.m.
Room: 315.
Program: This meeting will review Summer Stipends applications in Philosophy II, submitted to the Division of Fellowships and Seminars, for pojects beginning after May 1, 1984.

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; (2) information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy; and (3) information the disclosure of which would significantly frustrate implementation of proposed agency action, pursuant to authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee Meetings, dated January 15, 1978, I have determined that these meetings will be closed to the public pursuant to subsections (c) (4), (6) and (9)(B) of section 552b of Title 5, United States Code.

Further information about these meetings can be obtained from Mr. Stephen J. McCleary, Advisory Committee Management Officer, National Endowment for the Humanities, Washingtion, D.C. 20506, or call (202) 786-0322.

**Stephen J. McCleary,**

*Advisory Committee Management Officer.*

[FR Doc. 83-31640 Filed 11-28-83; 8:45 am]

BILLING CODE 7536-01-M

## NUCLEAR REGULATORY COMMISSION

**[Docket No. 50-155]**

### Consumers Power Co.; Consideration of Issuance of Amendment to Facility Operating License and Proposed No Significant Hazards Consideration Determination and Opportunity for Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. DPR-6, issued to Consumers Power Company (the licensee), for operation of the Big Rock Point Plant located in Charlevoix County, Michigan.

The amendment would revise the present limits in Table 4-1 on reactor vessel pressure versus temperature in the Big Rock Point Technical Specifications. The present limits are appropriate for 1.25 Effective Full Power Years (EFPY) from the end of the 1982 refueling outage. This limitation which corresponds to a total of approximately 11.2 EFPY will be reached on or about January 1, 1984. The proposed limits would be appropriate for operation out to 18 EFPY. These changes are in accordance with the licensee's application for amendment dated October 24, 1983.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of

a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The Commission has provided guidance concerning the application of these standards by providing certain examples which were published in the **Federal Register** on April 6, 1983 (48 FR 14870). One of the examples (vi) of actions involving no significant hazards considerations is a change which either may result in some increase to the probability or consequences of a previously-analyzed accident or may reduce in some way a safety margin, but where the results of the change are clearly within all acceptable criteria with respect to the system or component specified in the Standard Review Plan. The revision of the reactor vessel pressure/temperature limits to account for cumulative radiation exposure to the vessel is such a change. The licensee indicated in the October 24, 1983 request that the new limits are consistent with current criteria. The revision of Table 4–1 will be evaluated by the staff to assure that Table 4–1 satisfies the restrictions imposed by Appendices G and H of 10 CFR Part 50. Thus, the staff proposes to determine that the requested action would involve a no significant hazards consideration determination because it would not involve a significant increase in the probability or consequences of an accident previously evaluated, would not create the possibility of a new or different kind of accident from any previously evaluated, and would not involve a significant reduction in a margin of safety.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination. The Commission will not normally make a final determination unless it receives a request for a hearing.

Comments should be addressed to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attn: Docketing and Service Branch.

By December 29, 1983, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating licenses and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written petition for leave to intervene. Request for a hearing and petitions for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of Atomic Safety and Licensing Board Panel, will rule on the request and/or petition and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspects of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter, and the bases for each contention set forth with reasonable specificity. Contentions shall be limited to matters within the scope of the amendment under consideration. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendments before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves not significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch, or may be delivered to the Commission's Public Document Room, 1717 H Street NW. Washington, D.C., by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at (800) 325–6000 [in Missouri (800) 342–6700]. The Western Union operator should be given Datagram Identification Number 3737 and the following message to Dennis M. Crutchfield: petitioner's name and telephone number; date petition was mailed; plant name; and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and to Judd L. Bacon, Consumers Power Company, 212 West Michigan Avenue, Jackson, Michigan 49201, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended positions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the Atomic Safety and Licensing Board designated to rule on the petition and/or request, that the petitioner has made a substantial showing of good cause for the granting of a late petition and/or request. That determination will be based upon a balancing of the factors specified in 10 CFR 2.714(a)(1) (i)–(v) and 2.714(d).

For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, D.C., and at the Charlevoix Public Library, 107 Clinton Street, Charlevoix, Michigan 49720.

Dated at Bethesda, Maryland, this 23rd day of November 1983.

For the Nuclear Regulatory Commission.

**Dennis M. Crutchfield,**

*Chief, Operating Reactors Branch No. 5, Division of Licensing.*

[FR Doc. 83-31877 Filed 11-28-83; 8:45 am]

BILLING CODE 7590-01-M

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**[Docket No. 50-387]**

## Pennsylvania Power & Light Co. and Allegheny Electric Cooperative, Inc.; Consideration of Issuance of Amendment to Facility Operating License and Proposed No Significant Hazards Consideration Determination and Opportunity for Hearing

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. NPF-14, issued to Pennsylvania Power & Light Company and Allegheny Electric Cooperative, Inc. (the licensees), for operation of the Susquenhanna Steam Electric Station, Unit 1 located in Luzerne County, Pennsylvania.

The amendment would modify Technical Specification Tables 3.3.2-1 and 3.6.3-1 in accordance with the licensee's application for an amendment dated November 4, 1983. The modifications include:

(1) Reinstating isolation signal "X" on Trip Function 1.b., Drywell Pressure-High in Table 3.3.2-1. Isolation signal "X" on Trip Function 1.b. was approved by the NRC Staff in Amendment 4 to License NPF-14 and was inadvertently dropped from the table on issuance of Amendment 6 to License NPF-14.

(2) Deleteing RHR-Shutdown Cooling Return/LPCI Injection Valves HV-151F122 A and B fom the Automatic Isolation section of Table 3.6.3-1 and adding them to the Manual Isolation section of the same table. To clarify the functional description of these valves, the proposed change would also add "—Pressure Equalizing Valve" to the valve title in Table 3.6.3.-1.

(3) Correcting typographical errors in the isolation signals of the Suppression Pool Cooling/Spray Valves HV-151F011 A and B from signals "B" and "C" to signal "G". In addition, the description for these valves would be changed from "RHR—Suppression Pooling Cooling/Spray" to "RHR—Suppression Pool Cooling/Spray".

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

The Commission has provided guidance concerning the application of standards of no significant hazards determinations by providing certain examples (48 FR 14870). One of the examples of actions likely to involve no significant hazards considerations relates to a purely administrative change to Technical Specifications: for example, a change to achieve consistency throughout the Technical Specifications, correction of an error, or a change in nomenclature. A review of the licensee's submittal, dated November 4, 1983, in accordance with the Standard of 10 CFR 50.92, indicates that all the proposed changes are administrative in nature to correct errors or change nomenclature. The proposed amendment, therefore, falls within the category of the cited example and clearly does not involve a significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination. The Commission will not normally make a final determination unless it receives a request for a hearing.

Comments should be addressed to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attn.: Docketing and Service Branch.

By December 29, 1983, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written petition for leave to intervene. Request for a hearing and petitions for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made a party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be intended in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than fifteen (15) days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be

litigated in the matter, and the bases for each contention set forth with reasonable specificity. Contentions shall be limited to matters within the scope of the amendment under consideration. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and state comments received. Should the Commission take this action, it will publish a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington D. C. 20555, Attn: Docketing and Service Branch, or may be delivered to the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. by the above date. Where petitions are filed during the last ten (10) days of the notice period, it is requested that the petitioner promptly so inform the Commission by a toll-free telephone call to Western Union at (800) 325-6000 (in Missouri (800) 342-6700). The Western Union operator should be given Datagram Identification Number 3737 and the following message addressed to A. Schwencer: Petitioner's name and telephone number; date petition was mailed; plant name; and publication date and page number of this **Federal Register** notice. A copy of the petition should also be sent to the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and to Jay Silberg, Esquire, Shaw, Pittman, Potts & Trowbridge, 1800 M Street, NW., Washington, D.C. 20036, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or request for hearing will not be entertained absent a determination by the Commission, the presiding officer or the Atomic Safety and Licensing Board designated to rule on the petition and/or request, that the petitioner has made a substantial showing of good cause for the granting of a late petition and/or request. That determination will be based upon a balancing of the factors specified in 10 CFR 2.714(a)(1) (i)-(v) and 2.714(d).

For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C., and at the Osterhout Free Library, Reference Department, 71 South Franklin Street, Wilkes-Barre, Pennsylvania 18701.

Dated at Bethesda, Maryland this 21st day of November 1983.

For the Nuclear Regulatory Commission.

**A. Schwencer,**

*Chief, Licensing Branch No. 2, Division of Licensing.*

[FR Doc. 83-31878 Filed 11-28-83; 8:45 am]

BILLING CODE 7590-01-M

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**[Docket No. 50-142 OL (Proposed Renewal of Facility License)]**

## Regents of the University of California (UCLA Research Reactor); Cancellation of Evidentiary Hearing

November 21, 1983.

Please take notice that the evidentiary hearing in the above captioned matter scheduled to resume on Tuesday, November 29, 1983 at 9:30 a.m. local time at the Federal Trade Commission, Los Angeles Regional Office, Suite 13209, 11000 Wilshire Boulevard, Los Angeles, California 90024, has been cancelled.

For the Atomic Safety and Licensing Board.

**John H. Frye III,**

*Chairman, Administrative Judge.*

[FR Doc. 83-31880 Filed 11-28-83; 8:45 am]

BILLING CODE 7590-01-M

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**[Docket No. 50-395]**

## South Carolina Electric and Gas Co., and South Carolina Public Service Authority; Granting of Relief From Certain Requirements of ASME Code Section XI Inservice (Testing) Requirements

The U. S. Nuclear Regulatory Commission (the Commission) has granted relief from certain requirements of the ASME Code, Section XI, "Rules and Inservice Inspection of Nuclear Power Plant Components" to the South Carolina Electric and Gas Company and South Carolina Public Service Authority. The relief relates to the preservice hydrostatic tests for the Virgil C. Summer Nuclear Station, Unit 1 (the facility) located in Fairfield County, South Carolina. The ASME Code requirements are incorporated by reference into the Commission's rules and regulations in 10 CFR Part 50. The relief is effective as of its date of issuance.

The relief relates to certain preservice examination requirements, pursuant to the Commission's regulations in 10 CFR 50.55a(g)(6)(i). In lieu of hydrostatic tests, the licensees will perform nondestructive examinations consisting of visual and surface examination of the welds.

The requests for relief comply with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the related Safety Evaluation Report and letter to the licensee.

The Commission has determined that the granting of relief will not result in any significant environmental impact and that pursuant to 10 CFR 51.5(d)(4) and environmental impact statement or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of this action.

For further details with respect to this action, see (1) the licenses' letter dated August 9, 1983, (2) the Commission's letter to the licensees dated November

21, 1983, and, (3) the Commission's related Safety Evaluation Report. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, D.C. 20555 and at the Fairfield County Library, Garden and Washington Streets, Winnsboro, South Carolina 29180. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Licensing.

Dated at Bethesda, Maryland, this 21st day of November 1983.

For the Nuclear Regulatory Commission.

**Elinor G. Adensam,**

*Chief; Licensing Branch No. 4; Division of Licensing.*

[FR Doc. 83-31879 Filed 11-28-83; 8:45 am]

BILLING CODE 7590-01-M

## Advisory Committee on Reactor Safeguards, Subcommittee on Metal Components; Meeting

The ACRS Subcommittee on Metal Components will hold a meeting on December 13, 1983, Room 1046, 1717 H Street, NW, Washington, DC.

In accordance with the procedures outlined in the **Federal Register** on September 28, 1983 (48 FR 44291), oral or written statements may be presented by members of the public, recordings will be permitted only during those portions of the meeting when a transcript is being kept, and questions may be asked only by members of the Subcommittee and its Staff. Persons desiring to make oral statements should notify the cognizant Designated Federal Employee as far in advance as practicable so that appropriate arrangements can be made to allow the necessary time during the meeting for such statements.

The entire meeting will be open to public attendance except for those sessions which will be closed to protect proprietary information (Sunshine Act Exemption 4). One or more closed sessions may be necessary to discuss such information. To the extent practicable, these closed sessions will be held so as to minimize inconvenience to members of the public in attendance.

The agenda for subject meeting shall be as follows:

**Tuesday, December 13, 1983—8:30 a.m. Until the Conclusion of Business**

The Subcommittee will review the turbine disk ultrasonic inspection methods with Westinghouse and General Electric (closed session). The Pressure Vessel Research Council will present an overview of its activities in the area of pipe damping, spectral broadening, industry practice for piping design and dynamic stress criteria. In addition, the NRC Staff will present an update regarding their bolt integrity program.

During the initial portion of the meeting, the Subcommittee, along with any of its consultants who may be present, may exchange preliminary views regarding matters to be considered during the balance of the meeting.

The Subcommittee will then hear presentations by and hold discussions with representatives of the NRC Staff, its consultants, and other interested persons regarding this review.

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by a prepaid telephone call to the cognizant Designated Federal Employee, Mr. Elpidio Igne (telephone 202/634-1414) between 8:15 a.m. and 5:00 p.m., EST.

I have determined, in accordance with Subsection 10(d) of the Federal Advisory Committee Act, that it may be necessary to close some portions of this meeting to public attendance to protect proprietary information. The authority for such closure is Exemption (4) to the Sunshine Act, 5 U.S.C. 552b(c)(4).

Dated: November 21, 1983.

**John C. Hoyle,**

*Advisory Committee Management Officer.*

[FR Doc. 83-31881 Filed 11-28-83; 8:45 am]

BILLING CODE 7590-01-M

## Advisory Committee on Reactor Safeguards, Subcommittee on Metal Components; Meeting

The ACRS Subcommittee on Metal Components will hold a meeting on December 7, 1983, Conference Room D, EPRI IDE Center, 1300 Harris Blvd., Charlotte, NC.

In accordance with the procedures outlined in the **Federal Register** on September 28, 1983 (48 FR 44291), oral or written statements may be presented by members of the public, recordings will be permitted only during those portions of the meeting when a transcript is being kept, and questions may be asked only by members of the Subcommittee and its Staff. Persons desiring to make oral statements should notify the cognizant Designated Federal Official as far in advance as practicable so that appropriate arrangements can be made to allow the necessary time during the meeting for such statements.

The entire meeting will be open to public attendance.

The agenda for subject meeting shall be as follows:

**Wednesday, December 7, 1983—8:30 a.m. Until the Conclusion of Business**

The Subcommittee will discuss selection, evaluation and effectiveness of methods used to detect and repair cracks in BWR primary piping systems.

During the initial portion of the meeting, the Subcommittee, along with any of its consultants who may be present, may exchange preliminary views regarding matters to be considered during the balance of the meeting.

The Subcommittee will then hear presentations by and hold discussions with representatives of the NRC Staff, its consultants, BWR users and other interested persons regarding this issues.

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by a prepaid telephone call to the cognizant Designated Federal Official, Mr. Elpidio Igne (telephone 202/634-1414) between 8:15 a.m. and 5:00 p.m., EST.

Dated: November 21, 1983.

**John C. Hoyle,**

*Advisory Committee Management Officer.*

[FR Doc. 83-31882 Filed 11-28-83; 8:45 am]

BILLING CODE 7590-01-M

## Advisory Committee on Reactor Safeguards, Subcommittee on Advanced Reactor Meeting;

The ACRS Subcommittee on Advanced Reactors will hold a meeting on December 14, 1983, Room 1118, 1717 H Street, NW, Washington, DC. The Subcommittee will continue its review of the NRC Research Programs in the area of Advanced Reactors, particularly liquid metal fast breeder reactors, for the ACRS Report to the Congress on the FY 1985-1986 research budget.

In accordance with the procedures outlined in the **Federal Register** on September 28, 1983 (48 FR 44291), oral or written statements may be presented by members of the public, recordings will be permitted only during those portions of the meeting when a transcript is being kept, and questions may be asked only by members of the Subcommittee, its consultants, and Staff. Persons desiring to make oral statements should notify the Designated Federal Employee as far in advance as practicable so that

appropriate arrangements can be made to allow the necessary time during the meeting for such statements.

The entire meeting will be open to public attendance.

The agenda for subject meeting shall be as follows:

**Wednesday, December 14, 1983—1:00 p.m. Until the Conclusion of Business**

During the initial portion of the meeting, the Subcommittee, along with any of its consultants who may be present, may exchange preliminary views regarding the topics to be discussed.

The Subcommittee will then hear presentations by and hold discussions with representatives of the NRC Staff, their consultants, and other interested persons regarding this review.

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by a prepaid telephone call to the cognizant Designated Federal Employee, Mr. Paul Boehnert (telephone 202/634-3267) between 8:15 a.m. and 5:00 p.m., EDT.

Dated: November 21, 1983.

**John C. Hoyle,**

*Advisory Committee Management Officer.*

[FR Doc. 83-31883 Filed 11-28-83; 8:45 am]

BILLING CODE 7590-01-M

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## Advisory Committee on Reactor Safeguards; Proposed Meetings

In order to provide advance information regarding proposed meetings of the ACRS Subcommittees and of the full Committee, the following preliminary schedule is published to reflect the current situation, taking into account additional meetings which have been scheduled and meetings which have been postponed or cancelled since the last list of proposed meetings published October 26, 1983 (48 FR 49563). Those meetings which are definitely scheduled have had, or will have, an individual notice published in the **Federal Register** approximately 15 days (or more) prior to the meeting. Those Subcommittee meetings for which it is anticipated that there will be a portion or all of the meeting open to the public are indicated by an asterisk (*). It is expected that the sessions of the full Committee meeting designated by an asterisk (*) will be open in whole or in part to the public. ACRS full Committee meetings begin at 8:30 a.m. and Subcommittee meetings usually begin at 8:30 a.m. The time when items listed on the agenda will be discussed during full Committee meetings and when Subcommittee meetings will start will be published prior to each meeting. Information as to whether a meeting has been firmly scheduled, cancelled, or rescheduled, or whether changes have been made in the agenda for the December 1983 ACRS full Committee meeting can be obtained by a prepaid telephone call to the Office of the Executive Director of the Committee (telephone 202/634-3267, Attn.: Barbara Jo White) between 8:15 a.m.

**ACRS Subcommittee Meetingsand 5:00 p.m., Eastern Time.**

**Human Factors*, November 30, 1983, Washington, DC. The purpose of the meeting is to review: (1) Revisions to Regulatory Guide 1.149, "Nuclear Power Plant Simulators for Use in Operator Examinations; " (2) Revisions to Regulatory Guide 1.8, "Personnel Qualification and Training for Nuclear Power Plants;" (3) A new Regulatory Guide related to the Application of the Systems Approach to Training at Nuclear Plants; (4) Revisions to Regulatory Guide 1.134, "Medical Evaluation of Nuclear Power Plant Personnel Requiring Operator Licenses"; (5) Revisions to Regulatory Guide 1.114, "Guidance on Being Operator at the Controls;" and (6) A proposed modification to 10 CFR 50, Appendix A adding a human factors general design criterion. Notice of this meeting was published November 14, 1983.

* *Qualification Program for Safety-Related Equipment*, December 1, 1983, Washington, DC. The Subcommittee will discuss Regulatory Guide 1.89, "Qualification of Electrical Equipment Important to Safety in Nuclear Power Plants." Notice of this meeting was published November 14, 1983.

* *Combined Reactor Radiological Effects, Air Systems and Waste Management Program*, December 1, 2 and 3, 1983, Washington, DC. The Subcommittees will review: (1) NRC research programs in radiological effects, waste management, and air systems for preparation of pertinent chapters of the ACRS report to Congress on the FY 1985-1986 NRC Safety Research Program, (2) DOE general guidelines on recommending nuclear waste repository sites (10 CFR Part 960), and (3) other related topics.

* *Quality and Quality Assurance During Design and Constructioin*, December 6, 1983, Washington, DC. The Subcommittee will discuss with the NRC Staff its activities for assuring quality in the design and construction of nuclear power plants (QA initiatives); its ongoing and planned QA-related research; and the status of Regulatory Guide 1.28, "Quality Assurance Program Requirements (Design and Construction)." Notice of this meeting was published November 17, 1983.

* *Human Factors*, December 7, 1983, Washington, DC. The purpose of the meeting will be threefold.First, the NRC Staff will highlight the status of ongoing activities described in NUREG-0985, "U.S. Nuclear Regulatory Commission Human Factors Program Plan." Secondly, the Staff will describe their existing human reliability data base as well as its uses. Human reliability data base development and potential for improved data will be discussed. Finally, the Subcommittee will review the NRC's human factors research program and budget for FY 1985-1986.

* *Three Mile Island 1*, December 7, 1983,Washington, DC. The Subcommittee will review the proposed revised operating organization/staff.

* *Metal Components*, December 7, 1983, Charlotte, NC. The Subcommittee will discuss selection, evaluation and effectiveness of methods used to detect and repair cracks in BWR primary piping systems.

* *Fluid Dynamics*, December 8, 1983, Washington,DC. The Subcommittee will discuss recent flow-related incidents at the Palo Verde, St. Lucie Unit 1 and Milllstone Unit 2 reactors that resulted in equipment damage to the plants' primary systems.

**Extreme External Phenomena*, December 8 and 9, 1983, San Francisco, CA. The Subcommittee will be conducting a workshop on quantification of seismic design margins. The main topics of discussion will be the adequacy of the available methodology and the ongoing NRC and Industry programs in this area. The agenda will include a discussion period with interested persons attending the meeting in the audience.

**Class 9 Accidents*, December 13, 1983, Washington, DC—CANCELLED.

**Metal Components*, December 13, 1983, Washington, DC. The Subcommittee will review the turbine disk ultrasonic inspection method with Westinghouse and General Electric (closed session). The pressure vessel research council will present an overview of its activities in the area of pipe damping, spectral broadening, industry practice for piping design and dynamic stress criteria. In addition, the NRC Staff will present an update of their bolt integrity program.

**Regulatory Policies and Practices*, December 14, 1983, Washington, DC. The Subcommittee will discuss the proposed decentralization of operating

reactor licensing activities and the current status of Regulatory Reform activities within the NRC.

*Advanced Reactors*, December 14, 1983, Washington, DC. The Subcommittee will continue its review of the NRC Research Programs in the area of Advanced Reactors, particularly liquid metal fast breeder reactors, for the ACRS Report to the Congress on the FY 1985–1986 research budget.

*National Bureau of Standards (NBS) Reactor*, December 21, 1983, Washington, DC. The Subcommittee will review the renewal of the operating license for the National Bureau of Standards reactor at a power level of 20 MW, an increase from 10 MW.

*Shearon Harris Nuclear Power Plant Units 1 and 2*, January 3 and 4, 1984, Raleigh, NC. The Subcommittee will review the application of the Carolina Power and Light Company for an operating license.

*Maintenance Practices and Procedures*, January 10, 1984, Washington, DC. The Subcommittee will review the current status of maintenance practices and procedures.

*Qualification Program for Safety-Related Equipment*, January 11, 1984, Washington, DC. The Subcommittee will review the status of Generic Issue A–46, "Seismic Qualification of Equipment for Operating Reactors."

*Diablo Canyon Nuclear Power Plant Units 1 and 2*, January 18 and 19, 1984. San Luis Obispo, CA. The Subcommittee will review the design verification results and the significance of errors found and corrected at Diablo Canyon Nuclear Power Plant Units 1 and 2.

*Advanced Reactors*, January 25 and 26, 1984, Chicago, IL. The Subcommittee will continue the development of the report, "LMFBR Safety Philosophy and Issues."

*Emergency Core Cooling systems (ECCS)*, January 31, 1984, Washington, DC. The Subcommittee will continue the review of the General Electric SAFER ECCS EM Code.

*Combined Emergency Core Cooling Systems (ECCS) and Decay Heat Removal*, February 1 and 2, 1984, Washington, DC. The Subcommittee will discuss the status of feed-and-bleed capability in PWRs.

*Regulatory Activities*, Date to be determined, Washington, DC. The Subcommittee will discuss proposed General Revisions to Appendix J to 10 CFR Part 50, "Primary Reactor Containment Leakage Testing for Water-Cooled Power Reactors."

*AC/DC Power Systems Reliability*, Date to be determined, Washington, DC. The Subcommittee will discuss the status of the NRC Staff actions on Generic Issue B–56, "Diesel Reliability," and Generic Issue A–30, "Adequacy of Safety-Related DC Power Supplies."

**ACRS Full Committee Meeting**

December 15–17, 1983: Items are *tenatatively* scheduled.

*A. Subcommittee reports and discussion with representatives of NRC staff regarding:

• *Three Mile Island Nuclear Station, Unit 1*—proposed plant operation.

• *Decentralization of NRC Activities*—comments regarding proposed program for decentralization of NRC activities.

• *Radioactive Waste Disposal*—proposed DOE general guidelines for recommending nuclear waste repository sites.

*B. *Primary System Integrity*—Pipe cracking in BWR primary coolant systems.

*C. *Code of Federal Regulations*—Proposed revision of 10 CFR Part 20, Safeguards for Protection Against Radiation.

*D. *Activities of Nuclear Material Safety and Safeguards*—Briefing by Director, Office of Nuclear Material Safety and Safeguards regarding NMSS activities.

*E. *Proposed NRC Regulatory Guides*—Comments regarding proposed NRC Regulatory Guides on safety-related matters including R.G. 1.89, Environmental Qualification of Electrical Equipment; R.G. 1.28, Quality Assurance (Design and Construction).

*F. *Human Factors*—Report of ACRS Subcommittee on Human Factors regarding proposed NRC rules and Regulatory Guides regarding consideration of human factors in the design and operation of nuclear power plants.

*G. *Future ACRS Activities*—Discuss proposed ACRS Subcommittee and full Committee activities.

*H. *Selection of ACRS Officers*—Discuss qualification of and selection of ACRS officers for FY 1984.

*I. *Reactor Operating Experience*—Report by representatives of NRC Staff regarding recent reactor operating experiences including malfunction of electrical circuit breakers and a switchyard fire at the Oyster Creek Nuclear Plant.

*J. *ACRS Subcommittee Activities*—Reports of ACRS Subcommittees regarding activities including hydrodynamic forces in nuclear power plant systems and the NRC reactor safety research program.

*K. *Diablo Canyon Nuclear Power Plant*—Briefing by NRC Staff regarding preposed operation of this nuclear plant.

*L. *Severe Nuclear Power Plant Accidents*—Briefing by representatives of NRC Staff regarding development of decision-making process for consideration of severe nuclear power plant accidents.

January 12–14, 1984—Agenda to be announced.

February 9–11, 1984—Agenda to be announced.

Dated: November 23, 1983.

John C. Hoyle,

*Advisory Committee Management Officer.*

[FR Doc. 83–31884 Filed 11–28–83; 8:45 am]

BILLING CODE 7590–01–M

## OFFICE OF MANAGEMENT AND BUDGET

### Office of Federal Procurement Policy

### Implementation of Executive Order 12352, "Federal Procurement Reforms": Public Meeting and Request for Public Comment

**AGENCY:** Office of Federal Procurement Policy; Office of Management and Budget.

**ACTION:** Solicitation of views.

**SUMMARY:** Executive Order 12352, "Federal Procurement Reforms," was signed by President Reagan on March 17, 1982. It requires (1) agency heads to implement specific types of reforms in their procurement systems; (2) the completion of a single, simplified Federal Acquisition Regulation to replace the common procurement regulations of the Department of Defense, the General Services Administration, and the National Aeronautics and Space Administration; (3) the establishment of personnel policies and classification standards to meet the needs of agencies for a professional procurement workforce; and (4) OMB and agency heads to coordinate efforts to achieve procurement reform.

The first report to the President on the implementation of Executive Order 12352 told how these reforms would be accomplished. The report is available, upon request, from the contact point identified below.

The Federal Acquisition Regulation was published in the Septembr 19 **Federal Register** and will be implemented on April 1, 1984. The Office of Federal Procurement Policy and some of the larger federal agencies joined to form the Executive Committee on Federal Procurement Reforms to coordinate efforts on these new systems. Several guidance products have been

finalized and sent from this Committee to all agency heads to hasten the reform efforts. Many more guidelines are nearing finalization. A copy of the completed guidelines are available, upon request, from the contact point listed below.

As a part of the Government's continuing policy development program for a Uniform Federal Procurement System, the Office of Federal Procurement Policy is soliciting the views of all interested parties on the implementation efforts under Executive Order 12352, the Federal Acquisition Regulation, and other associated activities of the Office of Federal Procurement Policy.

**Date, Time, and Location of Meeting**

The meeting will be held December 16, 1983 in Room 2010 of the New Executive Office Building, 726 Jackson Place NW., Washington, D.C. The meeting will begin at 9:30 a.m. and adjourn at 11:30 a.m., unless more time is needed to provide all interested parties an opportunity to present their views. Because the security system requires advance identification of visitors, please call Ms. Healy on 202/395-3300 by December 14 to advise of your attendance.

**Presentation of Views at Meeting**

*Oral Presentations*

You may appear to make an oral presentation on your own behalf or as a representative of any entity or any interested group, whether public or private. If you wish to provide oral testimony, you should notify Ms. Marianne Healy by 9 December by calling 202/395-3300 or writing to the address below. Oral presentations will be limited to 10 minutes. A written summary of the oral presentation should be provided to the hearing officer on the day of the meeting.

*Written Presentation*

Written comments may be submitted by December 16. They should be addressed to the Office of Federal Procurement Policy at the address below.

**FOR FURTHER INFORMATION CONTACT:** Ms. Marianne Healy, Office of Federal Procurement Policy, Office of Management and Budget, 726 Jackson Place, NW., New Executive Office Building, Room 9025, Washington, D.C. 20503.

**Donald E. Sowle,**
*Administrator.*

[FR Doc. 83-31859 Filed 11-28-83; 8:45 am]
BILLING CODE 3110-01-M

## RAILROAD RETIREMENT BOARD

### Proclamation Regarding Railroad Unemployment Insurance Account

Pursuant to section 8(a) of the Railroad Unemployment Insurance Act, the Railroad Retirement Board has determined, and hereby proclaims, that the balance of the credit of the railroad unemployment insurance account as of the close of business September 30, 1983, was a net deficit of $559,572,498.54. Based on this balance and pursuant to the table in section 8(a) of the Railroad Unemployment Insurance Act, the contribution rate to finance the railroad unemployment insurance program for calendar year 1984 shall be 8.0 percent.

In witness whereof the members of the Railroad Retirement Board have hereunto set their hands and caused its seal to be affixed.

Done at Chicago, Illinois, this 21st day of November 1983.

**R. A. Gielow,**
*Chairman.*

**Earl Oliver,**
*Member.*

**C. J. Chamberlain,**
*Member.*

By the Railroad Retirement Board.

**James T. Brown,**
*Executive Director.*

[FR Doc. 83-31837 Filed 11-28-83; 8:45 am]
BILLING CODE 7905-01-M

## SECURITIES AND EXCHANGE COMMISSION

**[File No. 81-697]**

### Norwest Mortgage, Inc. (Formerly Banco Mortgage Company), as Seller and Servicer; Application

November 22, 1983.

Notice is hereby given that Norwest Mortgage, Inc. ("Applicant", formerly Banco Mortgage Company), has filed an application pursuant to Section 12(h) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), for exemption from certain reporting requirements under Section 13 of the Exchange Act and from operation of Section 16 of that Act.

The application states in part:

In the absence of an exemption, Applicant would be required to file reports adhering to all the item requirements of Forms 10-K, 10-Q and 8-K under the Exchange Act.

Applicant believes that the exemptive order requested by it is appropriate in that Form 10-Q and certain items of Form 10-K under the Exchange Act are inapplicable to holders of its mortgage pass-through certificates.

For a more detailed statement of the information presented, all persons are referred to the application, which is on file at the Offices of the Commission in the Public Reference Room, 450 Fifth Street, NW., Washington, D.C. 20549.

Notice is further given that any interested person, not later than December 16, 1983 may submit to the Commission in writing his or any substantial facts bearing on the application or the desirability of a hearing thereon. Any such communication or request should be addressed: Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, D.C. 20549, and should state briefly the nature of the interest of the person submitting such information or requesting the hearing, the reason for such request, and the issues of fact and law raised by the application which he desires to controvert.

Persons who request a hearing or advice as to whether a hearing is ordered will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof. At any time after said date, an order granting the application may be issued upon request or upon the Commission's own motion.

For the Commission, by the Division of Corporation Finance, pursuant to delegated authority.

**George A. Fitzsimmons,**
*Secretary.*

[FR Doc. 83-31914 Filed 11-28-83; 8:45 am]
BILLING CODE 8010-01-M

**[Release No. 34-20395; File No. SR-NYSE-83-55]**

### Self-Regulatory Organizations; Proposed Rule Change by New York Stock Exchange, Inc.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on November 15, 1983 the New York Stock Exchange, Inc. filed with the Securities and Exchange 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 intersted persons.

**I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change**

The proposed rule change consists of increases in the order size eligibility for the Exchange's order routing systems, as described below, with respect to AT&T and the issues created as a result of the divestiture. Such increases are proposed to be implemented on a nine-month pilot basis and will be effective on the day such issues commence trading on the Exchange on a when-issued basis, which is anticipated to be in mid-November, 1983.

- DOT system will accept market orders in sizes up to 1,099 shares in these issues, which is increased from the present system-wide size eligibility of 599 shares.
- OARS will accept market orders prior to the opening in sizes up to 30,099 shares in these issues, which is increased from the present system-wide size eligibility of 5,099 shares.
- LMT will accept limit orders in sizes up to 30,099 shares in these issues for day limit orders and 30,099 shares in these issues for GTC limit orders, which is increased from the present system-wide size eligibility of 500 shares and 5,000 shares, respectively.

**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 self-regulatory organization 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 self-regulatory organization 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*

(1) *Purpose.* The purpose of the proposed rule change is to provide greater system assistance for the processing of orders to purchase or sell shares in AT&T and the issues created as a result of the divestiture when those issues commence trading on the Exchange in mid-November, 1983. In anticipation of the increase in order flow which is expected as a result of the AT&T diverstiture, the Exchange is taking certain steps to ensure maximum capacity for order processing. Specifically, the Exchange is increasing the order size eligibility of its DOT, OARS and LMT systems, as indicated in Item I above, allowing for the acceptance of larger size orders through these systems in AT&T and divestiture issues.[1] This measure will provide greater capability for member firms to route orders directly to the Post—which the Exchange assumes member firms will take advantage of —thereby minimizing paper handling on the Floor. In addition, the specialist will be assisted operationally through the fact that a greater number of orders will be centrally routed directly to the Post.

The Exchange will monitor the activity in these issues both prior to and after the when-issued period. As a result of such monitoring, the Exchange may reduce the order size eligibility increases proposed herein for DOT, OARS or LMT if it deems that such increases are no longer necessary.

(2) *Statutory Basis.* The proposed rule change addresses systems modifications needed to process the heavy volume of order flow expected when trading commences in the AT&T divestiture issues. It is designed to provide more efficient order handling and reporting of transactions in such issues. Implementation of the order eligibility increases will be consistent with those provisions of the Securities Exchange Act of 1934 (the "Act") which encourage the use of new data processing and communications techniques which create the opportunity for more efficient and effective market operations. See Sections 11A(a)(1) and 17A(a)(1) of the Act.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The Exchange believes that these rule changes wil not 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*

The Exchange has not solicited written comments on these rule chages. The Exchange has not received any unsolicited written comments from members or other interested parties.

[1] See also filing SR-NYSE-83-49 which discusses the Exchange's proposal to ensure maximum capacity for odd-lot order processing in these issues.

**III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

The Commission has found good cause for approving the proposed rule change prior to the thirtieth day after the date of publication of notice of filing.

**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, D.C. 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 Section, 450 Fifth Street, NW., Washington, D.C. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted within 21 days after the date of this publication. For the Commission by the Division of Market Regulation, pursuant to delegated authority.

Dated: November 18, 1983.

**George A. Fitzsimmons,**

*Secretary.*

[FR Doc. 83-31909 Filed 11-28-83; 8:45 am]

BILLING CODE 8010-01-M

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**[Release No. 34-20401; File No. SR-NYSE-83-56]**

## Self-Regulatory Organizations; Proposed Requirement by New York Stock Exchange, Inc.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78 s (b)(1), notice is hereby given that on November 21, 1983, the New York Stock Exchange, Inc, filed with the Securities and Exchange Commission the proposed requirement 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 requirement from interested persons.

**I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Requirement**

Pursuant to Rule 431(a) the Exchange is proposing imposition of a 10% initial deposit requirement and a 7% maintenance requirement on *all* when-issued transactions in AT&T for "exempt accounts".

**II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Requirement**

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed requirement and discussed any comments it received on the proposed requirement. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization 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 Requirement*

In view of the magnitude of the AT&T divestiture and the extended when-issued trading period, there are numerous credit and capital concerns which necessitate the Exchange's adoption of special procedures in order to insure the continued financial viability of its member organizations. The adoption of the 10% initial deposit end the 7% minimum maintenance requirement on all when-issued transactions in AT&T for "exempt accounts" fall into this category of special procedures.

The collection of the deposit requirements must be accomplished within 7 business days. All "exempt-accounts" with when-issued positions shall be marked to the market on each net position, even though the account may be long the securities upon which the when-issued security is to be issued. Whenever mark-to-markets reduce an account's equity below the 7% maintenance requirement, the account must immediately deposit additional funds to remain in compliance with the 7% minimum. Member organizations may request "extensions of time" from the Exchange for initial or maintenance deposits using the same format and system applicable to Regulation T extensions.

To comply with the above initial and maintenance deposit requirements (including mark-to-markets), member organizations may accept cash or readily marketable securities. Where an exempt account has demonstrated a *legal* impediment to depositing cash and/or securities, member organizations, accept other financial instruments which would guarantee completion of the transactions (e.g., C.D.'s Bank Acceptances, Letters of Garantee, Depository Receipts, etc.). However, where letters of credit are utilized for these purposes no value will be given under SEC Rule 15c3–1.

*Statutgory Basis for the Proposed Requirement:* The proposed requirement is consistent with Section 6(c)(3)(A) of the Act because it is designed to insure that member organizations continue to meet the Exchange's standards of financial responsibility. It is also consistent with Section 6(b)(5) of the Act in that adherence to such standards results, generally, in the protection of investors and the public interest. Finally, the requirement will facilitate member organizations' compliance with SEC Rule 15c3–1 in that it will prevent excessive capital charges from arising as a resule of under-margined accounts.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

The proposed requirement does not impose any burden on competition.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Requirement Received from Members, Participants, or Others*

The Exchange has neither solicited nor received written comments on the proposed requirement.

**III. Date of Effectiveness of the Proposed Requirment and Timing for Commission Action**

The Commission has found good cause for approving the proposed rule change prior to the 30th day after the date of publication of notice of filing thereof in that when issued trading in the AT&T Divestiture issues began on November 21, 1983. The Commission believes that the NYSE's proposed requirements are necessary to lessen potential financial liquidity risks posed to broker/dealers if certain accounts are exempted from providing good faith credit deposits under NYSE Rule 431 in connection with when issued trading in the AT&T Divestiture securities. See Release #20401, November 18, 1983.

**IV. Solititation of Comments**

Interested persons are invited to submit written data, views and agrumtes concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street NW., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed requirement that are filed with the Commission, and all written communications relating to the proposed requirement 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 Branch, 450 Fifth Street, NW., Washington, D.C. Copies of such filing will also be available for inspection and copying at the principal office of the above mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted within 21 days after the date of this publication.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

Dated: November 18, 1983.

**George A. Fitzsimmons,**

*Secretary.*

[FR Doc. 83-31910 Filed 11-28-83; 8:45 am]

BILLING CODE 8010-01-M

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**[Release No. 34-20398; File No. SR-PHLX-83-19]**

## Self-Regulatory Organizations; Proposed Rule Changes By Philadelphia Stock Exchange, Inc.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on November 9, 1983 the Philadelphia Stock Exchange, Inc. filed with the Securities and Exchange Commission the proposed rule changes 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 changes from interested persons.

**Self-regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Changes**

The proposed rule change consists of procedures regarding the pricing of standard odd-lot market orders [1] in

[1] Odd-lot orders are orders to purchase or sell a security in an amount less than the unit of trading. For purposes of the application of the proposed procedures, "standard" odd-lot market orders are odd-lot orders to purchase, sell or sell short exempt "at the market" which contain no qualifying notations. Descriptions of such qualifying notations are noted in Rule 225.

AT&T and the equity issues created as a result of the AT&T divestiture. [2] Such procedures are proposed to be implemented on a nine month pilot basis on the Exchange, which is anticipated to be mid-November, 1983. These procedures are intended as "interim rules" for the operation of the pilot and would supersede any other rule inconsistent therewith.

The key aspects of the procedures are:

(i) Standard odd-lot market orders to purchase or sell shares of AT&T and the equity issues created as a divestiture which are received prior to the opening of trading, whether transmitted to the Exchange by means of the PACE Systenm [3] or by means other than the PACE System will be executed at New York Stock Exchange opening price. No odd-lot differential will be charged on these orders.

(ii) Standard odd-lot market orders to purchase or sell shares of AT&T and equity issues created as a result of the divestiture which are received after the New York Stock Exchange opening of the security named in the order whether transmitted to the Exchange by means of the PACE System or by means other than the PACE System will be executed based on the PACE quote. [4] No odd-lot differential will be charged on these orders.

(iii) After a regulatory trading halt on the New York Stock Exchange in any of the issues included in the pilot, standard odd-lot market orders received after the halt and prior to the resumption of trading on the New York Stock Exchange the New York Stock Exchange re-opening price. No odd-lot differential will be charged on these orders.

(iv) Upon a non-regulatory trading halt on the New York Stock Exchange in any of the issues included in the pilot, the Exchange will make a determination as to whether to continue or halt trading in such issues. In the event the Exchange determines to continue trading, standard odd-lot market orders will continue to be executed at the PACE quote. In the event the Exchange determines to holt trading and to resume trading upon resumption of trading on the New York Stock Exchange, standard odd-lot market orders received after the halt and prior to the resumption of trading will be executed at the re-opening price on the New York Stock Exchange. No odd-lot differential will be changed on these orders. In the event the Exchange determines to halt trading and subsequently determines to resume trading prior to resumption of trading on the New York stock Exchange, standard odd-lot market orders received prior to the resumption of trading will be executed at the price at which trading resumes without an odd-lot differential.

## II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Changes

In its filing with the Commission, the self-regulatory organization included stataments concering the purpose of and basis for the proposed rule changes and descussed any comments it received on the proposed rule changes. The text of these statements may be examined at the places specified in Item IV below. The self-regualtory organization 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*

(1) *Purpose.* The purpose of the proposed rule change is to provide a new system for the execution of standard odd-lot market orders to purchase or sell shares in AT&T and the equity issues created as a result of divestiture. The Exchange is filing the procedures proposed herein to process such orders when those issues start trading on the Exchange in mid-November, 1983. The procedures proposed herein are intended as "rules" and therefore constitute a "proposed rule change" within the meaning of SEC Rule 19b–4. If approved by the Commission, they would supersede any existing rules of the Exchange inconsistent therewith, including Rules 227 and 229.

In view of the projected increase in odd-lot order traffic which is expected as a result of the AT&T divestiture, the Exchange wishes to ensure maximium capacity for odd-lot order processing. In particular, the revised execution procedures will reduce the number of such orders required to be held in the electronic order file of the Exchange's PACE System while awaiting execution.

Currently, Exchange Rules 227 and 229 require standard odd-lot market orders in the issues in the pilot which are received prior to the opening of trading in the security named in the order to be executed at the New York Stock Exchange opening price, plus or minus, if any differential is charged, the amount of the differential. [5] Similarly, such rules presently would require standard odd-lot market orders in the issues in the pilot which are received after the opening of trading in the security named in the order to be executed at the next New York Stock Exchange round-lot sale after the order has been received, plus or minus, if any differential is charged, the amount of the differential.

During the nine month duration of the pilot, the Exchange will monitor the activity in the AT&T divestiture issues, especially with respect to the effect which the procedures described herein have on the pricing of odd-lots. Prior to the expiration of the nine month period, the exchange expects either to submit a formal codification of the procedures, revised as appropriate based on the Exchange's experience with the pilot, or request an extension of the time period for the pilot pending further study and evaluation. The Exchange may also terminate the pilot at any time.

The Exchange views the nine-month period as a valuable change to study the results of the pilot pricing system under actual market conditions both during the when-issued period, when projections indicate that volume of trading will be particularly heavy, and after the when issued period is over.

(2) *Statutory basis for the Proposed Rule Change.* The proposed rule change addresses the necessary procedural and systems modifications needed to process the increased volume of odd-lot traffic which is expected when trading commences in the AT&T divestiture issues. It is designed to provide more efficient executions and reporting of odd-lot orders which are included in the pilot. It will also provide for effecient clearance and settlement of these transactions. Implementation of the pilot will be consistent with those provisions of the Securities Exchange Act of 1934 (the "Act") which encourages the use of new data processing and communications techniques which create the opportunity for more efficient and effective market operations. It will also advance the prompt and accurate clearance and settlement of securities

[2] Specifically, the following issues will be affected by the proposed procedures: American Information Technologies Corporation, American Telephone & Telegraph Co., Bell Atlantic Corporation, BellSouth Corporation, NYNEX Corporation, Pacific Telesis Group, Southwestern Bell Corporation and U.S West, Inc. American Telephone & Telegraph Co. will trade both on a "regular way" and "when issues—exdistribution" basis until the "when issued" period is over. After such period, it will only trade "regular way."

[3] The PACE System is the Exchange's order delivery and automated execution system.

[4] The term "PACE quote" means the best bid/ask quote among the American, Boston, Cincinnati, Midwest, New York, Pacific and Philadelphia Stock Exchanges, as appropriate.

[5] Note that Rules 227 and 229 do not indicate that a differential must be charged on odd-lot orders. Rather, the decision as to whether a differential may be charged and the amount of any differential is left up to the specialist.

transactions. See Sections 11A(a)(1) and 17(A)(a)(1) of the Act.

*(B) Self Regulatory Organization's Statement on Burden on Competition*

The Exchange believes the proposed rule change is necessary to accomodate the increase in odd-lot order traffic which is expected as a result of the AT&T divestiture. Thus, the proposed rule change is in the interest if the public and the member firm community. Even if the proposal imposes a burden on competition, the Exchange believes the relative benefits will provide to investors far outweigh any such burden.

*(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others*

The Exchange has not solicited written comments of this rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

**III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

The Commission has found good cause for approving the proposed rule change prior to the thirtieth day after the date of publication of notice of filing.

**IV. Solicitation**

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 5th Street, NW., Washtington, D.C. 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 witheld from the pubbic in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section. Copies of such filing will also be available for inspection and copying at the principal office of the abovementioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted within 21 days after the day of this publication.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Dated: November 18, 1983.

**George A. Fitzsimmons,**

*Secretary.*

[FR Doc. 83-31913 Filed 11-28-83; 8:45 am]

BILLING CODE 8010-01-M

## SMALL BUSINESS ADMINISTRATION

**[Application No. 01/01-0322]**

### Moneta Capital Corp.; Application for a License To Operate as a Small Business Investment Company

An Application for a License to Operate as a Small Business Investment Company Under the Provisions of the Small Business Investment Act of 1958 as amended (15 U.S.C. 661 *et seq.*) has been filed by Moneta Capital Corporation (Moneta), 285 Governor Street, Providence, Rhode Island 02906, with Small the Business Administration (SBA) pursuant to 13 CFR 107.102 (1983).

The officers, directors and sole shareholder of the Applicant are as follows:

Northeast Capital Cororation Profit-Sharing Trust Under Indenture,[1] 100%

Arnold Kilberg, 642 Blackistone Boulevard, Providence, Rhode Island, President, Treasurer and Director

Domenic R. Boragine, 110 Waumsett Avenue, Cumberland, Rhode Island, Vice President, Secretary and Director

Thomas J. Grennen III, 10 Inez Drive, North Kingstown, Rhode Island, Vice President and Director

Moneta, a Rhode Island corporation, will begin operations with $500,000 paid-in capital and paid-in surplus. Moneta will conduct its activities primarily in the State of Rhode Island but will consider investments in other areas within the United States.

Matters involved in SBA's consideration of the application include the general business reputation and character of the proposed owners and management, and the probability of successful operation of the company under their management, including adequate profitability and financial soundness, in accordance with the Small Business Investment Act of 1958, as amended, and the SBA Rules and Regulations.

Notice is further given that any person may, not later than 15 days from the date of publication of this notice, submit to SBA written comments on the proposed Application. Any such communication should be addressed to the Deputy Associate Administrator for Investment, Small Business Administration, 1441 L Street, N.W., Washington, D.C. 20416.

A copy of this notice shall be published in a newspaper of general circulation in Providence, Rhode Island.

Dated: November 22, 1983.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

**Robert G. Lineberry,**

*Deputy Associate Administrator for Investment.*

[FR Doc. 83-31931 Filed 11-28-83; 8:45 am]

BILLING CODE 8025-01-M

[1] Arnold Kilberg is the sole beneficiary of the Trust.

**[Application No. 03/03-5159]**

### Securities First Corp.; Application for a License To Operate as a Small Business Investment Company

An application for a license to operate as a small business investment company under the provisions of Section 301(d) of the Small Business Investment Act of 1958, as amended (the Act), (15 U.S.C. 661 *et seq.*), has been filed by Securities First Corporation (Applicant), 1010 Arch Street, Philadelphia, Pennsylvania 19107, with the Small Business Administration (SBA), pursuant to § 107.102 of the regulations governing small business investment companies (13 CFR 107.102 (1983)).

The officers, directors and shareholders of the Applicant are as follows:

Gerard Meister, 20 Seneca Place, Jericho, NY 11753, President, Director, 10 percent

Sheldon S. Somerman, 316 Sinkler Road, Wyncote, PA 19098, Secretary, Director 10, percent

Norman M. Kanterman, 18 Herkimer Avenue, Jericho, NY 11753, Treasurer, Director, 10 percent

Richard S. Oller, 712 Germantown Pike, Lafayette Hill, PA 19444, Asst. Secretary, Director, 10 percent

The Applicant has two classes of stock authorized: 10,000 shares of no par common ($1.00 stated value per share) and 3 million shares of non-voting 3 percent cumulative preferred. It will begin operations with $1,050,000 of paid-in capital and paid-in surplus derived from the sale of 1,000 shares of common stock.

The Applicant, a Pennsylvania corporation, will conduct its operations primarily in Pennsylvania, New Jersey, New York and Delaware. It will provide assistance to qualified socially or economically disadvantaged small business concerns in various industries including, but not limited to: restaurants; manufacturing concerns; distributors

and dealers of applicances, electronics and furniture; grocery stores; health and beauty aide establishments; and, taxi cabs. No more then 50 percent of its portfolio will be in any one industry.

As a small business investment company under Section 301(d) of the Act, the Applicant has been organized and chartered solely for the purpose of performing the functions and conducting the activities contemplated under the Act, as amended from time to time, and will provide assistance solely to small business concerns which will contribute to a well-balanced national economy by facilitating ownership in such concerns by persons whose participation in the free enterprise system is hampered because of social or economic disadvantages.

Matters involved in SBA's consideration of the Applicant include the general business reputation and character of the proposed owners and management, and the probability of successful operation of the Applicant under this management, including adequate profitability and financial soundness, in accordance with the Act and SBA Rules and Regulations.

Notice is hereby given that any person may, not later than 15 days from the date of publication of this notice, submit to SBA written comments on the proposed Applicant. Any such communication should be addressed to the Deputy Associate Administrator for Investment, Small Business Administration, 1441 "L" Street, N.W., Washington, D.C. 20416.

A copy of this notice shall be published in a newspaper of general circulation in Philadelphia, Pennsylvania.

Dated: November 18, 1983.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

**Robert G. Lineberry,**

*Deputy Associate Administrator for Investment.*

[FR Doc. 83-31932 Filed 11-28-83; 8:45 am]

BILLING CODE 8025-01-M

## Surrender of License

Notice in hereby given that, pursuant to § 107.105 of Revision 6 of the Small Business Administration's (SBA) Rules and Regulations (48 FR 45014 (September 30, 1983)) governing Small Business Investment Companies (SBIC) and the Small Business Investment Act of 1958, as amended, (the Act) (15 U.S.C. 661 *et seq.*), the following SBIC's have surrendered their license:

Arrow Investment Corporation, Brookline, Massachusetts, License No. 01/01-0058

Beaconfield Investment Corporation, Cambridge, Massachusetts, License No. 01/01-0049

Capital for Technology, Inc., Hartford Connecticut, License No. 01/01-0034

Cummnication Fund, Inc., New York, New York, License No. 01/02-0073

Conresco Corporation, Providence, Rhode Island, License No. 01/02-0264

Greater New York Capital Corporation, New York, New York, License No. 02/02-0042

Hartford Community Capital Corp., Hartford, Connecticut, License No. 01/02-5265

Lake Success Capital Corporation, Westbury, New York, License No. 02/02-0140

Northern Business Capital Corporation, Norwalk Connecticut, License No. 01/02-0227

Pioneer Venture Corporation, New York, New York, License No. 02/02-0120

Prime Capital Corporation, Boston, Massachusetts, License No. 01/01-0276

Printers Capital Corporation, New York, New York, License No. 02/02-0048

Talco Capital Corporation, New York, New York, License No. 02/02-0027

Transcapital Corporation, Santure, PR, License No. 02/02-0018

Venture Capital Corp., Watertown, Massachusetts, License No. 01/01-5271

Therefore under the authority vested by the Act, and pursuant to the above cited Regulations, the licenses of the above listed companies are hereby accepted and they are no longer licensed to operate as an SBIC.

Dated: November 18, 1983.

**Robert G. Lineberry,**

*Deputy Associate Administrator for Investment.*

[FR Doc. 83-31933 Filed 11-28-83; 8:45 am]

BILLING CODE 8025-01-M

**[License No. 06/06-0184]**

## TSM Corp.; Application for Approval of Conflict of Interest Transaction Between Associates

Notice is hereby given that TSM Corp. (TSM), Suite 222, Executive Center Boulevard, El Paso, Texas 79902, a Federal Licensee under the Small Business Investment Act of 1958, as amended, has filed an application with the Small Business Administration pursuant to § 107.903 of the Regulations governing small business investment companies (13 CFR 107.903 (1983)) for approval of a conflict to interest transaction.

TSM proposes to loan $100,000 and purchase $15,000 preferred stock of Cross Roads Foods, Inc. (Cross Roads), 8041 North Mesa, El Paso, Texas 79912, for the purchase of equipment and inventory.

The conflict of interest arises because Joel G. Peterson, proposed owner of Cross Roads, was an employee of Tri-State Wholesale Associated Grocers, Inc., an associate of TSM. As a result, TSM's financing of Cross Roads falls within the purview of § 107.903(b)(1) of the SBA Regulations and requires prior written approval of SBA.

Notice is hereby given that any person may, not later than 15 days from the date of publication of this Notice, submit written comments to the Deputy Associate Administrator for Investment, Small Business Administration, 1441 "L" Street, NW., Washington, D.C. 20416.

A copy of this notice will be published in a newspaper of general circulation in El Paso, Texas area.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Dated: November 23, 1983.

**Robert G. Lineberry,**

*Deputy Associate Administrator for Investment.*

[FR Doc. 83-31930 Filed 11-28-83; 8:45 am]

BILLING CODE 8025-01-M

## Small Business Investment Company; Maximum Annual Cost of Money to Small Business Concerns

13 CFR 107.301(c) sets forth the SBA Regulations governing the maximum annual cost of money to small business concerns for Financing by small business investment companies.

Section 107.301(c)(2) requires that SBA publish from time to time in the **Federal Register** the current Federal Financing Bank (FFB) rate for use in computing the maximum annual cost of money pursuant to Section 107.301(c)(1). It is anticipated that a rate notice will be published each month.

13 CFR 107.301(c) does not supersede or preempt any applicable law that imposes an interest ceiling lower than the ceiling imposed by that regulation. Attention is directed to new subsection 308(i) of the Small Business Investment Act, added by section 524 of Pub. L. 96-221, March 31, 1980 (94 stat. 161), to that law's Federal override of State Usury ceilings, and to its forfeiture and penalty provisions.

Effective *December 1, 1983,* and until further notice, the FFB rate to be used

for purposes of computing the maximum cost of money pursuant to 13 CFR 107.301(c) is *11.775%* per annum.

Dated: November 23, 1983.

**Edwin T. Holloway,**

*Associate Administrator for Finance and Investment.*

[FR Doc. 83-31934 Filed 11-28-83; 8:45 am]

BILLING CODE 6025-01-M

## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

### Environmental Impact Statement; City of Portsmouth, Virginia

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

**ACTION:** Notice of Intent.

**SUMMARY:** The FHWA is issuing this notice to advise the public that an environmental impact statement will be prepared for a proposed highway project in the City of Portsmouth, Virginia.

**FOR FURTHER INFORMATION CONTACT:** George E. Kirk, Jr., District Engineer, Federal Highway Administration, P.O. Box 10045, Richmond, Virginia 23240-0045, telephone (804) 771-2380.

**SUPPLEMENTARY INFORMATION:** The FHWA, in cooperation with the Virginia Department of Highways and Transportation (VDH&T), will prepare an environmental impact statement (EIS) on a proposal to construct a four-lane limited access highway on ultimate six-lane right of way in the City of Portsmouth from the proposed Interstate Route I-664 interchange at the City of Suffolk/City of Portsmouth Corporate Limits to 0.326 mile east of the Norfolk, Franklin and Danville Railroad where it will connect with an existing four-lane highway over the Western Branch of the Elizabeth River. The proposed (Western Freeway) project will provide easy and rapid access to the developing residential, commercial and industrial areas of Churchland and West Norfolk; facilitate crosstown traffic movement; and establish an interface with the proposed Interstate Route I-664 crossing of Hampton Roads in order to facilitate intercity travel.

Alternatives under consideration include: (1) Taking no action (no build), (2) mass transit, (3) Transportation System Management (improving existing roads), and (4) construction of the proposed highway.

Letters describing the proposed action and soliciting comments will be sent to appropriate Federal, State and local agencies and to private organizations and citizens who have previously expressed interest in this proposal. No formal scoping meeting is planned at this time. The Draft EIS will be available for public and agency review and comment. Following publication of the Draft EIS, a public hearing will be held. Public notice will be given of the time and place of the hearing.

The ensure that the full range of issues related to this proposed action are addressed and all significant issues identified, comments and suggestions concerning this proposed action and the EIS should be directed to the FHWA at the address provided above.

Catalog of Federal Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The provisions of OMB Circular No. A-95 regarding State and local clearinghouse review of Federal and Federally assisted programs and projects apply to this program.

Issued on: November 21, 1983.

**George E. Kirk, Jr.,**

*District Engineer, Richmond, Virginia.*

[FR Doc. 83-31806 Filed 11-28-83; 8:45 am]

BILLING CODE 4910-22-M

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

**[Delegation Order No. 203]**

### Delegation of Authority

**AGENCY:** Internal Revenue Service, Treasury.

**ACTION:** Delegation of authority.

**SUMMARY:** The authority vested in the Commissioner of Internal Revenue Service by IRC 7802, 4988(c), and 4996, and Treasury Department Order 150-37, to determine the removal price for all taxable crude oil produced in the State of Alaska for the purpose of the Crude Oil Windfall Profit Tax Act of 1980 (as amended), IRC Sections 4986 through 4998 is delegated to the Regional Commissioner, Southwest Region.

**EFFECTIVE DATE:** November 23, 1983.

**FOR FURTHER INFORMATION CONTACT:** Robert H. Gill, OP:EX, 1111 Constitution Avenue, NW., Room 2025, Washington, D.C. 20224, 202-566-6751 (not a toll-free telephone number).

This document does not meet the criteria for significant regulations set forth in paragraph 8 of the Treasury directive appearing in the **Federal Register** for Wednesday, November 8, 1978.

**Percy Woodard, Jr.,**

*Assistant Commissioner (Examination).*

### Nationwide Authority to Make Determinations on Taxable Crude Oil Produced in Alaska

Pursuant to authority vested in the Commissioner of Internal Revenue by IRC 7802, 4988(c), and 4996, and Treasury Department Order No. 150-37, the nationwise authority to determine the removal price for all taxable crude oil produced in the State of Alaska for purposes of the Crude Oil Windfall Profit Tax Act of 1980 (as amended), IRC Sections 4986 through 4998, is hereby delegated to the Regional Commissioner, Southwest Region.

The authority of each District Director to adjust the removal price to reflect clearly the fair market value of oil removed pursuant to 26 CFR 51.4988-1(b)(3) must be in accord with "removal price" determinations made by the Regional Commissioner, Southwest Region.

This delegation does not extend to cases pending before the United States Tax Court, nor those within the jurisdication of the Department of Justice.

Delegation Order No. 190 is supplemented and amended consistent with the provisions of this Order.

This authority may not be redelegated.

James I. Owens,

*Acting Commissioner.*

[FR Doc. 83-31920 Filed 11-28-83; 8:45 am]

BILLING CODE 4830-01-M

# Sunshine Act Meetings

Federal Register
Vol. 48, No. 230
Tuesday, November 29, 1983

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).

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## 1

**FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION**

November 23, 1983.

**TIME AND DATE:** 10:00 a.m., Wednedsay, November 30, 1983.

**PLACE:** Room 600, 1730 K Street, NW., Washington, D.C.

**STATUS:** Open.

**MATTERS TO BE CONSIDERED:** The Commission will consider and act upon the following:

1. Consolidation Coal Company, Docket No. PENN 82-203-R, etc. (Issues include whether the judge erred in concluding that significant and substantial findings may be included in a section 104(a) citation, and whether the violations in issue were significant and substantial.)

**CONTACT PERSON FOR MORE INFORMATION:** Jean Ellen, Agenda Clerk, (202) 653-5632.

[S-1663-83 Filed 11-25-83; 2:47 pm]

BILLING CODE 6735-01-M

## 2

**FEDERAL RESERVE SYSTEM**

**FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT:** 48 FR 52541, November 18, 1983.

**PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING:** 10:00 a.m., Wednesday, November 23, 1983.

**CHANGES IN THE MEETING:** One of the items announced for inclusion at this meeting was consideration of any agenda items carried forward from a previous meeting; the following such closed item(s) was added:

Proposed purchase of computers within the Federal Reserve System. (This item was originally announced for a meeting on November 21, 1983.)

**CONTACT PERSON FOR MORE INFORMATION:** Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204.

Dated: November 23, 1983.

**James McAfee,**

*Associate Secretary of the Board.*

[S-1661-83 Filed 11-23-83; 4:23 pm]

BILLING CODE 6210-01-M

## 3

**FEDERAL RESERVE SYSTEM**

**TIME AND DATE:** 10:00 a.m., Monday, December 5, 1983.

**PLACE:** 20th Street and Constitution Avenue, NW., Washington, D.C. 20551.

**STATUS:** Closed.

**MATTERS TO BE CONSIDERED:**

1. Proposed changes to the Federal Reserve Bank Retirement Plan.
2. Proposed changes to the Plans administered under the Federal Reserve System's employee benefits program.
3. Federal Reserve Bank building design plans and budget for the Los Angeles Branch of the Federal Reserve Bank of San Francisco.
4. Personnel action (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
5. Any item carried forward from a previously announced meeting.

**CONTACT PERSON FOR MORE INFORMATION:** Mr. Joseph R. Coyne, Assistant to the Board; (202) 452-3204.

Dated: November 25, 1983.

**James McAfee,**

*Associate Secretary of the Board.*

[S-1665-83 Filed 11-25-83; 3:06 pm]

BILLING CODE 6210-01-M

## 4

**INTER-AMERICAN FOUNDATION**

**TIME AND DATE:**

December 5, 1983 6:00-9:00 p.m.,
December 6, 1983 9:00 a.m.-12:00 p.m.,

**PLACE:** 1515 Wilson Boulevard, Fifth Floor, Rosslyn, Virginia 22209.

**STATUS:** Open.

**MATTERS TO BE CONSIDERED:**

*December 5, 1983*

1. Introduction of Harold K. Phillips, nominee for Board of Directors
2. Chairman's Report
3. President's Report
4. Status Report on the Board Study of the goals, policies and procedures of the Inter-American Foundation

*December 6, 1983*

5. Minutes of the September 11-12, 1983 Meeting
6. Report of the Audit Committee
7. Election of new Advisory Council member
8. Board Member Travel Policy

**CONTACT PERSONS FOR MORE INFORMATION:** Steve Abrams (703) 841-3812.

[S-1664-83 Filed 11-25-83; 2:46 pm]

BILLING CODE 7025-01-M

## 5

**MERIT SYSTEMS PROTECTION BOARD**

**TIME AND DATE:** 10:30 a.m., Thursday, December 8, 1983.

**PLACE:** Eighth floor, 1120 Vermont Avenue NW., Washington, D.C.

**STATUS:** Closed.

**MATTERS TO BE CONSIDERED:**

1. *In Re Subpoena Addressed to the Office of Special Counsel,* (Betty Martin), MSPB Docket No. HQ12008310019.
2. *Leon York* v. *United States Postal Service,* No. 82-1564 (D.C. Cir. July 19, 1983) (on remand); *Charles Alfaro* v. *Department of Transportation,* MSPB Docket No NY075281F0428; *Grant* v. *Department of the Treasury,* MSPB Docket No. AT07528110699.
3. *Special Counsel* v. *James C. Cummings,* MSPB Docket No. HQ12068210019.
4. *John R. Landreth* v. *TVA,* MSPB Docket No. AT07528110876.
5. *Regulation Review: Warren Joseph* v. *OPM and IRS,* MSPB Docket No. HQ12058110067.
6. *Clayton Sarver* v. *Department of Treasury,* MSPB Docket No. SF07528210370ADD, SF07528210370COMP; *Arthur Brown* v. *Department of Justice,* MSPB Docket No. CH0752810187.

**CONTACT PERSON FOR ADDITIONAL INFORMATION:** Robert E. Taylor, Secretary, (202) 653-7200.

For the Board.

Dated: November 23, 1983.

**Herbert E. Ellingwood,**

*Chairman.*

[FR Doc. S-1662-83 Filed 11-25-83; 12:20 am]

BILLING CODE 7400-01-M

federal register

Tuesday
November 29, 1983

# Part II

# Department of Health and Human Services

## Public Health Service; Office of the Assistant Secretary for Health; Alcohol, Drug Abuse, and Mental Health Administration; National Institutes of Health; Centers for Disease Control; Health Resources and Services Administration; and Food and Drug Administration

## Privacy Act of 1974; Annual Publication of Systems of Records

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Public Health Service

### Office of the Assistant Secretary for Health

### Privacy Act of 1974; Annual Publication of Systems of Records

**AGENCY:** Public Health Service (PHS); Office of the Assistant Secretary for Health (OASH), HHS.

**ACTION:** OASH is publishing this document to meet the requirements of Pub. L. 97-375, the Congressional Reports Elimination Act. This new statute amends the Privacy Act (5 U.S.C. 552a, section 3(e)(4)) to limit republication to revised system notices only.

**SUMMARY:** This preamble summarizes significant changes to systems of individually identifiable records which have occurred since the 1982 annual publication. Three of these revised systems are published in their entirety below and are complete as of the date of signature. None of the modifications being made meet the OMB criteria either for a new or altered system report, or for an advance period of public comment.

OASH has added no new systems of records since the 1982 annual publication. Two systems have subsumed and deleted.

OASH is republishing the table of contents of all of its systems of records; an asterisk indicates that the system notice so designated has been modified and is republished below.

**SUPPLEMENTARY INFORMATION:**

**A. General Information**

1. The routine uses set forth in each notice describe permissible disclosures outside the Department of records in that system, which may be made without the consent of individuals who are the subjects of those records. Additional disclosures without consent of subject individuals are permitted by the Privacy Act itself in Section 3(b), as follows:

"(1) To those officers and employees of the agency which maintains the record who have a need for the record in the performance of their duties;

"(2) Required under section 552 of this title (the Freedom of Information Act);

"(3) For a routine use as (described in the routine use section of each specific system notice);

"(4) To the Bureau of the Census for purposes of planning or carrying out a census or survey or related activity pursuant to the provisions of title 13;

"(5) To a recipient who has provided the agency with advance adequate written assurance that the record will be used solely as a statistical research or reporting record, and the record is to be transferred in a form that is not individually identifiable;

"(6) To the National Archives of the United States as a record which has sufficient historical or other value to warrant its continued preservation by the United States Government, or for evaluation by the Administrator of General Services or his designee to determine whether the record has value;

"(7) To another agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States for civil or criminal law enforcement activity if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the agency which maintains the record specifying the particular portion desired and the law enforcement activity for which the record is sought;

"(8) To a person pursuant to a showing of compelling circumstances affecting the health or safety of an individual if, upon such disclosure, notification is transmitted to the last known address of such individual;

"(9) To either House of Congress, or, to the extent of matter within its jurisdiction, any committee or subcommittee thereof, any joint committee of Congress or subcommittee of any such joint committee;

"(10) To the Comptroller General, or any of his authorized representatives, in the course of the performance of the duties of the General Accounting Office;

"(11) Pursuant to the order of a court of competent jurisdiction; or

"(12) To a consumer reporting agency in accordance with section 3(d) of the Federal Claims Collection Act of 1966 (31 U.S.C. 952(d))."

Permissible disclosure (12) was added this year by Pub. L. 97-365, the Debt Collection Act of 1982, to allow disclosure of information to consumer reporting agencies to provide an incentive for debtors to repay delinquent Federal Government debts by making these debts part of their credit records. This "Special Disclosure" statement does not apply to any OASH system of records.

2. OASH has carefully reviewed each of its system notices this year with a view toward enhancing clarity and specificity as well as to incorporate normal updating changes. We are only republishing those system notices where the changes affect the public's need-to-know, such as an address change of the system location or of the system manager. All other changes, such as a change in organizational designation to reflect a reorganization, are being made to the data base only.

**B. Specific Information**

1. Changes in system notices which necessitate republication:

a. System 09-37-0001, Office of the Assistant Secretary for Health Correspondence Control System, HHS/OASH/OM. Change in System Location: The National Center for Health Services Research moved to a new address.

b. System 09-37-0009, Applied Statistics Training Institute Applicants and Students, HHS/OASH/OHRST. The Applied Statistics Training Institute (ASTI) lost its funding and no longer exists; however, the National Center for Health Statistics (NCHS) will continue to give some of the ASTI courses through its technical assistance program. We are also changing the organizational designation in the title from HHS/OASH/OHRST to HHS/OASH/NCHS, since the Office of Health Research Statistics and Technology (OHRST) has been abolished. Therefore, system 09-37-0009 is retitled "Applicants for National Center for Health Statistics Technical Assistance, HHS/OASH/NCHS," and all reference to ASTI is eliminated throughout the system notice.

c. System 09-37-0015, National Center for Health Services Research Grants Records System, HHS/OASH/OHRST, Change in System Location and Retention and Disposal section: The National Center for Health Services Research moved to a new address. We are also changing the organizational designation in the title from HHS/OASH/OHRST to HHS/OASH/NCHSR, since OHRST has been abolished. Furthermore, the Office of the General Counsel has determined that the routine use which permits discretionary disclosures of individually identified records under the Freedom of Information Act has become obsolete; therefore, this routine use has been deleted.

2. Changes to the data base which do not necessitate republication:

a. The Commissioned Personnel Operations Division (CPOD) is planning a comprehensive restructuring of several of its system notices, which will be published separately, and may have been published by the time this document appears. However, for the purpose of this publication, CPOD notices are current as of October 13, 1982.

b. The organizational designation in the title of the following systems has

been changed from HHS/OASH/OHRST to HHS/OASH/NCHS, since OHRST has been abolished:

09-37-0009—Applied Statistics Training Institute Applicants and Students, HHS/OASH/NCHS

09-37-0010—Health and Demographic Surveys Conducted in Probability Samples of the U.S. Population, HHS/OASH/NCHS

09-37-0011—Health Manpower Inventories and Surveys, HHS/OASH/NCHS

09-37-0012—Vital Statistics for Births, Deaths, Fetal Deaths, Marriages and Divorces Occurring in the United States during Each Year, HHS/OASH/NCHS

09-37-0013—Health Resources Utilization Statistics, HHS/OASH/NCHS

09-37-0014— Curricula Vitae of Consultants to the National Center for Health Statistics, HHS/OASH/NCHS

3. Deleted Systems: Systems 09-37-0004, PHS Commissioned Corps Training Files, HHS/OASH/OM, and system 09-37-0007, PHS Commissioned Corps Personnel Records, HHS/OASH/OM, were found to be subsystems of system 09-37-0002, PHS Commissioned Officer Personnel Data System HHS/OASH/OM, and were therefore subsumed under 09-37-0002 and subsequently deleted.

Readers who notice any inadvertent errors or omissions in OASH system notices are invited to bring them to my attention at the following address: Department of Health and Human Services, Public Health Service, Office of the Assistant Secretary for Health, Office of Management, 5600 Fishers Lane, Room 17-25, Rockville, Maryland 20857.

Dated: September 30, 1983.

**Wilford J. Forbush,**

*Deputy Assistant Secretary for Health Operations and Director, Office of Management.*

**Table of Contents**

*Office of The Assistant Secretary of Health*

The following table of contents lists all currently active systems of records.


* 09-37-0001 Office of the Assistant Secretary for Health Correspondence Control System, HHS/OASH/OM

09-37-0002 PHS Commissioned Officer Personnel Data System, HHS/OASH/OM, publ. **Federal Register**, Vol. 47, No. 109, p. 45676

09-37-0003 PHS Commissioned Corps Medical Records, HHS/OASH/OM, publ. **Federal Register**, Vol. 47, No. 109, p. 45677

09-37-0005 PHS Commissioned Corps Boards Proceedings, HHS/OASH/OM, publ. **Federal Register**, Vol. 47, No. 109, p. 45680

09-37-0006 PHS Commissioned Corps Grievance, Non-Board and Pre-Board Involuntary Retirement/Separation, and Disciplinary Files, HHS/OASH/OM, publ. **Federal Register**, Vol. 47, No. 109, p. 45681

09-37-0008 PHS Commissioned Corps Unofficial Personnel Files and Other Station Files, HHS/OASH/OM, publ. **Federal Register**, Vol. 47, No. 109, p. 45684

* 09-37-0009 Applicants for National Center for Health Statistics Technical Assistance, HHS/OASH/NCHS

09-37-0010 Health and Demographic Surveys Conducted in Probability Samples of the U.S. Population, HHS/OASH/NCHS publ. **Federal Register**, Vol. 47, No. 109, p. 45685

09-37-0011 Health Manpower Inventories and Surveys, HHS/OASH/NCHS, publ. **Federal Register**, Vol. 47, No. 109, p. 45687

09-37-0012 Vital Statistics for Births, Deaths, Fetal Deaths, Marriages and Divorces Occurring in the United States during Each Year, HHS/OASH/NCHS, publ. **Federal Register**, Vol. 47, No. 109, p. 45688

09-37-0013 Health Resources Utilization Statistics, HHS/OASH/NCHS, publ. **Federal Register**, Vol. 47, No. 109, p. 45689

09-37-0014 Curricula Vitae of Consultants to the National Center for Health Statistics, HHS/OASH/NCHS, publ. **Federal Register**, Vol. 47, No. 109, p. 45690

* 09-37-0015 National Center for Health Services Research Grants Records System, HHS/OASH/NCHSR


**09-37-0001**

**SYSTEM NAME:**

Office of the Assistant Secretary for Health Correspondence Control System, HHS/OASH/OM.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Public Health Service Executive Secretariat, Room 710H, Hubert H. Humphrey Building, 200 Independence Ave. SW., Washington, D.C. 20201

National Center for Health Statistics, Room 2-19, 3700 East-West Highway, Hyattsville, MD 20782

National Center for Health Services Research, Park Building, Room 3-28, 5600 Fishers Lane, Rockville, Maryland 20857

and

Federal Records Center, 4205 Suitland Road, Washington, D.C. 20409.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals who have contacted either the Assistant Secretary for Health, the Surgeon General, a Deputy Assistant Secretary, or a PHS Staff Office Director, or have been contacted in writing by one of these officials.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Hard copies of the actual correspondence, and computer or word processor print-out and tape or disk control system records of that correspondence.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

5 U.S.C. 301. Departmental Regulations.

**PURPOSE(S)**

To control and track all correspondence documents addressed or directed to the Assistant Secretary for Health or his subordinates as indicated above, as well as documents initiated by them, in order to assure timely and appropriate attention.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Correspondence records are maintained in hard copy. Control records are maintained on computer or word processor print-out, tape, and disk.

**RETRIEVABILITY:**

Hard copy records are indexed alphabetically by name of addressee and date of outgoing correspondence; or by name of sender and date of incoming correspondence; or by subject. Records may also be cross-referenced.

**SAFEGUARDS:**

Hard copy records are maintained in file cabinets that are lockable, or in rooms which are locked after office hours. During office hours, access to hard copy records is limited to authorized personnel. Access to the computerized subsystem is limited to specific individuals (correspondence assistants) through the use of passwords. These safeguards are in accordance with chapter 45-13 in the Department's General Administration Manual, supplementary chapter PHS.hf: 45-13, and with part 6 of the Department's ADP systems manual.

**RETENTION AND DISPOSAL:**

Records may be retired to a Federal Records Center and subsequently disposed of in accordance with the Office of the Assistant Secretary for

* Indicates that the system notice is being republished below.

Health records control schedule. The records control schedule may be obtained by writing to the appropriate System Manager at the address for that official which is indicated under System Location above.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, Public Health Service Executive Secretariat (address as above); Director, National Center for Health Statistics (address as above; Director, National Center for Health Services Research (address as above).

Policy coordination is provided by: Director, Office of Orgainization and Management Systems, Office of Management, Room 17-51 Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

**NOTIFICATION PROCEDURE:**

Inquiries should indicate the name of the individual with whom the Office of the Assistant Secretary for Health corresponded, the date of the incoming correspondence, if any, and the date of the outgoing correspondence. Inquiries should be addressed to the appropriate System Manager, listed above, not to the policy coordination official.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters must state that they are who they claim to be, and understand that obtaining information under false pretenses is subject to a maximum statutory penalty of 5,000.00 dollars.

**CONTESTING RECORD PROCEDURES:**

Contact the appropriate System Manager at the address for that official specified under System Location above, and reasonably identify the record, specify the information to be contested, the corrective action sought, and the reason for seeking the correction, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Records are derived from incoming correspondence to, and the outgoing correspondence of, the Assistant Secretary for Health or his subordinates as indicated above.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-37-0009**

**SYSTEM NAME:**

Applicants for National Center for Health Services Technical Assisance, HHS/OASH/NCHS.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Room 2-19, Center Building, 3700 East-West Highway, Hyattsville, Maryland 20782.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Applicants for and students of concentrated, intensive short-term courses related to health statistics. They are employees of Federal, State, and local governments and other persons in health-related fields engaged in collecting and analyzing vital and health statistics.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Applicant form which contains brief education information, current employment, and courses in which applicant is interested.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Public Health Service Act, Section 304(b)(1) (42 U.S.C. 242b).

**PURPOSE(S):**

To set up courses, notify applicants of acceptance or non-acceptance, and acceptance for a future course if necessary. Used exclusively within the National Center for Health Statistics (NCHS).

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Alphabetically filed in file cabinet.

**RETRIEVABILITY:**

Retrievable by name.

**SAFEGUARDS:**

Routine building security. Records are used only by staff administering the technical assitance programs. These safeguards are established in accordance with guidelines in DHHS Chapter 45-13 in the General Administration Manual, in supplementary Chapter PHS. hf: 45-13, and in the NCHS Staff Manual on Confidentiality.

**RETENTION AND DISPOSAL:**

Filé destroyed six months after each course is completed.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, National Center for Health Statistics, Center Building, Room 2-19, 3700 East-West Highway, Hyattsville, Maryland 20782.

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the System Manager.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Positive identification is required from anyone seeking access. Requestors should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under System Manager above, reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Voluntary submission of Application Form by person wishing to take the courses.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-37-0015**

**SYSTEM NAME:**

National Center for Health Services Research Grants Records System, HHS/OASH/NCHSR.

**SECURITY CLASSIFICATION**

None.

**SYSTEM LOCATION:**

National Center for Health Services Research, Park Building, Room 3-28, 5600 Fishers Lane, Rockville, Maryland 20857.

Federal Records Center, 4205 Suitland Road, Suitland, Maryland 20409.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Principal Investigators and associated research and administrative personnel.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Grant files, including summary reports, grant applications, grant award notices, summary comments of peer reviewers, salary information, staffing lists, general project correspondence, and Social Security Numbers (optional).

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Public Health Service Act, Title II, Administration, Section 304, (General Authority Respecting Health Statistics and Health Services Research

Evaluations, and Demonstrations (42 U.S.C. 242b)), Section 305, (National Center for Health Services Research (42 U.S.C. 242c)). Section 308, (General Provisions Respecting Sections 304, 305, 306, and 307 (42 U.S.C. 242m)), Title XII, Emergency Medical Services Systems, Section 1205, (Grants and Contracts for Research (42 U.S.C. 300d–4)).

**PURPOSE(S):**

The information in this system is used to facilitate day-to-day grants management operations and for purposes of review, analysis, planning and policy formulation by NCHSR staff members and by other components of DHHS.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Manual files (file folders).

**RETRIEVABILITY:**

Retrievable by name and grant number.

**SAFEGUARDS:**

Locked file cabinets, general building security. Only staff members of the Grants Operations and Administration Branch (GOAB) have regular access to system records. Other NCHSR staff may inspect and review records on a need-to-know basis only, with the approval—and in the presence—of GOAB staff. These safeguards are in compliance with DHHS Chapter 45–13 and Chapter PHS, hf: 45–13 of the General Administration Manual.

**RETENTION AND DISPOSAL:**

Approved grant applications and their respective files are retained at NCHSR for two years beyond the termination date of the project. Rejected grant applications are held for one year. The grant files are then retired to a Federal Records Center and subsequently disposed of in accordance with the PHS/OASH records control schedule. The records control schedule may be obtained by writing to the System Manager at the following address.

**SYSTEM MANAGER(S) AND ADDRESS:**

Chief, Grants Operations and Administration Branch; National Center for Health Services Research, Park Building, Room 3–28, 5600 Fishers Lane, Rockville, Maryland 20857.

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the System Manager at the above address.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Positive identification is required, except that no verification of identify shall be required where the record is one which is required to be disclosed under the Freedom of Information Act.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under System Manager above and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Applications, reports and correspondence from the research community, and statements from grant review committees.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

[FR Doc. 83-31242 Filed 11-28-83; 8:45 am]
BILLING CODE 4160-17-M

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## Public Health Service

## Alcohol, Drug Abuse, and Mental Health Administration

## Privacy Act of 1974; Annual Publication of Systems of Records

**AGENCY:** Department of Health and Human Services (DHHS); Public Health Service (PHS); Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA).

**ACTION:** ADAMHA is publishing this document to meet the requirements of Section 3(e)(4) of the Privacy Act (5 U.S.C. 552a), as amended by the Congressional Reports Elimination Act of 1982, providing for annual publication of the existence and character of revised systems of records which are subject to the Act.

**SUMMARY:** This preamble summarizes significant changes to systems of individually identifiable records which have occurred since the due date for submissions to the 1982 annual republication (August 13, 1982).

**SUPPLEMENTARY INFORMATION:**

### 1. Changes

Changes appearing in this year's publication include, but are not necessarily limited to, the following:

a. Deletion of the routine use pertaining to Freedom of Information disclosures from system notice 09–30–0008, "Saint Elizabeths Hospital Social Services Record System," HHS/ADAMHA/NIMH. This action was taken as a result of a newly issued Department directive which indicated that such disclosures are obsolete;

b. System notice 09–30–0031, "Saint Elizabeths Hospital Biometrics System," HHS/ADAMHA/NIMH was retitled, "Saint Elizabeths Hospital Management Information Reporting System," in order to clarify the content of data in the records;

c. Clarification of authority citation, changes in system location and addresses, greater specification of record retention and disposal procedures, as well as other editorial changes.

### 2. New Systems Not in 1982 Publication

09–30–0043, "Shipment records of Drugs of Abuse to Authorized Researchers," HHS/ADAMHA/NIMH, published October 7, 1982, **Federal Register** (FR), Vol. 47, No. 195, pp. 44432–44434.

### 3. System Notices Deleted

09–30–0034, "Professional Development Program Registries of the National Training Systems for Substance Abuse Services," HHS/ADAMHA/NIDA, was last published in the **Federal Register** on June 10, 1983, Vol. 48, No. 113, pp. 26892–26894. This system of records was deleted because of reduced funding. The records have been transferred to a non-Federal successor organization, the American Council on Education, which has

asumed all responsibility for the records.

09-30-0045, "Respondents in a Validity/Reliability Study of Self-Reported Drinking," HHS/ADAMHA/NIAAA. This system of records is being deleted because the records no longer exist in identifiable form.

ADAMHA is only republishing those systems of records that have been changed. Each system notice, including those being deleted, with the exception of two systems in which major alterations were made since the 1982 annual publication, was last published in the **Federal Register**, Vol. 47, No. 198, pp. 45427-45468, October 13, 1982.

The two systems of records that had major alterations were: 09-30-0027, "Grants: Research Training, Research Scientist Development, Education, Demonstration, Fellowships, Clinical Training, Community Services, Cooperative Agreements," HHS/ADAMHA/OA, last published in the **Federal Register**, October 12, 1982, Vol. 47, No. 197, pp. 44885-44887, and 09-30-0041, "Participants in Drug Abuse Research Studies Supporting New Drug Applications," HHS/ADAMHA/NIDA, last published in the **Federal Register**, June 9, 1983, Vol. 48, No. 112, pp. 26672-26674.

4. Readers who notice any errors or omissions in ADAMHA system notices are invited to bring them to my attention at the following address: Alcohol, Drug Abuse, and Mental Health Administration, 5600 Fishers Lane, Room 12-105, Rockville, Maryland 20857.

Dated: August 11, 1983.

**Joseph R. Leone,**

*Executive Officer.*

## 5. Table of Contents

The following is a list of system notices which ADAMHA currently maintains.


*09-30-0002 Statistical Research Data on Adolescent Runaways in Prince Georges County, Md., HHS/ADAMHA/NIMH

*09-30-0003 Medical Records Files of Patients Seen in Therapy Programs of the Mental Health Study Center, HHS/ADAMHA/NIMH

*09-30-0004 Intramural Research Program Records, HHS/ADAMHA/NIMH

09-30-0005 Saint Elizabeths Hospital Research Subjects Data Records, HHS/ADAMHA/NIMH

*09-30-0006 Saint Elizabeths Hospital Medical Support Programs File System, HHS/ADAMHA/NIMH

*09-30-0007 Saint Elizabeths Hospital Clinical Support Services Record System, HHS/ADAMHA/NIMH

*09-30-0008 Saint Elizabeths Hospital Social Services Record System, HHS/ADAMHA/NIMH

*09-30-0009 Saint Elizabeths Hospital Multidisciplinary Raw Data Consultation Files, HHS/ADAMHA/NIMH

*09-30-0010 Saint Elizabeths Hospital Juvenile Education Monitoring System, HHS/ADAMHA/NIMH

*09-30-0011 Saint Elizabeths Hospital Admission Service Non-Admission File System, HHS/ADAMHA/NIMH

*09-30-0012 Saint Elizabeths Hospital Pre-Service Education Records, HHS/ADAMHA/NIMH

*09-30-0013 Saint Elizabeths Hospital Training Videotape Records, HHS/ADAMHA/NIMH

*09-30-0014 Saint Elizabeths Hospital Financial System, HHS/ADAMHA/NIMH

*09-30-0015 Saint Elizabeths Hospital General Security System, HHS/ADAMHA/NIMH

*09-30-0016 Saint Elizabeths Hospital Patients' Personal Property Record, HHS/ADAMHA/NIMH

*09-30-0017 Saint Elizabeths Hospital Legal Office Record System, HHS/ADAMHA/NIMH

*09-30-0018 Saint Elizabeths Hospital Area D Community Mental Health Center Citizens Advisory Group Records, HHS/ADAMHA/NIMH

*09-30-0019 Saint Elizabeths Hospital Court-Ordered Forensic Investigatory Materials File, HHS/ADAMHA/NIMH

*09-30-0020 Administrative Records on Civilly Committed Drug Abusers under the Narcotic Addict Rehabilitation Act, HHS/ADAMHA/NIDA

*09-30-0021 Patient Medical Records on PHS Beneficiaries 1935-1974 and Civilly Committed Narcotic Addicts 1967-1978 Treated at PHS Hospitals, HHS/ADAMHA/NIDA

*09-30-0022 National Institute on Drug Abuse Addiction Reseach Center Federal Prisoner and Non-Prisoner Patient Files, HHS/ADAMHA/NIDA

*09-30-0023 Records of Contracts Awarded to Individuals, HHS/ADAMHA/OA

*09-30-0024 Saint Elizabeths Hospital General Administrative Record System, HHS/ADAMHA/NIMH

09-30-0026 Saint Elizabeths Hospital Research Project Records, HHS/ADAMHA/NIMH

*09-30-0027 Grants: Research, Research Training, Research Scientist Development, Education, Demonstration, Fellowships, Clinical Training, Community Services, Cooperative Agreements, HHS/ADAMHA/OA

*09-30-0028 Saint Elizabeths Hospital General Medical/Clinical Records System and Related Indexes, HHS/ADAMHA/NIMH

*09-30-0029 Records of Guest Workers, HHS/ADAMHA/OA

*09-30-0030 Records of Visiting Fellows, HHS/ADAMHA/OA

*09-30-0031 Saint Elizabeths Hospital Management Information Reporting System, HHS/ADAMHA/NIMH

*09-30-0033 Correspondence Files, HHS/ADAMHA/OA

09-30-0035 Three Mile Island Mental Health Survey Respondents Record, HHS/ADAMHA/NIMH

*09-30-0036 Mental Health Epidemiologic and Biometric Research, HHS/ADAMHA/NIMH

*09-30-0037 Psychotherapy of Opiate-Dependent Individuals, HHS/ADAMHA/NIDA

*09-30-0038 Subjects in Pharmacokinetic Studies of Drugs of Abuse, HHS/ADAMHA/NIDA

*09-30-0039 Treatment Outcome Prospective Study, HHS/ADAMHA/NIDA

09-30-0041 Participants in Drug Abuse Research Studies Supporting New Drug Applications, HHS/ADAMHA/NIDA

*09-30-0043 Shipment Records of Drugs of Abuse to Authorized Researchers, HHS/ADAMHA/NIDA


*These systems of records have been changed during this year's review and are being republished below.

BILLING CODE 4160-20-M

### 09-30-0002

**SYSTEM NAME:**

Statistical Research Data on Adolescent Runaways in Prince Georges County, Md., 1962-65. HHS/ADAMHA/NIMH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Mental Health Study Center
2340 University Boulevard, East
Adelphi, Maryland 20783

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Adolescent runaways in Prince Georges County, Md., 1962-65.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Information obtained from interviews with subject individuals and parents or guardians. Types of information included in the records are: age, sex, home address and phone number, home conditions, nature of problems, etc.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Public Health Service Act Section 301(42 U.S.C. 241).

**PURPOSE(S):**

Used by project officer for follow-up study of adolescent runaways.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office

made at the written request of that individual.

2. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Field notes, transcribed interviews, audio tapes of interviews.

**RETRIEVABILITY:**

Retrieved by number.

**SAFEGUARDS:**

Records kept in locked filing cabinets in a locked room. Indexes which link names and numbers are kept in separate locked cabinets. Only authorized research and support staff have access to the records. These safeguards are in accordance with DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 in the General Administration Manual.

**RETENTION AND DISPOSAL:**

Records may be retired to a Federal Records Center and subsequently disposed of in accordance with the ADAMHA Records Control Schedule. The records control schedule and disposal standard for these records may be obtained by writing the System Manager at the address below.

**SYSTEM MANAGER(S) AND ADDRESS:**

Chief, Mental Health Study Center
2340 University Boulevard, East
Adelphi, Maryland 20783

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the System Manager at the address above. Provide notarized signature as proof of identity. The request should include the name of the researcher, if possible. A parent or guardian who requests notification of a child's/incompetent person's record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child/incompetent person as well as his/her own identity.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

From the subject individuals themselves, and from their parents or guardians, with subject individuals' approval, cooperation and participation.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0003**

**SYSTEM NAME:**

Medical Record Files of Patients Seen in Therapy in Programs of the Mental Health Study Center. HHS/ADAMHA/NIMH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Mental Health Study Center
2340 University Boulevard, East
Adelphi, Maryland 20783
and at contractor facilities. A list of contractor locations is available from the system manager.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Patients seen in therapy in programs of the Mental Health Study Center, at the center or at various locations throughout Prince Georges County.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Consultation Record Form, intake questionnaire, progress notes, Patient Service Record Form, psychophysiologic and developmental tests, medical and social histories, physical examinations, clinical and behavioral observations and interview questionnaires, correspondence with community agencies, professionals on cases, and consent forms.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Public Health Service Act Section 301(42 U.S.C. 241).

**PURPOSE(S):**

Used for clinical intervention by therapists and, with individual consent, for behavioral and basic research.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Medical record forms, case notes, logs, files and indexes.

**RETRIEVABILITY:**

Retrieved by case number and name.

**SAFEGUARDS:**

Only authorized research and support staff have access to records which are kept in locked file drawers. Index records kept in separate locked cabinets. Contractors are required to comply with the provisions of the Privacy Act and with the Departmental Regulations. These safeguards are in accordance with DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 in the General Administration Manual.

**RETENTION AND DISPOSAL:**

Records may be retired to a Federal Records Center and subsequently disposed of in accordance with the ADAMHA Records Control Schedule. The disposal standard for these records may be obtained by writing the system manager at the address below.

**SYSTEM MANAGER(S) AND ADDRESS:**

Chief, Mental Health Study Center
2340 University Boulevard, East
Adelphi, Maryland 20783

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about himself/herself upon written request, with notarized signature, addressed to the System Manager identified above. The request should include the name of the researcher, as well as the name of the study, if it is a named study. An

individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion. A parent or guardian who requests notification of or access to a minor's record shall at the time the request is made designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The designate will receive the record in all cases and upon review will determine whether the record should be made available to the parent or guardian.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information being contested and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

From the patients themselves or from their parents or guardians with subject individuals' approval, cooperation, and participation.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0004**

**SYSTEM NAME:**

Intramural Research Program Records of Research Performed on In- and Out-Patients with Various Types of Mental Illness. HHS/ADAMHA/NIMH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20205 and
Saint Elizabeths Hospital
Washington, D. C. 20032

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

In- and out-patients with emotional, psychiatric, and neurophysiological disability, normal subjects, and research subjects.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Research data of wide variety including biochemical measures, psychophysiological and psychological tests, questionnaires, clinical and behavioral observations and interviews, physical examinations, and correspondence.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Public Health Service Act Sections 301, 302, and 303 (42 USC 241, 242,242a).

**PURPOSE(S):**

These records are used for diagnosis and treatment of patients with neuropsychiatric illnesses; behavioral research relating to the causes, diagnoses, and treatment of neuropsychiatric disorders; and basic research on behavioral processes and personality development.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. A record may be disclosed for a research purpose, when the Department:
(a) has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained;
(b) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring;
(c) has required the recipient to—(1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, and (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except—(A) in emergency circumstances affecting the health or safety of any individual, (B) for use in another research project, under these same conditions, and with written authorization of the Department, (C) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (D) when required by law;
(d) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

2. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

3. In the event of litigation where the defendant is (a) the Department, and component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

In original state; files, indexes, magnetic and other tapes.

**RETRIEVABILITY:**

Retrieved by name (coded).

**SAFEGUARDS:**

Only authorized medical and research staff have access to these records. Magnetic tapes, files, indexes, and other tapes that contain individually identifiable data are stored in a locked cabinet in a limited access area. Magnetic data are further protected by special account numbers and passwords. These safeguards are in accordance with DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 in the General Administration Manual, and Part 6, 'ADP System Security' in the HHS ADP Systems Security Manual.

**RETENTION AND DISPOSAL:**

Records may be retired to a Federal Records Center and subsequently disposed of in accordance with the ADAMHA Records Control Schedule. The records control schedule and disposal standard for these records may be obtained by writing the System Manager at the address below.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, Intramural Research Program
National Institute of Mental Health
Building 36, Room 1A-07
9000 Rockville Pike
Bethesda, Maryland 20205

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the System Manager at the address above. Provide notarized signature as proof of identity. The request should include as much of the following information as possible: (a) full name; (b) nature of illness (if any); (c) ward or laboratory; (d) title of study; (e) name of researcher conducting study. An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion. A parent or guardian who requests notification of child's/incompetent person's record shall at the time the request is made designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The designate will receive the record in all cases and upon review will determine whether the record should be made available to the parent or guardian.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Information gathered from individuals under study, either patient or normal subject, contract surveys, hospital records, medical and nursing staff notes.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0006**

**SYSTEM NAME:**

Saint Elizabeths Hospital Medical Support Program File System. HHS/ADAMHA/NIMH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Saint Elizabeths Hospital
Medicine and Laboratory Branches
Washington, D.C. 20032

Washington National Records Center
4205 Suitland Road
Washington, D.C. 20409

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

All present and past patients and employees of Saint Elizabeths Hospital who received medical treatment and laboratory services.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

The Division of Medical Support Programs is made up of two branches: (1) Medicine Branch; and (2) Laboratory Branch. Listed below are records and logs peculiar to the Division of Medical Support Programs only (not used outside the Division). The Medical Support Program File System does not include any material which is located in a patient's medical record.

Medicine Branch Records
1. Dental Department: X-ray films
2. Department of Medicine: Cancer Registry
3. Neurology Department: electroencephalographs and echoencephalographs
4. Department of Opthalmology: photographs of eyes, interesting cases (card file)
5. Department of Radiology: X-ray films
6. Department of Rehabilitation Medicine: physical therapy treatment files and blind rehabilitation records

Medicine Branch Logs
1. Evening-Night Physicians' Logs: Abstract of the cases handled during the tour of duty 5:00 p.m. to 8:30 a.m.
2. Death Information Book: Abstract of information regarding death of patient, notification of relatives, medical examiner and/or other third parties.
3. Clinic Appointment Logs: Patients, employees, and visitors with identifying number and reason for appointment to 15 specialty clinics.
4. Admission and Transfer Logs in Eldridge Building and in Rehabilitation Medicine Building: identifies patient by name, case number, psychiatric service, date of admission, ward admitted to, date of discharge, and psychiatric service returned to.
5. X-ray Admission and Examination Log: daily record of patients examined and diagnostic findings.
6. Register of Operations: daily record of patients operated, type of surgery, participating staff, type of anesthesia, and postoperative condition.

Laboratory Branch Record Book: photograph of patients, dates of photographs, and division location of patients.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

24 USC 161, et. seq.; 21 DC Code 562, Hospitalization of the Mentally Ill Act.

**PURPOSE(S):**

Dental management and training; diagnosis and examination of brain lesions; graphic comparison of time and brain changes; determination of extent of eye changes; epidemiological study reference; research; continuity of physical therapy, treatment record, and patient management; departmental administration and planning.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Information may be provided to physicians, dentists, laboratories, physical therapists, vocational rehabilitation therapists, etc. who are taking an active role in the further treatment of patients seen at the Medicine and/or Laboratory Branches of Saint Elizabeths Hospital, in order to insure continuity of care.

2. Information from the cancer registry is provided to the District of Columbia Cancer Registry as required by law.

3. Disclosure may be made to organizations deemed qualified by the Secretary to carry out quality assessment, medical audits or utilization review, to include Professional Standards Review Organizations.

4. Disclosures may be made in the course of employee discipline or competence determination proceedings to parties involved in the proceedings such as police, attorneys, and Office of Personnel Management employees.

5. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

6. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the

Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected (e.g., to the Department of Justice or other appropriate Federal agencies in defending claims against the United States when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are maintained in secured rooms in the following areas:

1. Dental X-ray films—file cabinets in the Main Dental Clinic Area.
2. Electroencephalographs and echoencephalograms—file cabinet in the Neurology Department Record Room.
3. Photographs of eyes of patients—file cabinet in the Eye Clinic.
4. Unusual Eye Case File—in a 5 x 3-inch card file in the Eye Clinic.
5. X-ray Films—open shelf files and filing cabinets in the X-ray Department.
6. Cancer Registry—file cabinets in the Department of Medicine.
7. Physical Therapy Treatment Files—file cabinets in the Rehabilitation Medicine Department.
8. Blind Rehabilitation Records—file cabinets in the Rehabilitation Medicine Department.

**RETRIEVABILITY:**

1. Dental X-ray films—hospital case number and name.
2. Electroencephalograph and echoencephalograph—name, case number and date of examination.
3. Photographs of eyes of patients—by name and case number.
4. Unusual eye case file—by disease or condition name.
5. X-ray films—patient's name and case number or employee's name, social security number (terminal digit system).
6. Cancer Registry—name and case number.
7. Physical Therapy Treatment Files—name and date of evaluation.
8. Blind Rehabilitation Records—name and case number.

**SAFEGUARDS:**

1. Dental X-ray films—supervision by personnel during day, locked at night.
2. Electroencephalograms and echoencephalographs—locked record room.
3. Photographs of eyes of patients—supervised by personnel during the day, locked at night.
4. Unusual eye case file—supervised by personnel by day, locked at night.
5. X-ray films—locked cabinet.
6. Cancer Registry—supervised by personnel by day, locked at night.
7. Physical Therapy Treatment Files—locked office.
8. Blind Rehabilitation Records—authorized personnel and locked office

**RETENTION AND DISPOSAL:**

Employee I.D. procedures have been implemented to assure that safeguards are in accordance with DHHS Chapter 45-13 and supplementary Chapter PHS.hf:45-13 in the General Administration Manual. Records may be retired to a Federal Records Center and subsequently disposed of in accordance with the ADAMHA Records Control Schedule. The records control schedule and disposal standard for these records may be obtained by writing the System Manager at the address below.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director of Medical Support Programs
W. W. Eldridge Building
Saint Elizabeths Hospital
Washington, D. C. 20032

**NOTIFICATION PROCEDURE:**

To determine if a record exists, contact
Privacy Act Coordinator
Office of the Director of the Medicine Branch
W. W. Eldridge Building
Saint Elizabeths Hospital
Washington, D.C. 20032

Provide a notarized signature if request is made by mail, or suitable identification if request is made in person.

All of the following information must be provided when requesting notification:

(a) Full name;
(b) Approximate dates of enrollment or employment at St. Elizabeths Hospital;
(c) The nature of the material desired.

A parent or guardian who requests notification of a child's/incompetent person's record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child/incompetent person as well as his/her own identity.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

1. Dental X-ray films—Patients: inpatients and outpatients within hospital records and/or outside facility.
2. Electroencephalographic and echoencephalographic—graphs are derived electronically from the patient's brain.
3. Photographs of eyes of patients—photographs taken during internal or external examination of patients' eyes.
4. Unusual eye case file—result of examination in Eye Clinic.
5. X-ray films—films obtained during patients or employees' term in hospital and/or from outside sources; i.e., private physician or hospital.
6. Cancer Registry—clinical records of private physicians, outside hospital.
7. Physical Therapy Treatment Files—physical therapist's notes, doctor's notes, prescription records.
8. Blind Rehabilitation Records—staff observation of progress.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0007**

**SYSTEM NAME:**

Saint Elizabeths Hospital Clinical Support Services Record System. HHS/ADAMHA/NIMH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

This is a widely decentralized system of records at Saint Elizabeths Hospital. Records are kept in the offices of the various clinical support services operating at the Hospital. Included in this system are:

1. Occupational Therapy Section-Atkins Hall
2. Educational Rehabilitation Unit-Atkins Hall

3. Speech and Audiology Branch-Rehabilitation Medicine Building
4. Industrial Therapy Section-Atkins Hall
5. Dance Therapy Section-William A. White Building
6. Recreational Therapy-Hagan Hall
7. Musicology Unit-Dix Pavilion
8. Chaplaincy Program-Chapel
9. Psychodrama Unit - Hitchcock Hall
10. Individual Psychotherapists' Offices-In various Divisions, Saint Elizabeths Hospital, Washington D.C. 20032.

Records are stored at Washington National Records Center, 4205 Suitland Road, Washington, D.C. 20409.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

All past and present patients of Saint Elizabeths Hospital.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Patient demographic data; records of patient participation in each of the above-named clinical support programs; therapists' informal notes of observations and evaluations of patient activities; clinical impressions; attendance records, test results, abstracts of notes and observations taken from the patient's medical record.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

24 USC 161, et seq.; 21 DC Code 562, Hospitalization of the Mentally Ill Act.

**PURPOSE(S):**

1. To facilitate the treatment of patients at Saint Elizabeths Hospital.
2. To assess the physical, educational, vocational, recreational and psychological needs of patients at Saint Elizabeths Hospital and to provide for those needs.
3. To evaluate the effectiveness of the clinical support programs and to provide a basis for their continuing improvement.
4. To facilitate clinical support services, teaching programs and scientific research.

Indexes based on the clinical support services record system are used for the following purposes:

a. speedy identification and location of specific patients;
b. monitoring the completeness of patient records;
c. monitoring the changing status of patients either in terms of transfers within the Hospital or outside the Hospital;
d. easy identification of basic demographic data used for statistical and/or research purposes;
e. quick review of current treatment regimen.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Information is routinely disclosed to persons not employees of SEH, who have a responsibility for the examination and/or treatment of SEH patients;

2. Disclosure may be made to organizations deemed qualified by the Secretary to carry out quality assessment, medical audits or utilization review.

3. Disclosures may be made in the course of employee discipline or competence determination proceedings to parties involved in the proceedings such as police, attorneys, and Office of Personnel Management employees.

4. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

5. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected (e.g., to the Department of Justice or other appropriate Federal agencies in defending claims against the United States when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual).

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File folders, index cards, punchcards, record logs and file cabinets.

**RETRIEVABILITY:**

Name, hospital number, dates of activities, location of activity.

**SAFEGUARDS:**

1. Available only to properly trained hospital personnel.
2. Access limited to authorized personnel only, through implementation of an employee photo I.D. program. Enforced by security guards; rooms are locked when unoccupied. These safeguards are in accordance with DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 in the General Administration Manual.

**RETENTION AND DISPOSAL:**

Records may be retired to a Federal Records Center and subsequently disposed of in accordance with the ADAMHA Records Control Schedule. The records control schedule and disposal standard for these records may be obtained by writing the System Manager at the address below.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, Clinical Support Programs
Center Building
Saint Elizabeths Hospital
Washington, D.C. 20032

**NOTIFICATION PROCEDURE:**

A patient or former patient may learn if a record exists upon written request, with notarized signature if request is made by mail, or with suitable identification if request is made in person, directed to:

Privacy Act Coordinator
Office of the Director of Clinical Support Programs
Center Building
Saint Elizabeths Hospital
Washington, D. C. 20032

All of the following information must be provided when requesting notification:

(a) Full name;
(b) Approximate dates of enrollment at St. Elizabeths Hospital;
(c) The name of the division where the requester resided, or received treatment as an outpatient;
(d) The identity of the clinical support service and the approximate dates of participation in the program;
(e) If possible, the name of the individual therapist;
(f) If possible, the patient's hospital number.

A parent or guardian who requests notification of or access to a child's/incompetent person's record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child/

incompetent person as well as his/her own identity.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Past and present patients of Saint Elizabeths Hospital, various employees of the Hospital and the patients' medical/clinical record.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0008**

**SYSTEM NAME:**

Saint Elizabeths Hospital Social Services Record System. HHS/ADAMHA/NIMH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

A widely decentralized system at Saint Elizabeths Hospital. Individual records are kept in the offices of social workers responsible for patients on the rolls of the various Hospital Divisions. Social workers' offices are located in each inpatient and outpatient division or clinic at Saint Elizabeths Hospital, Washington, D.C. 20032. Records of individuals in transition programs may be located at contractor sites. For a current listing of contractor sites, contact the System Manager. Records are stored at Washington National Records Center, 4205 Suitland Road, Washington, D.C. 20409.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

All past and present patients on the rolls of Saint Elizabeths Hospital; home sponsors; caretakers; owners and operators of facilities providing services to patients.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Files on inpatients and outpatients containing demographic data; social workers' contact with families and the community including social, marital and family status, job status; identifying information containing name, address, telephone numbers, social security numbers, Medicaid numbers, date of birth, legal status, financial information hospital number, V.A. numbers, Health Insurance numbers, Civil Service Numbers, family composition; statement on background, names of relatives, conservators with addresses and telephone numbers; correspondence sent other agencies; information regarding psychiatric and medical condition; social histories; progress notes (carbon copies of notes may be placed in ward chart) hand written progress notes not in chart, return to hospital notes, interval histories, placement and planning notes; information regarding psychiatric and medical condition, financial resources, treatment plans, correspondence to relatives, friends, other agencies, etc. Telephone interviews or conversations, incident reports and copies of reportable occurrences, group therapies and individual therapies by social workers, daycare status and group activities, religious histories; intra-agency evaluative and assessment data and reports received from other sources, outside agencies that provide supportive services; essential information regarding services sought or received.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

24 USC 161, et seq.; 21 DC Code 562, Hospitalization of the Mentally Ill Act.

**PURPOSE(S):**

Information is used:

1. In planning to assess the patient's overall ability to be placed and to adjust or function in the type of environment to which he or she has been referred.
2. For accountability to other hospital personnel and reference for recording or sharing information with staff and other necessary persons upon request.
3. To share information with team, reference for casework services and reference for completing forms.
4. To monitor patient's progress and periodically assess placement situations in outplacement facilities. To monitor outplacement facilities outside the hospital and assist in placement of patients by providing accurate, up-to-date information regarding available facilities; and to determine the status of compliance of a facility with certain standards through appropriate licensing agencies. To familiarize staff with outplacement facilities. To assess outplacement operators, administrators or owners ability to provide the level of care needed by individual patients. To share patient's background and appropriate information with outplacement owners, operators and sponsors.
5. To expedite family involvement in planning patient care and to expedite mobilization of community resources on behalf of the patient.
6. As a resource in diagnosis, treatment, planning prognosis goals and communication with other disciplines.
7. As resource material gathered by the social workers used to prepare narrative summaries for the patient's medical records.
8. To keep informed about social services provided patients; patient problem areas in the unit for purpose of evaluating services provided and need for action, and for reporting to the Clinical Directors or person in charge of service.
9. As resource material for diagnostic planning and implementation of treatment plan and documentation of services offered.
10. For reference in order to complete summaries for medical records; to have readily available pertinent information with which to respond to personal and telephone contacts; to provide needed information to hospital staff, officials of other agencies reponsible for the provision of adjunct services.
11. To provide inservice training for continued professional development.
12. To provide Hospital staff and patients with essential information for selecting appropriate living arrangements for patients in the community.
13. To provide information to placement workers from other community service organizations in order to facilitate patient placements and to develop necessary community support services.
14. To serve as a uniform system for location of staff, indication of qualifications and areas of responsibility, in order to assist in provision of resources (financial and other) to patients.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Information is routinely disclosed to the following sources for the purposes of obtaining financial assistance for patients, locating community recreation resources, providing job placement and training for patients, securing alternative placements in other institutions, providing education, securing living and care arrangements and aiding in follow-up care, and providing required reports

to court, state government or Federal government agencies:

a. Foster home sponsors, caretakers, owners and operators of facilities providing services to patients
b. Agencies of the District of Columbia Government
c. The Superior Court for the District of Columbia
d. The United States District Court for the District of Columbia
e. The Veteran's Administration
f. The Office of Personnel Management
g. Anchor Mental Health Association
h. State Departments of Social Services throughout the United States;

2. Information disclosed routinely to persons, who are not employees of SEH, on a need to know basis, who have a responsibility for the care and treatment of patients of SEH.

3. In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether federal (e.g., Department of Justice), State or local (e.g., State and local licensing boards) charged with the responsiblity of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto.

4. A record from this system of records may be disclosed as a 'routine use' to a federal, state or local agency maintaining civil, criminal or other relevant enforcement records or other pertinent records, such as current licenses, if necessary to obtain a record relevant to an agency decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant or other benefit.

5. Where Federal agencies having the power to subpoena other federal agencies' records, such as the Internal Revenue Service or the Civil Rights Commission, issue a subpoena to the Department for records in this system of records, the Department will make such records available.

6. Where the appropriate official of the Department, pursuant to the Department's Freedom of Information Regulation determines that it is in the public interest to disclose a record which is otherwise exempt from mandatory disclosure, disclosure may be made from this system of records.

7. The Department contemplates that it will contract with a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor shall be required to maintain Privacy Act safeguards with respect to such records.

8. A record may be disclosed for a research purpose, when the Department:

(a) has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained;
(b) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring;
(c) has required the recipient to—(1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, and (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except—(A) in emergency circumstances affecting the health or safety of any individual, (B) for use in another research project under these same conditions, and with written authorization of the Department, (C) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (D) when required by law;
(d) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

9. Disclosures may be made to organizations deemed qualified by the Secretary to carry out quality assessment, medical audits or utilization review.

10. Disclosures may be made in the course of employee discipline or competence determination proceedings to parties involved in the proceedings such as police, attorneys, and Office of Personnel Management employees.

11. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

12. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected (e.g., to the Department of Justice or other appropriate Federal agencies in defending claims against the United States when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual).

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Index cards, folders, notebooks, file cabinets, desk drawers, Rolodex, Kardex, index boxes, logs, file folders, boxes, hanging desk files, manilla folders, wooden box, and vertical files.

**RETRIEVABILITY:**

By patient's name and staff's name.

**SAFEGUARDS:**

Offices locked, file cabinets locked, desk drawers locked. Material available only to appropriately trained social services professional and support staff, implemented through an employee photo I.D. program in accordance with DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 in the General Administration Manual.

**RETENTION AND DISPOSAL:**

Records may be retired to a Federal Records Center and subsequently disposed of in accordance with the ADAMHA Records Control Schedule.

The records control schedule and disposal standard for these records may be obtained by writing the System Manager at the address below.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director of Social Services
A Building, Room 221
Washington, D.C. 20032

**NOTIFICATION PROCEDURE:**

Active or discharged patients in this system of records may learn if a record exists upon written request, with notarized signature if request is made by mail, or with suitable identification if request is made in person, directed to:

Privacy Act Coordinator
Office of the Director of Social Services
A Building, Room 221
Saint Elizabeths Hospital
Washington, D.C. 20032

All of the following information must be provided when requesting notification:

(a) full name;
(b) the approximate dates of contact with the hospital;
(c) the nature of the material desired;
(d) hospital number, if possible.

A parent or guardian who requests notification of a child's/incompetent person's record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child/incompetent person as well as his/her own identity.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Past and present patients of Saint Elizabeths Hospital, home sponsors, caretakers, owners, and operators of facilities providing services to Saint Elizabeths patients, other employees of Saint Elizabeths Hospital, employees of various agencies of the District of Columbia and the United States.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0009**

**SYSTEM NAME:**

Saint Elizabeths Hospital Multidisciplinary Raw Data Consultation Files. HHS/ADAMHA/NIMH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Widely decentralized at Saint Elizabeths Hospital. Raw data is stored according to location of the consulting discipline within Saint Elizabeths Hospital, Washington, D.C. 20032. Records are stored at the Washington National Records Center, 4205 Suitland Road, Washington, D.C. 20409.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Past and present patients at Saint Elizabeths Hospital.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Raw test data, plus copies of formal reports based on the raw test data. (The original reports are included in patient's medical/clinical record).

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

24 USC 161, et seq.; 21 D.C. Code 562, Hospitalization of the Mentally Ill Act.

**PURPOSE(S):**

1. Detailed reference by consultants, following clinical requests for reassessment or more detailed information of patients previously tested.
2. Detailed comparison of test-retest results in cases where clinically indicated or requested.
3. Occasional compilations of specific clinical characteristics of statistical groupings, such as by disease, entity, age, sex, etc. for clinical research and improvement of clinical reporting.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

2. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected (e.g., to the Department of Justice or other appropriate Federal agencies in defending claims against the United States when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual).

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File folders and index cards, file cabinets.

**RETRIEVABILITY:**

Each consulting discipline stores and manages its own files. Some are stored by patients' names alphabetized, some by patients' numbers, some by other types of categorizing, such as disease categories, year consultation was performed, referring clinical service, or an arbitrary numerical sequence. The latter usually involve a cross-indexing card file by patient name and/or patient number.

**SAFEGUARDS:**

Files accessible only to qualified members of the consulting staff of the particular discipline, and are kept in staffed or otherwise locked offices. These safeguards are in accordance with DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 in the General Administration Manual.

**RETENTION AND DISPOSAL:**

Records may be retired to a Federal Records Center and subsequently disposed of in accordance with the ADAMHA Records Control Schedule. The records control schedule and disposal standard for these records may be obtained by writing the System Manager at the address below.

**SYSTEM MANAGER(S) AND ADDRESS:**

Superintendent
A Building, Room 109
Saint Elizabeths Hospital
Washington, D.C. 20032

**NOTIFICATION PROCEDURE:**

A patient or former patient may learn if a record exists upon written request, with notarized signature if request is made by mail, or with suitable identification if request is made in person, directed to:

Privacy Act Coordinator
Office of Superintendent
A Building, Room 109
Saint Elizabeths Hospital
Washington, D.C. 20032

All of the following information must be provided when requesting notification:

(a) full name;
(b) approximate dates of enrollment at St. Elizabeth's Hospital;
(c) the nature of the material desired;
(d) if possible, the name of the person who collected the data. A parent or guardian who requests notification of a child's/incompetent person's record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, must be sent. The parent or guardian must verify relationship to the child/incompetent person as well as his/her own identity.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Clinical testing of patients referred for consultation.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0010**

**SYSTEM NAME:**

Saint Elizabeths Hospital Juvenile Education Monitoring System. HHS/ADAMHA/NIMH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Dix Building
Saint Elizabeths Hospital
Washington, D.C. 20032 and
Washington National Records Center
4205 Suitland Road
Washington, D.C. 20409

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

All patients under 18 years of age on rolls of Saint Elizabeths Hospital.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Inpatient and outpatient educational records. The educational records contain identifying data, name, date, and place of birth, age, sex, race, legal category, leave and residential status, admission, discharge date, identification of relative, hospital identification, educational information, current functional level, educational achievement, medical, neurological, and/or psychological problems with significant influence, patient adjustment to educational program, past/present academic educational plan or program. Reports or notes of others who contribute to a patient's educational development.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

24 U.S.C. 161 and Mills v. Bd. of Education of the Dist. of Columbia, 348 F. Supp. 866 (DCDC 1972).

**PURPOSE(S):**

1. To monitor academic education programs of patients under 18 years of age on rolls of Saint Elizabeths Hospital.
2. To document a patient's educational achievement, to provide for continuous monitoring.
3. To provide a continuous psycho-educational program for the individual patient, including a follow-up program for reference upon future hospitalization.
4. For use by agency personnel for periodic assessment of the quality of educational achievement.
5. To assist the staff in providing for a patient's educational needs.
6. To occasionally provide the basis for action in the course of employee discipline or competence determination proceedings.
7. To facilitate teaching programs and scientific research; to further knowledge in the areas of diagnosis and treatment, comparative studies and special educational programs.
8. Indexes based on the educational records are routinely used for:

a. speedy identification and location of specific patients;
b. monitoring the completeness of patient-educational records, particularly those under 18;
c. monitoring the changing status of patients, either in terms of transfers within the Hospital or outside the Hospital;
d. easy identification of basic demographic data used for statistical and/or research purposes;
e. quick review of current treatment regimen in individual cases.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

2. Disclosures may be made in routine reports prepared for D.C. School Board personnel.

3. Disclosures may be made on patient's behalf, in matters such as educational achievement needs, to third parties whose involvement would be of benefit to the patient, such as to D.C. School Board personnel for students with specialized educational placement needs.

4. Disclosures may be made to courts of local jurisdictions in mandatory reports under Federal and local law.

5. Information may be transmitted to the Department of Special Education of the District of Columbia Public School System, to assist in coordinating educational efforts as mandated by Mills v. Board of Education of D.C., 348 F. Supp. 866 (D.C.D.C. 1972).

6. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected (e.g., to the Department of Justice or other appropriate Federal agencies in defending claims against the United States when the claim is based upon individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual).

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are in the Dix Building. File folders with general educational record and correspondence files are kept in metal file cabinets. Index cards, monitoring cards, kardex are in their appropriate containers.

**RETRIEVABILITY:**

Index by patient's name, Hospital number, division.

**SAFEGUARDS:**

1. Available only to properly trained and screened personnel.
2. Access limited to authorized educational and hospital staff only. Enforced by security personnel. Rooms are locked when unoccupied. These safeguards are in accordance with DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 in the General Administration Manual.

**RETENTION AND DISPOSAL:**

Records may be retired to a Federal Records Center and subsequently disposed of in accordance with the ADAMHA Records Control Schedule. The records control schedule and disposal standard for these records may be obtained by writing the System Manager at the address below.

**SYSTEM MANAGER(S) AND ADDRESS:**

Acting Director for The Child and Adolescent Division
Dix Building, Room 308
Saint Elizabeths Hospital
Washington, D.C. 20032

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about himself/herself upon written request, with notarized signature if request is made by mail, or with suitable identification if request is made in person, directed to:
Privacy Act Coordinator
Office of the Acting Director for The Child and Adolescent Division
Dix Building
Saint Elizabeths Hospital
Washington, D.C. 20032

All of the following information must be provided when requesting notification:
(a) Full name and home address
(b) Approximate dates of enrollment at Saint Elizabeths Hospital
(c) Division where treatment is or was provided, and education level
(d) The nature of the material desired

A parent or guardian who requests notification of a child's/incompetent person's record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child/incompetent person as well as his/her own identity.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Educational records: a compilation of sociological, medical and historical data of a patient. The information recorded as given by the patient, his relatives, or other third parties interested in the patient; from existing records used as reference; from educational tests, such as tests administered by physicians, psychiatrists, teachers, social workers; other therapists who entered their observations and assessment by means of progress notes, reports etc.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0011**

**SYSTEM NAME:**

Saint Elizabeths Hospital Emergency Psychiatric Service Non-Admission File System. HHS/ADAMHA/NIMH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Emergency Psychiatric Service
Dix Building
Saint Elizabeths Hospital
Washington, D.C. 20032

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals who have presented themselves at the Emergency Pyschiatric Service but who were not admitted to the rolls of Saint Elizabeths Hospital.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Personal identifying data collected during admissions screening interview, information from previous hospitalizations, of clinic enrollment, and information about individuals collected from telephone conversations with interested persons.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

24 USC 161, et seq.; 21 D.C. Code 501, et seq., Hospitalization of the Mentally Ill Act.

**PURPOSE(S):**

To provide additional screening material in cases of repeated applications for admission of the same patient.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected (e.g., to the Department of Justice or other appropriate Federal agencies in defending claims against the United States when the claim is based upon individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual).

2. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Documents maintained in file cabinets.

**RETRIEVABILITY:**

Filed alphabetically by name.

**SAFEGUARDS:**

Access limited to authorized hospital, medical, social service and support

personnel only, enforced by security force. Rooms are locked when unoccupied. These safeguards are in accordance with DHHS Chapter 45-13 and supplementary PHS.hf:45-13 in the General Administration Manual.

**RETENTION AND DISPOSAL:**

The records control schedule and disposal standard for these records may be obtained by writing the System Manager at the address below.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, Emergency Psychiatric Service
Saint Elizabeths Hospital
Washington, D.C. 20032

**NOTIFICATION PROCEDURE:**

A person denied admission may learn if a record exists about himself/herself upon written request, with notarized signature if request is made by mail, or with suitable identification if request is made in person, directed to:

Privacy Act Coordinator
Office of the Director
Emergency Psychiatric Service
Saint Elizabeths Hospital
Washington, D.C. 20032

All of the following information must be provided when requesting notification:
(a) Full name;
(b) Approximate date the person sought admission;
(c) The nature of the material desired.

A parent or guardian who requests notification of a child's/incompetent person's record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child/incompetent person as well as his/her own identity.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Interviews with persons applying for admission but ultimately not admitted, hospital records of prior admissions, and information provided by other persons related to or interested in the person seeking admission.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0012**

**SYSTEM NAME:**

Saint Elizabeths Hospital Pre-Service Education Records. HHS/ADAMHA/NIMH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Saint Elizabeths Hospital
Washington, D.C. 20032
and Washington National Records Center
4205 Suitland Road
Washington, D.C. 20409

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Students and trainees in medical and nonmedical mental health education programs, including persons who receive stipends and those who do not.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Record categories include: (1) application data including transcripts, references, special health records where indicated, evaluation of prior training or education; (2) assessment and evaluation data regarding educational experiences at SEH; and (3) correspondence.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Public Health Service Act, Section 301(42 U.S.C. 241).

**PURPOSE(S):**

Records are used for: evaluation for selection and appointment; supervisory guidance and assessment; reference requests; specialized teaching resources, and program evaluation.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosure may be made to organizations deemed qualified by the Secretary to carry out quality assessment, medical audits, or utilization review.

2. Disclosures may be made in the course of employee discipline or competence determination proceedings to parties involved in the proceedings such as police, attorneys, and Office of Personnel Management employees.

3. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected (e.g., to the Department of Justice or other appropriate Federal agencies in defending claims against the United States when the claim is based upon individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual).

4. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Written documents in file folders and filing cabinets; audio and video tape reels in locked storage cabinets.

**RETRIEVABILITY:**

System is filed by name of individual, dates of training, disciplinary area in which training was received, primary supervisor, and whether the training was stipended or non-stipended.

**SAFEGUARDS:**

Records are maintained in monitored offices and are only available to authorized hospital training instructors and support personnel. These safeguards are in accordance with DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 in the General Administration Manual.

**RETENTION AND DISPOSAL:**

Records may be retired to a Federal Records Center and subsequently disposed of in accordance with the ADAMHA Records Control Schedule. The records control schedule and disposal standard for these records may be obtained by writing the System Manager at the address below.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, Overholser Division of Training
Saint Elizabeths Hospital
Washington, D.C. 20032

**NOTIFICATION PROCEDURE:**

Individual student or trainee may learn if a pre-service education record exists upon written request, with notarized signature if request is made by mail, or with suitable identification if request is made in person, directed to:
Privacy Act Coordinator
Office of Director
Overholser Division of Training,
Saint Elizabeths Hospital
Washington, D.C. 20032

All the following identifying information must be provided when requesting notification:
(a) full name;
(b) inclusive dates of training;
(c) specific disciplinary area in which training was received and organizational unit where assigned;
(d) name of primary supervisor;
(e) status in terms of stipended or non-stipended.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Information is obtained from the individual trainee or student, persons supplying reference data, supervisory and administrative personnel, and other persons directly involved with the individual's educational program.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0013**

**SYSTEM NAME:**

Saint Elizabeths Hospital Training Videotape Records. HHS/ADAMHA/NIMH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Saint Elizabeths Hospital
Washington, D.C. 20032
and
Washington National Records Center
4205 Suitland Road
Washington, D.C. 20409

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

SEH patients, trainees and staff of SEH.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Videotapes of interviews, activities, or other interactions between SEH patients and professional trainees and staff of SEH; authorizations (informed consent) signed by patients.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Public Health Service Act, Section 301(42 U.S.C. 241).

**PURPOSE(S):**

Training and education of staff.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

2. In the event of litigation where the defendent is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for the records were collected (e.g., to the Department of Justice or other appropriate Federal agencies in defending claims against the United States when the claim is based upon individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual).

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Videotape reels, authorizations retained in file folders.

**RETRIEVABILITY:**

Name of patient, name of interviewer.

**SAFEGUARDS:**

Locked files in monitored offices. Access only to authorized supervisory, clinical training and support personnel. These safeguards are in accordance with DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 in the General Administration Manual.

**RETENTION AND DISPOSAL:**

Records may be retired to a Federal Records Center and subsequently may be disposed of in accordance with the ADAMHA Records Control Schedule. The records control schedule and disposal standard for these records may be obtained by writing the System Manager at the address below.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, Overholser Division of Training
Saint Elizabeths Hospital
Washington, D,C. 20032

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about himself/herself upon written request, with notarized signature if request is made by mail, or with suitable identification if request is made in person, directed to:
Privacy Act Coordinator
Office of the Director, Overholser Division of Training
Saint Elizabeths Hospital
Washington, D.C. 20032

All of the following information must be provided when requesting notification:
(a) full name;
(b) approximate data of videotaping;
(c) name of interviewer;
(d) the capacity in which the requester had contact with the hospital; e.g., patient, staff member, trainee;
(e) if possible, in the case of patients, the hospital number;
(f) location of unit where videotaping occurred.

A parent or guardian who requests notification of a child's/incompetent person's record shall designate a family physician or other health professional (other than a family member) to whom

the record, if any, will be sent. The parent or guardian must verify relationship to the child/incompetent person as well as his/her own identity.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

SEH patients, trainees and staff.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0014**

**SYSTEM NAME:**

Saint Elizabeths Hospital Financial System. HHS/ADAMHA/NIMH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Finance Office, Room 200,
Administration Building
Saint Elizabeths Hospital
Washington, D.C. 20032
and
Washingtion National Records Center
4205 Suitland Road
Washington, D.C. 20409
Billing records may also be located at contractor sites.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Present and former employees and patients.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Deposits; receipts; disbursements; balances; NCR ledger cards; vouchers; information on expenses of travel and education; billings; background history; reimbursement claims; Industrial Therapy Program data: Internal Revenue Service Form W-4 and D.C. Government Form D-4, Payroll Summary sheets and individual patient ledger cards for patient workers in Patient Worker Industrial Therapy Program (PWITP), and indebtedness letters.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Hospitalization of the Mentally Ill Act, 21 DC Code 511 et seq.; 24 USC 165 and 166; 31 USC 66A and 628a.

**PURPOSE(S):**

To record expenditures and reimbursements for services and goods and all other financial transactions consistent with the management of the Hospital. Information in these records is also used within the Finance Office to determine the amount of pay a patient earns for his Industrial Therapy assignment, and for completing patients' time sheets, payroll summary sheets, income tax withholding forms, and monthly or quarterly earnings and tax returns.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office at the written request of that individual.

2. Disclosures may be made in order to pay travel claims and educational institutions, expenses; to collect from the D.C. Government and Federal agencies for care and treatment; and to collect for quarters, lost or damaged property & other indebtedness to the Government.

3. Disclosures may be made to references for outside employment, to referral sources for determining if job placement meets a patient's therapeutic needs, and to outside agencies in order to obtain referrals.

4. Disclosures may be made to prospective employers and other similar recipients as evidence of the individual's increased responsibility, and to followup reasons for a patient's absence from his Industrial Therapy assignments.

5. In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether federal (e.g., Department of Justice), State or local (e.g., State and local licensing boards), charged with the responsiblity of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto.

6. Where federal agencies having the power to subpoena other federal agencies' records, such as the Internal Revenue Service or the Civil Rights Commission, issue a subpoena to the Department for records in this system of records, the Department will make such records available.

7. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected (e.g., to the Department of Justice or other appropriate Federal agencies in defending claims against the United States when the claim is based upon individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual).

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File folders in metal filing cabinets, index cards, and IBM cards.

**RETRIEVABILITY:**

Voucher date and number; numerically (receipts for patient's funds); alphabetically by name; Health Insurance Number and Hospital Case Number (Health Insurance records); bill number (for billings).

**SAFEGUARDS:**

Access is limited to personnel who process the data. Offices are locked when not occupied. These safeguards are in accordance with DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 in the General Administration Manual.

**RETENTION AND DISPOSAL:**

Records may be retired to a Federal Records Center and subsequently disposed of in accordance with the ADAMHA Records Control Schedule. The records control schedule and disposal standard for these records may be obtained by writing the System Manager at the address below.

**SYSTEM MANAGER(S) AND ADDRESS:**

Finance Officer
Administration Building, Room 200
St. Elizabeths Hospital
Washington, D.C. 20032

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about himself/herself upon written request, with notarized signature if request is made by mail, or with suitable identification if request is made in person, directed to:

Privacy Act Coordinator
Finance Office, Room 200,
Administration Building
Saint Elizabeths Hospital
Washington, D.C. 20032

All of the following information must be provided when requesting notification:
(a) full name;
(b) dates of the contact with Saint Elizabeths Hospital;
(c) the Branch, Division, or Office with which the requester had contact;
(d) the capacity in which the requester had contact with the hospital, e.g., patient, employee, vendor, representative of professional organization, etc;
(e) the nature of the material desired. A parent or guardian who requests notification of a child's/incompetent person's record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, must be sent. The parent or guardian must verify relationship to the child/incompetent person as well as his/her own identity.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Patient name plates, patient's accounts, receipts for patients' funds (generated when cash or other funds are accepted from a patient), patients' payroll data from the Industrial Therapy Section.

Patients' clinical records, interviews with ward staff, patient and work supervisor. Patient vouchers from patient, employees, Finance Section, Personnel Branch, Agency Cashier, patients' relatives, committees, conservators and other Government agencies. Patients' account data from the Agent Cashier.

Health Insurance data from the Patient's Medical Record, Social Security Administration, relatives and conservators, and Registrar.

Billings for care and treatment, quarters, etc. and indebtedness to the Government, Information Systems Branch, Housekeeping Section, Agent Cashier, and Administrative Services Section.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0015**

**SYSTEM NAME:**

Saint Elizabeths Hospital General Security System. HHS/ADAMHA/NIMH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Security Headquarters
Allison - B Building
St. Elizabeths Hospital
Washington, D.C. 20032
and
Washington National Records Center
4205 Suitland Road
Washington, D.C. 20409

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Former and current patients, employees, relatives, volunteers and visitors.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Identifying information including one or more of name, hospital number, photo, key number, vehicle sticker number, authorization to admit, dates and times of visits, addresses and other personal data.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

24 USC 161, et seq.

**PURPOSE(S):**

To monitor authorized access and exit of individuals and vehicles to and from buildings and grounds of Hospital: accountability of building and room key assignments and vehicle sticker assignments; identification for search of missing persons.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether federal (e.g., Department of Justice), State or local (e.g., State or local licensing boards), charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto.

2. Disclosures may be made in the course of employee dicipline or competence determination proceedings to parties such as police, attorneys, and Office of Personnel Management employees.

3. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected (e.g., to the Department of Justice or other appropriate Federal agencies in defending claims against the United States when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual).

4. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Index cards, file folders, picture files.

**RETRIEVABILITY:**

Name, hospital number, sticker and key number, and chronologically.

**SAFEGUARDS:**

Access is limited to authorized security and hospital personnel. Area is secured by 24-hour security guard. These safeguards are in accordance with DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 in the the General Administration Manual.

**RETENTION AND DISPOSAL:**

Records may be retired to a Federal Records Center and subsequently disposed of in accordance with the ADAMHA Records Control Schedule. The records control schedule and disposal standard for these records may be obtained by writing the System Manager at the address below.

**SYSTEM MANAGER(S) AND ADDRESS:**

Captain, Security Force
St. Elizabeths Hospital
Washington, D.C. 20032

**NOTIFICATION PROCEDURE:**

A patient, former patient, employee, former employee, relative of patient, volunteer or visitor may learn if a record exists about himself/herself, upon written request, with notarized signature if request is made by mail, or with suitable identification if request is made in person, directed to:

Privacy Act Coordinator
Security Force
St. Elizabeths Hospital
Washington, D.C. 20032

All of the following information must be provided when requesting notification:
(a) full name;
(b) the capacity in which the requester had contact with St. Elizabeths Hospital;
(c) the approximate dates of contact with the hospital;
(d) the nature of the material desired.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Hospital staff, medical records, patients and relatives of patients.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0016**

**SYSTEM NAME:**

Saint Elizabeths Hospital Patients' Personal Property Record System. HHS/ADAMHA/NIMH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Patients Property Unit
Glenside Building
Saint Elizabeths Hospital
Wash., D.C. 20032
and
Washington National Records Center
4205 Suitland Road
Washington, D.C. 20409

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Former and Current Patients.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Inventory of patient's private property on admission, newly acquired property, released property and unclaimed property. 2. Comments on condition of private property, damages, lost and storage status. 3. Receipts of authorization for purchases and vendors' receipts.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

24 USC 161, et seq.

**PURPOSE(S):**

Documenting entries and releases of personal property; accounting and verifying documented inventories and purchases; internal referrals by patient property office staff and legally appointed administrators.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

2. In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether federal (e.g., Department of Justice), State or local (e.g., State and local licensing boards), charged with the responsiblity of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto.

3. Disclosures may be made in the course of employee discipline or competence determination proceedings to parties involved in the proceedings such as police, attorneys, and Office of Personnel Management employees.

4. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected (e.g., to the Department of Justice or other appropriate Federal agencies in defending claims against the United States when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual).

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Folders and cards.

**RETRIEVABILITY:**

By name, alphabetized.

**SAFEGUARDS:**

Only patient property staff have access to locked file cabinets. At night building is locked and secured by 24-hour security guards. These safeguards are in accordance with DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 in the General Administration Manual.

**RETENTION AND DISPOSAL:**

Records may be retired to a Federal Records Center and subsequently disposed of in accordance with the ADAMHA Records Control Schedule. The records control schedule and disposal standard for these records may

be obtained by writing the System Manager at the address below.

**SYSTEM MANAGER(S) AND ADDRESS:**

Supervisory Storage Management Specialist
Patients Property Unit
Glenside Building
Saint Elizabeths Hospital
Washington, D.C. 20032

**NOTIFICATION PROCEDURE:**

A patient or former patient may learn if a record exists upon written request, with notarized signature if request is made by mail, or with a suitable identification if request is made in person, directed to:

Privacy Act Coordinator
Property Unit
Glenside Building
Saint Elizabeths Hospital
Washington, D.C. 20032

All of the following data must be provided when requesting notification:
(a) full name;
(b) approximate dates of enrollment at Saint Elizabeths Hospital;
(c) if possible, the patient's hospital number;
(d) the nature of the material desired. A parent or guardian who requests notification of a child's/incompetent person's record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, must be sent. The parent or guardian must verify relationship to the child/incompetent person as well as his/her own identity.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Admission report lists, ward reports, patients' correspondence files.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0017**

**SYSTEM NAME:**

Saint Elizabeths Hospital Legal Office Record System. HHS/ADAMHA/NIMH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Legal Advisor's Office, Room 226
Administration Building
Saint Elizabeths Hospital
Washington, D.C. 20032
and
Washington National Records Center
4205 Suitland Road
Washington, D.C. 20409

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Former and current patients and employees.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Information concerning the legal status and aspects of former and current patients and employees.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

42 U.S.C. 3504.

**PURPOSE(S):**

To determine, monitor, and follow up legal status, rights, and problems of individual employees and patients. Used as resource material in preparation for civil actions or proceedings.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosures may be made in negotiations with U.S. Attorney's Office, D.C. Courts, Mental Health Commission, Corporation Counsel, Justice Department, attorneys and others concerned with the legal considerations of patients and employees.
2. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.
3. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purposes for which the records were collected (e.g., to the Department of Justice or other appropriate Federal agencies in defending claims against the United States when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual).

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File folders and index cards.

**RETRIEVABILITY:**

Patient or employee name.

**SAFEGUARDS:**

Access restricted to Legal Office staff with photo I.D. Locked at night. Building secured with 24-hour guard. These safeguards are in accordance with DHHS Chapter 45-13 and supplementary Chapter 45-13 in the General Administration Manual.

**RETENTION AND DISPOSAL:**

Records may be retired to a Federal Records Center and subsequently disposed of in accordance with the ADAMHA Records Control Schedule. The records control schedule and disposal standard for these records may be obtained by writing the System Manager at the address below.

**SYSTEM MANAGER(S) AND ADDRESS:**

Legal Advisor
Administration Building
Saint Elizabeths Hospital
Washington, D.C. 20032

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about himself/herself, subject to the limitations of 5 USC 552a(d)(5), upon written request, with notarized signature if the request is made by mail, or with suitable identification if request is made in person, directed to:
Privacy Act Coordinator
Legal Advisor's Office
Saint Elizabeths Hospital
Washington, D.C. 20032
All of the following information must be provided when requesting notification:
(a) full name;
(b) the capacity in which the requester had contact with St. Elizabeths Hospital;
(c) the approximate dates of contact with the hospital;

(d) the nature of the material desired. A parent or guardian who requests notification of a child's/incompetent person's record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, must be sent. The parent or guardian, must verify relationship to the child/incompetent person as well as his/her own identity.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Patient records, commitment folders, staff reports, Auditor's Office of D.C. Superior Court, Court System of D.C., Mental Health Commission, U.S. Attorney's Office, Corporation Counsel and private attorneys.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0018**

**SYSTEM NAME:**

Saint Elizabeths Hospital Area D Community Mental Health Center Citizens Advisory Group Records. HHS/ADAMHA/NIMH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Area D Community Mental Health Center
Saint Elizabeths Hospital
Washington, D.C. 20032

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Members of Citizens Advisory Committee, agencies, organizations, school students and citizens interested in CMHC activities.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Names, addresses, telephone numbers, occupations, transmittal letters and various memoranda.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963 (42 U.S.C. 2661 et seq.).

**PURPOSE(S):**

To maintain a directory of persons and organizations and a file of communications with those who act in an advisory capacity to Area D Community Mental Health Center.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Mailing lists with names and addresses are exchanged with Area D citizens groups.

2. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

3. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected (e.g., to the Department of Justice or other appropriate Federal agencies in defending claims against the United States when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual).

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File folders, index cards and paper tapes in cabinets.

**RETRIEVABILITY:**

By name.

**SAFEGUARDS:**

Access is limited to authorized community mental health center personnel only. All personnel screened. Files locked after business hours. These safeguards are in accordance with DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 in the General Administration Manual.

**RETENTION AND DISPOSAL:**

Records may be retired to a Federal Records Center after three years.

**SYSTEM MANAGER(S) AND ADDRESS:**

Associate Director for Community Liaison and Public Education
Area D - CMHC, R Building
St. Elizabeths Hospital
Washington, D.C. 20032

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to:

Privacy Act Coordinator
Assoc. Director for Community Liaison and Public Education
Area D Community Mental Health Center
St. Elizabeths Hospital
Washington, D.C. 20032

All the following information must be provided when requesting notification:
(a) full name;
(b) capacity in which requester had contact with the CMHC Area D Citizen Advisory group;
(c) nature of information desired.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Information is voluntarily written on sign-in sheets at various community meetings and solicited through surveys.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0019**

**SYSTEM NAME:**

Saint Elizabeths Hospital Court-Ordered Forensic Investigatory Materials File. HHS/ADAMHA/NIMH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Active Patients:
Saint Elizabeths Hospital
John Howard Pavilion

Washington, D.C. 20032

Inactive patients (discharged or deceased): In the basement of Dix Building, Saint Elizabeths Hospital; and inactive patient records older than four years are stored in the Washington National Records Center, 4205 Suitland Road, Washington, D.C. 20409.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Past and present patients committed to Saint Elizabeths Hospital pursuant to the District of Columbia and United States Criminal Codes. Included are alleged criminal offenders sent for pre-trial examination; persons committed after having been found not guilty by reason of insanity; and mentally ill sentenced prisoners transferred from penal institutions.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Court orders; criminal records; police reports; reports from the FBI and the Secret Service; prison records; reports from the United States Attorney and/or Corporation Counsel; correspondence from courts, defense attorneys and prosecutors; probation and parole reports; and, correspondence from Saint Elizabeths Hospital to the Courts, prosecution, defense and correctional authorities.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

24 D.C. Code Sections 301(a), 301(b), 301(d), 302; 24 U.S.C. 161 and 211 et seq.

**PURPOSE(S):**

To aid in evaluation of patients regarding their competency and criminal responsibility, to aid in treatment of criminally committed patients, and to comply with court-ordered reporting.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Psychiatric evaluations based in part on this record are forwarded to referring courts, pursuant to court order, with copies to defense and prosecuting attorneys.

2. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to affect directly the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected (e.g., to the Department of Justice or other appropriate Federal agencies in defending claims against the United States when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual).

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Stored in file folders in file cabinets.

**RETRIEVABILITY:**

Retrieved by patient name and hospital number.

**SAFEGUARDS:**

Available only to properly trained and screened personnel. Access limited to authorized individuals only. Enforced by security personnel. Rooms are locked when unoccupied. These safeguards are in accordance with DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 in the General Administration Manual.

**RETENTION AND DISPOSAL:**

Records may be retired to a Federal Records Center after five years.

**SYSTEM MANAGER(S) AND ADDRESS:**

Chief, Pre-trial Section or
Chief, Post-trial Section
Division of Forensic Programs
Saint Elizabeths Hospital
Washington, D.C. 20032

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the System Manager at the address above. An individual who requests notification of, a medical record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion. A parent or guardian who requests notification of a child's/incompetent person's record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, must be sent. The parent or guardian must verify relationship to the child/incompetent person as well as his/her own identity.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. Access to record systems which have been granted an exemption from the Privacy Act access requirement may be made at the discretion of the System Manager. Appeal of access refusal may be made to the Administrator, Alcohol, Drug Abuse, and Mental Health Administration.

**CONTESTING RECORD PROCEDURES:**

If access has been granted, contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Courts, police department, FBI, Secret Service, prisons, U. S. Attorney, Corporation Counsel, defense attorneys, prosecuting attorneys, and correctional authorities.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

Exemption from notification, record access and contest provisions granted under (j)(2) of the Privacy Act.

**09-30-0020**

**SYSTEM NAME:**

Administrative Records on Civilly Committed Drug Abusers Under the Narcotic Addict Rehabilitation Act. HHS/ADAMHA/NIDA.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Prevention and Communications
National Institute on Drug Abuse
Room 10A-56, Parklawn Bldg.
5600 Fishers Lane
Rockville, Md. 20857

Federal Records Center
1557 St. Joseph Avenue
East Point, Georgia 30344

Washington National Records Center
4205 Suitland Road
Washington, D.C. 20409

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Civilly committed narcotic addicts, 1967-1978.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Administrative records of rehabilitation status, court orders and petitions to the court.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Narcotic Addict Rehabilitation Act, Titles I and III (28 U.S.C. 2901 et seq.. and 42 U.S.C. 3411 et seq.).

**PURPOSE(S):**

To enable the Federal Government to monitor patient progress from time of entrance into treatment program until discharge by court.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

We may disclose those records collected prior to the enactment of the HHS regulations (August 1, 1975) concerning the confidentiality of drug abuse and alcohol patient records (42 CFR Part 2),

in the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records at National Institute on Drug Abuse are stored on microfilm in locked file cabinets. Records sent to Federal Records Center are stored in GSA-approved storage containers.

**RETRIEVABILITY:**

Filed by patient hospital number; crossed-indexed by patient name.

**SAFEGUARDS:**

Only the system manager and personnel trained in microfilm retrieval have access to these files. Access to the files is limited; files are locked at all times, unless in use. The safeguards described are in accordance with DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 in the General Administration Manual.

**RETENTION AND DISPOSAL:**

The hard copy of the records has been retired to the Federal Records Center. These records and the microfilm (contains only a portion of the hard copy administrative record) will be subsequently disposed of five years after the repeal of the Narcotic Addict Rehabilitation Act.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director
Division of Prevention and Communications
National Institute on Drug Abuse
Room 10A-56, Parklawn Bldg.
5600 Fishers Lane
Rockville, Md. 20857

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the System Manager at the address above. An individual may learn if a record exists about himself or herself upon written request with notarized signature. The request should include, if known: patient record number, patient's address during treatment, birth date, and approximate dates in treatment.

**RECORD ACCESS PROCEDURES:**

Same as Notification Procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under Notification Procedures above, and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Patients; patients' drug treatment program counselors; court records.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0021**

**SYSTEM NAME:**

Patient Medical Records on PHS Beneficiaries 1935-1974 and Civilly Committed Narcotic Addicts 1967-1978 Treated at the PHS Hospitals, Fort Worth, Texas and Lexington, Kentucky, HHS/ADAMHA/NIDA.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Prevention and Communications
National Institute on Drug Abuse
Room 10A-56, Parklawn Bldg.
5600 Fishers Lane
Rockville, Md. 20857

Division of Mental Health Services
National Institute of Mental Health
Room 11-105, Parklawn Bldg.
5600 Fishers Lane
Rockville, Md. 20857

Federal Records Center
1557 St. Joseph Avenue
East Point, Georgia 30344

Washington National Records Center
4205 Suitland Road
Washington, D.C. 20409

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

PHS beneficiaries treated 1935-1974 and civilly committed narcotic addicts treated 1967-1978 at the PHS hospitals at Lexington, Kentucky and Fort Worth, Texas.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Patient medical records.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Public Health Service Act Sections 321-326, 341(a)and(c), (42 U.S.C. 248-253,257(a)and(c)); Narcotic Addict Rehabilitation Act, Titles I and III, (28 U.S.C. 2901 et seq. and 42 U.S.C. 3411 et seq.).

**PURPOSE(S):**

To provide information to health care providers of the Public Health Service, in order for them to monitor and insure continuity of care.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

We may disclose those records collected prior to the enactment of the HHS regulations (August 1, 1975) concerning the confidentiality of drug abuse and alcohol patient records (42 CFR Part 2), in the event of litigation where the defendant is (a) the Department, any component of the Department or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect operations of the Department or any of its components; or (c) any Department employee in his or her

individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records at the National Institute on Drug Abuse are stored on microfilm in locked file cabinets. Records sent to the Federal Records Center are stored in GSA-approved storage containers.

**RETRIEVABILITY:**

Filed by patient hospital number; crossed-indexed by patient name.

**SAFEGUARDS:**

Only the system manager and support staff with the Division of Prevention and Communications are allowed access to these files. Files are locked at all times, unless in use. The safeguards described are in accordance with DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 in the General Administration Manual.

**RETENTION AND DISPOSAL:**

The hard copy of the records has been retired to a Federal Records Center. These records and microfilm (which contain only a portion of the hard copy administrative records except patient records from 1935-1974) will be subsequently disposed of in accordance with the ADAMHA Records Control Schedule. The records control schedule and disposal standard for these records may be obtained by writing the System Manager at the address below.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director
Division of Prevention and Communications
National Institute on Drug Abuse
Room 10A-56, Parklawn Bldg.
5600 Fishers Lane
Rockville, Md. 20857

Chief, Mental Health Care & Services Financing Branch
National Institute of Mental Health
Room 11-105, Parklawn Bldg
5600 Fishers Lane
Rockville, Md. 20857

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the System Manager at the address above. Provide a notarized signature as proof of identity. The request should include, if known: patient record number, any alias used, hospital name and/or location, and approximate dates when in the hospital.

An individual who requests notification of a medical record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion. A parent or guardian who requests notification of a child's/incompetent person's record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, must be sent. The parent or guardian must verify relationship to the child/incompetent person as well as his/her own identity.

**RECORD ACCESS PROCEDURES:**

Same as Notification Procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Patients, hospital staff, drug treatment program counselors, and court records.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0022**

**SYSTEM NAME:**

National Institute on Drug Abuse, Addiction Research Center, Federal Prisoner and Non-Prisoner Patient Files. HHS/ADAMHA/NIDA.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

NIDA Addiction Research Center
4940 Eastern Avenue, Room 5D-East Wing
Baltimore, MD 21224

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Adult Federal prisoners (involved in research projects from 1968-1976) and adult non-prisoner volunteers (involved in research projects from 1980-present) in intramural drug addiction research program.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

The categories of records involved are administrative, medical and research records.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Public Health Service Act, Sections 301, 341(a), and 344(d)(42 U.S.C. 241(a), 257(a) and 260(d)); Drug Abuse Prevention, Treatment, and Rehabilitation Act, Section 501 (21 U.S.C. 1191).

**PURPOSE(S):**

To enable Federal drug abuse researchers to evaluate and monitor subjects' health during participation in a research project.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File folders within locked file cabinets.

**RETRIEVABILITY:**

Filed alphabetically by subject name.

**SAFEGUARDS:**

Only authorized Addiction Research staff (project director and his/her research team) are allowed access to these files. Files and file room are locked after business hours. The safeguards described are in accordance with DHHS Chapter 45-13 and

supplementary Chapter PHS.hf: 45-13 in the General Administration Manual.

Because much of the data collected in these research projects are sensitive and confidential, special safeguards have been established. Certificates of confidentiality have been issued under 42 CFR Part 2a to those projects initiated since February 1980. This authorization enables persons engaged in research on mental health, including research on the use and effect of psychoactive drugs, to protect the privacy of research subjects by withholding their names or other identifying characteristics from all persons not connected with the conduct of the research. Persons so authorized may not be compelled in any Federal, state, or local civil criminal, administrative, legislative, or other proceeding to identify such individuals. In addition, these records are subject to 42 CFR Part 2, the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations (42 CFR 2.56), which state:

'Where the content of patient records has been disclosed pursuant to these regulations for the purpose of conducting scientific research...information contained therein which would directly or indirectly identify any patient may not be disclosed by the recipient thereof either voluntarily or in response to any legal process whether Federal or State.'

**RETENTION AND DISPOSAL:**

Records will be disposed of in accordance with the ADAMHA Records Control Schedule. The disposal standard for these records may be obtained by writing the System Manager at the address below.

**SYSTEM MANAGER(S) AND ADDRESS:**

Scientific Director
NIDA Addiction Research Center
4940 Eastern Avenue
in care of Baltimore City Hospitals
Baltimore, MD 21224

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the System Manager at the address above. Provide a notarized signature as proof of identity. The request should include the patient's register number and/or the number of years of incarceration, full name at time of participation in the research project, date(s) of research participation, and title of research project or name of drug being studied. An individual who requests notification of a medical record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

**RECORD ACCESS PROCEDURES:**

Same as Notification Procedures. Requesters should also reasonably specify the record contents being sought. An individual who requests notification of a medical record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Patients; drug treatment programs; Bureau of Prisons; case workers; psychiatrists; research laboratories; and pharmacies and hospitals. Many of these records are confidential and privileged communications as guaranteed under Section 344(d) of the PHS Act.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0023**

**SYSTEM NAME:**

Records of Contracts Awarded to Individuals. HHS/ADAMHA/OA.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

National Institute on Drug Abuse
Contracts Management Branch
Room 10-49, Parklawn Bldg.
5600 Fishers Lane
Rockville, MD 20857

National Institute on Alcohol Abuse and Alcoholism
Contracts Management Branch
Room 14-C-06, Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

National Institute of Mental Health
Contracts Management Branch, OPS
Room 18-101, Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Procurement Section
Saint Elizabeths Hospital
Washington, D.C. 20032

Washington National Records Center
4205 Suitland Road
Washington, D.C. 20409

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

An individual who receives a contract as well as individuals who apply or compete for an award but do not receive the award and their consultants.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Curriculum vitae, salary information, evaluations of proposals by contract review committees.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Public Health Service Act Section 301 (42 U.S.C. 241 and 41 U.S.C. 252(c)). NIDA: Drug Abuse Prevention, Treatment and Rehabilitation Act, Sections 410 and 501 (21 U.S.C. 1177 and 1191). NIAAA: Community Mental Health Centers Act, Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 Sections 101 and 311 (42 U.S.C. 4551 and 4577). NIMH: Public Health Service Act Section 455 (42 U.S.C. 289(k-l)).

**PURPOSE(S):**

To document the history of each contract procurement action and award made within ADAMHA to an individual. The records are also used by contract review committee members when evaluating a proposal submitted by an individual.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

2. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that

Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Documents filed in folders in enclosed and/or locked file cabinets.

**RETRIEVABILITY:**

By contract number and cross-indexed by individual's name.

**SAFEGUARDS:**

Released only to authorized Federal contract and support personnel. These safeguards are in accordance with DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 in the General Administration Manual.

**RETENTION AND DISPOSAL:**

Records are retired to a Federal Records Center and subsequently disposed of in accordance with the ADAMHA Records Control Schedule. The records control schedule and disposal standard for these records may be obtained by writing the System Manager at the address below.

**SYSTEM MANAGER(S) AND ADDRESS:**

National Institute on Drug Abuse
Chief, Contracts Management Branch, OPS
Room 10-49, Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

National Institute on Alcohol Abuse and Alcoholism
Chief, Contracts Management Branch
Room 14-C-06, Parklawn Building
5600 Fishers Lane
Rockville, Md. 20857

National Institute of Mental Health
Chief, Contracts Management Branch
Room 18-101, Parklawn Building
5600 Fishers Lane
Rockville, Md. 20857

Procurement Officer
Saint Elizabeths Hospital
Washington, D.C. 20032

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the System Manager at the address above. An individual may learn if a record exists about himself/herself upon written request with notarized signature. The request should include, if known, contractor's name, contract number, and approximate date contract was awarded.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under notification procedures above and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Contract proposals and supporting contract documents, contract review committees, site visitors.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0024**

**SYSTEM NAME:**

Saint Elizabeths Hospital General Administrative Record Systems. HHS/ADAMHA/NIMH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Office of the Superintendent, Room 109
Saint Elizabeths Hospital
2700 Martin Luther King, Jr. Ave. S.E.
Washington, D.C. 20032
and
Washington National Records Center
4205 Suitland Road
Washington, D.C. 20409
A current listing of contractor sites is available from the System Manager listed below.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Former, current, and potential patients and employees.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

(1) Data having potential legal consequences included in investigation reports; (2) letters; (3) memos; (4) minutes of meetings and conferences; (5) organizational charts and assignments; (6) copies of disclosures of medical, biographical, employment, and educational information made from said investigation reports, letters, etc.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

24 USC 161, 21 DC Code 1501, 21 DC Code 562, Hospitalization of the Mentally Ill Act, 5 USC 7902, Executive Order 11807, 9/28/74 and Presidential Safety Policy 10/24/69.

**PURPOSE(S):**

To facilitate the management of the daily administrative functions within the hospital. These functions include the management of the Fire Department, the House-Keeping Section, the Public Information Office, the Clinical Programs, Division of Administration, administration of medical, legal and criminal investigations, accident reports, conservator files, court calendars, evaluation and program assessment of the adequacy of the therapeutic activity, employee performance, conference procedures, organization charts, patient and employee assignments, and source material for congressional and other requests approved by the record System Manager.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosure may be made pursuant to 24 USC 168a to the following federal and local agencies: the District of Columbia, The United States Bureau of Prisons, The Veterans Administration, The United States Soldiers Home, and The State Department to report treatment provided to specific patients, or to report evaluation of potential patients for admission.

2. In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether federal (e.g., Department of Justice), State or local (e.g., State and local licensing boards), charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto.

3. A record from this system of records may be disclosed to a federal agency, in response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the

record is relevant and necessary to the requesting agency's decision on the matter.

4. Where federal agencies having the power to subpoena other federal agencies' records, such as the Internal Revenue Service or the Civil Rights Commission, issue a subpoena to the Department for records in this system of records, the Department will make such records available.

5. Where a contract between a component of the Department and a labor organization recognized under E.O. 11491 provides that the agency will disclose personal records relevant to the organization's mission, records in this system of records may be disclosed to such organization.

6. Disclosure may be made to organizations deemed qualified by the Secretary to carry out quality assessment, medical audits or utilization review.

7. Disclosures may be made in the course of employee discipline or competence determination proceedings to parties involved in the proceedings such as police, attorneys, and Office of Personnel Management employees.

8. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

9. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected (e.g., to the Department of Justice or other appropriate Federal agencies in defending claims against the United States when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual).

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File folders, index cards, subject record book, punch cards, magnetic tapes, charts.

**RETRIEVABILITY:**

Indexed and retrieved by name, hospital case number, Civil Service grade, criminal case number. Records are also filed chronologically.

**SAFEGUARDS:**

Access restricted to administrative and support staff, personnel surveillance, locked files. For computer media records, a password code system is in effect. These safeguards are in accordance with DHHS Chapter 45-13 and supplementary chapter PHS.hf: 45-13 in the General Administration Manual.

**RETENTION AND DISPOSAL:**

Records may be retired to a Federal Records Center and subsequently disposed of in accordance with the ADAMHA Records Control Schedule. The records control schedule and disposal standard for these records may be obtained by writing the System Manager at the address below.

**SYSTEM MANAGER(S) AND ADDRESS:**

Superintendent
Saint Elizabeths Hospital, Room 109
Washington, D.C. 20032

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about himself/herself upon written request, with notarized signature if request is made by mail, or with suitable identification if request is made in person, directed to:

Privacy Act Coordinator
Office of the Superintendent, Room 109
Saint Elizabeth's Hospital
Washington, D.C. 20032

All of the following information must be provided when requesting notification: (a) full name; (b) dates of the contact with Saint Elizabeths Hospital; (c) the Branch, Division, or Office with which the requester had contact; (d) the capacity in which the requester had contact with the hospital, e.g., patient, employee, vendor, representative of professional organization, etc; (e) the nature of the material desired. A parent or guardian who requests notification of a child's/incompetent person's record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, must be sent. The parent or guardian must verify relationship to the child/incompetent person as well as his/her own identity.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under notification procedures above and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Patient and Employee records, HHS, ADAMHA, NIMH, and SEH forms, correspondence, Public Media, Staff Consultants, Relatives, Auditors' Reports, Conservators, U.S. Postal Service, U.S. and D.C. Courts, Public Defenders Service, D.C. Mental Health Commission, other persons or outside Agencies and Organizations offering information or initiating requests, volunteers offering services, interviews, minutes of conferences, seminars and meetings.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0027**

**SYSTEM NAME:**

Grants: Research, Research Training, Research Scientist Development, Education, Demonstration, Fellowships, Clinical Training, Community Services, Cooperative Agreements. HHS/ADAMHA/OA.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

National Institute on Drug Abuse
Grants Management Branch
Room 10-29, Parklawn Bldg.
5600 Fishers Lane
Rockville, Maryland 20857

National Institute on Alcohol Abuse and Alcoholism
Grants Management Branch
Room 16-86, Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

National Institute of Mental Health
Grants Management Branch, OPS
Room 7C-02, Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

Washington National Records Center
4205 Suitland Road
Washington, D.C. 20409

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Principal investigators, program directors, trainees, fellows, research scientist development awardees, and other employees of applicant or grantee institutions.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Grant and cooperative agreement applications and review history, including curriculum vitae, salary information, summary of review committee deliberations and supporting documents, progress reports, financial records, payback records of research training awardees (i.e., recipients under the National Research Services Awards Program), and payback records of clinical training awardees.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 301 (42 U.S.C. 241) Public Health Service Act, Section 410, Drug Abuse Prevention, Treatment, and Rehabilitation Act (42 U.S.C. 1177), Section 301 (42 U.S.C. 241) and Section 303 (42 U.S.C. 242a); Public Health Service Act, Sections 101, 311, Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act, (42 U.S.C. 4591), Sections 301, 303, 433(a), 455, and 472 (a)(1)(a), Public Health Service Act, (42 U.S.C. 241, 242a, 289C, 289k-1 and 289l-1), and Federal Grant and Cooperative Agreement Act of 1977 (41 U.S.C. 501 et seq.).

**PURPOSE(S):**

Records are maintained as official documentation relevant to the review, award, and administration of grant programs. Specifically, records are: 1. used by staff program and management specialists for purpose of awarding and monitoring grant funds; 2. used to maintain communication with former trainees/fellows who have incurred an obligation for research training under the National Research Service Awards Program (42 U.S.C. 289l-1) or for clinical training (42 U.S.C. 242a).

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Referrals may be made of assignments of research investigators and project monitors on specific research projects to the National Technical Information Service (NTIS), Department of Commerce, to contribute to the Smithsonian Science Information Exchange.

2. Disclosure may be made to qualified experts not within the definition of Department employees for opinion during the application review process.

3. Disclosure may be made to ADAMHA contractors for the purpose of carrying out quality assessment, program evaluation, and management reviews. Contractors are required to maintain Privacy Act safeguards with respect to the records.

4. In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether Federal (e.g., the Department of Justice) or State (e.g., the State's Attorney's Office), charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto for litigation.

5. Disclosure may be made to a Federal agency, in response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the record is relevant and necessary to the requesting agency's decision on the matter.

6. Where federal agencies having the power to subpoena other federal agencies' records, such as the Internal Revenue Service or the Civil Rights Commission, issue a subpoena to the Department for records in this system of records, the Department will make such records available.

7. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

8. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected (e.g., to the Department of Justice or other appropriate Federal agencies in defending claims against the United States when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual).

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Noncomputerized documents are filed in folders in enclosed file cabinets and open shelves. Information on 3 x 5 cards in file cabinets. Computerized records exist in tape and disk form.

**RETRIEVABILITY:**

By grant numbers and cross-indexed by name.

**SAFEGUARDS:**

Personnel authorized to have access to the files are limited to: the chief of the Grants Management Branch and staff authorized by him/her: grants specialists, grants technicians, program officials, assigned computer personnel and possible contractor staff including the project director and research associates. Computerized records are password protected; passwords are changed from time to time. Contractors working on computerized records are given passwords to access data only on a need to know basis. Computerized records are maintained in a secured area. During normal work hours, this area is staffed by authorized personnel who must show identification for entry. At other times, the computer area is locked. Hard copy files are stored in rooms which are locked at night. There is 24-hour guard patrol in the building. These safeguards are in accordance with DHHS Chapter 45-13, and supplementary Chapter PHS.hf: 45-13 in the General Administration Manual, and Part 6, 'ADP System Security' in the HHS ADP Systems Manual.

**RETENTION AND DISPOSAL:**

Records are retired to a Federal Records Center two years after

termination of support and the completion of final audit.

**SYSTEM MANAGER(S) AND ADDRESS:**

National Institute on Drug Abuse
Chief, Grants Management Branch, OA
Room 10-29, Parklawn Building
5600 Fisher's Lane
Rockville, Md. 20857

National Institute on Alcohol Abuse and Alcoholism
Chief, Grants Management Branch
Room 16-86, Parklawn Building
5600 Fishers Lane
Rockville, Md. 20857

National Institute of Mental Health
Chief, Grants Management Branch
Room 7C-02, Parklawn Building
5600 Fishers Lane
Rockville, Md. 20857

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the System Manager at the above address. Verifiable proof of identity is required.

**RECORD ACCESS PROCEDURES:**

Same as notification procedure. Requesters should also reasonably specify the record contents being sought, and should provide the official grant number when possible.

**CONTESTING RECORD PROCEDURES:**

Contact the appropriate system manager at the address specified above and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Applicants, grantees, fellows, trainees, personnel at grantee institution on whom the record is maintained, Federal advisory committees, site visitors, consultants, references.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0028**

**SYSTEM NAME:**

Saint Elizabeths Hospital General Medical/Clinical Records System and Related Indexes. HHS/ADAMHA/NIMH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

This is a widely decentralized system of records. Inactive patient records are located in the basement of the Dix Building. Active patient records are located in the division where the patient is residing, including possibly contractor locations. A current listing of contractor sites is available from the System Manager. SEH Clinical divisions are listed below under System Manager. Records are stored at the Washington National Records Center, 4205 Suitland Road, Washington, D.C. 20409.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

All past and present patients of Saint Elizabeths Hospital.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Inpatient and outpatient psychiatric medical/clinical records. The medical/clinical record contains identifying data (name, date and place of birth, age, sex, race, marital status, legal category, social security number, leave and residential status, admission and discharge dates, identification of relatives and hospital identification number) and medical/clinical information (physician's admission note, results of physical examinations, descriptions of patient's present and past physical and mental health, diagnosis, prognosis, consultant's opinions, social history, treatment plan, results of diagnostic tests and procedures, notes of patient's response to treatment, progress notes, nurses' notes, incident reports, and reports or notes of others who contributed to a patient's treatment and/or social work efforts, and correspondence with Saint Elizabeths Hospital concerning such a patient.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

24 USC 161, et seq.; 21 DC Code 562, Hospitalization of the Mentally Ill Act.

**PURPOSE(S):**

1. To document a patient's illness, chief complaint, history, physical examination, diagnostic test and procedure reports, to plan treatment whether as an inpatient or an outpatient.

2. To promote continuity of care for follow-up of treatment; for reference upon future treatment and care.

3. To provide a basis for reports mandatory under Federal and local laws.

4. In some instances, to provide as a basis for action in the course of employee discipline or competence determination proceedings.

5. To transact hospital business in filing insurance claims, verification of patient's competency, disability, or retirement benefits, verification of leave status and residence.

6. To serve as a basis for hospital administrative planning and evaluation of its programs.

7. To serve as impersonal documents for the hospital staff continuing education and studies.

8. To be used by hospital staff for assessment of the quality of treatment, for medical audit and utilization review.

9. To be used for the legal defense of the hospital and its staff in cases where a claim is based on patient's mental or physical conditions and arising from the patient's treatment at Saint Elizabeths Hospital.

10. To be used for statistical reports, monthly analysis of clinical division services, monthly, quarterly, annual reports.

11. To serve as a basis for reports to accrediting agencies, Joint Commission on Accreditation of Hospitals, American Hospital Association, American Psychiatric Association, Medicare Licensure, etc.

12. To prepare indexes based on medical/clinical records that are routinely used for: (a) speedy identification and location of specific patients; (b) monitoring the completeness of patient records, particularly records of patients discharged or deceased; (c) monitoring the changing status of patients in terms of either transfers within the hospital or outside the hospital; (d) easy identification of basic demographic data used for statistical and/or research purposes; and, (e) quick review of current treatment regimen in some cases.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made:

1. To facilitate treatment of patient when admitted to other facilities; to send records to new physcians.

2. To personnel who are not employees of the hospital for accreditation or licensure of the hospital.

3. Of reports to a referring source such as a physician or a court; and to

authorized parties, who have legitimate interests in the patient, who are not employeed by or connected with Saint Elizabeths Hospital, such as the Interstate Services Section of the District of Columbia government.

4. To Assistant United States Attorneys, Assistant Corporation Counsel, defense attorneys, and the Mental Health Commission, who request a patient's medical records in cases where a physician-patient privilege is waived by statute, in order that information necessary to perform statutory governmental functions in civil commitment, adult criminal, and juvenile proceedings, will be available to the parties and the fact-finders.

5. In the case of a patient who lacks the capacity to give informed consent to the release of his or her medical records, and who has no legal guardian to act on his or her behalf, disclosure may be made to appropriate individuals or organizations so that such individuals or organizations may provide a benefit or service to the patient, such as (but not limited to) welfare benefits or occupational services.

6. For a research purpose, when the department: (a) has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (b) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (c) has required the recipient to -- (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, and (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature or retaining such information, and (3) make no further use or disclosure of the record except—(A) in emergency circumstances affecting the health or safety of any individual, (B) for use in another research project, under these same conditions, and with written authorization of the Department, (C) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (D) when required by law; (d) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

7. To organizations deemed qualified by the Secretary to carry out quality assessment, medical audits or utilization review, including Professional Standards Review Organizations.

8. Disclosures may be made in the course of employee discipline or competence determination proceedings to parties involved in the proceedings such as police, attorneys, and Office of Personnel Management Employees.

9. To a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.

10. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected (e.g., to the Department of Justice or other appropriate Federal agencies in defending claims against the United States when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual.)

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

1. Active Patients—File folders with general medical record and correspondence file are kept in metal file cabinets. Index cards, monitoring cards, kardex and addressograph plates are kept in their appropriate containers.

2. Inactive Patients (Discharged and Deceased Patients)—Clinical and correspondence records are filed in separate coded folders with unit numbering system. Patients index—3x5 card file of all patients hospitalized or treated at SEH in a Kardveyer; Diagnostic Indexes—a 5x7 separate index card file stored in a Visu-Triver.

**RETRIEVABILITY:**

Data are retrieved by patient's name and hospital number.

**SAFEGUARDS:**

1. Available only to properly trained and screened personnel.

2. Access limited to authorized individuals only. Enforced by Security personnel. Rooms are locked when unoccupied. These safeguards are in accordance with DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 in the General Administration Manual.

**RETENTION AND DISPOSAL:**

Records will be retired to a Federal Records Center five years after date of discharge.

**SYSTEM MANAGER(S) AND ADDRESS:**

I. For Records of Inactive Patients:

Superintendent
Room 105, Administration Building
Saint Elizabeths Hospital
Washington, D.C. 20032

II. For Records of Active Patients:

Director
Area D Community Mental Health Center
Dix Building, Saint Elizabeths Hospital
Washington, D.C. 20032

Director
Division of Child and Adolescent Services
Dix Building, Saint Elizabeths Hospital
Washington, D.C. 20032

Director
Noyes Division
Noyes 7, Saint Elizabeths Hospital
Washington, D.C. 20032

Director
Forensic Division
John Howard Pavilion, Saint Elizabeths Hospital
Washington, D.C. 20032

Director
Godding Division
Godding 6, Saint Elizabeths Hospital
Washington, D.C. 20032

Director
Marr Division
Nichols Building, Saint Elizabeths Hospital
Washington, D.C. 20032

Director
Mental Health Program for the Deaf
L Building, Saint Elizabeths Hospital
Washington, D.C. 20032

Director
Medicine Branch
W W Eldridge Bldg., Saint Elizabeths Hospital
Washington, D.C. 20032

Director
O'Malley Division
Q Building, Saint Elizabeths Hospital
Washington, D.C. 20032

Director
Richardson Division
P Building, Saint Elizabeths Hospital
Washington, D.C. 20032

Clinical Director
William A. White Division
William A. White Building
Saint Elizabeths Hospital
Washington, D.C. 20032

**NOTIFICATION PROCEDURE:**

A patient or former patient may learn if a record exists upon written request, with notarized signature if request is made by mail, or with suitable proof of identity if request is made in person, directed to, as appropriate:

Active Patients:
Privacy Act Coordinator
Office of the Director (Division where person receives treatment; see list under 'System Manager')
Saint Elizabeths Hospital
Washington, D.C. 20032

Inactive Patients:
Privacy Act Coordinator
Office of Medical Records Branch
A Building
Saint Elizabeths Hospital
Washington, D.C. 20032

All of the following information must be provided when requesting notification: (a) full name; (b) for discharged patients, approximate dates enrollment at Saint Elizabeths Hospital; (c) if possible, the patient's hospital number; (d) the nature of the material desired. A parent or guardian who requests notification of a child's/incompetent person's record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child/incompetent person as well as his/her own identity.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under notification procedures above and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Medical records are a compilation of sociological, medical, clinical and historical data of a patient. They are a complete report of an illness resulting from an accumulation of a large amount of information about a patient. The information recorded was given by the patient, his/her relatives, or other third persons interested in the patient, from existing records used as reference, from clinical tests (different departments such as lab, X-ray, EEG, etc.), physicians, psychiatrists, nurses, social workers, other therapists who entered their observations and assessments by means of progress notes, reports, etc.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0029**

**SYSTEM NAME:**

Record of Guest Workers. HHS/ADAMHA/OA.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Alcohol, Drug Abuse, and Mental Health Administration
5600 Fishers Lane, Parklawn Building, Room 12-95
Rockville, Md. 20857

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals using ADAMHA facilities who are not employees.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Personal information including name, address, date and place of birth, education, employment, purpose for which ADAMHA facilities are desired, outside sponsor and ADAMHA sponsor.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Public Health Service Act, Section 301, 42 USC 241.

**PURPOSE(S):**

To document individual's presence at ADAMHA and as a record that the individual is not performing services for ADAMHA and is therefore not an employee.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosure may be made to the U.S. Office of Personnel Management for program evaluation purposes.
2. Disclosure may be made to institutions providing financial support for subject individual.
3. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.
4. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Stored in file folders.

**RETRIEVABILITY:**

Retrieved by name.

**SAFEGUARDS:**

Locked files accessible only to authorized individuals, i.e., employees of Division of Personnel Management and ADAMHA managers and supervisors with legitimate interest in guest worker. These safeguards are in accordance with DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 in the General Administration Manual.

**RETENTION AND DISPOSAL:**

Retained for three years after completion of visit, then destroyed.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director
Division of Personnel Management, ADAMHA
5600 Fishers Lane, Parklawn Bldg., Rm. 12-95
Rockville, Md 20857

**NOTIFICATION PROCEDURE:**

To determine if a record exists, contact the System Manager at the address above. Individuals who request notification in person must supply one proof of identity containing individual's complete name and one other identifier with picture (e.g., driver's license, building pass). Individuals who request notification by mail must supply notarized signature as proof of identity.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Subject individual and ADAMHA sponsor.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0030**

**SYSTEM NAME:**

Record of Visiting Fellows. HHS/ADAMHA/OA.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Alcohol, Drug Abuse, and Mental Health Administration
Division of Personnel Management
5600 Fishers Lane, Room 12-95, Parklawn Building
Rockville, Md. 20857

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals undergoing training who are not employees.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Personal information including name, address, date and place of birth, education, qualifications for training, stipend information, visa information.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Public Health Service Act, Section 301 (42 USC 241) and (42 USC) 482l-1

**PURPOSE(S):**

To refer candidates to selecting officials for placement and to maintain information concerning their employment while at ADAMHA.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Disclosure may be made to the U.S. Office of Personnel Management for program evaluation purposes.
2. Disclosure may be made to the General Accounting Office for fund disbursement determinations.
3. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of that individual.
4. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Stored in file folders.

**RETRIEVABILITY:**

Retrieved by name.

**SAFEGUARDS:**

Kept in locked file accessible only to authorized individuals, i.e. employees Division of Personnel Management and ADAMHA managers and supervisors with a legitimate interest in individual as an employee. The safeguards described are in accordance with DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 in the General Administration Manual.

**RETENTION AND DISPOSAL:**

Retained for three years after completion of fellowship, then destroyed.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director
Division of Personnel Management, ADAMHA
5600 Fishers Lane, Parklawn Bldg., Rm. 12-95
Rockville, Md. 20857

**NOTIFICATION PROCEDURE:**

To determine if a record exists, contact the System Manager at the address above. Individuals who request notification in person must supply one proof of identity containing individual's complete name and one other identifier with picture (e.g., driver's license, building pass). Individuals who request notification by mail must supply notarized signature as proof of identity.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Fellowship applicant.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0031**

**SYSTEM NAME:**

Saint Elizabeths Hospital Management Information Reporting System. HHS/ADAMHA/NIMH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Management Information Reporting Branch
Saint Elizabeths Hospital
Administration Building
Billing records may also be located at contractor sites.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Former & Current Patients.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Patient name, hospital number, demographic and individual characteristics, tracking or patient movement and billing information.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

24 USC 161, et seq.

**PURPOSE(S):**

Data is used for patient billing and to generate special and recurring reports for administrators, health professionals, managers, and researchers for their program management, planning, analysis, evaluation and research.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Information is disclosed to D.C. Mental Health Areas for continuity of care, after care and community follow-up.

2. A record may be disclosed for a research purpose, when the Department:

(a) has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained;

(b) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring;

(c) has required the recipient to -- (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, and (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except -- (A) in emergency circumstances affecting the health or safety of any individual, (B) for use in another research project, under these same conditions, and with written authorization of the Department, (C) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (D) when required by law;

(d) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

3. Data is provided to volunteers involved in the treatment process of the hospital.

4. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the written request of the individual.

5. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Saint Elizabeths Hospital forms, file folders, punch cards and magnetic tape.

**RETRIEVABILITY:**

Hospital case number, name, pre-determined codes. Some subsystems kept in chronological order.

**SAFEGUARDS:**

Employee training, restricted access, locked at night. For computerized records there is a password system in effect. These safeguards are in accordance with DHHS Chapter 45-13 and Supplementary Chapter PHS.hf: 45-13 in the General Administration Manual and Part 6, 'ADP System Security' in the HHS ADP Systems Manual.

**RETENTION AND DISPOSAL:**

Records may be retired to a Federal Records Center and subsequently disposed of in accordance with the ADAMHA Records Control Schedule. The records control schedule and disposal standard for these records may be obtained by writing the System Manager at the address below.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, Management Information Reporting Branch
Administration Bldg., St. Elizabeths Hospital
Wash., D.C. 20032

**NOTIFICATION PROCEDURE:**

A patient or former patient may learn if a record exists upon written request, with notarized signature, directed to:

Privacy Act Coordinator
Management Information Reporting Branch
Administration Bldg., Saint Elizabeths Hospital
Washington, D.C. 20032

All of the following information must be provided:

(a) full name;

(b) approximate dates of enrollment at Saint Elizabeths Hospital;

(c) the nature of the material desired. A parent or guardian who requests notification of a child's/incompetent person's record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, must be sent. The parent or guardian must verify relationship to the child/incompetent person as well as his/her own identity.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under notification procedures above and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Saint Elizabeths Hospital forms prepared by staff.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0033**

**SYSTEM NAME:**

Correspondence Files. HHS/ADAMHA/OA.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

ADAMHA Executive Secretariat
Room 12-94, Parklawn Building
5600 Fishers Lane
Rockville, Md. 20857

Executive Secretariat, National Institute on Drug Abuse
Room 10A-23 Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

Executive Secretariat, National Institute on Alcohol Abuse and Alcoholism
Room 16-97, Parklawn Building
5600 Fishers Lane
Rockville, Md. 20857

Washington National Records Center
4205 Suitland Road
Washington, D.C. 20409

Executive Secretariat, National Institute of Mental Health
Room 17C-10, Parklawn Building
5600 Fishers Lane
Rockville, Md. 20857

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals who request information on ADAMHA programs.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Correspondence.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

21 U.S.C. 1191; 42 U.S.C. Sections 289k-1, 3511, 4551, Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act, as amended (P.L.93-282).

**PURPOSE(S):**

To provide reference retrieval and control to assure timely and appropriate attention.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from the congressional office made at the request of that individual.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Correspondence records maintained in hard copy; control records maintained on computer printout, tape, and disk.

**RETRIEVABILITY:**

Hard copy records indexed alphabetically by name and date of outgoing correspondence, by subject, and/or by computerized numerical code. Records are cross-referenced in detail on computer.

**SAFEGUARDS:**

Records are maintained in file cabinets in a locked, secure location. Access to computer system is limited to authorized personnel through the use of passwords. These safeguards are in accordance with DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 in the General Administration Manual and Part 6, 'ADP System Security' in the HHS ADP System Manual.

**RETENTION AND DISPOSAL:**

Records are retired to the Federal Records Center after three years.

**SYSTEM MANAGER(S) AND ADDRESS:**

Same as location.

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about himself or herself by contacting the applicable system manager at the address above. Give name and approximate date of records requested. Individuals who request notification in person must supply one proof of identity containing individual's complete name and one other identifier with picture (e.g., driver's license, building pass). Individuals who request notification by mail must supply notarized signature as proof of identity.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the appropriate official at the address specified under Notification Procedures above and reasonably identify the record. Specify the information to be contested, and state the corrective action sought, with supporting justificaton.

**RECORD SOURCE CATEGORIES:**

Records are derived from incoming and outgoing correspondence.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0036**

**SYSTEM NAME:**

Mental Health Epidemiologic and Biometric Research Data, HHS/ADAMHA/NIMH

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Records are located at the research facilities which collect or provide research data for this system under contract to the agency. Contractors may include: research centers, clinics, hospitals, universities, research foundations, and coordinating centers. Records may also be located at the research facilities of the Division of Biometry and Epidemiology, National Institute of Mental Health. A current list of sites is available by writing to the System Manager at the address below.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals who are the subjects of research in epidemiologic, clinical, methodologic, and longitudinal research studies of mental health and mental disorders. These individuals are selected as representative of the general population or of special groups. Special groups might include, but are not limited to: clients referred for or receiving medical or mental health services; providers of health/mental health services; demographic sub-groups as applicable, such as age, sex, ethnicity, race, occupation, geographic location; and groups exposed to hypothesized risks, such as relatives of individuals with disorders, individuals who have experienced life stresses, or individuals with previous history of illness.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

The system contains varying items about the individual as relevant to a particular research study. Examples include, but are not limited to, items about the health/mental health of the individual, demographic data, past and present life experiences, personality characteristics, social functioning, utilization of health/mental health services, family history, physiological measures, and characteristics and activities of health/mental health care providers.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 301 of the Public Health Service Act, 42 U.S.C. 241, General Research and Investigation Authorities.

**PURPOSE(S):**

The purpose of the system of records is to collect and maintain a data base for research activities of the Division of Biometry and Epidemiology (DBE) of the National Institute of Mental Health (NIMH). Analyses of these data involve groups of individuals with given

characteristics and do not refer to specific individuals. The generation of information and statistical analyses will ultimately lead to a better description and understanding of mental disorders, their treatment and prevention, and the promotion of mental health.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. A record may be disclosed for a research purpose, when the Department:

(a) has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; e.g., disclosure of alcohol or drug abuse patient records will be made only in accordance with the restrictions of confidentiality statutes and regulations 42 U.S.C. 4582, 21 U.S.C. 1175, and 42 CFR, Parts 2 and 2a, and where applicable, no disclosures will be made inconsistent with an authorization of confidentiality under 42 U.S.C. 242a and 42 CFR Part 2a;

(b) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional expose of the record might bring;

(c) has required the recipient to—(1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, and (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except—(A) in emergency circumstances affecting the health or safety of any individual, (B) for use in another research project, under these same conditions, and with written authorization of the Department, (C) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (D) when required by law; and

(d) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by, these provisions.

2. Disclosure may be made to a congressional office from the record of an individual in response to a verified inquiry from a congressional office made at the written request of that individual.

3. In the event of litigation, where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee; the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected (e.g., disclosure may be made to the Department of Justice or other appropriate Federal agencies in defending claims against the United States when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of the individual's participation in activities of a Federal Government supported research project).

4. The Department contemplates that it will contract with a private firm for the purpose of collecting, analyzing, aggregating, or otherwise refining records in this system. Relevant records will be disclosed to such contractor. The contractor shall be required to maintain Privacy Act safeguards with respect to such records.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are stored in various ways including file folders, computer cards, computer tapes or disks, microfiche, audio or video tapes, and index cards. Normally, the factual data, with study code numbers, are stored on computer tape or disk, while the key to personal identifiers is stored separately, without factual data, in paper files.

**RETRIEVABILITY:**

During data collection stages and followup, if any, retrieval by personal identifier (e.g., name or medical record number) is necessary. During the data analysis stage, data are normally retrieved by the variables of interest (e.g., diagnosis, age, occupation).

**SAFEGUARDS:**

(a) Physical—Physical security is achieved by storing records in locked rooms, locked file cabinets, and/or secure computer facilities. Access to personal identifiers is safeguarded by locked files and by separating data from identifiers as much as possible. Data stored in computers is secured in various ways, including access through the use of key words known only to authorized personnel.

(b) Procedural—Collection and maintenance of the information is done in a manner consistent with legislation and regulations in the protection of human subjects, informed consent, and confidentiality. When DBE or a contractor provides anonymous data to research scientists for analysis, study numbers which can be matched to personal identifiers will be eliminated or replaced by the Division or the contractor with random numbers which cannot be so matched.

(c) Authorized Personnel—Access to identifiers and to the code which matches study members with them is strictly limited to the authorized personnel whose duties require such access. Procedures for determining authorized access to identified data are established as appropriate for each location. Personnel who may be so authorized include those directly involved in data collection and in the design of research studies, e.g., interviewers and interviewer supervisors; project managers; statisticians involved in designing sampling plans.

The safeguards are in accordance with Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 in the General Administration Manual, and Part 6, 'ADP System Security' in the HHS ADP Systems Manual.

**RETENTION AND DISPOSAL:**

Identifiers are retained only as long as they are needed for the purposes of the current research project, and for follow-up studies generated by the present study. Disposal of identifiers is done according to the storage medium (e.g., erase computer tape, shred or burn index cards, etc.). A staff person designated by the System Manager will oversee and will describe and confirm the disposal in writing.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, Division of Biometry & Epidemiology
National Institute of Mental Health
Alcohol, Drug Abuse and Mental Health Administration
Parklawn Building
Room 18C-26, 5600 Fishers Lane
Rockville, MD 20857

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the System Manager at the address above. Provide individual's name; current address; date of birth; date, place and nature of participation in specific research study; name of individual or organization administering the research study (if known); name or description of the research study (if known); address at the time of participation; and a notarized statement by two witnesses attesting to the individual's identity.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

An individual who requests notification of, or access to, a medical record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information being contested, and state corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

The system contains information obtained directly from the subject individual by interview (face-to-face or telephone), by written questionnaire, or by other tests, recording devices or observations, consistent with legislation and regulation regarding informed consent and protection of human subjects. Information is also obtained from other sources, such as health and mental health care providers, relatives, guardians, and clinical medical research records.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0037**

**SYSTEM NAME:**

Psychotherapy of Opiate-Dependent Individuals, HHS/ADAMHA/NIDA.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Drug Dependence Treatment and Research Center
Philadelphia Veterans Administration Hospital (116D)
University and Woodland Avenues
Philadelphia, Pennsylvania 19104

University of Pennsylvania
39th Street and Woodland Avenue
Philadelphia, Pennsylvania 19104

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Research subjects are adult clients admitted to a participating drug abuse treatment program offered by and located in the Philadelphia Veterans Administration Hospital, between September 30, 1977, and September 29, 1981.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Name and address of study subjects and their responses to interview instruments and tests in the following areas: sociodemographic characteristics; and psychiatric diagnosis; symptom, social functioning, and personality measures. Information on the drug abuse treatment and psychotherapy provided, and therapists' evaluations, are also included.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Drug Abuse Prevention, Treatment and Rehabilitation Act, Sections 410 and 503 (21 U.S.C. 1177 and 1193); Public Health Act, Section 301 (42 U.S.C. 241).

**PURPOSE(S):**

The system was created to provide a data base to be used by NIDA for research leading to a better knowledge and understanding of the psychiatric status of opiate-dependent individuals and to determine the efficacy of psychotherapy as part of a treatment program for such individuals. We do not anticipate any disclosure of individually identifiable information to other persons or organizations within the Department of Health and Human Services. Should a request for disclosure occur within the Department, such as provided by Section 3(b) of the Privacy Act, disclosure would not be permitted except in accordance with confidentiality regulations.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

A record may be disclosed for a research purpose, when the Department:

(a) has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained;

(b) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring:

(c) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except: (A) in emergency circumstances affecting the health or safety of any individual, (B) for use in another research project, under these same conditions, and with written authorization of the Department, (C) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (D) when required by law.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are maintained on interview forms, audiotapes, keypunch cards, magnetic tapes, and disks.

**RETRIEVABILITY:**

Research records and locational information for followup are maintained

in numerical order by assigned client number. A list is also maintained by name and assigned client number for cross reference.

**SAFEGUARDS:**

An authorization under Section 303(a) of the Public Health Service Act as amended (42 U.S.C. 242a(a), implemented by confidentiality regulations (42 CFR Part 2a), has been issued to the contractor to assure that the contractor may not be compelled in any legal proceeding to identify the research subjects. In addition, these records are subject to the protective restrictions of the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations (42 CFR 2.56).

Project documentation, including cross reference list, completed interview forms, audiotapes, and computerized data files, is maintained under strict controls in a secure room at the contractors' facilities to ensure data integrity and confidentiality. The list, interview forms and audiotapes are stored in a locked and secure work space until data is entered on magnetic media and verified. Then, the forms and cross reference list are destroyed by burning or shredding, and audiotapes are erased. After study source documents are disposed of, no connection can be made between computer file data and the individual. Magnetic tapes and disks are kept in a vault area. During all stages of processing and storage, senior project personnel control access to and removal and replacement of all documents from specified working and storage areas. Access is permitted only upon the written authority of the Principal Investigator or Co-Principal Investigators. The contractor has developed an extensive computer facilities security system which is used by programmers to protect computer account codes and data from access by unauthorized users.

The safeguards are in accordance with DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 in the General Administration Manual, and Part 6, 'ADP System Security' in the HHS ADP Systems Manual.

**RETENTION AND DISPOSAL:**

After all data collection and processing are completed (which is anticipated to be no more than five years after expiration date of the contract), the NIDA project officer will authorize, in writing, the destruction of the personal identifiers and source documents unless the information is needed for research purposes.

**SYSTEM MANAGER(S) AND ADDRESS:**

Project Officer, Psychotherapy of Opiate-Dependent Individuals
Treatment Research Branch
Division of Clinical Research
National Institute on Drug Abuse
5600 Fishers Lane, Room 10A-30
Rockville, Maryland 20857

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the System Manager at the address above. An individual may learn if a record exists about himself or herself upon written request with notarized signature. The request should include, if known: name of the researcher, name of the study, location of the research site, approximate date of data collection, any alias used by individual, and assigned client number.

An individual who requests notification of, or access to, a medical record, shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

**RECORD ACCESS PROCEDURES:**

Same as Notification Procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Research subjects, drug treatment programs, clinical evaluators, counselors, psychiatrists, psychotherapists, family members, research assistants, pharmacies, hospitals.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0038**

**SYSTEM NAME:**

Subject-Participants in Pharmacokinetic Studies on Drugs of Abuse, HHS/ADAMHA/NIDA

**SECURITY CLASSIFICATION:**

None

**SYSTEM LOCATION:**

Department of Psychiatry
School of Medicine
University of North Carolina
Chapel Hill, North Carolina 27514

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Normal, healthy adults who voluntarily participate in studies on the pharmacokinetics of drugs of abuse, at the University of North Carolina, during the period November 1979 through approximately November 1983.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Research records on each subject-participant contain the following information: name; clinician's records including medical history, laboratory test results, physical examinations, psychological profile, and drug use profile; drug study data including records of drugs administered, exposures to radioactivity, and drug reactions; and date of study in which the subject participated.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Drug Abuse Prevention, Treatment, and Rehabilitation Act, Section 503 (21 U.S.C. 1193) and Public Health Service Act, Section 301(a) (42 U.S.C. 241(a)).

**PURPOSE(S):**

The primary purpose of this system is to support research on the pharmacokinetics of drugs of abuse. The term 'pharmacokinetics' refers to the manner in which the human body processes a drug.

The clinical investigator uses data of a medical nature that is contained in the system to make determinations regarding drug dosages and/or radiochemical exposures appropriate to the individual human subject-participants, in order to preserve and protect the health of each. The system also provides base-line data for studying the drug effects.

The Food and Drug Administration (FDA) also may use the records in routine inspections FDA conducts in accordance with its responsibilities to develop standards on the composition, quality, safety, and efficacy of drugs administered to humans, and to monitor experimental usage of drugs.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. We may disclose to a congressional office the record of an individual in response to a verified inquiry from the congressional office made at the written request of the individual.

2. In the event of litigation where the defendent is (a) the Department, any

component of the Department, or any employee of the Department in his or her official capacity, (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components, or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected. For example, records may be disclosed to the Department of Justice in defending claims against the U.S. when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of the activities of PHS and its contractors in regard to such individual.

3. The School of Medicine of the University of North Carolina, an ADAMHA contractor, uses the records in this system to accomplish the research purpose for which the records are collected. The contractor is required to maintain Privacy Act safeguards with respect to such records.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

The contractor maintains the records on paper in file folders.

**RETRIEVABILITY:**

The contractor indexes and retrieves the records by the subject-participant's name.

**SAFEGUARDS:**

The contractor keeps all records in a locked metal file cabinet in premises with limited accessibility. Only the clinical investigator has the key to the locked files. Only authorized contract personnel can see or use the records. Persons other than subject-participants, who request individually identifiable data from a record, must provide written consent from the subject-participant permitting the requested disclosure. The only exception would be for disclosure to persons or organizations permitted by the Privacy Act, Section 3(b) to obtain personally identifiable data. These safeguards are in accordance with the DHHS Chapter 45-13 and supplementary Chapter PHS.hf:45-13 in the General Administration Manual. In addition, the contract staff complies with contractor's (School of Medicine of the University of North Carolina) standard procedures for safeguarding data.

**RETENTION AND DISPOSAL:**

The records will be kept no later than October 1987 (five years after the anticipated completion of the studies). At that time, the NIDA project officer will authorize the clinical investigators to destroy the records by shredding or burning.

**SYSTEM MANAGER(S) AND ADDRESS:**

Project Officer
Pharmacokinetic Studies on Drugs of Abuse (Contract No. 271-80-3705)
Division of Preclinical Research
National Institute on Drug Abuse
Alcohol, Drug Abuse, and Mental Health Administration
5600 Fishers Lane, Room 10A-49
Rockville, MD 20857

**NOTIFICATION PROCEDURE:**

To determine if a record exists, an individual should provide a written request with notarized signature to:

Research Physician for NIDA's Contract No. 271-80-3705
Pharmacokinetic Studies on Drugs of Abuse
School of Medicine
University of North Carolina
Chapel Hill, North Carolina 27514

Provide the following information: Subject-participant's full name and a letter of request (or permission, if the requester is not the subject-participant) with notarized signature of the individual who is the subject of the record, approximate date(s) of experiment(s) in which the individual participated, and drug name (if known). In addition, an individual who requests notification of, or access to, a medical record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its content at the representative's discretion.

**RECORD ACCESS PROCEDURES:**

Same as Notification Procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the System Manager at the address above and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

The subject-participants and the contractor personnel conducting the research studies.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-30-0039.**

**SYSTEM NAME:**

Drug Abuse Treatment Outcome Prospective Study (TOPS), HHS/ADAMAHA/NIDA

**SECURITY CLASSIFICATION:**

None

**SYSTEM LOCATION:**

Computer Applications Center
Research Triangle Institute
Box 12194
Research Triangle Park, North Carolina 27709.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Voluntary adult clients of federally-funded treatment programs, including Treatment Alternative Street Crime (TASC) programs of the Department of Justice, who have requested to be included in TOPS. Data collection began in 1979 and will continue through 1984.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

The categories are: demographic data, treatment outcome data, treatment process data, client locator information, and personal identifiers (name and assigned numerical identifier).

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Drug Abuse Prevention, Treatment, and Rehabilitation Act, Section 503 (21 U.S.C. 1193); Public Health Service Act, Section 301(a) (42 U.S.C. 241(a)).

**PURPOSE(S):**

The purpose of the system is to compile information on drug abusers who obtain treatment in federally-funded drug abuse treatment programs in order to derive information on the effectiveness of treatment environments and abusers' behavior and characteristics subsequent to treatment. Researchers and drug abuse service providers may use the aggregate data to address issues and generate hypotheses to understand better the interactions among the client, clinic, and community

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Within the restrictions set forth in HHS regulations concerning the confidentiality of drug abuse patient records (42 CFR 2.56), we may disclose a record for a research purpose, when the Department: (a) has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (b) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (c) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except: (A) in emergency circumstances affecting the health or safety of any individual, (B) for use in another research project, under these same conditions, and with written authorization of the Department, (C) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (D) when required by law; (d) has secured a written statement attesting to the recipient's understanding of, and willingness to, abide by these provisions.

2. The Research Triangle Institute, an ADAMHA contractor, uses the records in this system to accomplish the research purpose for which the records are collected. In the event of followup studies or continuation studies because the contract has been terminated for convenience by the Government, we may disclose records in this system to a subsequent ADAMHA contractor. We would require the new contractor to maintain Privacy Act safeguards with respect to such records.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Interview forms, magnetic tapes, and disks.

**RETRIEVABILITY:**

Records are indexed and retrieved by name and unique numerical identifier. In order to relate the data collected to specific individuals, one must use the link file discussed under Safeguards.

**SAFEGUARDS:**

We used the National Bureau of Standards guidelines and Part 6, HHS ADP Systems Manual, 'ADP Systems Security' in developing the computer safeguard procedures which follow. Safeguards for nonautomated records are in accordance with DHHS Chapter 45-13 and supplementary Chapter PHS.hf: 45-13 in the General Administration Manual. In addition, project staff complies with the contractor's (Research Triangle Institute) standard procedures for safeguarding data.

The contractor provides only aggregate information to NIDA. We do not anticipate any disclosure of individually identifiable information to other persons or organizations within the Department of Health and Human Services. Nor does the contractor provide individually identifiable information to the Department of Justice, with which NIDA has a cooperative agreement for this study.

The data management task leader, the project leader, or the project director provide technical supervision of all data collection and processing activities. Individually identified forms are stored in a secure, vault-like room provided for this purpose. Authorized personnel have access to the room by one locked door with controlled entry, i.e., only on the written authority of the professional staff member in charge.

Because some of the data collected in this study, such as data on drug use, are sensitive and confidential, special safeguards have been established. A Certificate of Confidentiality has been issued under 42 CFR Part 2a. This authorization enables persons engaged in research on mental health, including research on the use and effect of psychoactive drugs, to protect the privacy of research subjects by withholding the names or other identifying characteristics from all persons not connected with the conduct of the research. Persons so authorized may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals. In addition, these records are subject to 42 CFR Part 2, the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations (42 CFR 2.56), which state: 'Where the content of patient records has been disclosed pursuant to (these regulations) for the purpose of conducting scientific research . . . information contained therein which would directly or indirectly identify any patient may not be disclosed by the recipient thereof either voluntarily or in response to any legal process whether Federal or State.'

Another safeguard is that the forms containing subject identification information for client followup and data matching purposes do not include any reference to the purpose of the study. Identification and location information is kept separate from any information that would suggest that the respondent has been in a drug treatment program.

Information on completed forms is entered immediately on the computer. Computerized records are kept in a vault area with access limited as above. Completed forms and computerized data are released only to authorized persons. Only aggregate data are provided and used in the preparation of necessary and appropriate reports.

A link file system is used. This system has three components: (1) personal information, (2) data base information, and (3) the link file, which contains identifying number pairs which can be used to match data with individuals. The advantage of this system is that the data-base can be used directly for report generation, etc., without the use of decrypting subroutines or access to the personal information or matching link files.

In addition, the computer center being utilized has developed an extensive security system to protect computer account codes and data. This system is described in a publication that is available from the System Manager upon request.

**RETENTION AND DISPOSAL:**

The contractor destroys interview forms by shredding or burning immediately after contractor staff have completed and verified direct entry on magnetic tape or disk storage. The contractor will destroy individual identification and location data by shredding or burning, under the explicit written authorization of the System Manager, which is anticipated to be no longer than five years after the termination of the study unless the

information is needed for research purposes. We will retain aggregate data tapes for research purposes. These tapes will not have any individually identifiable information. In accordance with the ADAMHA Records Control Schedule, these tapes will be retained for five years after completion of the project. At that time, the tapes will be retired to the Federal Records Center and destroyed when they are 10 years old or when they are no longer needed for research purposes.

**SYSTEM MANAGER(S) AND ADDRESS:**

Treatment Outcome Prospective Study (TOPS)
Associate Director for Clinical Medicine
Division of Clinical Research
National Institute on Drug Abuse
Alcohol, Drug Abuse, and Mental Health Administration
5600 Fishers Lane, Room 10A-38
Rockville, Maryland 20857

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the System Manager at the address above. An individual may learn if a record exists about himself/herself upon written request, with notarized signature. The request should include, if known, name of the researcher, location of the research site, approximate date of data collection, any alias used, and subject identification number.

An individual who requests notification of a medical record shall, at the time the request in made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

**RECORD ACCESS PROCEDURES:**

Same as Notification Procedures. Requesters should also reasonably specify the record contents being sought.

Persons other than subject individuals, who request individually identifiable data from a record must provide written consent from the subject individual permitting the requested disclosure. The only exception (if not in conflict with confidentiality regulations) would be for disclosure to persons or organizations permitted by the Privacy Act, Section 3(b), to obtain personally identifiable data.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Research subjects, and staff in participating drug abuse treatment programs, written clinical evaluations, counselors, psychiatrists, psychotherapists, family members, research assistants, hospitals.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None

09-30-0043

**SYSTEM NAME:**

Shipment Records of Drugs of Abuse to Authorized Researchers, HHS/ADAMHA/NIDA

**SECURITY CLASSIFICATION:**

None

**SYSTEM LOCATION:**

Research Technology Branch
Division of Research
National Institute on Drug Abuse
Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Research Triangle Institute
Research Triangle Park
North Carolina 27709

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individual researchers and organizations who are registered with the Drug Enforcement Administration (DEA), Department of Justice (DOJ), some since 1966, and who have voluntarily submitted documentation to the National Institute on Drug Abuse (NIDA) in order to obtain, through the NIDA Drug Supply Program (DSP), drugs of abuse for use in a research project.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

While the records in this system are research project-related, they support the eligibility of individual researchers to receive drugs of abuse. Types of information contained in the records are: researcher's name, curriculum vitae, research protocol, DEA and (if applicable) Nuclear Regulatory Commission registration numbers (when a radiolabeled compound is requested and shipped), business address (location of research project) and telephone number, summary of research project(s), requests for substance(s), name and amount of each compound requested and shipped, dates material is shipped and received, shipment numbers, and order form numbers.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Drug Abuse Prevention, Treatment, and Rehabilitation Act, Section 503 (21 U.S.C. 1193); Public Health Service Act, Section 301(a) (42 U.S.C. 241(a)); Controlled Substances Act of 1970 (21 U.S.C. 801 et seq.); Atomic Energy Act of 1954, as amended, Section 81 (42 U.S.C. 2111); and Energy Reorganization Act of 1974, Section 201 (42 U.S.C. 5841). Energy Reorganization Act of 1974, Section 201 (42 U.S.C. 5841).

**PURPOSE(S):**

To facilitate operation of DSP which is a centralized research support service through which the United States Government supplies to the national and international scientific community for research purposes, most Schedule I and many Schedule II-V controlled and noncontrolled substances as specified in the Controlled Substances Act (CSA) of 1970 (21 U.S.C. 801 et seq.). Controlled substances are chemicals and other substances, and their immediate precursors, that the Attorney General has determined to have such potential for abuse as to warrant regulation under the CSA. Some of these substances are radiolabeled materials. Radiolabeled materials are substances to which a small amount of radioactivity is added for use in various studies, such as drug metabolism and mechanisms of drug actions.

This system of records was established to facilitate DSP by enabling NIDA:

1. To verify that requests for drugs of abuse, some of which are radiolabeled, are from authorized individuals/organizations for use in a research project;

2. To verify that the amounts of the materials requested by researchers for animal, in vivo, and in vitro research are justified and available;

3. To supply controlled substances in amounts approved by the Food and Drug Administration (FDA) to researchers conducting research with human subjects;

4. To ship these materials securely in accordance with CSA and the Atomic Energy Act; and

5. To maintain records of these transactions.

FDA also may use the records in routine inspections in accordance with FDA's responsibilities to develop standards on the composition, safety, and efficacy of drugs administered to humans, and to monitor experimental usage of drugs.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. We may disclose the record of an individual to a congressional office in response to a verified inquiry from the congressional office made at the written request of the individual.
2. We may disclose information to DEA, DOJ, to enable DEA to carry out its responsibilities as described in the Controlled Substances Act of 1970.
3. An ADAMHA contractor routinely uses the records in this system to ship controlled substances to authorized recipients. Such contractor is required to maintain Privacy Act safeguards with respect to these records.
4. An ADAMHA contractor may have access to the records in this system in the performance of its software modification/correction tasks specified in its contract. Such contractor is required to maintain Privacy Act safeguards with respect to these records.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

NIDA maintains 'hard copy' records in file folders and automated records on computer disk.

**RETRIEVABILITY:**

Authorized NIDA and contractor personnel index and retrieve the computerized records by a researcher code number assigned by a computer program at the time a new record is established. Authorized NIDA personnel index and retrieve 'hard copy' records by researcher's name. NIDA maintains a computerized, alphabetical cross-reference list that matches names and numbers.

**SAFEGUARDS:**

The 'hard copy' records and main computer are physically located at the Parklawn Building, Rockville, Maryland. The computerized records are kept in a room with limited admittance. The room is locked after working hours. The 'hard copy' records are stored in locked file cabinets in a room with very limited admittance. This room is also locked after working hours. The Parklawn Building has a 24-hour guard patrol service.

The Chief, Research Technology Branch and his or her support staff, program assistant and clerk-typist, and the contracts' Project Directors and their support staffs have access to the records. The contract personnel, have access, by remote terminal, only to the automated shipment processing portion of the DSP records. These records do not contain any personal information except researchers' names and business addresses. The terminals are housed in a secured work area with limited admittance. Contract personnel use a password identification system to obtain access; NIDA changes the passwords periodically.

The safeguards described in the preceding paragraphs are in accordance with DHHS Chapter 45-13 and Supplementary Chapter PHS.hf: 45-13, in the General Administration Manual, and Part 6, 'ADP Systems Security,' in the HHS ADP Systems Manual.

**RETENTION AND DISPOSAL:**

NIDA maintains an individual's record for five years after the researcher's last request for, or shipment of, a drug of abuse. We consider the record inactive after that, and erase it from the computer disk by a delete routine. The delete routine automatically deletes the computerized cross-reference as well. We destroy the 'hard copy' record by shredding. The system is checked once a year for inactive records.

**SYSTEM MANAGER(S) AND ADDRESS:**

Project Director, Drug Supply Program
Research Technology Branch
Division of Preclinical Research
Parklawn Building, Room 10A-19
5600 Fishers Lane
Rockville, Maryland 20857

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the System Manager at the address above. An individual may learn if a record exists about himself or herself upon written request. The request should include the researcher's name and business address at the time of last shipment. The request must be signed in ink by the individual researcher. Verifiable proof of identity is required.

**RECORD ACCESS PROCEDURES:**

Same as Notification Procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under Notification Procedures above and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Initial source is the individual researcher. Some of the DEA registration information provided by a researcher is verified through a DEA computer check. FDA provides information concerning type and amount of controlled substance(s) to be shipped to an individual researcher for research projects involving human subjects.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None

[FR Doc. 83-31243 Filed 11-28-83; 8:45 am]
BILLING CODE 4160-20-T

## Public Health Service

## National Institutes of Health

## Privacy Act of 1974; Annual Publication of Systems of Records

**AGENCY:** Public Health Service; National Institutes of Health, HHS.

**ACTION:** The National Institutes of Health (NIH) is publishing this document to meet the requirements of Pub. L. 97-375, the Congressional Reports Elimination Act. This new statute amends the Privacy Act (5 U.S.C. 552a, Section 3(e)(4)) to limit republication to revised system notices only.

**SUMMARY:** The National Institutes of Health (NIH) is publishing this decument to establish changes to notices of systems of records which have been revised following a comprehensive review of all systems of records maintained by NIH. None of these changes requires a report of altered system to be sent to the Congress and the Office of Management and Budget. The notices are complete and accurate as of August 26, 1983.

Furthermore, we are summarizing additions of new systems which have been published since the last annual publication, establishment of new routine uses, and deletions of old systems terminated since the 1982 publication. We are also publishing a complete list of all systems of records which NIH currently maintains.

**SUPPLEMENTARY INFORMATION:** The following information summarizes the current status of all systems of records which NIH maintains:

A. Revised System Notices. We have revised system notices republished below as follows:

(1) Two system notices have been updated to reflect a change in the system location and system manager address:

09-25-0013, Clinical Research: Preadmission Medical Records, HHS/NIH/CC.

09-25-0049, Clinical Research: Atlanta Federal Prison Malaria Research Projects, HHS/NIH/NIAID.

(2) A special disclosure statement to consumer reporting agencies has been added to two system notices: 09-25-0036, Grants: IMPAC (Grant/Contract Information), HHS/NIH/DRG, and 09-25-0112, Grants: Research, Research Training, Fellowship and Construction Applications and Awards, HHS/NIH/OD. This provision allows disclosure of information to consumer reporting agencies on individuals who have failed to meet payback obligations incurred under awards made under the authority of the National Research Service Awards Program. Such disclosure will provide an incentive for individuals to repay delinquent Federal Government debts by making these debts part of their credit records.

(3) We have modified system of records 09-25-0151, Administration: Alert Records Concerning Investigations or Determinations of Misconduct by Current or Potential Recipients of Funds for Biomedical Research, HHS/NIH/OD, to clarify controls over the collection and use of information in this system.

(4) The "Retention" section has been updated in several systems of research records to clarify that these records are kept as long as they are useful in scientific research.

(5) "Record Access Procedures" section in all the system notices we are republishing has been expanded to state that requesters may obtain listings of accountable diclosures that have been made of their records.

(6) Editorial changes have been made to several system notices to make them clearer and more accurate.

B. New Systems of Records. The following new systems of records became effective between October 1, 1982, and August 26, 1983. They did not appear in the 1982 annual publication.

09-25-0152, Biomedical Research: Records of Subjects in National Institute of Dental Research Contracted Epidemiological and Biometric Studies, HHS/NIH/NIDR, published in the **Federal Register**, October 1, 1982, pp. 43429-43432.

09-25-0153, Biomedical Research: Records of Subjects in Biomedical and Behavioral Studies of Child Health and Human Development, HHS/NIH/NICHD, published in the **Federal Register**, July 25, 1983, pp. 33748-33751.

C. Deleted Systems of Records. The following systems of records which appeared in the last annual publication have been deleted. System of records 09-25-0116 is now being deleted; systems of records 09-25-0043, 09-25-0084, 09-25-0123, and 09-25-0127 were terminated since the annual publication.

(1) 09-25-0043, Clinical Research: Pharyngeal Development Patients, HHS/NIH/NIDR. (The records in this system have been destroyed.) (**Federal Register**, March 31, 1983, pp. 9586.)

09-25-0084, Administration: Curricula Vitae of Scientists, Consultants, and Board and Commission Members, HHS/NIH/NIADDK. (These records are no longer maintained and the data on hand was distributed by disease and/or organization memberships.) (**Federal Register**, March 31, 1983, pp. 13497.)

(3) 09-25-0116, Contracts: Medical Consultants Under Professional Services Contracts, HHS/NIH/NIAID. (The records in this system have been destroyed.)

(4) 09-25-0123, Clinical Research: Clinical Trials Dealing with Fertility-Regulating Methods, HHS/NIH/NICHD. (Data collection in this system is complete, and NICHD has removed from the records all information identifying individuals.) (**Federal Register**, March 31, 1983, pp. 9586.)

(5) 09-25-0127, Clinical Trials Dealing with Phototherapy for Neonatal Hyperbilirubinemia, HHS/NIH/NICHD. (Data collection in this system is complete, and NICHD has removed from the records all information identifying individuals.) (**Federal Register**, March 31, 1983, pp. 9586.)

D. Altered Systems of Records: Notice of alteration of system of records 09-25-0074, Clinical Research: Division of Cancer Biology and Diagnosis Patient Trials, HHS/NIH/NCI, was published in the **Federal Register**, June 9, 1983, pp. 26670-26672. This system of records was modified into an umbrella system.

Notices for the following systems of records were published in the **Federal Register**, July 5, 1983, pp. 30759-30763, in order to establish new routine uses in each of these systems:

(1) 09-25-0008, Administration: Radiation Workers Monitoring, HHS/NIH/ORS.

(2) 09-25-0010, Research Resources: Registry of Individuals Potentially Exposed to Microbial Agents, HHS/NIH/NCI.

(3) 09-25-0077, Clinical Research: Biological Carcinogenesis Branch Human Specimen Program, HHS/NIH/NCI.

(4) 09-25-0099, Clinical Research: Patient Medical Records, HHS/NIH/CC.

We are only republishing those system notices which have been changed; current system notices other then the new ones cited, including the one now being deleted, were last published in the **Federal Register**, October 13, 1982, pp. 45773-45856.

Dated: September 2, 1983.

**James B. Wyngaarden, M.D.,**

*Director.*

**Table of Contents**

The following table of contents lists all currently active systems of records.

*09-25-0001, Clinical Research: Patient Records, HHS/NHLBI.

*09-25-0002, Clinical Research: Patient Phonocardiogram Records, HHS/NIH/NHLBI.

09-25-0003, Administration: Authorized Radionuclide Users File, HHS/NIH/ORS.

09-25-0004, Administration: Registry of Individuals Exposed to Chemical Carcinogens, HHS/NIH/ORS.

09-25-0005, Administration: Library Circulation and User I.D. File, HHS/NIH/OD.

09-25-0007, Administration: NIH Safety Shoes and Safety Glasses Issuance Program, HHS/NIH/ORS.

09-25-0008, Administration: Radiation Workers Monitoring, HHS/NIH/ORS.

*09-25-0009, Clinical Research: Radiotherapy Patient File, HHS/NIH/ORS.

09-25-0010, Research Resources: Registry of Individuals Potentially Exposed to Microbial Agents, HHS/NIH/NCI.

*09-25-0011, Clinical Research: Blood Donor Records, HHS/NIH/CC.

09-25-0012, Clinical Research: Candidate Normal Volunteer Records, HHS/NIH/CC.

*09-25-0013, Clinical Research: Preadmission Medical Records HHS/NIH/CC.

09-25-0014, Clinical Research: Student Records, HHS/NIH/CC.

*09-25-0015, Clinical Research: Collaborative Clinical Epilepsy Research, HHS/NIH/NINCDS.

09-25-0016, Clinical Research: Collaborative Perinatal Project HHS/NIH/NINCDS.

*09-25-0019, Clinical Research: Genetic Counseling HHS/NIH/NINCDS.

*09-25-0020, Clinical Research: Genetics of Neurological Disorders HHS/NIH/NINCDS.

09-25-0021, Clinical Research: Guam Patient/Control Registry, HHS/NIH/NINCDS.

*09-25-0026, Clinical Research: Nervous System Studies, HHS/NIH/ NINCDS.

*09-25-0028, Clinical Research: Patient Medical Histories, HHS/NIH/ NINCDS.

*09-25-0031, Clinical Research: Serological and Virus Data in Studies Related to The Central Nervous System, HHS/NIH/NINCDS.

09-25-0033, International Activities: Fellowships Awarded by Foreign Organizations, HHS/NIH/FIC.

09-25-0034, International Activities: Scholars Program, HHS/NIH/FIC.

09-25-0035, International Activities: International Health Exchange Programs Participants, HHS/NIH/FIC.

*09-25-0036, Grants: IMPAC Grant/Contract Information), HHS/NIH/DRG.

09-25-0037, Clinical Research: Gerontology Research Center Longitudinal Aging Study, HHS/NIH/NIA.

09-25-0038, Clinical Research: Patient Data, HHS/NIH/NIADDK.

09-25-0039, Clinical Research: Diabetes Mellitus Research Study of Southwestern American Indians, HHS/NIH/NIADDK.

09-25-0040, Clinical Research: Southwestern American Indian Patient Data, HHS/NIH/NIADDK.

09-25-0041, Clinical Research: Scientists Requesting Hormone Distribution, HHS/NIH/NIADDK.

09-25-0042, Clinical Research: National Institute of Dental Research Patient Records, HHS/NIH/NIDR.

09-25-0044, Clinical Research: Sensory testing Research Program, HHS/NIH/NIDR.

09-25-0046, Clinical Research: Catalog of Clinical Specimens from Patients, Volunteers and Laboratory Personnel, HHS/NIH/NIAID.

09-25-0048, Clinical Research: Serology-Epidemiology Parasite Research, HHS/NIH/NIAID.

*09-25-0049, Clinical Research: Atlanta Federal Prison Malaria Research Projects, HHS/NIH/NIAID.

09-25-0051, Grants: NIH Fellowship Payroll, HHS/NIH/DFM.

09-25-0053, Clinical Research: Vision Studies, HHS/NIH/NEI.

09-25-0054, Administration: Property Accounting, HHS/NIH/ORS.

09-25-0057, Clinical Research: Burkitt's Lymphoma Registry, HHS/NIH/NCI.

09-25-0060, Clinical Research: Division of Cancer Treatment Clinical Investigations, HHS/NIH/NCI.

09-25-0064, Clinical Research: Japanese Hawaiian Cancer Studies, HHS/NIH/NCI.

09-25-0068, Clinical Research: National Cancer Institute/American Cancer Society National Breast Cancer Screening of Antihypertensives, HHS/NIH/NCI.

09-25-0069, NIH Clinical Center Admissions of the National Cancer Institute, HHS/NIH/NCI.

09-25-0074, Clinical Research: Division of Cancer Biology and Diagnosis Patient Trials, HHS/NIH/NCI.

09-25-0075, Administration: Principal Investigators Submitting Proposals for Protection from Research Risks, HHS/NIH/OD.

09-25-0077, Clinical Research: Biological Carcinogenesis Branch Human Specimen Program, HHS/NIH/NCI.

09-25-0078, Administration: Consultant File, HHS/NIH/NHLBI.

09-25-0087, Administration: Employees and Consultants, HHS/NIH/NIAID.

09-25-0088, Clinical Research: Researchers Using H-2 Soluble Antigen and H-2 Antiserum, HHS/NIH/NIAID.

09-25-0089, Clinical Research: HLA Antiserum and Tray Users, HHS/NIH/NIAID.

09-25-0091, Administration: General Files on Employees, Donors and Correspondents, HHS/NIH/NEI.

09-25-0093, Administration: Authors, Reviewers and Members of the Journal of the National Cancer Institute, HHS/NIH/NCI.

09-25-0096, Contracts: National Cancer Institute Contract Management System Principal Investigators, Project Officers and Contract Specialists, HHS/NIH/NCI.

09-25-0099, Clinical Research: Patient Medical Records, HHS/NIH/CC.

09-25-0100, Clinical Research: Neuropharmacology Studies, HHS/NIH/NINCDS.

09-25-0102, Administration: Grants Associates Program Working Files, HHS/NIH/DRG.

09-25-0105, Administration: Health Records of Employees, Visiting Scientists, Fellows, Contractors and Relatives of Inpatients, HHS/NIH/OD.

09-25-0106, Administration: Executive Secretariat Correspondence Records, HHS/NIH/OD.

09-25-0108, Personnel: Guest Workers/Visiting Fellows/Student Scientists/Scientists Emeriti, HHS/NIH/DPM.

*09-25-0112, Grants: Research, Research Training, Fellowship and Construction Applications and Awards. HHS/NIH/OD.

09-25-0115, Administration: Curricula Vitae of Consultants and Clinical Investigators, HHS/NIH/NIAID.

09-25-0117, International Activities: U.S.—Japan Program Panel Members, HHS/NIH/NIAID.

09-25-0118, Contracts: Professional Services Contractors, HHS/NIH/NCI.

09-25-0121, International Activities: Senior International Fellowships Program, HHS/NIH/FIC.

09-25-0124, Administration: Pharmacology Research Associates, HHS/NIH/NIGMS.

09-25-126, Clinical Research: National Heart, Lung, and Blood Institute Epidemiological and Biometric Studies, HHS/NIH/NHLBI.

09-25-0128, Clinical Research: Neural Prosthesis & Biomedical Engineering Studies, HHS/NIH/NINCDS.

09-25-0129, Clinical Research: Clinical Research Studies Dealing with Hearing, Speech, Language and Chemosensory Disorders, HHS/NIH/NINCDS.

09-25-0130, Clinical Research Studies in the Division of Cancer Cause and Prevention, HHS/NIH/NCI.

09-25-0131, Clinical Research: Clinical Epidemiologic Studies in the Division of Cancer Cause and Prevention, HHS/NIH/NCI.

09-25-0133, Clinical Research: Kidney Transplant Histocompatibility Study (KTHS), HHS/NIH/NIADDK.

09-25-0134, Clinical Research: Epidemiology Studies, National Institute of Environmental Health Sciences, HHS/NIH/NIEHS.

09-25-0135, Grants: PROPHET System Applicants Research Prospectuses, HHS/NIH/DRR.

09-25-0138, Biomedical Research: Studies of Possible Influence on Cognitive and Emotional Development of Children, HHS/NIH/NICHD.

09-25-0140, International Activities: Scientific Visitors at the National Institutes of Health, HHS/NIH/FIC.

09-25-0141, Patient and Donor Records in the Blood Component Support Program for the Division of Cancer Treatment, HHS/NIH/NCI.

09-25-0142, Clinical Research: Records of Subjects in Intramural Research, Epidemiology, Demography and Biometry Studies on Aging, HHS/NIH/NIA.

09-25-0143, Biomedical Research: Records of Subjects in Clinical, Epidemiologic and Biometric Studies of the National Institute of Allergy and Infectious Diseases, HHS/NIH/NIAID.

09-25-0147, Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the National Heart, Lung, and Blood Institute, HHS/NIH/NHLBI.

09-25-0148, Contracted and Contract-Related Research: Records of Subjects in Clinical, Epidemiological and Biomedical Studies of the National Institute of Neurological and Communicative Disorders and Stroke, HHS/NIH/NINCDS.

09-25-0149, Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the National Institute of General Medical Sciences, HHS/NIH/NIGMS.

09-25-0150, Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the National Institute of Environmental Health Sciences, HHS/NIH/NIEHS.

*09-25-0151, Administration: Alert Records Concerning Investigations or Determinations of Misconduct by Current or Potential Recipients of Funds for Biomedical Research, HHS/NIH/OD.

09-25-0152, Biomedical Research: Records of Subject in National Institute of Dental Research Contracted Epidemiological and Biometric Studies, HHS/NIH/NIDR.

09-25-0153, Biomedical Research: Records of Subjects in Biomedical and Behavioral Studies of Child Health and Human Development, HHS/NIH/NICHD.

*Systems which have been changed and are being republished.

**09-25-0001**

**SYSTEM NAME:**

Clinical Research: Patient Records, HHS/NIH/NHLBI.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Building 10 National Institutes of Health
9000 Rockville Pike, Bethesda, MD 20205

Write to System Manager at that address below for the address of the Federal Records Center where records from this system may be stored.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Patients of the National Heart, Lung, and Blood Institute (NHLBI) under study at the National Institutes of Health (NIH).

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Medical histories, diagnostic studies, laboratory data, treatment.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

"Research and Investigation," "National Heart, Lung, and Blood Institute," and "Research and Training in Diseases of the Heart, Blood Vessels, Lung, and Blood and in the Management of Blood Resources," of the Public Health Service Act (42 U.S.C. 214, 287, 287a).

**PURPOSE OF THE SYSTEM:**

1. For use by physicians in evaluation and treatment of patients under study at NIH.

2. To furnish patient data to patients, their families, and with patients' consent, to their private physicians.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made of HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for with the records are collected. The recipients are required to comply with the requirements of the Privacy Act with respect to such records.

Certain infectious diseases may be reported to state government as required by law.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that agency to present and effective defense: *Provided*, That such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File folders, card index, laboratory books, computer memory.

**RETRIEVABILITY:**

Indexed by name or patient number.

**SAFEGUARDS:**

Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to authorized physicians and their assistants.

Physical Safeguards: Records are kept in secure locked metal or wood file cabinets and, in some instances, in locked offices.

Procedural Safeguards: Access to files is strictly controlled by files staff. Access to computerized records is controlled by keyword codes available only to authorized users.

These safeguards are developed in accordance with chapter 45-13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary chapter PHS.hf:45-13, and part 6, ADP Systems Security, of the HHS ADP Systems Manual.

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule (HHS Records Management Manual, Appendix B-361), item 3000-G-3, which allows records to be kept as long as they are useful in scientific research.

**SYSTEM MANAGER AND ADDRESS:**

Administrative Officer, Division of Intramural Research, NHLBI, Building 10, NIH, 9000 Rockville Pike, Bethesda, MD 20205.

**NOTIFICATION PROCEDURE:**

To determine if a record exists, contact: Privacy Act Coordinator, NHLBI, Building 31, Room 5A50, NIH, 9000 Rockville Pike, Bethesda, MD 20205.

An individual who requests notification of or access to a medical record shall, at the time the request is made, designate in writing, a responsible representative, who may be a physician, who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. You may also request a list of accountable disclosures that have been made of your record.

**CONTESTING RECORD PROCEDURE:**

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant.

**RECORD SOURCE CATEGORIES:**

Referring physicians, hospitals and medical centers, patients and families, results of procedures and tests of NIH patients.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-25-0002**

**SYSTEM NAME:**

Clinical Research: Patient Phonocardiogram Records, HHS/NIH/NHLBI.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Building 10, Room 6N258, NIH, 9000 Rockville Pike, Bethesda, MD 20205.

Write to System Manager at the address below for the address of the Federal Records Center where records from this system may be stored.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Heart surgery patients in the NIH Clinical Center with prosthetic valve dysfunction

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Medical records.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

"Research and Investigation" of the Public Health Service Act (42 U.S.C. 241).

**PURPOSE OF THE SYSTEM:**

For research to develop non-invasive diagnostic techniques for detecting prosthetic valve dysfunction.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:**

Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for

which the records are collected. The recipients are required to comply with the requirements of the Privacy Act with respect to such records.

Information may be used to respond to congressional inquiries for constituents concerning admission to the NIH Clinical Center.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that agency to present an effective defense: *Provided,* That such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are stored on magnetic tapes, in log books, and in file folders.

**RETRIEVABILITY:**

Records are retrieved by name.

**SAFEGUARDS:**

(1) Authorized users: Records are available only to physicians and to authorized medical records personnel.

(2) Physical Safeguards: Phonocardiograms are kept in the patient medical records file.

(3) Procedural safeguards: Access to files is strictly controlled by files staff or other designated officials.

These safeguards are developed in accordance with chapter 45–13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary chapter PHS.hf: 45–13, and part 6, ADP System Security, of the HHS ADP Systems Manual.

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research.

**SYSTEM MANAGER AND ADDRESS:**

Senior Surgeon, Surgery Branch, NHLBI, Building 10, Room 6N256, 9000 Rockville Pike, Bethesda, MD 20205

**NOTIFICATION PROCEDURE:**

To determine if a record exists, contact: Privacy Act Coordinator, NHLBI, Building 31, Room 5A50, NIH, 9000 Rockville Pike, Bethesda, MD 20205.

An individual who requests notification of or access to a medical record shall, at the time the request is made, designate in writing, a responsible representative, who may be a physician, who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. You may also request a list of accountable disclosures that have been made of your record.

**CONTESTING RECORD PROCEDURES:**

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant.

**RECORD SOURCE CATEGORIES:**

Attending physicians and collaborating researchers and patients.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09–25–0009**

**SYSTEM NAME:**

Clinical Research: Radiotherapy Patient File, HHS/NIH/ORS.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Building 21, Room 108, NIH, 9000 Rockville Pike, Bethesda, MD 20205

Write to System Manager at the address below for the address of the Federal Records Center where records from this system may be stored.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

NIH patients who have received radiotherapy doses.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Radiotherapy patients records including quantity of material given, type of material, workers involved in patient handling and any radiation exposure received by workers.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

"Safety Programs," and "Research and Investigation" of the Public Health Service Act (5 U.S.C. 7902; 42 U.S.C. 241).

**PURPOSE OF THE SYSTEM:**

To provide a legal record (for Nuclear Regulatory Commission and Food and Drug Administration review) of patients receiving therapeutic levels of radioactive materials.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Records may be disclosed to the Nuclear Regulatory Commission in the exercise of its authority to regulate possession, use and disposal of radioactive materials (10 CFR Parts 20, 30, 35, et al.)

Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected. The recipients are required to comply with the requirements of the Privacy Act with respect to such records.

Information may be used to respond to congressional inquiries for constituents concerning admission to the NIH Clinical Center.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense: Provided, That such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are stored in file cabinets.

**RETRIEVABILITY:**

Records are retrieved by patient name.

**SAFEGUARDS:**

Authorized Users: Access to information stored is limited to the system manager and Radiation Safety Branch (RSB) staff.

Physical Safeguards: Office records are kept in closed cabinets in offices which are locked during off-duty hours.

Procedural Safeguards: Access to files is controlled by responsible employees.

Contractors who maintain records in this system are instructed to make no disclosure of the records except as authorized by the system manager.

These safeguards are developed in accordance with chapter 45–13, "Safeguarding Records Contained in Systems or Records," of the HHS General Administration Manual, and supplementary chapter PHS.hf: 45–13.

**RETENTION AND DISPOSAL:**

Records are kept for six years after the final administration of radiotherapy to a patient. During the six years, records may be stored at a Federal Records Center.

**SYSTEM MANAGER AND ADDRESS:**

Chief, Health Physics Section, Radiation Safety Branch, Building 21, Room 135, NIH, 9000 Rockville Pike, Bethesda, MD 20205

**NOTIFICATION PROCEDURE:**

Write to the System Manager to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. You may also request a list of accountable disclosures that have been made of your record.

**CONTESTING RECORD PROCEDURE:**

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant.

**RECORD SOURCE CATEGORIES:**

Clinical Center, NIH; Radiopharmacy, NIH; individual patient.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09–25–0011**

**SYSTEM NAME:**

Clinical Research: Blood Donor Records, HHS/NIH/CC.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Building 10A, Room 1E33, NIH, 9000 Rockville Pike, Bethesda, MD 20205

Washington National Records Center, 4205 Suitland Road, Suitland, MD 20409

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Donors of blood and blood components to be used in the NIH Clinical Center for patient infusions.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Past donations, blood types, phenotype. Laboratory results on each unit-record are hepatitis B antigen testing, serologic reactions on all blood samples, donations of blood or blood components.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

"Preparation of Biological Products" of the Public Health Service Act (42 U.S.C. 263).

**PURPOSE OF THE SYSTEM:**

1. To provide a means for contacting blood donors for patient care and research.

2. To provide a medical history of all donors for the transfusion records of each blood unit.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected. The recipients are required to comply with the requirements of the Privacy Act with respect to such records.

Certain infectious diseases may be reported to state government as required by law.

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that agency to present an effective defense: *Provided*, That such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are stored in a computer file, on donor cards, and on microfilm.

**RETRIEVABILITY:**

Records are retrieved by name and Social Security Number for verification where the latter is voluntarily provided.

**SAFEGUARDS:**

Authorized Users: Access is granted only to the Blood Bank physicians, the Blood Bank's chief nurse and chief technologist, secretary to the Chief, Blood Bank, and the computer operator.

Physical Safeguards: Record facilities are locked when system personnel are not present.

Procedural Safeguards: Access to manual files is limited to authorized users. Access to computerized records is controlled by the use of security codes known only to the authorized users.

These safeguards are developed in accordance with chapter 45–13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary chapter PHS.hf: 45–13, and part 6, ADP Systems Security, of the HHS ADP Systems Manual.

**RETENTION AND DISPOSAL:**

Donor cards are retained for 18 months and then microfilmed. Microfilm is retained indefinitely in accordance with the NIH Records Control Schedule, item 3000–E–50.

**SYSTEM MANAGER AND ADDRESS:**

Chief, Blood Bank, CC, Building 10A, Room 1E33, NIH, 9000 Rockville Pike, Bethesda, MD 20205

**NOTIFICATION PROCEDURE:**

Write to the System Manager to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical record shall, at the time the request is made, designate in writing, a responsible representative, who may be a physician, who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

**RECORD ACCESS PROCEDURES:**

To obtain access to a record, contact the system manager at the address specified above. Requesters should provide the same information as is required under the notification procedures above. You may also request a list of accountable disclosures that have been made of your record.

**CONTESTING RECORD PROCEDURES:**

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant.

**RECORD SOURCE CATEGORIES:**

Data are collected from the individual.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09–25–0013**

**SYSTEM NAME:**

Clinical Research: Preadmission Medical Records, HHS/NIH/CC.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Building 10, Room 5C305, 9000 Rockville Pike, Bethesda, MD 20205.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Potential patients.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Medical history and letters from individuals and referring physicians.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

"Research and Investigation" and "Hospitals" of the Public Health Service Act (42 U.S.C. 241, 248).

**PURPOSE OF THE SYSTEM:**

To determine appropriateness of individual for participation in clinical research projects.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Information may be used to respond to congressional inquiries for constituents concerning admission to the NIH Clinical Center.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are stored in folders.

**RETRIEVABILITY:**

Records are retrieved by name.

**SAFEGUARDS:**

Authorized Users: The patient referral staff maintains the records in this system and grants regular access only to physicians and dentists participating in patient care at the Clinical Center, NIH.

Physical Safeguards: All record facilities are locked when system personnel are not present.

Procedural Safeguards: Access to the file is strictly controlled by the files staff. Records may be removed from the file only at the request of the system manager or other authorized employees.

These safeguards are developed in accordance with chapter 45–13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, and supplementary chapter PHS.hf: 45–13.

**RETENTION AND DISPOSAL:**

Years at NIH: 3. Disposal methods include burning or shredding paper materials or erasing computer tapes.

**SYSTEM MANAGER AND ADDRESS:**

Chief, Office of Clinical Reports & Inquiries, Building 10, Room 5C305, 9000 Rockville Pike, Bethesda, MD 20205.

**NOTIFICATION PROCEDURE:**

Write to the System Manager to determine if a record exists. The requester must also verify his or her identity by providing either a notarization of the request or a writtten certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquistion of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing, a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child or incompetent person as well as his or her own identity.

**RECORD ACCESS PROCEDURES:**

To obtain access to a record, contact: Director, Clinical Center, Building 10, Room 2C–124, NIH, 9000 Rockville Pike, Bethesda, MD 20205.

And provide the information described under Notification Procedures above. Requesters should also reasonably specify the record contents being sought. You may also request a list of accountable disclosures that have been made of your record.

**CONTESTING RECORD PROCEDURE:**

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to

show how the record is inaccurate, incomplete, untimely or irrelevant.

**RECORD SOURCE CATEGORIES:**

Referring physicians, subject individuals, families or members of Congress.

**SYSTEM EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-25-0015**

**SYSTEM NAME:**

Clinical Research: Collaborative Clinical Epilepsy Research, HHS/NIH/NINCDS.

**SECURITY CLASSIFICATION:**

None

**SYSTEM LOCATION:**

Building 12, NIH 9000 Rockville Pike, Bethesda, MD 20205

And at hospitals, medical schools, universities, research institutions, commercial organizations, state agencies, and collaborating government agencies. Write to the system manager for a list of current locations.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Patients participating in clinical epilepsy research sponsored by the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS).

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Clinical data.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

"Research and Investigation," "Establishment of Institutes" and "Functions" of the Public Health Service Act (42 U.S.C. 241, 289a, 289c).

**PURPOSE OF THE SYSTEM:**

Clinical research on epilepsy, specifically neurophysiological studies of patients and new drug studies designed to improve treatment of epilepsy.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected. The recipients are required to comply with the requirements of the Privacy Act with respect to such records.

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that agency to present an effective defense: *Provided*, That such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are stored in file folders, and on magnetic tape and discs.

**RETRIEVABILITY:**

Records are retrieved by identifying number.

**SAFEGUARDS:**

Authorized Users: Employees who maintain records in this system are instructed to grant access to HHS researchers or the staff of the Epilepsy Branch. No other use is permitted without specific permission of the System Manager.

Physical Safeguards: Records are kept in a location which is locked during non-duty hours.

Procedural Safeguards: Records are used in the system location only and are returned to file cabinets at the end of each working day. Location is attended at all times during working hours. Personnel having access to system have received Privacy Act training. Contractors, grantees and collaborators who maintain records in this system are instructed to make no further disclosure of the records except as authorized by the system manager.

The particular safeguards implemented at each site are developed in accordance with chapter 45-13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary chapter PHS.hf: 45-1: and part 6, ADP Systems Security, o HHS ADP Systems Manual.

**RETENTION AND DISPOSAL:**

Years at NIH: 10. Years at Federal Records Center: 15: Contractors, grantees and collaborators who rece disclosures of records from this syst retain the records only as long as necessary to accomplish the purpos which the disclosures are made.

**SYSTEM MANAGER AND ADDRESS:**

Chief, Epilepsy Branch, NINCDS, Federal Building, Room 114, 7550 Wisconsin Avenue, Bethesda, MD 20205

**NOTIFICATION PROCEDURE:**

To determine if a record exists, w to: Head, Administrative Manageme Section, NINCDS, Building 31, Room 8A47, NIH, 9000 Rockville Pike, Bethesda, MD 20205.

The requester must also verify his her identity by providing either a notarization of the request or a writt certification that the requester is wh or she claims to be and understands the knowing and willful request for acquisition of a record pertaining to individual under false pretenses is a criminal offense under the Act, subj to a five thousand dollar fine.

An individual who requests notification of or access to a medica dental record shall, at the time the request is made, designate in writin responsible representative who will willing to review the record and inf the subject individual of its content the representative's discretion.

A parent or guardian who request notification of, or access to, a child' incompetent person's medical recor shall designate a family physician o other health professional (other tha family member) to whom the record any, will be sent. The parent or gua must verify relationship to the child incompetent person as well as his o own identity.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being so You may also request a list of accountable disclosures that have b made of your record.

**CONTESTING RECORD PROCEDURES:**

Write to the official specified und notification procedures above, and reasonably identify the record and specify the information being conte the corrective action sought, and yo reasons for requesting the correctio

along with supporting information to show the record is inaccurate, incomplete, untimely or irrelevant.

**RECORD SOURCE CATEGORIES:**

Clinical treatment records from physicians, nurses and other sources of care.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-25-0019**

**SYSTEM NAME:**

Clinical Research: Genetic Counseling, HHS/NIH/NINCDS.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Federal Building, NIH, 7550 Wisconsin Ave., Bethesda, MD 20205

Write to the system manager at the address below for the address of any Federal Records Center where records from this system may be stored.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals referred to NIH by their physicians for advice about genetic problems in their families.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Family histories, medical histories, laboratory findings, physicians reports.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

"Research and Investigation," Establishment of Institutes" and "Functions" of the Public Health Service Act (42 U.S.C. 241, 289a, 289c).

**PURPOSE OF THE SYSTEM:**

Research by HHS scientists and approved collaborators to assess the effectiveness and value of genetic counseling for individuals referred by physicians for advice about genetic problems in their families.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected. The recipients are required to comply with the requirements of the Privacy Act with respect to such records.

Certain infectious diseases are reported to state government as required by law.

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that agency to present an effective defense: *Provided,* That such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are stored in file folders.

**RETRIEVABILITY:**

Records are retrieved by name.

**SAFEGUARDS:**

Authorized Users: Employees who maintain records in this system are instructed to grant access only to HHS researchers or their authorized collaborators.

Physical Safeguards: Records are locked in a cabinet during non-working hours in a location also locked during non-working hours.

Procedural Safeguards: Persons having access to this system are trained in Privacy Act requirements. Location is attended at all times during working hours.

These safeguards are developed in accordance with chapter 45-13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, and supplementary chaper PHS. hf: 45-13.

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule (HHS Records Management Manual, Appendix B-361), item 3000-G-3, which allows records to be kept as long as they are useful in scientific research.

**SYSTEM MANAGER AND ADDRESS:**

Research Geneticist, Developmental Neurology Branch, Federal Building, Room 7C10A, 7550 Wisconsin Ave., Bethesda, MD 20205

**NOTIFICATION PROCEDURE:**

To determine if a record exists, contact: Head, Administrative Management Section, NINCDS Building 31, Room 8A47, NIH 9000 Rockville Pike Bethesda, MD 20205

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense uncer the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing, a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. You may also request a list of accountable disclosures that have been made of your record.

**CONTESTING RECORD PROCEDURES:**

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant.

**RECORD SOURCE CATEGORIES:**

Referring physicians.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-25-0020**

**SYSTEM NAME:**

Clinical Research: Genetics of Neurological Disorders, HHS/NIH/NINCDS.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Federal Building, NIH, 7550 Wisconsin Ave., Bethesda, MD 20205

Write to the system manager at the address below for the address of any Federal Records Center where records from this system may be stored.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals with hereditary nervous system disorders and their unaffected relatives in the NIH study.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Family histories, medical histories, laboratory findings.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

"Research and Investigation," "Establishment of Institutes" and "Functions" of the Public Health Service Act (42 U.S.C. 241, 289a, 289c).

**PURPOSE OF THE SYSTEM:**

Reserach by HHS scientists on the genetics of diseases and disorders of the nervous system including inheritance, rates of gene mutation, population characteristics, detection of the heterozygous state, and defects in metabolism.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected. The recipients are required to comply with the requirements of the Privacy Act with respect to such records.

Information may be used to respond to congressional inquiries for constituents concerning admission to the NIH Clinical Center.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that agency to present an effective defense: *Provided*, That such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are stored in file folders and on index cards.

**RETRIEVABILITY:**

Records are retrieved by name and ID number.

**SAFEGUARDS:**

Authorized Users: Employees who maintain records in this system are instructed to grant access only to HHS researchers or their authorized collaborators.

Physical Safeguards: Records are locked in a cabinet during non-working hours in a location also locked during non-working hours.

Procedural Safeguards: Persons having access to this system are trained in Privacy Act requirements. Location is attended at all times during working hours.

These safeguards are developed in accordance with chapter 45–13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, and supplementary chapter PHS.hf: 45–13.

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research.

**SYSTEM MANAGER AND ADDRESS:**

Research Geneticist, Developmental Neurology Branch, Federal Building, Room 8C16A, 7550Wisconsin Ave, Bethesda, MD 20205

**NOTIFICATION PROCEDURE:**

To determine if a record exists, contact: Head, Administrative Management Section, NINCDS, Building 31, Room 8A47, NIH, 9000 Rockville Pike, Bethesda, MD 20205.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical record shall, at the time the request is made, designate in writing, a responsible representative, who may be a physician, who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's or incompetent person's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child of incompetent person as well as his or her own identity.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. You may also request a list of accountable disclosures that have been made of your record.

**CONTESTING RECORD PROCEDURE:**

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant.

**RECORD SOURCE CATEGORIES:**

Patients, relatives, physicians, hospital records.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09–25–0021**

**SYSTEM NAME:**

Clinical Research: Guam Patient/Control Registry, HHS/NIH/NINCDS.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Building 36, Room 5D03, NIH, 9000 Rockville Pike, Bethesda, MD 20205

Write to the system manager at the address below for the address of any Federal Records Center where records form this system may be stored.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Research patients of NIH on Guam.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Medical and demographic data.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

"Research and Investigation," "Establishment of Institutes," and "Functions" of the Public Health Service Act (42 U,S,C. 241, 289a, 289c).

**PURPOSE OF THE SYSTEM:**

Biomedical research on patients by HHS scientists who study selected diseases and conditions found on the island of Guam in the Pacific.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected. The recipients are required to comply with the requirements of the Privacy Act with respect to such records.

Certain infectious diseases are reported to Territorial authorities as required by law.

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that agency to present an effective defense: *Provided*, That such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are stored in file folders, on punch cards, magnetic tape, index cards, and print-out sheets.

**RETRIEVABILITY:**

Records are retrieved by name and ID number.

**SAFEGUARDS:**

Authorized Users: Employees who maintain records in this system are instructed to grant access only to HHS researchers or their authorized collaborators.

Physical Safeguards: Location is locked during non-working hours and records are returned to location at end of working day.

Procedural Safeguards: Persons having access to records are informed of the Privacy Act requirements and location is attended at all times during the working day.

These safeguards are developed in accordance with chapter 45–13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary chapter PHS.hf: 45–13, and part 6, ADP Systems Security, of the HHS ADP Systems Manual.

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research.

**SYSTEM MANAGER AND ADDRESS:**

Director, Intramural Reserarch, National Institute of Neurological and Communicative Disorders and Stroke, (NINCDS), Building 36, Room 5A05, NIH, 9000 Rockville Pike Bethesda, MD 20205.

**NOTIFICATION PROCEDURE:**

To determine if a record exists, contact: Head, Administrative Management Section, NINCDS, Building 31, Room 8A475, NIH, 9000 Rockville Pike Bethesda, MD 20205.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designated in writing, a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. You may also request a list of accountable disclosures that have been made of your record.

**CONTESTING RECORD PROCEDURE:**

Wrte to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant.

**RECORD SOURCE CATEGORIES:**

Individuals and their families.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09–25–0026**

**SYSTEM NAME:**

Clinical Research: Nervous System Studies, HHS/NIH/NINCDS.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Building 36, Room 5B20, NIH, 9000 Rockville Pike, Bethesda, MD 20205.

Write to the system manager at the address below for the address of any Federal Records Center where records from this system may be stored.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Research patients in NIH-related studies having nervous system disorders.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Medical and demographic data.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

"Research and Investigation," "Establishment of Institutes" and "Functions" of the Public Health Service Act (42 U.S.C. 214, 289a, 289c).

**PURPOSE OF THE SYSTEM:**

Clinical research by HHS scientists on patients with special diseases of the nervous system, with particular emphasis on those diseases known or thought to be caused by slow or latent viruses.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected. The

recipients are required to comply with the requirements of the Privacy Act with respect to such records.

Certain infectious diseases are reported to state government as required by law.

Information may be used to respond to congressional inquiries for constituents concerning admission to the NIH Clinical Center.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it seems desirable or necessary to the Department of Justice to enable that agency to present an effective defense: *Provided,* That such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are stored in file folders, on magnetic tape, and on computer print-out sheets.

**RETRIEVABILITY:**

Records are retrieved by name, disease and attending physician name.

**SAFEGUARDS:**

Authorized Users: Employees who maintain records in this system are instructed to grant access only to scientists on the staff of the Central Nervous System Studies Laboratory and their assistants.

Physical Safeguards: Records are kept in a locked location.

Procedural Safeguards: Personnel having access to system are informed of Privacy Act requirements.

These safeguards are developed in accordance with chapter 45–13, "Safeguading Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary chapter PHS. hf: 45–13, and part 6, ADP Systems Security, of the HHS ADP Systems Manual.

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research.

**SYSTEM MANAGER AND ADDRESS:**

Chied, Central Nervous System Studies Lab., Building 31, Room 5B20, NIH, 9000 Rockville Pike, Bethesda, MD 20205.

**NOTIFICATION PROCEDURE:**

To determine if a record exists, contact: Head, Administrative Management Section, NINCDS, Building 31, Room 8A47, NIH, 9000 Rockville Pike Bethesda, MD 20205.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing, a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. You may also request a list of accountable disclosures that have been made of your record.

**CONTESTING RECORD PROCEDURES:**

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reason for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant.

**RECORD SOURCE CATEGORIES:**

Attending physicians.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09–25–0028**

**SYSTEM NAME:**

Clinical Research: Patient Medical Histories, HHS/NIH/NINCDS.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Building 10 & Building 31, NIH, 9000 Rockville Pike, Bethesda, MD 20205.

Write to the system manager at the address below for the address of any Federal Records Center where records from this system may be stored.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Past and present patients of the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), and individuals being referred for admission to the NIH Clinical Center.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Medical histories and diagnoses.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

"Research and Investigation," "Establishment of Institutes," and "Functions" of the Public Health Service Act (42 U.S.C. 241, 289a, 289c).

**PURPOSE OF THE SYSTEM:**

Clinical research on various diseases of the nervous system by HHS scientists and their authorized collaborators, with the specific aim of improving patient care and treatment by evaluating therapeutic procedures.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to HHS contractors grantees and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected. The recipients are required to comply with the requirements of the Privacy Act with respect to such records.

Certain infectious diseases are reported to state governmemt as required by law.

Information may be used to respond to congressional inquiries for constituents concerning admission to the NIH Clinical Center.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to

directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon an individuals mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that agency to present an effective defense: *provided* That such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are stored in file folders.

**RETRIEVABILITY:**

Records are retrieved by name.

**SAFEGUARDS:**

Authorized Users: Employees who maintain records in this system are instructed to grant access only to HHS researchers and their authorized collaborators.

Physical Safeguards: Records are kept locked in a file cabinet when not in use and in a location which is locked during non-working hours.

Procedural Safeguards: Records are returned to the files at the close of each working day and are used only in the system location or in a designated work area.

The particular safeguards implemented at each site are developed in accordance with chapter 45–13, "Safeguarding Records Contained in Systems of Records." of the HHS General Administration Manual, and supplementary chapter PHS.hf: 45–13.

**RETENTION AND DISPOSAL:**

Records are retained and disposed of under the authority of the NIH Records Control Schedule (HHS Records Management Manual, Appendix B–361), item 3000–G–3, which allows records to be kept as long as they are useful in scientific research.

**SYSTEM MANAGER AND ADDRESS:**

Director of Intramural Research, NINCDS, Building 36, Room 5A05, NIH, 9000 Rockville Pike, Bethesda, MD 20205.

**NOTIFICATION PROCEDURE:**

To determine if a record exists, contact: Head, Administrative Management Section, NINCDS, Building 31, Room 8A47, NIH, 9000 Rockville Pike, Bethesda, MD 20205.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing, a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. You may also request a list of accountable disclosures that have been made of your record.

**CONTESTING RECORD PROCEDURE:**

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant.

**RECORD SOURCE CATEGORIES:**

Referring and attending physicians, hospital records.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09–25–0031**

**SYSTEM NAME:**

Clinical Research: Serological and Virus Data in Studies Related to the Central Nervous System, HHS/NIH/NINCDS.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Building 36, Room 5D04, NIH, 9000 Rockville Pike, Bethesda, MD 20205, and at hospitals and clinics, educational and research institutions, Federal, State or local government agencies,and private facilities under contract to the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS). Write to system manager for a list of current locations.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Patients with possible perinatal, acute or chronic diseases and normal volunteers in NIH-related studies pertaining to the central nervous system.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Laboratory findings for viruses.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

"Research and Investigation," "Establishment of Institutes," and "Functions" of the Public Health Service Act (42 U.S.C. 241, 289a, 289c).

**PURPOSE OF THE SYSTEM:**

Clinical research by HHS scientists and their authorized collaborators and research on blood serum, specifically to discover the role of infections (particularly those caused by virus) in diseases of the central nervous system and also to study the role of vaccines in these diseases.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to HHS contractors, grantees and collaborating researchers and their staff in order to accomplish the research purpose for which the records are collected. The recipients are required to comply with the requirements of the Privacy Act with respect to such records.

Certain infectious diseases are reported to State Government as required by law.

Information may be used to respond to Congressional inquiries for constituents concerning admission to the NIH Clinical Center.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example in defending against a claim based upon and individual's mental or physical condition and alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that agency to present an effective defense: *Provided,* That such disclosure is compatible with the

purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are stored on papers and in file folders.

**RETRIEVABILITY:**

Records are retrieved by name and number.

**SAFEGUARDS:**

Authorized Users: Employees who maintain records in this system are instructed to grant access only to HHS scientists and their assistants and authorized collaborators.

Physical Safeguards: Records are kept in cabinets which are locked at all times that system is not in use, in a location which is also locked when system is not in use.

Procedural Safeguards: Personnel having access to system have been trained in Privacy Act requirements. Records are used in a designated work area and the system location is attended at all times during working hours. Contractors, grantees and collaborators who maintain records in this system are instructed to make no further disclosure of the records except as authorized by the system manager.

The particular safeguards implemented at each site are developed in accordance with chapter 45–13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, and supplementary chapter PHS.hf: 45–13.

**RETENTION AND DISPOSAL:**

Years at NIH: 15. Years at Federal Records Center: 20. Contractors, grantees and collaborators who receive disclosures of records from this system retain the records only as long as necessary to accomplish the purpose for which the disclosures are made.

**SYSTEM MANAGER(S) AND ADDRESS:**

Chief, Infectious Diseases Branch, Intramural Research Program, Building 36, Room 5D04, NIH, 9000 Rockville Pike, Bethesda, MD 20205.

**NOTIFICATION PROCEDURE:**

To determine if a record exists, contact: Head, Admin. Management Section, NINCDS, Building 31, Room 8A47, NIH, 9000 Rockville Pike, Bethesda, MD 20205.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and underdstands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. You may also request a list of accountable disclosures that have been made of your record.

**CONTESTING RECORD PROCEDURES:**

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, imcomplete, untimely or irrelevant.

**RECORD SOURCE CATEGORIES:**

Hospital records, volunteers and laboratory data.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09–25–0036**

**SYSTEM NAME:**

Grants: IMPAC (Grant/Contract Information), HHS/NIH/DRG.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Westwood Building, 5333 Westbard Avenue, Bethesda, MD 20205,

and

Building 12, NIH Computer Center, 9000 Rockville Pike, Bethesda, MD 20205

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Applicant and Principal Investigators; Program Directors; NRSA Trainees and Fellows; Research Career Awardees; and Public Advisory Committee Members.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Applications, awards, associated records and trainee appointments.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

"Research and Investigation," of the Public Health Service Act (42 U.S.C. 241).

**PURPOSE OF THE SYSTEM:**

(1) To support grant programs of all Public Health Service agencies and the Office of Health Research, Statistics and Technology, PHS. Services are provided in the areas of grant application assignment and referral, initial review, council review, award processing and grant accounting. The data base is used to provide complete, accurate, and up-to-date reports to all levels of management.

(2) To maintain communication with former fellows and trainees who have incurred a payback obligation through the National Research Service Award Program.

(3) To maintain current and historical information pertaining to the establishment of chartered public advisory committees of the National Institutes of Health and of the Alcohol, Drug Abuse, and Mental Health Administration, and the appointment of their members.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Referrals may be made of assignments of research investigators and project monitors to specific research projects to the National Technical Information Service (NTIS), Department of Commerce, to contribute to the Smithsonian Science Information Exchange, Inc.

To the cognizant audit agency for auditing.

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

To qualified experts not within the definition of Department employees as prescribed in Department Regulations for opinions as a part of the application review process.

To a Federal agency, in response to its request, in connection with the letting of a contact, or the issuance of a license, grant or other benefit by the requesting agency, to the extent that the record is relevant and necessary to the requesting agency's decision in the matter.

A record may be disclosed for a research purpose, when the Department:

(A) Has determined that the use or disclosure does not violate legal or policy limitations under which the

record was provided, collected, or obtained;

(B) Has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring.

(C) Has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law;

(D) Has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

The Department contemplates that it may contract with a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. Relevant records will be disclosed to such a contractor. The contractor will be required to maintain Privacy Act safeguards with respect to such records.

To the grantee institution in connection with performance or administration under the conditions of the award.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense: *Provided* That such disclosure is compatible with the purpose for which the records were collected.

**DISCLOSURE TO CONSUMER REPORTING AGENCIES:**

*Disclosures pursuant to 5 U.S.C. 552a(b)(12):* Disclosures may be made from this system to "consumer reporting agencies" as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) or the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)). NIH may disclose to consumer reporting agencies information on individuals who have failed to meet payback obligations incurred under awards made under authority of the National Research Service Awards Program (41 U.S.C. 289L-1) in order to provide an incentive for individuals to repay, by making these debts part of their credit records, and to enable NIH to improve the quality of the National Research Service Awards Program decisions by taking into account the financial reliability of applicants. Information disclosed will be limited to (1) data identifying the individual, the amount, status and history of the obligation, and that the obligation arose from an award made under the National Research Service Awards Program.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are stored on discs and magnetic tapes.

**RETRIEVABILITY:**

Records are retrieved by name, application, grant or contract ID number.

**SAFEGUARDS:**

Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to PHS extramural staff. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

Physical Safeguards: Physical access to the DRG Remote Job Entry work area is restricted. Offices are locked during off-duty hours.

Procedural Safeguards: Access to source data files is strictly controlled by files staff. Records may be removed from files only at the request of the system manager or other authorized employee. Access to computer files is controlled by the use of registered accounts, registered initials, keywords, etc. The computer systgem maintains an audit record of all attempted and successful requests for access.

These safeguards are developed in accordance with chapter 45-13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary chapter PHS.hf: 45-13, and part 6, ADP System Security, of the HHS ADP System Manual.

**RETENTION AND DISPOSAL:**

Records are retained in accordance with the NIH Records Control Schedule, item 4000-A-2, which allows IMPAC records to be kept as long as there is an administrative need for the information.

**SYSTEM MANAGER(S) AND ADDRESS:**

Chief, Statistics and Analysis Branch, Division of Research Grants, Westwood Building, 5333 Westbard Avenue, Bethesda, MD 20205.

**NOTIFICATION PROCEDURE:**

To determine if a record exists write to: Privacy Act Coordinator, Division of Research Grants, Westbard Building, 5333 Westwood Avenue, Bethesda, MD 20205.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought. You may also request a list of accountable disclosures that have been made of your record.

**CONTESTING RECORD PROCEDURES:**

Write to the official specified under notification procedures above, and resonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant.

**RECORD SOURCE CATEGORIES:**

Individual, individual's educational institution and references.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

09-25-0049

SYSTEM NAME:

Clinical Research: Atlanta Federal Prison Malaria Research Projects, HHS/NIH/NIAID.

SECURITY CLASSIFICATION

None.

SYSTEM LOCATION:

Building 5, Room 114, NIH, 9000 Rockville Pike, Bethesda, MD 20205.

Write to system manager at the address below for the address of the Federal Records Center where records from this system may be stored.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Prisoners in the Atlanta Federal Prison who have volunteered to participate in malaria research studies of the National Institute of Allergy and Infectious Diseases (NIAID).

CATEGORIES OF RECORDS IN THE SYSTEM:

Medical history records.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

"Research and Investigation" and "National Institute of Allergy and Infectious Diseases" of the Public Health Service Act (42 U.S.C. 241, 289a, 289c).

PURPOSE OF THE SYSTEM:

For malaria research studies of the NIAID.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Certain infectious diseases are reported to state governments as required by law.

A record may be disclosed for a research purpose, when the Department:

(A) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained;

(B) Has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring;

(C) Has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law;

(D) Has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, for example, when a claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense: *Provided*, That such disclosure is compatible with the purpose for which the record were collected.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are stored in file folders.

RETRIEVABILITY:

Records are retrieved by name.

SAFEGUARDS:

Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to HHS scientists conducting research, and staff whose duties require the use of such information. Authorized users are located in the Malaria Section, Laboratory of Parasitic Diseases, NIAID Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager.

Physical Safeguards: Offices are locked during off-duty hours. Procedural Safeguards: Access to files is strictly controlled by files staff. Records may be removed from files only at the request of the system manager or other authorized employee.

These safeguards are developed in accordance with chapter 45-13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, and supplementary chapter PHS.hf: 45-13.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule (HHS Records Management Manual, Appendix B-361), item 3000-G-3, which allows records to be kept as long as they are useful in scientific research.

SYSTEM MANAGER(S) AND ADDRESS:

Head, Malaria Section, NIAID, Building 5, Room 114, NIH, 9000 Rockville Pike, Bethesda, MD 20205.

NOTIFICATION PROCEDURE:

To determine if a record exists write to: Privacy Act Coordinator, NIAID, Westwood Building, Room 704, Westbard Avenue, Bethesda, MD 20205.

The requester must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

An individual who requests notification of or access to a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

RECORD ACCESS PROCEDURE:

Same as notification procedure above. Requesters should also reasonably specify the record contents being sought You may also request a list of accountable disclosures that have been made of your record.

**CONTESTING RECORD PROCEDURE:**

Write to the official specified under notification procedures above, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with suporting information to show how the record is inaccurate, incomplete, untimely or irrelevant.

**RECORD SOURCE CATEGORIES:**

Individuals, referring physicians, collaborating scientists, hospitals.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**SYSTEM NAME:**

Grants: Research, Research Training, Fellowship and Construction Applications and Awards, HHS/NIH/OD.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

See Appendix I.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Grant applicants and Principal Investigators; Program Directors; Institutional and Individual Fellows; Research Career Awardees.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Grant applications and review history, awards, financial records, progress reports and related correspondence.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

"Research and Investigation," "National Library of Medicine," "National Cancer Institue, " "National Heart, Lung and Blood Institute," "National Institute of Dental Research," "National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases "National Institute of Neurological and Communicative Diseases and Stroke, and Other Institutes, " "National Institute of Child Health and Human Development," "National Institute of General Medical Sciences," "National Eye Institute," and "National Institute on Aging," of the Public Health Service Act, (42 U.S.C. 241, 276, 281, 287, 288, 289 (a), (d), (e), (i), 289(k-2)).

**PURPOSE OF THE SYSTEM:**

1. Information provided is used by NIH staff for review, award, and administration of grant programs.

2. Information is also used to maintain communication with former fellows who have incurred an obligation through the National Research Service Award Program.

3. Staff may also use curriculum vitae to identify candidates who may serve as ad hoc consultants or committee and council members in the grant peer review process.

4. As a part of the cost analysis of a proposed grant, a budget review is conducted of the percentage of time and effort listed under personnel category, equipment and supply categories, and other items listed under "other" category.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made:

(1) Of assignments of research investigators and project monitors to specific research projects to the National Technical Information Service (NTIS), Department of Commerce, to contribute to the Smithsonian Science Information Exchange, Inc.

(2) To the cognizant audit agency for auditing;

(3) In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likly to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

(4) To a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual;

(5) To qualified experts not within the definition of Department employees as prescribed in Department Regulations for opinions as a part of the application review process;

(6) To a Federal agency, in response to its request, in connection with the letting of a contract, or the issuance of a license, grant or other benefit by the requesting agency, to the extent that the record is relevant and necessary to the requesting agency's decision on the matter;

(7) A record may be disclosed for a research purpose, when the Department: (A) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

(8)To a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in a system. Relevant records will be disclosed to such a contractor. The contractor shall be required to maintain Privacy Act safeguards with respect to such records;

(9) To the grantee institution in connection with performance or administration under the terms and conditions of the award, or in connection with problems that might arise in performance or administration if an award is made on a grant proposal.

**DISCLOSURE TO CONSUMER REPORTING AGENCIES:**

*Disclosures pursuant to 5 U.S.C. 552a(b)(12):* Disclosures may be made from this system to "consumer reporting agencies" as defined in the Fair Credit Reporting Act (15 U.S.C.1681a(f)) or the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)).

NIH may disclose to consumer reporting agencies information on individuals who have failed to meet payback obligations incurred under

awards made under authority of the National Research Service Awards Program (41 U.S.C. 289L-1). In order to provide an incentive for individuals to repay, by making these debts part of their credit records, and to enable NIH to improve the quality of the National Research Service Awards Program decisions by taking into account the financial reliability of applicants. Information disclosed is limited to data identifying the individual, the amount, status and history of the obligation, and that the obligation arose from an award made under the National Research Service Awards Program.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Stored in file folders, on computer tapes and discs, cards and in notebooks.

**RETRIEVABILITY:**

Retrieved by name and grant number.

**SAFEGUARDS:**

A variety of physical and procedural safeguards are implemented, as appropriate, at the various locations of this system:

Authorized Users: Employees who maintain records in this system are instructed to grant regular access only to officials whose duties require use of the information. These officials include review groups, grants management staff, other extramural program staff, health scientist administrators, data processing and analysis staff and management officials with oversight responsibilities for extramural programs. Other one-time and special access is granted on an individual basis as specifically authorized by the system manager. Authorization for access to computerized files is controlled by the system manager or designated official and is granted on a need-to-know basis. Lists of authorized users are maintained.

Physical Safeguards: Secured facilities, locked rooms, locked cabinets, personnel screening; records stored in order of grant numbers which are randomly assigned.

Procedural Safeguards: Access to file rooms and files is strictly controlled by files staff or other designated officials; charge-out cards identifying users are required for each file used; inactive records are transferred to controlled storage in Federal Records Center in a timely fashion; retrieval of records from inactive storage is controlled by the system manager or designated official and by the NIH Records Management Officer; computer files are password protected and access is actively monitored by the Computer Center to prevent abuse. Employees are given specialized training in the requirements of the Privacy Act as applied to the grants program.

These safeguards are developed in accordance with chapter 45-13, "Safeguarding Records Contained in Systems of Records," of the HHS General Administration Manual, supplementary chapter PHS.hf: 45-13, and part 6, ADP Systems Security, of the HHS ADP System Manual.

**RETENTION AND DISPOSAL:**

Years at NIH: 1 year after close out except for Construction Grants which are retained for 3 years after close-out. Years at Federal Records Center: 5 years except for Construction Awards, 12 years.

**SYSTEM MANAGER AND ADDRESS:**

See Appendix II.

**NOTIFICATION PROCEDURE:**

Write to official at the address specified in Appendix II to determine if a record exists. The requester must also verify his or her identify by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

**RECORD ACCESS PROCEDURE:**

Write to the official at the address specified in Appendix IV to obtain access to a record, and provide the same information as is required under the Notification Procedures above. Requesters should also reasonably specify the record contents being sought. Individuals may also request lists of accountable disclosures that have been made of their record(s).

**CONTESTING RECORD PROCEDURE:**

Contact the official at the address specified in Appendix II, and reasonably identify the record and specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant.

**RECORD SOURCE CATEGORIES:**

Information submitted by applicant; supplemented by outside reviewers and internal staff.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**Appendix I—System Location**

National Cancer Institute, Westwood Building, Room 833, 5333 Westbard Avenue, Bethesda, MD 20205

National Heart, Lung, and Blood Institute, Westwood Building, Room 7A11, 5333 Westbard Avenue, Bethesda, MD 20205

National Library of Medicine, Building 38A, Room 5N509, 8600 Rockville Pike, Bethesda, MD 20209

National Institute of Allergy and Infectious Diseases, Westwood Building, Rooms 722 and 735, 5333 Westbard Avenue, Bethesda, MD 20205

National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, Westwood Building, Room 610, 5333 Westbard Avenue, Bethesda, MD 20205

National Institute of Child Health and Human Development, Landow Building, Room A621, 7910 Woodmont Avenue, Bethesda, MD 20205

National Institute of Aging, Building 31, Rm 5C39, 9000 Rockville Pike, Bethesda, MD 20205

National Institute of Dental Research, Westwood Building, Room 518, 5333 Westbard Avenue, Bethesda, MD 20205

National Institute of Environmental Health Sciences, Building 12, Room 1204, Research Triangle Park, North Carolina 27709

National Institute of General Medical Sciences, Westwood Building, Room 938, 5333 Westbard Avenue, Bethesda, MD 20205

National Institute of Neurological and Communicative Disorders and Stroke, Federal Building, Room 10A12, 7550 Wisconsin Avenue, Bethesda, MD 20205

National Eye Institute, Building 31, Room 6A47, 9000 Rockville Pike, Bethesda, MD 20205

Division of Research Resources, Building 31, Room 5B34, 9000 Rockville Pike, Bethesda, MD 20205

Washington National Records Center, 4205 Suitland Road, Suitland, MD 20409

**Appendix II—System Manager and Address**

National Cancer Institute, Grants Privacy Act Coordinator, Room 8A18, Westwood Building, 5333 Westbard Avenue, Bethesda, MD 20205

National Heart, Lung, and Blood Institute, Administrative Officer, Division of Extramural Affairs, Room 5A15, Westwood Building

National Libarary of Medicine, Associate Director for Extramural Programs, Building 38A, Room 5N505

National Institute of Allergy and Infectious Diseases, Chief, Grants Management Branch; Westwood Building, Room 710, and Head, Data Control Section, Westwood Building, Room 733

National Institute of Arthiritis, Diabetes, and Digestive and Kidney Diseases, Grants Management Officer, Room 639, Westwood Building

National Institute of Child Health and Human Development, Chief, Office of Grants and Contracts, Room A621, Landow Building
National Institute on Aging Grants Management Officer, Room 5C39, Building 31
National Institute of Dental Research, Grants Management Officer, NIDR, Room 518, Westwood Building
National Institute of Environmental Health Sciences, Grants Management Officer Room 1209, Building 12, NIEHS
National Institute of General Medical Sciences, Grants Management Officer, NIGMS, Room 938, Westwood Building
National Institute of Neurological and Communicative Disorders and Stroke, Grants Management Officer, Room 1004A, Federal Building
National Eye Institute Grants Management Officer, Room 6A52, Building 31
Division of Research Resources, Director, Office of Grants and Contracts Management, Room 5B34, Building 31

**Appendix III—Notification Procedures**

National Cancer Institute, Chief, Grants Administration Branch, Room 8A18, Westwood Building
National Heart, Lung, and Blood Institute, Privacy Act Coordinator, NHLBI, Room 5A50, Building 31
National Library of Medicine, See Appendix II
National Institute of Allergy and Infectious Diseases, See Appendix II
National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, Administrative Officer, Room 9A46, Building 31
National Institute of Child Health and Human Development, See Appendix II
National Institute on Aging, See Appendix II
National Institute of Dental Research See Appendix II
National Institute of Environmental Health Sciences, See Appendix II
National Institute of General Medical Sciences, See Appendix II
National Institute of Neurological and Communicative Disorders and Stroke, See Appendix II
National Eye Institute, See Appendix II
Division of Research Resources, See Appendix II

**Appendix IV—Record Access Procedures**

National Cancer Institute, Chief, Grants Administration Branch, Room 8A18, Westwood Building
National Heart, Lung, and Blood Institute, See Appendix III
National Library of Medicine, See Appendix II
National Institute of Allergy and Infectious Diseases, Privacy Act Coordinator, Room 705, Westwood Bldg.
National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, See Appendix III
National Institute of Child Health and Human Development, See Appendix II
National Institute on Aging, See Appendix II
National Institute of Dental Research, Grants Management Officer, NIDR, Room 518, Westwood Building
National Institute of Environmental Health Sciences, See Appendix II
National Institute of General Medical Sciences, Privacy Act Coordinator, Room 9A05, Westwood Building
National Institute of Neurological and Communicative Disorders and Stroke, Head, Administration Mgmt. Section, Room 8A47, Building 31
National Eye Institute, Administrative Officer, Room 6A31, Building 31
Division of Research Resources, Privacy Act Coordinator, Room 5B13, Building 31

**09-25-0151**

**SYSTEM NAME:**

Administration: Alert Records Concerning Investigations or Determinations of Misconduct by Current or Potential Recipients of Funds for Biomedical Research, HHS/NIH/OD.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Management Survey and Review Building 31
Office of Extramural Research and Training, Shannon Building, National Institutes of Health (NIH), 9000 Rockville Pike, Bethesda, MD 20205

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

(1) Applicants for or recipients of research grants or contracts on whom sanctions affecting eligibility or special conditions for receipt of research funds have been imposed for a specified period of time as a result of formal investigations for misconduct;

(2) Applicants for or recipients of research grants or contracts who are subjects of formal investigations for misconduct, if the Deputy Director for Extramural Research and Training (DDERT), NIH, has determined that the alleged misconduct is serious enough or that the investigation has produced sufficient information to warrant attention when the award of research funds to such individuals is considered.

(3) Rearchers separated from Federal employment, voluntarily or involuntarily, when the separation resulted from an improper action which would, for a specified period of time, disqualify the researcher from eligibility for research grants or contracts, or would require special precautions or assurances for award of a grant or contract.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

This system consists of two subsystems:

(1) Records on pending or ongoing investigations identifying the alleged misconduct, the individual or institution under investigation, any current research awards to that individual or institution and the entity responsible for the investigation.

(2) Records summarizing sanctions imposed for a specified period of time affecting individuals' or institutions' eligibility for research awards as a result of investigations for misconduct. Such sanctions might include suspension or debarment of the individual or institution from research awards or research activities imposed in accordance with 45 CFR Part 76 or 21 CFR Part 312, or special controls on an individual's or institution's research, such as special award conditions, special reporting requirements or increased requirements for monitoring by the Institutional Review Board at the organization where the individual does research.

Either subsystem may contain responses from subject individuals or institutions.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Authority for this system comes from the legislation which authorizes NIH to award grants and contracts for biomedical research and from NIH's concomitant responsibility to assure that funds disbursed for grants and contracts are spent for authorized purposes and that recipients of such funds conform to all appropriate laws and regulations. (Public Health Service Act, 42 U.S.C. 241, 242(L), 275 et seq., 28 et seq.).

**PURPOSE OF THE SYSTEM:**

(1) NIH uses Alert system records on formally imposed sanctions to ensure that such sanctions are enforced. NIH may inform members of technical merit review groups of the results of investigations only if the disclosure bears directly on the scientific merit of an application or proposal under consideration, or if necessary to ensure an unbiased review when information concerning the conduct investigated has been disclosed from other sources, such as the press.

(2) NIH uses Alert system records on pending or ongoing investigations to make informed decisions on appropriate actions regarding awards of research funds to individuals under investigation as follows:

(a) The Directors of bureaus, institute or divisions of NIH, or the designees of these officials, in consultation with the DDERT, weigh information on investigations in deciding whether it is appropriate to award, delay, restrict or deny award of research funds to an

ndividual or institution under nvestigation.

(b) To obtain independent advice on ppropriate actions with respect to ndividuals under investigation, these fficials or their designees inform the nembers of the National Advisory Council or Board, legally established to dvise the organization on its programs nd activities, of the existence and tatus of an investigation. Such lisclosure is made in closed session when the Council or Board is considering actual or proposed funding of research by the individual or nstitution.

(c) These officials or their designees nay inform members of technical merit eview groups of pending or ongoing nvestigations only if necessary to nsure an unbiased review when nformation concerning the conduct nder investigation has been disclosed rom other sources, such as the press.

**OUTINE USES OF RECORDS MAINTAINED IN HE SYSTEM, INCLUDING CATEGORIES OF SERS AND THE PURPOSES OF SUCH USES:**

To qualified experts not within the lefinition of Department employees as rescribed in Department Regulations or opinions as a part of the application eview process.

To a Federal agency, in response to its equest, in connection with the letting of contract, or the issuance of a license, rant or other benefit by the requesting gency, to the extent that the record is elevant and necessary to the requesting gency's decision in the matter.

Disclosure may be made to a ongressional office from the record of n individual in response to an inquiry rom the congressional office made at he request of that individual.

**OLICIES AND PRACTICES FOR STORING, ETRIEVING, ACCESSING, RETAINING, AND ISPOSING OF RECORDS IN THE SYSTEM:**

**TORAGE:**

Records are stored in file folders.

**ETRIEVABILITY:**

Records are retrieved by name.

**AFEGUARDS:**

Authorized Users: Records are vailable only to the System Manager or he Deputy Director for Extramural Research and Training, NIH, to the Director of the bureau, institute or division of NIH which has funded or is considering funding research by a ubject individual or institution, or to he designee(s) of these officials. These fficials or their designees may disclose nformation to members of National Advisory Councils, Boards, or technical nerit review groups only when such disclosure is relevant and necessary to review of research funding. Any disclosure to other individuals must be authorized by the system manager.

Procedural Safeguards: Access to records is strictly controlled by the system manager and the officials specified under 'Authorized Users.' Individuals who receive disclosures from this system are informed that the information is confidential. They are instructed to address all questions and inquiries from any party either to the System Manager, the Deputy Director for Extramural Research and Training, NIH, or to the Director of the bureau, institute or division for reply. Disclosures to Boards, Councils or review groups are made in closed session.

**PHYSICAL SAFEGUARDS:**

Records are kept in locked file cabinets in offices which are locked when not attended. These measures follow the standards established in chapter 45–13 of the HHS General Administration Manual and supplementary chapter PHS hf: 45–13.

**RETENTION AND DISPOSAL:**

Records on an investigation in progress are retained until the investigation is completed. If the investigation results in a determination that no misconduct occurred, or that any misconduct was not significant enough to warrant official sanction, the record relating to that investigation is destroyed. If an investigation results in official sanction, a record of such sanction is maintained for the duration of the sanction and is then destroyed. Disposal is by burning or shredding.

**SYSTEM MANAGER AND ADDRESS:**

Director, Division of Management Survey and Review, National Institutes of Health, Building 31, Room 4C02, 9000 Rockville Pike, Bethesda, MD 20205

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the System Manager at the address above; provide your full name and state that the inquiry concerns Privacy Act system of records number 09–25–0151.

The requestor must also verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

**RECORD ACCESS PROCEDURES:**

Write to the System Manager at the address above and provide the same information as required for notification. Requesters should also reasonably specify the record contents being sought. Individuals may also request listings of accountable disclosures of their records.

**CONTESTING RECORD PROCEDURES:**

Write to the system manager and reasonably identify the record and the information being contested; and state your reasons for requesting the change, along with supporting information to show that the record is untimely, incomplete, irrelevant or inaccurate.

**RECORD SOURCE CATEGORIES:**

Information in these records is obtained from organizations responsible for investigations, from subject individuals, and from NIH organizations which formerly employed researchers separated from Federal service as a result of improper actions.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

[FR Doc. 83-31244 Filed 11-28-83; 8:45 am]
BILLING CODE 4140-01-M

## Public Health Service

## Centers for Disease Control

## Privacy Act of 1974; Annual Publication of Systems of Records

**AGENCY:** Public Health Service, Centers for Disease Control, HHS.

**ACTION:** Privacy Act: Annual republication of notices of systems of records.

**SUMMARY:** The Centers for Disease Control (CDC) is publishing this document to meet the requirement of the Privacy Act, as amended by the Congressional Reports Elimination Act (Pub. L. 97–375), to republish the notices of systems of records which have been revised.

This publication provides a table of contents which contains the numerical designations and titles of all systems of records maintained by CDC and its organizational components, including the National Institute for Occupational Safety and Health (NIOSH). In addition, the notices of systems of records which have been revised following a comprehensive review are indicated by an asterisk in the Table of Contents and are published below in their entirety. CDC's system notices were last published in the **Federal Register**, Vol. 47, No. 198, pp. 45469–45513, October 13,

1982. One additional new system of records: 09-20-0161, "Records of Health Professional in Disease Prevention and Control Training Programs," HHS/CD/CPS, has been published in the **Federal Register** Vol. 48, No. 127, pp. 30187-30188, June 30, 1983.

Twenty-five of the forty-two notices which were published in the 1982 annual compilation have been modified to clarify the descriptions and to ensure that they are complete, accurate, and timely. None of these changes requires a report of altered system to be sent to the Congress and the Office of Management and Budget. The notices are complete and accurate as of August 15, 1983.

**SUPPLEMENTARY INFORMATION:** The notices being republished include several changes which have been made since the 1982 annual publication, as summarized here.

A. Clarification of System Purpose and Title: The purpose and title categories have been clarified in system 09-20-0096 to more accurately describe this system's current fu nction in providing medical benefits to eligible persons. The changes in wording do not involve any change in the scope of the system notice as originally published in the **Federal Register.**

B. Correction of System Authority: The system authority category has been revised in systems 09-20-0001, 09-20-0147, 09-20-0148, 09-20-0149, 09-20-0150-09-20-0151, and 09-20-0152 to replace the outdated title of the pertinent statute with its current title, which is "Federal Mine Safety and Health Act of 1977."

C. Deletion of System Location: The system location and system manager categories have been revised in system 09-20-0106 to delete references to the CDC organizational component previously located in Phoenix, Arizona. The records fron this organizational component have been returned to CDC's Center for Infectious Diseases at the address shown in the system notice.

Similarly, the system location and system manager categories have been revised in system 09-20-0055 to delete references to the NIOSH Grants Administration and Review Branch previously located in Rockville, Maryland. The records from this organizational component have been transferred to CDC's Procurement and Grants Office at the address shown in the system notice.

D. Organization Name Change: The system location and system manager categories have been revised in systems 09-20-0156, 09-20-0157, and 09-20-0158 to show the organization's new name, Laboratory Program Office, and to provide the correct mailing address to which laboratory workers may submit requests for their proficiency examination results.

E. Safeguards: The safeguards category has been revised where needed to reflect the appropriate implementation guideline citation.

F. Disclosures without consent of subject individuals are permitted by the Privacy Act itself in Section 3(b), as follows:

"(1) To those officers and employees of the agency which maintains the record who have a need for the records in the performance of their duties;

"(2) Required under section 552 of this title (the Freedom of Information Act);

"(3) For a routine use as defined in * * * (The Privacy Act and described in the routine use section of the specific notices of systems of records published in the **Federal Register**);

"(4) To the Bureau of the Census for purpose of planning or carrying out a census or survey or related activity pursuant to the provisions of title 13;

"(5) To a recipient who has provided the agency with advance adequate written assurance that the record will be used solely as a statistical research or reporting record, and the record is to be individually identifiable;

"(6) To the National Archives of the United States as a record which has sufficient historical or other value to warrant its continued preservation by the United States Government, or for evaluation by the Administrator of General Services or his designee to determine whether the record has such value;

"(7) To another agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the agency which maintains the record specifying the particular portion desired and the law enforcement activity for which the record is sought;

"(8) To a person pursuant to a showing of compelling circumstances affecting the health or safety of an individual if, upon such disclosure, notification is transmitted to the last known address of such individual;

"(9) To either House of Congress, or to the extent of matter within its jurisdiction, any committee or subcommittee thereof, any joint committee of Congress or subcommittee of any such joint committee;

"(10) To the Comptroller General, or any of his authorized representatives, in the course of the performance of the duties of the General Accounting Office;

"(11) Pursuant to the order of a court of competent jurisdiction * * *".

"[12] To a consumer reporting agency in accordance with section 3(d) of the Federal Claims Collection Act of 1966 (31 U.S.C. 952(d))."

Permissible disclosure [12] was added this year by Pub. L. 97-365, the Debt Collection Act of 1982, to allow disclosures of information to consumer reporting agencies to provide an incentive for debtors to repay delinquent Federal Government debts by making these debts part of their credit records. This "Special Disclosure" statement does not apply to any CDC system of records.

G. Readers who notice any inadvertent error or omission in CDC system notices are invited to bring them to the attention of: Sara S. Owens, Privacy Act Officer, Centers for Disease Control, 1600 Clifton Road, NE., Bldg. 1, Room B-68, Atlanta, Georgia 30333.

Dated: August 18, 1983.

**Elvin Hilyer,**

*Assistant Executive Officer, Centers for Disease Control.*

**Table of Contents**

*Centers for Disease Control*

The following table of contents lists all currently active systems of records.

09-20-0000 Cooperative Mycoses Study. HHS/CDC/OCD.
* 09-20-0001 Certified Interpreting Physician File. HHS/CDC/NIOSH.
* 09-20-0027 Radiation Exposure Records for NIOSH Employees. HHS/CDC/NIOSH.
* 09-20-0055 Research/Demonstration, and Training Grants, and Cooperative Agreements Application Files. HHS/CDC/NIOSH.
* 09-20-0059 Division of Training Mailing List. HHS/CDC/NIOSH.
* 09-20-0083 Diagnostic Methods for Identification of Occupational Diseases through Biopsy and/or Autopsy Specimens HHS/CDC/NIOSH.
09-20-0086 Surveillance of Persons on Isoniazid Preventive Treatment for Tuberculosis. HHS/CDC/CPS.
09-20-0087 Surveillance of Inadvertent Vaccination during Preganancy. HHS/CDC/CPS.
09-20-0088 Subacute Sclerosing Panencephalitis Surveillance. HHS/CDC/CPS.
09-20-0089 Studies of Treatment of Tuberculosis and other Mycobacterioses. HHS/CDC/CPS.
09-20-0090 Studies of Testing for Tuberculosis and other Mycobacterioses. HHS/CDC/CPS.

* The system notices which have been revised following the review process are republished below in their entirety.

09-20-0093 Tuberculosis Preventive Therapy Studies. HHS/CDC/CPS.
09-20-0094 Studies of Drug Resistant Tuberculosis Cases/Contacts. HHS/CDC/CPS.
09-20-0095 Varicela Zoster Immune Globulin Records on High Risk Immunosuppressed Children Exposed to Chickenpox. HHS/CDC/CPS.
* 09-20-0096 Records of Tuskegee Study Health Benefit Recipients. HHS/CDC/CPS.
09-20-0097 Studies of the Effects of BCG Vaccinations for Tuberculosis. HHS/CDC/CPS.
09-20-0098 Congenital Rubella Registry. HHS/CDC/CPS.
09-20-0102 Alien Mental Waiver Program. HHS/CDC/CPS.
09-20-0103 Alien Tuberculosis Follow-up Program. HHS/CDC/CPS.
* 09-20-0106 Specimen Handling for Testing and Related Data. HHS/CDC/CID.
* 09-20-0107 Dengue and Research Studies. HHS/CDC/CID.
09-20-0112 CDC Exchange Visitor and Guest Researcher Records. HHS/CDC/OAM.
09-20-0113 Epidemic Investigation Case Records. HHS/CDC/CID.
* 09-20-0117 Medical and Test Record Results of Individuals Involved in NIOSH Laboratory Studies. HHS/CDC/NIOSH.
* 09-20-0118 Study at Work-Sites where Agents Suspected of Being Occupational Hazards Exist. HHS/CDC/NIOSH.
09-20-0136 Epidemiologic Studies and Surveillance of Disease Problems. HHS/CDC/CID.
* 09-20-0137 Passport File. HHS/CDC/FMO.
09-20-0138 Epidemic Intelligence Service Officers Files. HHS/CDC/EPO.
* 09-20-0147 Occupational Health Epidemiological Studies. HHS/CDC/NIOSH.
* 09-20-0148 Results of Occupational Hearing Studies. HHS/CDC/NIOSH.
* 09-20-0149 General Industry Morbidity Studies. HHS/CDC/NIOSH.
* 09-20-0150 Morbidity Studies in Coal Mining Activities. HHS/CDC/NIOSH.
* 09-20-0151 Mortality Studies in Coal Mining Activities. HHS/CDC/NIOSH.
* 09-20-0152 Mortality Studies in Non-Coal Mining Activities. HHS/CDC/NIOSH.
* 09-20-0153 General Industry Mortality Studies. HHS/CDC/NIOSH.
* 09-20-0154 Medical and Laboratory Studies. HHS/CDC/NIOSH.
* 09-20-0155 Morbidity Studies in Metal and Non-Metal Mining Activities. HHS/CDC/NIOSH.
* 09-20-0156 Cytotechnologist Proficiency Answer Sheets and Test Results (Medicare). HHS/CDC/LPO.
* 09-20-0157 Clinical Laboratory Technologists Proficiency Answer Sheets and Test Results (Medicare). HHS/CDC/LPO.
* 09-20-0158 Independent Laboratory Directors Proficiency Answer Sheets and Exam Results (Medicare). HHS/CDC/LPO.
* 09-20-0159 Records of Subjects in Certification, Testing and Safety Studies of Personal Protective Devices for Hazardous Work Environments. HHS/CDC/NIOSH.
09-20-0160 Records of Subjects in Health Education Studies. HHS/CDC/CHPE.
09-20-0161 Records of Health Professionals in Disease Prevention and Control Training Programs. HHS/CDC/CPS.

**09-20-0001**

**SYSTEM NAME:**

Certified Interpreting Physician File. HHS/CDC/NIOSH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH), 944 Chestnut Ridge Road, Morgantown, West Virginia 26505

Data are also occasionally located at contractor sites as studies are developed, data collected, and reports written. A list of contractor sites where individually identifiable data are currently located is available upon request to the System Manager.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Physicians who have been certified to interpret x-rays under the Federal Mine Health and Safety Act of 1977.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Physician's qualifications.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Federal Mine Health and Safety Act of 1977, Section 501 (30 U.S.C. 951).

**PURPOSE(S):**

The main purpose is to provide certified physicians to read x-rays. Data is provided to the Social Security Administration to be used in approving Title IV benefits under the Act.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Name and address supplied to coal operators and x-ray facilities so that they may contact physicians to do work for them.

Name, address and Social Security number supplied to Department of Labor to be used in approving Title IV Benefits under the Act.

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

Records subject to the Privacy Act are disclosed to private firms for data entry, computer systems analysis and computer programming services. The contractors promptly return all data entry records, and all computer work is done on Government-owned computers. The contractors are required to maintain Privacy Act safeguards.

In the event of litigation initiated at the requrst of NIOSH, the Institute may disclose such records as it deems desirable or necessary to the Department of Justice to enable the Deparment to effectively represent the Institute, provided such disclosure is compatible with the purpose for which the records were collected. The only types of litigative proceedings that NIOSH is authorized to request are (1) enforcement of a subponea issued to an employer to provide relevant information, or (2) contempt citation against an employer for failure to comply with a warrant obtained by the Institute.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Computer printouts, microfilm, computer tape, computer disk.

**RETRIEVABILITY:**

Name or social security number is the index used to retrieve records. Social security numbers which are supplied on a voluntary basis are used for retrieval.

**SAFEGUARDS:**

24-hour guard service in building, locked building, locked rooms, personnel screening, locked computer room and computer tape vaults, locked file cabinets, computer tapes are password protected.

Computerized records are protected by personnel screening, locked computer room, locked tape vaults, and lack of telecommunications.

For computerized records, safeguards are in accordance with HHS/ADP System Security Manual, Part 6. The

safeguards described for nonautomated records are in accordance with Chapter 45-13 in the General Administration Manual, and the Supplementary PHS chapter.

**RETENTION AND DISPOSAL:**

Records are retained indefintely unless disposal of a record is requested by the individual physician. Disposal methods include erasing computer tapes and burning or shredding printouts.

**SYSTEM MANAGER(S) AND ADDRESS:**

Program Management Officer, Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH), 944 Chestnut Ridge Road, Morgantown, West Virginia 26505.

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about herself/himself upon written request, with notarized signature if request is made by mail, or with suitable identification (i.e., driver's license, passport) if request is made in person. All individuals requesting records are informed that anyone who knowingly and willfully requests access to a record pertaining to an individual under false pretenses is committing a criminal offense under the Act and subject to a maximum fine of $5,000. To determine if a record exists, write to: Director, Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH), 944 Chestnut Ridge Road, Morgantown, West Virginia 26505

An individual who requests notification of or access to medical records shall, at the time the request is made, (1) provide a written notarized request designating a responsible representative who is willing to review the record and inform the subject individual of its contents at the representative's discretion, (2) supply the name of the study, if known, (3) provide the approximate date and place of the study, if known, and (4) provide the approximate date and place of treatment or questionnaire administration.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under notification procedures above, and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Information is obtained directly from the individual.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-20-0027**

**SYSTEM NAME:**

Radiation Exposure Records for NIOSH Employees. HHS/CDC/NIOSH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Safety Research (DSR), National Institute for Occupational Safety and Health (NIOSH), 944 Chestnut Ridge Road, Morgantown, West Virginia 26505

Division of Technical Services (DTS), NIOSH, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226

Data are also occasionally located at contractor sites, as studies are developed, data collected, and reports written. A list of contractor sites, where individually identifiable data are currently located, is available upon request to the System Manager.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Present and past NIOSH employees.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Name, X-ray exposure levels.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Occupational Safety and Health Act Section 19 (29 U.S.C. 668).

**PURPOSE(S):**

The purpose of this system is to maintain x-ray exposure records to prevent toxic exposure to harmful rays.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense: *Provided*, Such disclosure is compatible with the purpose for which the records were collected. For example, records may be released to the Department of Justice in defending claims against the U.S. when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual.

Records subject to the Privacy Act are disclosed to private firms for data entry, computer systems analysis and computer programming services. The contractors promptly return all data entry records, and all computer work is done on Government-owned computers. The contractors are required to maintain Privacy Act safeguards.

In the event of litigation initiated at the request of NIOSH, the Institute may disclose such records as it deems desirable or necessary to the Department of Justice to enable the Department to effectively represent the Institute, provided such disclosure is compatible with the purpose for which the records were collected. The only types of litigative proceedings that NIOSH is authorized to request are (1) enforcement of a subpoena issued to an employer to provide relevant information, or (2) contempt citation against an employer for failure to comply with a warrant obtained by the Institute.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Manual files.

**RETRIEVABILITY:**

Name is the index used to retrieve records from this system.

**SAFEGUARDS:**

24-hour guard service in building, locked building, locked rooms, personnel screening, locked file cabinets.

For computerized records, safeguards are in accordance with HHS/ADP System Security Manual, Part 6. The safeguards described for nonautomated records are in accordance with Chapter 45-13 in the General Administration Manual, and the supplementary PHS chapter.

**RETENTION AND DISPOSAL:**

Record copy maintained from three to ten years in accordance with retention schedules. Source documents for computer disposed of when no longer needed in the study, as determined by the system manager, and as provided in the signed consent form, as appropriate. Disposal methods include burning or shredding paper materials.

**SYSTEM MANAGER(S) AND ADDRESS:**

Physicist, Office of the Director, Division of Safety Research (DSR), National Institute for Occupational Safety and Health (NIOSH), 944 Chestnut Ridge Road, Morgantown, West Virginia 26505

Industrial Hygienist, Office of Administrative and Management Services (OAMS), National Institute for Occupational Safety and Health (NIOSH), Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about herself/himself upon written request, with notarized signature if request is made by mail, or with suitable identification (i.e., driver's license, passport) if request is made in person. All individuals requesting records are informed that anyone who knowingly and willfully requests access to a record pertaining to an individual under false pretenses is committing a criminal offense under the Act and subject to a maximum fine of $5,000.

To determine if a record exists, write to: Director, Division of Safety Research (DSR), National Institute for Occupational Safety and Health (NIOSH), 944 Chestnut Ridge Road, Morgantown, West Virginia 26505.

An individual who requests notification of or access to medical records shall, at the time the request is made, (1) provide a written notarized request designating a responsible representative who is willing to reveiw the record and inform the subject individual of its contents at the representative's discretion, (2) supply the name of the study, if known, (3) provide the approximate date and place of the study, if known, and (4) provide the approximate date and place of treatment or questionnaire administration.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under notification procedures above, and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Information is obtained directly from the individual.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-20-0055**

**SYSTEM NAME:**

Research/Demonstration, and Training Grants, and Cooperative Agreements Application Files. HHS/CDC/NIOSH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Research Grants, National Institute of Health, Westbard Building, Westbard Avenue, Bethesda, Maryland, 20014

Grants Management Office, Procurement and Grants Office, Room 107, 255 East Paces Ferry Road, NE, Centers for Disease Control, Atlanta, Georgia 30333

Division of Training and Manpower Development, National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, Cincinnati, Ohio, 45226

Grants Management Officer, Procurement and Grants Office, Room 107, 255 East Paces Ferry Road, NE, Centers for Disease Control, Atlanta, Georgia 30333

and;

Federal Records Center, 4205 Suitland Road, Suitland, Maryland 20409

Data are also occasionally located at grantee sites as studies are developed, data collected, and reports written. A list of grantee sites where individually identifiable data are currently located is available upon request to the System Manager.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Applicants for occupational safety and health research and demonstration grants, and training grants.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Draft and final grant application and review history, awards, financial records and progress reports and related correspondence.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Occupational Safety and Health Act, Sections 20 and 21 (29 U.S.C. 669, 670).

**PURPOSE(S):**

The purpose of this system is to review grant applications for research and training and to administer funded grants. This information is provided to the National Institutes of Health and to components of NIOSH for review.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Referrals may be made of assignments of research investigators and project monitors on specific research projects to the National Technical Information Service (NTIS), Department of Commerce, to contribute to the Smithsonian Science Information Exchange.

To the cognizant audit agency for auditing.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense: *Provided*, Such disclosure is compatible with the purpose for which the records were collected.

To a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

To qualified experts not within the definition of Department employees as prescribed in Department regulations for opinions as a part of the application review process.

To a Federal agency, in response to its request, in connection with the letting of a contract, or the issuance of a license, grant or other benefit by the requesting agency, to the extent that the record is relevant and necessary to the requesting agency's decision on the matter.

To individuals and organizations deemed qualified by PHS to carry out specific research related to the review and award processes of PHS.

To the grantee institution relative to performance or administration under the terms and conditions of the award.

Records subject to the Privacy Act are disclosed to private firms for data entry, computer systems analysis and computer programming services. The contractors promptly return all data entry records, and all computer work is done on Government-owned computers The contractors are required to maintain Privacy Act safeguards.

In the event of litigation initiated at the request of NIOSH, the Institute may disclose such records as it deems desirable or necessary to the Department of Justice to enable the Department to effectively represent the Institute, provided such disclosure is compatible with the purpose for which the records were collected. The only types of litigative proceedings that NIOSH is authorized to request are (1) enforcement of a subpoena issued to an employer to provide relevant information, or (2) contempt citation against an employer for failure to comply with a warrant obtained by the Institute.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE.**

5 x 8 cards, computer tapes and discs, notebooks and file folders.

**RETRIEVABILITY:**

Name is the index used to retrieve information.

**SAFEGUARDS:**

The records are maintained in locked cabinets with access limited to authorized personnel (system manager, principal investigator assigned to the project, project officer.)

Computerized records are protected by personnel screening, password protection, locked computer rooms, and locked tape vaults.

For computerized records, safeguards are in accordance with HHS/ADP System Security Manual, Part 6. The safeguards described for nonautomated records are in accordance with Chapter 45-13 in the General Administration Manual, and the supplementary PHS chapter.

**RETENTION AND DISPOSAL:**

Information is kept for one year beyond termination and then sent to the Federal Records Center for five years, after which it is destroyed. Unfunded applications are treated in the same manner. Draft applications are kept for one year or until an official application is received and then destroyed.

**SYSTEM MANAGER(S) AND ADDRESS:**

Grants management Officer. Procurement and Grants Management Office, Centers for Disease Control, Room 107, 255 East Paces Ferry Road, NE, Atlanta, Georgia 30333.

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about himself or herself by contacting the System Manager at the address above. Requesters in person must provide driver's license or other positive identification. Individuals who do not appear in person must either (1) submit a notarized request to verify their identity or (2) must certify that they are the individuals they claim to be and that they understand that the knowing and willfull request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Privacy Act subject to a $5,000 fine.

**RECORD ACCESS PROCEDURES:**

Contact the System Manager. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under notification procedures above, and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Information is obtained directly from the individual.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-20-0059**

**SYSTEM NAME:**

Driving of Training Mailing List. HHS/CDC/NIOSH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Training and Manpower Development (DTMD), National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, Cincinnati, Ohio 45226.

Data are also occasionally located at contractor sites as studies are developed, data collected, and reports written. A list of contractor sites where individually identifiable data are currently located is available upon request to the System Manager.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Persons who have taken a NIOSH training course or who ask to be placed on the list.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Name and address.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Occupational Safety and Health Act, Section 21 (29 U.S.C. 670).

**PURPOSE(S):**

The purpose of this system is to advise prospective students of upcoming NIOSH training course.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

Records subject to the Privacy Act are disclosed to private firms for data entry, computer systems analysis and computer programming services. The contractors promptly return all data entry records, and all computer work is done on Government-owned computers. The contractors are required to maintain Privacy Act safeguards.

In the event of litigation initiated at the request of NIOSH, the Institute may disclose such records as it deems desirable or necessary to the Department of Justice to enable the Department to effectively represent the Institute, provided such disclosure is compatible with the purpose for which the records were collected. The only types of litigative proceedings that NIOSH is authorized to request are (1) enforcement of a subpoena issued to an employer to provide relevant

information, or (2) contempt citation against an employer for failure to comply with a warrant obtained by the Institute.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Computer tapes, addressograph plates.

**RETRIEVABILITY:**

Name and Student Number are the indexes used to retrieve records from this system.

**SAFEGUARDS:**

24-hour guard service in building, locked building, locked rooms, personnel screening, locked filed cabinets, locked computer room and computer tape vaults, password protection on computerized files.

For computerized records, safeguards are in accordance with HHS/ADP System Security Manual, Part 6. The safeguards described for nonautomated records are in accordance with Chapter 45-13 in the General Administration Manual, and the supplementary PHS chapter.

**RETENTION AND DISPOSAL:**

Record copy maintained from three to ten years in accordance with retention schedules. Source documents for computer disposed or when no longer needed in the study, as determined by the system manager, and as provided in the signed consent form, as appropriate. Disposal methods include erasing computer tapes and burning or shredding paper materials.

**SYSTEM MANAGER(S) AND ADDRESS:**

Audio Visual Production Officer, Division of Training and Manpower Development (DTMD), National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, Cincinnati, Ohio 45226.

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about himself or herself by contacting by the System Manager at the address above. Requesters in person must provide driver's license or other positive identification. Individuals who do not appear in person must either (1) submit a notarized request to verify their identify, or (2) must certify that they are the individuals they claim to be and that they understand that the knowing and willful request for or acquisition or a record pertaining to an individual under false pretenses is a criminal offense under the Privacy Act subject to a $5,000 fine.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under notification procedures above, and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Information is obtained directly from the individual.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-20-0083**

**SYSTEM NAME:**

Diagnostic Methods for Identification of Occupational Diseases through Biopsy and/or Autopsy Specimens. HHS/CDC/NIOSH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Biomedical and Behavioral Science (DBBS), National Institute for Occupational Safety and Health (NIOSH), Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

Also, occasionally data may be located at the facilities of collaborating researchers where analyses are performed, data collected and reports written. A list of these facilities is available upon request to the system manager. Data may be located only at those facilities that have an adequate data security program and the collaborating researcher must return the data to NIOSH or destroy individual identifiers at the conclusion of the project.

A list of contractor sites where individually identifiable data are currently located is available upon request to the System Manager.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Industrial workers.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Medical records, and information necessary to interpret the medical records.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Occupational Safety and Health Act Section 20 (29 U.S.C. 669).

**PURPOSE(S):**

The purpose of this system is to diagnose occupational diseases by tissue examination and analysis.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Test results are furnished to the physican who requests analysis.

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

Portions of records (name, Social Security number if known, date of birth, and last known address) may be disclosed to one or more other sources selected from those listed in Appendix I, as applicable. This may be done solely for obtaining a determination as to whether or not an individual has died. The purpose of determining death is so that NIOSH may obtain death certificates, which state the cause of death, from the appropriate Federal, State, or local agency. Cause of death enables NIOSH to evaluate whether excess occupationally related mortality is occurring.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense: *Provided,* Such disclosure is compatible with the purpose for which the records were collected. For example, records may be released to the Department of Justice in defending claims against the U.S. when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual.

Records subject to the Privacy Act are disclosed to private firms for data entry, computer systems analysis and computer programming services. The contractors promptly return all data entry records, and all computer work is done on Government-owned computers. The contractors are required to maintain Privacy Act safeguards.

In the event of litigation initiated at the request of NIOSH, the Institute may disclose such records as it deems desirable or necessary to the Department of Justice to enable the Department to effectively represent the Institute, provided such disclosure is compatible with the purpose for which the records were collected. The only types of litigative proceedings that NIOSH is authorized to request are (1) enforcement of a subpoena issued to an employer to provide relevant information, or (2) contempt citation against an employer for failure to comply with a warrant obtained by the Institute.

Disclosure may be made to NIOSH collaborating researchers (NIOSH contractors, grantees, or other Federal or State scientists) in order to accomplish the research purpose for which the records are collected. The collaborating researchers must agree in writing to comply with the confidentiality provisions of the Privacy Act and NIOSH must have determined that the researchers' data security procedures will protect confidentiality.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Manual files.

**RETRIEVABILITY:**

Name or code is used to retrieve records from this system.

**SAFEGUARDS:**

Building guards, personnel screening, computerized records are protected by locked computer rooms, locked tape, vaults, and password protection.

For computerized records, safeguards are in accordance with HHS/ADP System Security Manual, Part 6. The safeguards described for nonautomated records are in accordance with Chapter 45-13 in the General Administration Manual, and the supplementary PHS chapter.

**RETENTION AND DISPOSAL:**

Record copy maintained from three to ten years in accordance with retention schedules. Source documents for computer disposed of when no longer needed in the study, as determined by the System Manager, and as provided in the signed consent form, as appropriate.

**SYSTEM MANAGER(S) AND ADDRESS:**

Chief, Pathology Section, Division of Biomedical and Behavioral Science (DBBS), National Institute for Occupational Safety and Health (NIOSH), Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about herself/himself upon written request, with notarized signature if request is made by mail, or with suitable identification (i.e., driver's license, passport) if request is made in person. All individuals requesting records are informed that anyone who knowingly and willfully requests access to a record pertaining to an individual under false pretenses is committing a criminal offense under the Act and subject to a maximum fine of $5,000.

To determine if a record exists, write to: Director, Division of Biomedical and Behavioral Science (DBBS), National Institute for Occupational Safety and Health, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

An individual who requests notification of or access to medical records shall, at the time the request is made, (1) provide a written notarized request designating a responsible representative who is willing to review the record and inform the subject individual of its contents at the representative's discretion, (2) supply the name of the study, if known, (3) provide the appropriate date and place of the study, if known, and (4) provide the approximate date and place of treatment or questionnaire administration.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under notification procedures above, and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Private and industrial physicians.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None

**Appendix I—Potential Sources for Determination of Vital Status**

*Military Records*

Appropriate State Motor Vehicle Registration Departments
Appropriate State Drivers License Departments
Appropriate State Government Divisions of:
Assistance Payments (Welfare), Social Services, Medical Services, Food Stamp Program, Child Suppport, Board of Corrections, Aging.
Indian Affairs, Workman's Compensation, Disability Insurance
Veteran's Administration Files
Appropriate employee union or association records
Appropriate company pension or employmen records
Company group insurance records
Appropriate State Vital Statistics Offices
Life Insurance Companies
Railroad Retirement Board
Area Nursing Homes
Area Indian Trading Posts
Mailing List Correction Cards (U.S. Postal Service)
Letters and telephone conversations with relatives
Letters and telephone conversations with former employees of the same establishment as cohort member
Appropriate local newspaper (obituaries)

**BILLING CODE 4160-19-M**

**09-20-0096**

**SYSTEM NAME:**

Records of Tuskegee Study Health Benefit Recipients, HHS/CDC/CPS.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Center for Prevention Services, Centers for Disease Control, Building 1, Room 3007, Atlanta, Georgia 30333

and

Federal Records Center, 1557 St. Joseph Avenue, East Point, Georgia 30344

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Adult participants in the study and their family members.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Medical records.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Public Health Service Act, Section 301 (42 U.S.C. 241).

**PURPOSE(S):**

To determine eligibility and provide medical benefits for participants and qualified family members.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

A record may be disclosed for a research purpose, when the Department:

(a) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained;

(b) Has determined that the research purpose (1) cannot be reasonably

accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring;

(c) Has required the recipient to—(1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, and (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except—(A) in emergency circumstances affecting the health or safety of any individual, (B) for use in another research project, under these same conditions, and with written authorization of the Department, (C) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destoryed at the earliest opportunity consistent with the purpose of the audit, or (D) when required by law;

(d) Has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

Information may be furnished to courts of competent jurisdiction and to attorneys for legal purposes.

Records may be disclosed to health departments and other public health or cooperating medical authorities in connection with program evaluations and related collaborative efforts to deal more effectively with diseases and conditions of public health significance.

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense: *Provided*, Such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File Folders

**RETRIEVABILITY:**

Records are retrieved alphabetically by name.

**SAFEGUARDS:**

Locked building, locked rooms, personnel screening. Limited access to only authorized personnel, i.e., management officials and staff who review and approve payments of medical costs. These safegurads are used for all records covered by this system notice. The safegurads described for these nonautomated records are in accordance with Chapter 45-13 in the General Administration Manual, and the supplementary PHS chapter.

**RETENTION AND DISPOSAL:**

Number of years held at CDC: Indefinite period. Records may be retired to a Federal Record Center and subsequently disposed of in accordance with CDC's Records Control schedule. The records control schedule may be obtained by writing to the system manager at the address below.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, Center for Prevention Services, Centers for Disease Control, Freeway Office Park, Room 313, Atlanta, Georgia 30333.

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about himself or herself by contacting the System Manager at the address above. Requesters in person must provide driver's license or other positive identification. Individuals who do not appear in person must either (1) submit a notarized request to verify their identity, or (2) must certify that they are the individuals they claim to be and that they understand that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Privacy Act subject to a $5,000 fine.

In addition, an individual who requests notification of, or access to, a medical record shall at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's medical record shall designate a family physicain or other health professional (other that a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child by means of a birth certificate or court order, as well as verify that he or she is who he or she claims to be.

Finally, all of the following information must be provided when requesting notification: (1) Full name; (2) approximate date(s) of the contact(s) with the Centers for Disease Control representative; (3) nature of the questionnaire or study in which the requester participated.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under System Manager above and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Participants and family members of participants entitled to medical care; Social Security Administration for Medicare information; and state welfare departments for information on Medicaid.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-20-0106**

**SYSTEM NAME:**

Specimen Handling for Testing and Related Data. HHS/CDC/CID.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Center for Infectious Diseases, Centers for Disease Control, Building 4, Room B-35, Atlanta, Georiga 30333

Epidemiology Program Office, Centers for Disease Control, Building 1, Room 5009, Atlanta, Georgia 30333

San Juan Laboratories, Center for Infectious Diseases, San Juan, Puerto Rico 00936

Center for Prevention Services, Centers for Disease Control, Freeway Office Part, Room 309, Atlanta, Georgia 30333

and

Federal Records Center, 1557 St. Joseph Avenue, East Point, Georgia 30344.

A list of contractor sites where individually identifiable data are currently located is available upon request to the System Manager.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Adults and children whose specimens have been submitted to CDC for testing.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Results of diagnostic tests involving microbiology, clinical chemistry, hematology, immunology, genetics and pathology.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Public Health Service Act, Section 301 (42 U.S.C. 241).

**PURPOSE(S):**

For documentation of test results which are returned to submitter. Used between specialty units for research purposes; and for epidemiological investigations for epidemic causes, prevention, family groupings of disease, and geographical location of specific diseases; also, used by epidemiologists and researchers in determining drug resistance of specific organisms.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

A record may be disclosed for a research purpose, when the Department:

(a) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained;

(b) Has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring;

(c) Has required the recipient to—(1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, and (20 remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except—(A) in emergency circumstances affecting the health or safety of any individual, (B) for use in another research project, under these same conditions, and with written authorization of the Department, (C) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (D) when required by law;

(d) Has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

To individuals and organizations deemed qualified by the Secretary to carry out quality assessment, medical audits, and utilization review.

The Department is under contract with private firms for the purposes of collating, analyzing, aggregating, or otherwise refining records for this system. Relevant records are maintained by the contractors. The contractors are required to maintain Private Act safeguards with respect to such records.

Records may be disclosed to Health Departments and other public health or cooperating medical authorities in connection with program evaluations and related collaborative efforts to deal more effectively with disease and conditions of public health significance.

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense: *Provided,* Such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Original Form—file folders; microfilm copies—computer storage.

**RETRIEVABILITY:**

Retrieved by name or destignated number furnished by the submitter, CDC identifying number, and/or microfilm number.

**SAFEGUARDS:**

24-hour guard service in buildings, locked buildings, locked rooms, personnel screening, locked computer rooms and tape vaults, password protection of computerized records, limited access to designated scientists, researchers and system managers. Two or more of these safeguards are used for all records covered by this system motice. The particular safeguards used are selected as appropriate for the type of records covered by each individual study or specific project. For computerized records, safeguards are in accordance with HHS/ADP System Security Manual, Part 6. The safeguards described for nonautomated records are in accordance with Chapter 45–13 in the General Administration Manual, and the supplementary PHS Chapter.

**RETENTION AND DISPOSAL:**

Number of years held at CDC: 10 years and then destroyed by paper recycling process.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, Center for Infectious Diseases, Centers for Disease Control, Building 1, Room 6007, 1600 Clifton Road, NE, Atlanta, Georgia 30333

Director, Epidemiology Program Office, Centers for Disease Control, Room 5009, Building 1, 1600 Clifton Road, NE, Atlanta,Georgia 30333

Director, San Juan Laboratories, Center for Infectious Diseases, Centers for Disease Control, San Juan, Puerto Rico 00936

Director, Center for Prevention Services, Centers for Disease Control, Building 1, room 2047, 1600 Clifton Road, NE, Atlanta, Georgia 30333.

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about himself or herself by contacting the first System Manager at the address above. Personis interested in obtaining diagnostic test results should contact the first system manager listed. Requesters in person must provide driver's license or other positive identification. Individuals who do not appear in person must either (1) submit a notarized request to verify their identity or (2) must certify that they are the individuals they claim to be and that they understand that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Privacy Act subject to a $5,000 fine.

In addition, an individual who requests notification of, or access to, a medical record shall at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion. A parent or guardian who requests notification of, or access to, a child's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child by means of a birth certificate or court order, as well as verify that he or she is who he or she claims to be.

Finally, all of the following information must be provided when requesting notification: (1) Full name; (2) approximate date(s) of the contact(s) with the Centers for Disease Control representative; (3) nature of the questionnaire or study in which the requester participated

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under System Manager above and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supportiong justification.

**RECORD SOURCE CATEGORIES:**

Approved public health laboratories, Federal medical facilities, some private physicians.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None

**09-20-0107**

**SYSTEM NAME:**

Dengue and Research Studies. HHS/CDC/CID.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

San Juan Laboratories, Center for Infectious Diseases, Centers for Disease Control, San Juan, Puerto Rico 00936

and

Federal Records Center, 1557 St. Joseph Avenue, East Point Georgia 30344.

A list of contractor sites where individually identifiable data are currently located is available upon request to the System Manager.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Adults and children who participated as patients and controls in these ongoing studies during the past 20 years.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Demographic and health behavioral information on individuals in study community.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Public Health Service Act, Section 301 (42 U.S.C. 241).

**PURPOSE(S):**

The record system is used in the evaluation of the control programs for dengue.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

A record may be disclosed for a research purpose, when the Department:

(a) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained;

(b) Has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of th record might bring;

(c) Has required the recipient to—(1) establish reasonable administrataive, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, and (2) remove or destroy theinformation that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except—(A) in emergency circumstances affecting the health or saety of any individual, (B) for use in another research project, under these same conditions, and with written authorization of the Department, (C) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (D) when required by law:

(d) Has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

To individuals and organizations deemed qualified by the Secretary to carry out quality assessment, medical audits or utilization review.

The Department is under contract with private firms for the purposes of collating, analyzing, aggregating or otherwise refining records in this system. Relevent records are maintained by the contractors. The contractors are required to maintain Privacy Act safeguards with respect to such records.

Information may be transferred to Puerto Rico Health Department.

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Stored on computer discs, cards and listings.

**RETRIEVABILITY:**

Indexed and retrieved by I.D. number.

**SAFEGUARDS:**

24-hour guard service in buildings, locked buildings, locked rooms, personnel screening, locked computer rooms and tape vaults, password protection of computerized records, limited access to only authorized personnel, i.e., project managers, designated researchers, and computer operators. Two or more of these safeguards are used for all records covered by this system notice. The particular safeguards used are selected as appropriate for the type of records covered by each individual study or specific project. For computerized records, these safeguards are established in accordance with HHS/

ADP System Security Manual, Part 6. The safeguards described for nonautomated records are in accordance with Chapter 45-13 in the General Administration Manual, and the supplementary PHS chapter.

**RETENTION AND DISPOSAL:**

Number of years held at CDC: 2 years. May be transferred to Federal Records Center when no longer needed for evaluation and analysis. Destroyed by paper recycling process after 10 years, unless needed for further study.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, Center for Infectious Diseases, Centers for Disease Control, Building 1, Room 6007, 1600 Clifton Road, NE, Atlanta, Georgia 30333.

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about himself or herself by contacting the System Manager at the address above. Requesters in person must provide driver's license or other positive identification. Individuals who do not appear in person must either (1) submit a notarized request to verify their identity, or (2) must certify that they are the individuals they claim to be and that they understand that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Privacy Act subject to a $5,000 fine.

In addition, an individual who requests notification of, or access to, a medical record shall at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

A parent or guardian who requests notification of, or access to, a child's medical record shall designate a family physician or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child by means of a birth certificate or court order, as well as verify that he or she is who he or she claims to be.

Finally, all of the following information must be provided when requesting notification: (1) Full name; (2) approximate date(s) of the contact(s) with the Centers for Disease Control representative; (3) nature of the questionnaire or study in which the requester participated.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonbly specify the record contents being sought.

**CONTESTING RECORD PROCEDURES.**

Contact the official at the address specified under System Manager above and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Directly from participants in the studies.

**SYSTEM EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-20-0117**

**SYSTEM NAME:**

Medical and Test Record Results of Individuals Involved in NIOSH Laboratory Studies. HHS/CDC/NIOSH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Biomedical and Behavioral Sciences (DBBS), National Institute for Occupational Safety and Health (NIOSH), Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

Also, occasionally data may be located at the facilities of collaborating researchers where analyses are performed, data collected and reports written. A list of these facilities is available upon request to the system manager.

Data may be located only at those facilities that have an adequate data security program and the collaborating researcher must return the data to NIOSH or destroy individual identifiers at the conclusion of the project.

A list of contractor sites where individually identifiable data are currently located is available upon request to the System Manager.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Volunteer subjects from the general population.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Occupational history, medical history, results of medical tests, demographic data, results of psychological and psychometric tests, and data necessary to interpret the medical results.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Occupational Safety and Health Act Section 20 (29 U.S.C. 669).

**PURPOSE(S):**

This system is to develop composite data summaries to support the development of criteria for occupational safety and health standards, and to provide other recommendations for improving worker safety and health.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense: *Provided,* such disclosure is compatible with the purpose for which the records were collected. For example, records may be released to the Department of Justice in defending claims against the U.S. when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual.

Records subject to the Privacy Act are disclosed to private firms for data entry, computer systems analysis and computer programming services. The contractors promptly return all data entry records, and all compter work is done on Government-owned computers. The contractors are required to maintain Privacy Act safeguards.

In the event litigation initiated at the request of NIOSH, the Institute may disclose such records as it deems desirable or necessary to the Department of Justice to enable the Department to effectively represent the Institute, provided such disclosure is compatible with the purpose for which the records were collected. The only types of litigative proceedings that

NIOSH is authorized to request are (1) enforcement of a subpoena issued to an employer to provide relevant information, or (2) contempt citation against an employer for failure to comply with a warrant obtained by the Institute.

Diclosure may be made to NIOSH collaborating researchers (NOISH contractors, granteees, or other Federal or State scientists) in order to accomplish the research purpose for which the records are collected. The collaborating researchers must agree in writing to comply with the confidentiality provisions of the Privacy Act and NIOSH must have determined that the researcher's data security procedures will protect confidentiality.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Manual files, computer cards, computer tapes, computer listings, microfilm.

**RETRIEVABILITY:**

Name and case number are the indexes used to retrieve records from this system.

**SAFEGUARDS:**

Evening guard service in building, locked building; locked rooms, personnel screening, locked computer room and computer tape vaults, locked file cabinets; password protection on computerized files.

Two or more of these safeguards are used for all records covered by this system notice. The particular safeguards used as selected as appropriate for the type of records required by each individual study.

For computerized records, safeguards are in accordance with HHS/ADP System Security Manual, Part 6. The safeguards described for nonautomated records are in accordance with Chapter 45-13 in the General Administration Manual, and the supplementary PHS chapter.

**RETENTION AND DISPOSAL:**

Personal identifiers are destroyed as soon as they are no longer necessary for the protection of the individuals involved. Computer tapes are erased; paper records are shredded or burned.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, Division of Biomedical and Behavioral Science (DBBS), National Institute for Occupational Safety and Health (NIOSH), Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about herself/himself upon written request, with notarized signature if request is made by mail, or with suitable identification (i.e., driver's license, passport) if request is made in person. All individuals requesting records are informed that anyone who knowingly and willfully requests access to a record pertaining to an individual under false pretenses is committing a criminal offense under the Act and subject to a maximum fine of $5,000.

To determine if a record exists, contact the system manager at the address above.

An individual who requests notification of or access to medical records shall, at the time the request is made, (1) provide a written notarized request designating a responsible representative who is willing to review the record and inform the subject individual of its contents at the representative's discretion, (2) supply the name of the study, if known, (3) provide the approximate date and place of the study, if known, and (4) provide the approximate date and place of treatment or questionnaire administration.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under notification procedures above, and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Information is obtained directly from the individual.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-20-0118**

**SYSTEM NAME:**

Study at Work-Sites where Agents Suspected of Being Occupational Hazards Exist. HHS/CDC/NIOSH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Biomedical and Behavioral Science, (DBBS), National Institute for Occupational Safety and Health (NIOSH), Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

Also, occasionally data may be located at the facilities of collaborating researchers where analyses are performed, data collected and reports written. A list of these facilities is available upon request to the system manager. Data may be located only at those facilities that have an adequate data security program and the collaborating researcher must return the data to NIOSH or destroy individual identifiers at the conclusion of the project.

A list of contractor sites where individually identifiable data are currently located is available upon request to the System Manager.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Subjects employed at specific sites under study.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Occupational history, medical history, results of medical tests, demographic data, employee records, psychological and psychometric tests, and data necessary to interpret the medical results.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Occupational Safety and Health Act Section 20 (29 U.S.C. 669).

**PURPOSE(S):**

This system is to determine the relationship between worker exposure to hazardous agents or stressors and occupational disease. This information is used to recommend procedures to reduce the incidence of occupational disease.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records

as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense: *Provided,* Such disclosure is compatible with the purpose for which the records were collected. For example, records may be released to the Department of Justice in defending claims against the U.S. when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual.

Records subject to the Privacy Act are disclosed to private firms for data entry, computer systems analysis and computer progamming services. The contractors promptly return all data entry records, and all computer work is done on Government-owned computers. The contractors are required to maintain Privacy Act safeguards.

In the event of litigation initiated at the request of NIOSH, the Institute may disclose such records as it deems desirable or necessary to the Department of Justice to enable the Department to effectively represent the Institute, provided such disclosure is compatible with the purpose for which the records were collected. The only types of litigative proceedings that NIOSH is authorized to request are (1) enforcement of a subpoena issued to an employer to provide relevant information, or (2) contempt citation against an employer for failure to comply with a warrant obtained by the Institute.

Disclosure may be made to NIOSH collaborating researchers (NIOSH contractors, grantees, or other Federal or State scientists) in order to accomplish the research purpose for which the records are collected. The collaborating researchers must agree in writing to comply with the confidentiality provisions of the Privacy Act and NIOSH must have determined that the researchers' data security procedures will protect confidentiality.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Manual files, computer cards, computer tapes, computer listings, microfilm.

**RETRIEVABILITY:**

Name and case number are the indexes used to retrieve records from this system.

**SAFEGUARDS:**

Evening guard service in building, locked building; locked rooms, personnel screening, locked computer room and computer tape vaults, locked file cabinets; password protection on computer files.

Two or more of these safeguards are used for all records covered by this system notice. The particular safeguards used are selected as appropriate for the type of records required by each individual study.

For computerized records, safeguards are in accordance with HHS/ADP System Security Manual, Part 6. The safeguards described for nonautomated records are in accordance with Chapter 45-13 in the General Administration Manual, and the supplementary PHS chapter.

**RETENTION AND DISPOSAL:**

Personal identifiers are destroyed as soon as the system has stabilized, and statistical summaries can be run. Computer tapes are erased; paper records are shredded or burned.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, Division of Biomedical and Behavioral Science (DBBS), National Institute for Occupational Safety and Health (NIOSH), Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about herself/himself upon written request, with notarized signature if request is made by mail, or with suitable identification (i.e., driver's license, passport) if request is made in person. All individuals requesting records are informed that anyone who knowingly and willfully request access to a record pertaining to an individual under false pretenses is committing a criminal offense under the Act and subject to a maximum fine of $5,000.

To determine if a record exists, contact the system manager at the address above.

An individual who requests notification of or access to medical records shall, at the time the request is made, (1) provide a written notarized request designating a responsible representative who is willing to review the record and inform the subject individual of its contents at the representative's discretion, (2) supply the name of the study, if known, (3) provide the approximate date and place of the study, if known, and (4) provide the approximate date and place of treatment or questionnaire administration.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under notification procedures above, and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Information is obtained directly from the individual and from employee records.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**BILLING CODE 4160-19-M**

**09-20-0137**

**SYSTEM NAME:**

Passport File. HHS/CDC/FMO.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Financial Management Office, Centers for Disease Control, Room 107-B, 255 East Paces Ferry Road, NE, Atlanta, Georgia 30333.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

CDC employees.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Passport status records.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Title 5, Government Organization and Employees, (5 U.S.C. 301)

**PURPOSE(S):**

To show status of passports of CDC employees who travel to foreign countries on official business.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File folders.

**RETRIEVABILITY:**

Retrieved by name.

**SAFEGUARDS:**

Locked buildings, locked rooms, personnel screening, limited access to Financial Management Office personnel only. The safeguards described for these nonautomated records are in accordance with Chapter 45–13 in the General Administration Manual, and the supplementary PHS chapter.

**RETENTION AND DISPOSAL:**

Number years held at CDC: 5. When passports expire or when they are cancelled, they are returned to the subject individual. If the individual does not wish to receive the cancelled or expired passport, the document is destroyed by sherdding.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, Financial Management Office, Centers for Disease Control, Room 200, 255 East Paces Ferry Road, NE, Atlanta, Georgia 30333.

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about himself of herself by contacting the System Manager at the address above. Requesters in person must provide driver's license or other positive identification. Individuals who do not appear in person must either (1) submit a notarized request to verify their identity, or (2) must certify that they are the individuals they claim to be and that they understand that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Privacy Act subject to a $5,000 fine.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under System Manager above and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

CDC employees.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-20-0147**

**SYSTEM NAME:**

Occupational Health Epidemiological Studies. HHS/CDC/NIOSH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Surveillance, Hazard Evaluation, and Field Studies (DSHEFS), National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, Cincinnati, Ohio 45226, and

Federal Records Center, 3150 Bertwynn Drive, Dayton, Ohio 45439.

Also, occasionally data may be located at the facilities of collaborating researchers where analyses are performed, data collected and reports written. A list of these facilities is available upon request to the system manager. Data may be located only at those facilities that have an adequate data security program and the collaborating researcher must return the data to NIOSH or destory individual identifies at the conclusion of the project.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Industrial workers exposed to physical and/or chemical agents that may damage the human body in any way. Some examples are: (1) Organic carcinogens, (2) inorganic carcinogens, (3) mucosal or dermal irritants, (4) fibrogenic materials, (5) acute toxic agents including sensitizing agents, (6) neurotoxic agents, (7) mutogenic (male and female) and tergogenic agents, (8) bio-accumulating non-carcinogen agents, and (9) chronic vascular desease-causing agents.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Physical exams, sputum cytology results, questionnaires, demographic information, smoking history, occupational histories, previous and current employment records, urine test records, X-rays, medical history, pulmonary function test records, medical disability forms, blood test records, drivers license data, hearing test results, spirometry results are examples of the records in this system. The specific types of records collected and maintained are determined by the needs of the individual study.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Public Health Service Act, Section 301 (42 U.S.C. 241); Occupational Safety and Health Act Section 20 (29 U.S.C. 669); Federal Mine Safety and Health Act of 1977, Section 501 (30 U.S.C. 951).

**PURPOSE(S):**

Studies carried out under this system are to evaluate mortality of occupationally related deseases to determine the cause and prevention of diseases of industrial origin, and lead toward future prevention of occupationally related diseases.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

Portions of records (name, Social Security number if known, date of birth, and last known address) may be disclosed to one or more other sources selected from those listed in Appendix I, as applicable. This may be done solely for obtaining a determination as to whether or not an individual has died. The purpose of determining death is so that NIOSH may obtain death certificates, which state the cause of death, from the appropriate Federal, State or local agency. Cause of death enables NIOSH to evaluate whether excess occupationally related mortality is occurring.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided, such disclosure is compatible with the purpose for which the records were collected. For example, records may be released to the Department of Justice in defending claims against the U.S. when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual.

Records subject to the Privacy Act are disclosed to private firms for data entry, computer systems analysis and computer programming services. The contractors promptly return all data entry records. Computer work may be done either on contractor-owned or Government-owned computers. The contractors are required to maintain Privacy Act safeguards.

Test data which indicates the existence of cancer may be provided to the State Cancer Registry where the State has a legally constituted cancer registry program which provides for the confidentiality of information.

Certain communicable diseases may be reported to State and/or local Health Departments where the State has a legally constituted reporting program for communicable diseases and which provides for the confidentiality of the information.

In the event of litigation initiated at the request of NIOSH, the Institute may disclose such records as it deems desirable or necessary to the Department of Justice to enable the Department to effectively represent the Institute, provided such disclosure is compatible with the purpose for which the records were collected. The only types of litigative proceedings that NIOSH is authorized to request are (1) enforcement of a subpoena issued to an employer to provide relevant information, or (2) contempt citation against an employer for failure to comply with a warrant obtained by the Institute.

Disclosure may be made to NIOSH collaborating researchers (NIOSH contractors, grantees, or other Federal or State scientists) in order to accomplish the research purpose for which the records are collected. The collaborating researchers must agree in writing to comply with the confidentiality provisions of the Privacy Act and NIOSH must have determined that the researchers' data security procedures will protect confidentiality.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Manual files, computer files, card files, microfilm, microfiche, and other files as appropriate.

**RETRIEVABILITY:**

Name, assigned number, plant name, year tested are some of the indices used to retrieve records from these systems. Other retrieval methods are utilized as individual research dictates.

**SAFEGUARDS:**

Locked buildings, locked rooms, locked file cabinets, personnel screening, locked computer room and computer tape vaults, 24-hour guard service, password protection of computerized records, limited access to only authorized personnel. Two or more of the safeguards are used for all records covered by this system notice. The particular safeguards used are selected as appropriate for the type of records covered by an individual study.

For computerized records, safeguards are in accordance with HHS/ADP System Security Manual, Part 6. The safeguards described for nonautomated records are in accordance with Chapter 45-13 in the General Administration Manual, and the supplementary PHS chapter.

**RETENTION AND DISPOSAL:**

Records are maintained from three to twenty years in accordance with retention schedules. Every attempt is made to strip personal identifiers from records and destroy the records when they are no longer needed. Any paper records which are disposed of are shredded or burned and computer tapes are erased.

**SYSTEM MANAGER(S) AND ADDRESS:**

Program Management Officer (PMO), Division of Surveillance, Hazard Evaluations, and Field Studies (DSHEFS), National Institute for Occupational Safety and Health (NIOSH), F-1, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about herself/himself upon written request, with notarized signature if request is made by mail, or with suitable identification (i.e., driver's license, passport) if request is made in person. All individuals requesting records are informed that anyone who knowingly and willfully requests access to a record pertaining to an individual under false pretenses is committing a criminal offense under the Act and subject to a maximum fine of $5,000.

To determine if a record exists, write to: Director, Division of Surveillance, Hazard Evaluations, and Field Studies (DSHEFS), National Institute for Occupational Safety and Health (NIOSH), F-1, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

An individual who requests notification of or access to medical records shall, at the time the request is made, (1) provide a written notarized request designating a responsible representative who is willing to review the record and inform the subject individual of its contents at the representative's discretion, (2) supply the name of the study, if known, (3) provide the approximate date and place of the study, if known, and (4) provide the approximate date and place of treatment or questionnaire administration.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under notification procedures above, and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Vital status information is obtained from Federal, State and local governments and other available sources selected from those listed in Appendix I. Information is obtained directly from the individual and employer records, whenever possible.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**Appendix I—Potential Sources for Determination of Vital Status**

Military Records
Appropriate State Motor Vehicle Registration Departments
Appropriate State Drivers License Departments
Appropriate State Government Divisions of:
- Assistance Payments (Welfare), Social Services, Medical Services;
- Food Stamp Program, Child Support, Board of Corrections, Aging;

Indian Affairs, Workman's Compensation, Disability Insurance
Retail Credit Association Follow up
Veteran's Administration Files
Appropriate employee union or association records
Appropriate company pension of employment records
Company group insurance records
Appropriate State Vital Statistics Offices
Life Insurance Companies
Railroad Retirement Board
Area Nursing Homes
Area Indian Trading Posts
Mailing List Correction Cards (U.S. Postal Service)
Letters and telephone conversations with relatives
Letters and telephone conversations with former employees of the same establishment as cohort member
Appropriate local newspaper (obituaries)
Social Security Administration
Internal Revenue Service

**09-20-0148**

**SYSTEM NAME:**

Results of Occupational Hearing Studies. HHS/CDC/NIOSH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Biomedical and Behavioral Science (DBBS), National Institute for Occupational Safety and Health (NIOSH), Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

Also, occasionally data may be located at the facilities of collaborating researchers where analyses are performed, data collected and reports written. A list of these facilities is available upon request to the system manager. Data may be located only at those facilities that have an adequate data security program and the collaborating researcher must return the data to NIOSH or destroy individual identifiers at the conclusion of the project.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Workers exposed to noise at a harmful or potentially hazardous level and individuals selected as control groups.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Physical examinations, results of laboratory tests (physiological, acceleration measures, performance tests); results of hearing tests, hearing acuity test, occupational histories, medical history, demographic data, related medical information. The specific types of records collected and maintained are determined by the needs of the individual study.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Occupational Safety and Health Act, Section 20 (29 U.S.C. 669); Federal Mine Safety and Health Act of 1977, Section 501 (30 U.S.C. 951)

**PURPOSE(S):**

This system is to assist in the development of standards for occupational exposure to hazards.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her offical capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected. For example, records may be released to the Department of Justice in defending claims against the U.S. when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual.

Records subject to the Privacy Act are disclosed to private firms for data entry, computer systems analysis and computer programming services. The contractors promptly return all data entry records, and all computer work is done on Government-owned computers. The contractors are required to maintain Privacy Act safeguards.

In the event of litigation initiated at the request of NIOSH, the Institute may disclose such records as it deems desirable or necessary to the Department of Justice to enable the Department to effectively represent the Institute, provided such disclosure is compatible with the purpose for which the records were collected. The only types of litigative proceedings that NIOSH is authorized to request are (1) enforcement of a subpoena issued to an employer to provide relevant information, or (2) contempt citation against an employer for failure to comply with a warrant obtained by the Institute.

Disclosure may be made to NIOSH collaborating researchers (NIOSH contractors, grantees, or other Federal or State scientists) in order to accomplish the research purpose for which the records are collected. The collaborating researchers must agree in writing to comply with the confidentiality provisions of the Privacy Act and NIOSH must have determined that the researchers' data security procedures will protect confidentiality.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Manual files, computer tape, microfilm, computer cards, index audiogram files, audiogram questionnaire forms.

**RETRIEVABILITY:**

Name, case number and study number are the indices used to retrieve records from this system.

**SAFEGUARDS:**

24-hours guard service in buildings, locked buildings, personnel screening, access limited to authorized personnel. In most instances information is related to individual identifiers by case numbers. The file of individual case number relationships is available to a limited group of people. Computerized records are protected by locked computer rooms, locked computer tape vaults, and password protection.

For computerized records, safeguards are in accordance with HHS/ADP System Security Manual, Part 6. The safeguards described for nonautomated records are in accordance with Chapter 45–13 in the General Administration Manual, and the supplementary PHS chapter.

**RETENTION AND DISPOSAL:**

Record copy maintained up to ten years in accordance with retention schedules. Source documents for computer disposed of when no longer needed in the study, as determined by the system manager, and as provided in the signed consent form as appropriate. Disposal methods include erasing computer tapes and burning or shredding printouts.

**SYSTEM MANAGER(S) AND ADDRESS:**

Industrial Hygiene Engineer, Noise Section, Physical Agents Effects Branch, Division of Biomedical and Behavorial Sciences (DBBS), National Institute for Occupational Safety and Human (NIOSH), 4676 Columbia Parkway, Cincinnati, Ohio 45226

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about herself/himself upon written request, with notarized signature if request if made by mail, or with suitable identification (i.e., driver's license, passport) if request is made in person. All individuals requesting records are informed that anyone who knowingly and willfully requests access to a record pertaining to an individual under false pretenses is committing a criminal offense under the Act and subject to a maximum fine of $5,000.

To determine if a record exists, write to: Director, Division of Biomedical and Behavorial Sciences (DBBS), National Institute for Occupational Safety and Health (NIOSH), 4676 Columbia Parkway, Robert A. Taft Laboratories, Cincinnati, Ohio 45226.

An individual who requests notification of or access to medical records shall, at the time the request is made, (1) provide a written notarized request designating a responsible representative who is willing to review the record and inform the subject individual of its contents at the representative's discretion, (2) supply the name of the study, if known, (3) provide the approximate date and place of the study, if known, and (4) provide the approximate date and place of treatment or questionnaire administration.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under notification procedures above, and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Information is obtained directly from the individual, and employee records.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-20-0149**

**SYSTEM NAME:**

General Industry Morbidity Studies. HHS/CDC/NIOSH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH), Morgantown, West Virginia 26505.

Also, occasionally data may be located at the facilities of collaborating researchers where anaylses are performed, data collected and reports written. A list of these facilities is available upon request to the system manager. Data may be located only at those facilities that have an adequate data security program and the collaborating researcher must return the data to NIOSH or destroy individual identifiers at the conclusion of the project.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Persons working, or having worked at workplaces not identified as surface mining or below ground mining operations and exposed or potentially exposed to substances which are known or suspected respiratory irritants or carcinogens. Also included are those individuals in the general population who have been selected as a control group.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Precious and current employment records, medical and occupational histories, demographic data, X-rays, smoking histories, results of medical tests such as pulmonary function data and spirometry test results, permission forms, industrial environmental data, and questionnaires. The specific types of records collected and maintained are determined by the research needs of the specific study.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Occupational Safety and Health Act Section 20 (29 U.S.C. 669); Federal Mine Safety and Health Act of 1977, Section 501 (30 U.S.C. 951).

**PURPOSE(S):**

The purpose of this system is to investigate occupationally related diseases and to determine the cause and prevention of such diseases.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Data may be sent to State Vital Statistics Divisions to obtain death certificates, and to Missing Person Location Agencies to find those individuals who cannot otherwise be located.

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected. For example, records may be released to the Department of Justice in defending claims against the U.S. when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual.

Records subject to the Privacy Act are disclosed to private firms for data entry, computer systems analysis and computer programming services. The contractors promptly return all data entry records, and all computer work is done on Government-owned computers. The contractors are required to maintain Privacy Act safeguards.

Test data which indicates the existence of cancer may be provided to the State Cancer Registry where the State has a legally constituted cancer registry program which provides for the confidentiality of information.

Certain communicable diseases may be reported to State and/or local Health Departments where the State has a legally constituted reporting program for communicable diseases and which provides for the confidentiality of the information.

In the event of litigation initiated at the request of NIOSH, the Institute may disclose such records as it deems desirable or necessary to the Department of Justice to enable the Department to effectively represent the Institute, provided such disclosure is compatible with the purpose for which the records were collected. The only types of litigative proceedings that NIOSH is authorized to request are (1) enforcement of a subpoena issued to an employer to provide relevant information, or (2) contempt citation against an employer for failure to comply with a warrant obtained by the Institute.

Disclosure may be made to NIOSH collaborating researchers (NIOSH contractors, grantees, or other Federal or State scientists) in order to accomplish the research purpose for which the records are collected. The collaborating researchers must agree in writing to comply with the confidentiality provisions of the Privacy Act and NIOSH must have determined that the researchers' data security procedures will protect confidentiality.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Computer tape, cards, and printouts, microfiche, X-rays, and manual files.

**RETRIEVABILITY:**

Plant name, study, name, and/or assigned numerical identifiers are some of the indices used to retrieve records

from this system. Social Security numbers, supplied on a voluntary basis may occasionally be used for data retrieval.

**SAFEGUARDS:**

24-hour guard service in buildings, locked buildings, locked rooms, personnel screening, locked computer rooms, and tape vaults, password protection of computerized records, limited access to only authorized personnel. Two or more of these safeguards are used for all records covered by this system notice. The particular safeguards used are selected as appropriate for the type of records covered by each individual study.

For computerized records, safeguards are in accordance with HHS/ADP System Security Manual, Part 6. The safeguards described for nonautomated records are in accordance with Chapter 45-13 in the General Administration Manual, and the supplementary PHS chapter.

**RETENTION AND DISPOSAL:**

Record copy maintained in accordance with retention schedules. Source documents for computer disposed of when no longer needed in the study, as determined by the system manager, and as provided in the signed consent form, as appropriate. Disposal methods include burning or shredding paper materials, and erasing computer tapes.

**SYSTEM MANAGER(S) AND ADDRESS:**

Program Management Officer, Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH), 944 Chestnut Ridge Road, Morgantown, West Virginia 26505.

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about herself/himself upon written request, with notarized signature if request is made by mail, with suitable identification (i.e., driver's license, passport) if request is made in person. All individuals requesting records are informed that anyone who knowingly and willfully requests access to a record pertaining to an individual under false pretenses is committing a criminal offense under the Act and subject to a maximum fine of $5,000.

To determine if a record exists, write to: Director, Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH), 944 Chestnut Ridge Road, Morgantown, West Virginia 26505.

An individual who requests notification of or access to medical records shall, at the time the request is made, (1) provide a written notarized request designating a responsible representative who is willing to review the record and inform the subject individual of its contents at the representative's discretion, (2) supply the name of the study, if know, (3) provide the approximate date and place of the study, if known, and (4) provide the approximate date and place of treatment or questionnaire administration.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under notification procedures above, and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Vital status information is obtained from Federal, State and local governments and other available sources. Information is obtained from the individual and from employer records.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-20-0150**

**SYSTEM NAME:**

Morbidity Studies in Coal Mining Activities. HHS/CDC/NIOSH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH), 944 Chestnut Ridge Road, Morgantown, West Virginia 26505.

Also, occasionally data may be located at the facilities of collaborating researchers where analyses are performed, data collected and reports written. A list of these facilities is available upon request to the system manager. Data may be located only at those facilities that have an adequate data security program and the collaborating researcher must return the data to NIOSH or destroy individual identifiers at the conclusion of the project.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Persons working or having worked at coal mining operations and exposed or potentially exposed to substances which are known or suspected respiratory irritants or carcinogens. Also included are those individuals in the general population who have been selected as a control group.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Previous and current employment records, medical and occupational histories, demographic data, X-rays, smoking histories, results of medical tests such as pulmonary function data, spirometry test results, permission forms, industrial environmental data, and questionnaries. The specific types of records collected and maintained are determined by the research needs of the specific study.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Federal Mine Health and Safety Act of 1977, Section 501 (30 U.S.C. 951); Section 203 (30 U.S.C. 843); Occupational Safety and Health Act Section 20 (29 U.S.C. 669).

**PURPOSE(S):**

The purpose of this system is to investigate occupationally related diseases and to determine the cause and prevention of such diseases.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its component's; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense: *Provided*, Such disclosure is compatible with the purpose for which the records were collected. For example, records may be released to the Department of Justice in defending claims against the U.S. when the claim

is based upon individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual.

Some data is sent to the Mining Enforcement and Safety Administration, Department of the Interior to report incidence of pneumoconiosis.

Records subject to the Privacy Act are disclosed to private firms for data entry, computer systems analysis and computer programming services. The contractors promptly return all data entry records, and all computer work is done on Government-owned computers. The contractors are required to maintain Privacy Act safeguards.

Test data which indicates the existence of cancer may be provided to the State Cancer Registry where the State has a legally constituted cancer registry program which provides for the confidentiality of information.

Certain communicable diseases may be reported to State and/or local Health Departments where the State has a legally constituted reporting program for communicable diseases and which provides for the confidentiality of the information.

In the event of litigation initiated at the request of NIOSH, the Institute may disclose such records as it deems desirable or necessary to the Department of Justice to enable the Department to effectively represent the Institute, provided such disclosure is compatible with the purpose for which the records were collected. The only types of litigative proceedings that NIOSH is authorized to request are (1) enforcement of a subpoena issued to an employer to provide relevant information, or (2) contempt citation against an employer for failure to comply with a warrant obtained by the Institute.

Disclosure may be made to NIOSH collaborating researchers (NIOSH contractors, grantees, or other Federal or State scientists) in order to accomplish the research purpose for which the records are collected. The collaborating researchers must agree in writing to comply with the confidentiality provisions of the Privacy Act and NIOSH must have determined that the researchers' data security procedures will protect confidentiality.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Computer tape, cards, and printouts, microfiche, X-rays, and manual files.

**RETRIEVABILITY:**

Plant name, study, name, and/or assigned numerical identifiers are some of the indices used to retrieve records from this system. Social Security numbers, supplied on a voluntary basis, may occasionally be used for data retrieval.

**SAFEGUARDS:**

24-hour guard service in buildings, locked buildings, locked rooms, personnel screening, locked computer room and tape vaults, password protection of computerized records, limited access to only authorized personnel. Two or more of these safeguards are used for all records covered by this system notice. The particular safeguards used are selected as appropriate for the type of records covered by each individual study.

For computerized records, safeguards are in accordance with HHS/ADP System Security Manual, Part 6. The safeguards described for nonautomated records are in accordance with Chapter 45–13 in the General Administration Manual, and the supplementary PHS chapter.

**RETENTION AND DISPOSAL:**

Record copy maintained in accordance with retention schedules. Source documents for computer disposed or when no longer needed in the study, as determined by the system manager, and as provided in the signed consent form, as appropriate. Disposal methods include burning or shredding paper materials, and erasing computer tapes.

**SYSTEM MANAGER(S) AND ADDRESS:**

Program Management Officer (PMO), Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH), 944 Chestnut Ridge Road, Morgantown, West Virginia 26505.

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about herself/himself upon written request, with notarized signature if request is made by mail, or with suitable identification (i.e., driver's license, passport) if request is made in person. All individuals requesting records are informed that anyone who knowingly and willfully requests access to a record pertaining to an individual under false pretenses is committing a criminal offense under the Act and subject to a maximum fine of $5,000.

To determine if a record exists, write to: Director, Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH), 944 Chestnut Ridge Road, Morgantown, West Virginia 26505.

An individual who requests notification of or access to medical records shall, at the time the request is made, (1) provide a written notarized request designating a responsible representative who is willing to review the record and inform the subject individual of its contents at the representative's discretion, (2) supply the name of the study, if known, (3) provide the approximate date and place of the study, if known, and (4) provide the approximate date and place of treatment or questionnaire administration.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under notification procedures above, and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Information is obtained directly from the individual and from employee records.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09–20–0151**

**SYSTEM NAME:**

Mortality Studies in Coal Mining Activities. HHS/CDC/NIOSH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH), 944 Chestnut Ridge Road, Morgantown, West Virginia 26505.

Also, occasionally data may be located at the facilities of collaborating researchers where analyses are performed, data collected and reports written. A list of these facilities is available upon request to the system manager. Data may be located only at those facilities that have an adequate data security program and the collaborating researcher must return the data to NIOSH or destroy individual identifiers at the conclusion of the project.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Persons working, or having worked at coal mining operations and exposed or potentially exposed to substances which are known or suspected respiratory irritants or carcinogens. Also included are those individuals in the general population who have been selected as a control group.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Previous and current employment records, medical and occupational histories, demographic data, X-rays, smoking histories, results of medical tests such as pulmonary function data and spirometry test results, permission forms, industrial environmental data, and questionnaires. The specific types of records collected and maintained are determined by the research needs of the specific study.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Public Health Service Act, Section 301 (42 U.S.C. 241). Federal Mine Health and Safety Act of 1977, Section 501 (30 U.S.C. 951).

**PURPOSE(S):**

The purpose of this system is to investigate occupationally related diseases and to determine the cause and prevention of such diseases.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Data may be sent to State Vital Statistics Divisions to obtain death certificates, and to Missing Person Location Agencies to find those individuals who cannot otherwise be located.

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

Portions of records (name, social security number if known, date of birth, and last known address) may be disclosed to one or more other sources selected from those listed in Appendix I, as applicable. This may be done solely for obtaining a determination as to whether or not an individual has died. The purpose of determining death is so that NIOSH may obtain death certificates, which state the cause of death, from the appropriate Federal, State, or local agency. Cause of death enables NIOSH to evaluate whether excess occupationally-related mortality is occurring.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Departmernt has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected. For example, records may be released to the Department of Justice in defending claims against the U.S. when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual.

Records subject to the Privacy Act are disclosed to private firms for data entry, computers systems analysis and computer programming services. The contractors promptly return all data entry records, and all computer work is done on Government-owned computers. The contractors are required to maintain Privacy Act safeguards.

In the event of litigation initiated at the request of NIOSH, the Institute may disclose such records as it deems desirable or necessary to the Department of Justice to enable the Department to effectively represent the Institute, provided such disclosure is compatible with the purpose for which the records were collected. The only types of litigative proceedings that NIOSH is authorized to request are (1) enforcement of a subpoena issued to an employer to provide relevant information, or (2) contempt citation against an employer for failure to comply with a warrant obtained by the Institute.

Disclosure may be made to NIOSH collaborating researchers (NIOSH contractors, grantees, or other Federal or State scientists) in order to accomplish the research purpose for which the records are collected. The collaborating researchers must agree in writing to comply with the confidentiality provisions of the Privacy Act and NIOSH must have determined that the researchers' data security procedures will protect confidentiality.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Computer tape, cards, and printouts, microfiche, X-rays, and manual files.

**RETRIEVABILITY:**

Plant name, study, name, and/or assigned numerical identifiers are some of the indices used to retrieve records from this system. Social security numbers, supplied on a voluntary basis may occasionally be used for data retrieval.

**SAFEGUARDS:**

Locked buildings, locked rooms, 24 hour guard service, locked file cabinets, locked computer rooms and tape vaults, password protection of computerized records, limited access to only authorized personnel. Two or more of these safeguards are used for all records covered by this system notice. The particular safeguards used are selected as appropriate for the type of records covered by an individual study.

For computerized records, safeguards are in accordance with HHS/ADP System Security Manual, Part 6. The safeguards described for nonautomated records are in accordance with Chapter 45–13 in the General Administration Manual, and the supplementary PHS chapter.

**RETENTION AND DISPOSAL:**

Record copy maintained in accordance with retention schedules. Source documents for computer disposed of when no longer needed in the study, as determined by the system manager, and as provided in the signed consent from, as appropriate. Disposal methods include burning or shredding paper materials and erasing computer tapes.

**SYSTEM MANAGER(S) AND ADDRESS:**

Program Management Officer (PMO), Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH), 944 Chestnut Ridge Road, Morgantown, West Virginia 26505.

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about herself/himself upon written request, with notarized signature if request is made by mail, or with suitable identification (i.e., driver's license, passport) if request is made in person. All individuals requesting records are informed that anyone who knowingly and willfully requests access to a record pertaining to an individual

under false pretenses is committing a criminal offense under the Act and subject to a maximum fine of $5,000.

To determine if a record exists, write to: Director, Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH), 944 Chestnut Ridge Road, Morgantown, West Virginia 26505.

An individual who requests notification of or access to medical records shall, at the time the request is made, (1) provide a written notarized request designating a responsible representative who is willing to review the record and inform the subject individual of its contents at the representative's discretion, (2) supply the name of the study, if known, (3) provide the approximate date and place of the study, if known, and (4) provide the approximate date and place of treatment or questionnaire administration.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under notification procedures above, and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Information is obtained directly from the individual and from death certificates.

**SYSTEM EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**Appendix I—Potential Sources for Determination of Vital Status**

*Military Records*

Appropriate State Motor Vehicle Registration Departments
Appropriate State Drivers License Departments
Appropriate State Government Divisions of;
Assistance Payments (Welfare), Social Services, Medical Services;
Food Stamp Program, Child Support, Board of Corrections, Aging;
Indian Affairs, Workman's Compensation, Disability Insurance
Veteran's Administration Files
Appropriate employee union or association records
Appropriate company pension or employment records
Company group insurance records
Appropriate State Vital Statistics Offices
Life Insurance Companies
Railroad Retirement Board
Area Nursing Homes
Area Indian Trading Posts
Mailing List Correction Cards (U.S. Postal Service)
Letters and telephone conversations with relatives
Letters and telephone conversations with former employees of the same establishment as cohort member
Appropriate local newspaper (obituaries)
Social Security Administration
Internal Revenue Service

**09-20-0152**

**SYSTEM NAME:**

Mortality Studies in Non-Coal Mining Activities. HHS/CDC/NIOSH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH), 944 Chesnut Ridge Road Morgantown, West Virginia 26505.

Also, occasionally data may be located at the facilities of collaborating researchers where analyses are performed, data collected and reports written. A list of these facilities is available upon request to the system manager. Data may be located only at those facilities that have an adequate data security program and the colloborating researcher must return the data to NIOSH or destroy individual identifiers at the conclusion of the project.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Persons working, or having worked at mining operations other than coal operations and exposed or potentially exposed to substances which are known or suspected respiratory irritants or carcinogens. Also included are those individuals in the general population who have been selected as a control group.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Previous and current employment records, medical and occupational histories, demographic data, X-rays, smoking histories, results of medical tests such as pulmonary function data and spirometry test results, permission forms, industrial environmental data, and questionnaires. The specific types of records collected and maintained are determined by the research needs of the specific study.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Public Health Service Act, Section 301 (42 U.S.C. 241); Federal Metal and Nonmetallic Mine Safety Act, Section 4 (30 U.S.C. 723); Occupational Safety and Health Act, Section 20 (29 U.S.C. 669).

**PURPOSE(S):**

The purpose of this system is to investigate occupationally related diseases and to determine the cause and prevention of such diseases.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Data may be sent to State Vital Statistics Divisions to obtain death certificates, and to Missing Person Location Agencies to find those individuals who cannot otherwise be located.

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

Portions of records (name, Social Security number if known, date of birth, and last known address) may be disclosed to one or more other sources selected from those listed in Appendix I, as applicable. This may be done solely for obtaining a determination as to whether or not an individual has died. The purpose of determining death is so that NIOSH may obtain death certificates, which state the cause of death, from the appropriate Federal, State, or local agency. Cause of death enables NIOSH to evaluate whether excess occupationally related mortality is occurring.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense: *Provided,* Such dislosure is compatable with the purpose for which the records were collected. For example, records may be released to the Department of Justice in defending claims against the U.S. when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual.

Records subject to the Privacy Act are disclosed to private firms for data entry, computer systems analysis and computer programming services. The

contractors promptly return all data entry records, and all computer work is done on Government-owned computers. The contractors are required to maintain Privacy Act safeguards.

In the event of litigation initiated at the request of NIOSH, the Institute may disclose such records as it deems desirable or necessary to the Department of Justice to enable the Department to effectively represent the Institute, provided such disclosure is compatible with the purpose for which the records were collected. The only types of litigative proceedings that NIOSH is authorized to request are (1) enforcement of a subpoena issued to an employer to provide relevant information, or (2) contempt citation against an employer for failure to comply with a warrant obtained by the Institute.

Disclosure may be made to NIOSH collaborating researchers (NIOSH contractors, grantees, or other Federal or State scientists) in order to accomplish the research purpose for which the records are collected. The collaborating researchers must agree in writing to comply with the confidentiality provision of the Privacy Act and NIOSH must have determined that the researchers' data security procedures will protect confidentiality.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Computer tape, cards and printouts, microfiche, X-rays, and manual files.

**RETRIEVABILITY:**

Plant name, study, name, and/or assigned numerical identifiers are some of the indices used to retrieve records from this system. Social security numbers, supplied on a voluntary basis may occasionally be used for data retrieval.

**SAFEGUARDS:**

24-hour guard service in buildings, locked buildings, locked rooms, personnel screening, locked computer rooms and tape vaults, password protection of computerized records, limited access to only authorized personnel. Two or more of these safeguards are used for all records covered by this system. The particular safeguards used are selected as appropriate for the type of records covered by each individual study.

For computerized records, safeguards are in accordance with HHS/ADP System Security Manual, Part 6. The safeguards described for nonautomated records are in accordance with Chapter 45-13 in the General Administration Manual, and the supplementary PHS chapter.

**RETENTION AND DISPOSAL:**

Record copy maintained in accordance with retention schedules. Source documents for computer disposed of when no longer needed in the study, as determined by the system manager, and as provided in the signed consent form as appropriate. Disposal methods include erasing computer tapes and burning or shredding paper materials.

**SYSTEM MANAGER(S) AND ADDRESS:**

Program Management Officer (PMO), Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH), 944 Chestnut Ridge Road, Morgantown, West Virginia 26505.

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about herself/himself upon written request, with notarized signature if request is made by mail, or with suitable identification (i.e., driver's license, passport) if request is made in person. All individuals requesting records are informed that anyone who knowingly and willfully requests access to a record pertaining to an individual under false pretenses is committing a criminal offense under the Act and subject to a maximum fine of $5,000.

To determine if a record exists, write to: Director, Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (HIOSH), 944 Chestnut Ridge Road, Morgantown, West Virginia 26505.

An individual who requests notification of or access to medical records shall, at the time the request is made, (1) provide a written notarized request designating a responsible representative who is willing to review the record and inform the subject individual of its contents at the representative's discretion, (2) supply the name of the study, if known, (3) provide the approximate date and place of the study, if known, and (4) provide the approximate date and place of treatment or questionnaire administration.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the recore contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under notification procedures above, and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Information is obtained from the individual, company personnel record, from death certificates, and from industry and union records.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**Appendix I—Potential Sources for Determination of Vital Status**

*Military Records*

Appropriate State Motor Vehicle Registration Departments
Appropriate State Driver License Departments
Appropriate State Government Divisions of:
Assistance Payments (Walfare), Social Services, Medical Services;
Food Stamp Program, Child Support, Board of Corrections, Aging;
Indian Affairs, Workman's Compensation, Disability Insurance
Veteran's Adminstration Files
Appropriate employee union or association records
Appropriate company pension or employment records
Company group insurance records
Appropriate State Vital Statistics Offices
Life Insurance Companies
Railroad Retirement Board
Area Nursing Homes
Area Indian Trading Posts
Mailing List Correction Cards (U.S. Postal Service)
Letters and telephone conversations with relatives
Letters and telephone conversation with former employees of the same establishment as cohort member
Appropriate local newspaper (obituaries)
Social Security Administration
Internal Revenue Service

**09-20-0153**

**SYSTEM NAME:**

General Industry Mortality Studies. HHS/CDC/NIOSH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH), 944 Chestnut Ridge Road, Morgantown, West Virginia 26505.

Also, occasionally data may be located at the facilities of collaborating researchers where analyses are performed, data collected and reports written. A list of these facilities is available upon request to the system

manager. Data may be located only at those facilities that have an adequate data security program and the collaborating researcher must return the data to NIOS or destroy individual identifiers at the conclusion of the project.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Persons working, or having worked at workplaces not identified as surface mining or below ground mining operations and exposed or potentially exposed to substances which are known or suspected respiratory irritants or carcinogens. Also included are those individuals in the general population who have been selected as a control group.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Previous and current employment records, medical and occupational histories, demographic data, X-rays, smoking histories, results of medical tests such as pulmonary function data and spirometry test results, permission forms, industrial environmental data, and questionnaries. The specific types of records collected and maintained are determined by the research needs of the specific study.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Occupational Safety and Health Act, Section 20 (29 U.S.C. 669); Public Health Service Act, Section 301 (42 U.S.C. 141).

**PURPOSE(S):**

The purpose of this system is to investigate occupationally related diseases and to determine the cause and prevention of such diseases.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Data may be sent to State Vital Statistics Divisions to obtain death certificates, and to Missing Person Location Agencies to find those individuals who cannot otherwise be located.

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

Portions of records (name, Social Security number if known, date of birth, and last known address) may be disclosed to one or more other sources selected from those listed in Appendix I, as applicable. This may be done solely for obtaining a determination as to whether or not an individual has died. The purpose of determining death is so that NIOSH may obtain death certificates, which state the cause of death, from the appropriate Federal, State, or local agency. Cause of death enables NIOSH to evaluate whether excess occupationally related mortality is occurring.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense: *Provided,* Such disclosure is compatible with the purpose for which the records were collected. For example, records may be released to the Department of Justice in defending claims against the U.S when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual.

Records subject to the Privacy Act are disclosed to private firms for data entry, computer systems analysis and computer programming services. The contractors promptly return all data entry records, and all computer work is done on Government-owned computers. The contractors are required to maintain Privacy Act safeguards.

In the event of litigation initiated at the request of NIOSH, the Institute may disclose such records as it deems desirable or necessary to the Department of Justice to enable the Department to effectively represent the Institute, provide such disclosure is compatible with the purpose for which the records were collected. The only types of litigative proceedings that NIOSH is authorized to request are (1) enforcement of a subpoena issued to an employer to provide relevant information, or (2) contempt citation against an employer for failure to comply with a warrant obtained by the Institute.

Disclosure may be made to NIOSH collaborating researchers (NIOSH contractors, grantees, or other Federal or State scientists) in order to accomplish the research purpose for which the records are collected. The collaborating researchers must agree in writing to comply with the confidentiality provisions of the Privacy Act and NIOSH must have determined that the researchers' data security procedures will protect confidentiality.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Computer tape, cards, and printouts, microfiche, X-rays, and manual files.

**RETRIEVABILITY:**

Plant name, study, name, and/or assigned numerical identifiers are some of the indices used to retrieve records from this system. Social Security numbers, supplied on a voluntary basis may occasionally be used for data retrieval.

**SAFEGUARDS:**

24-hour guard service in buildings, locked buildings, locked rooms, personnel screening, locked computer room and tape vaults, password protection of computerized records, limited access to only authorized personnel. Two or more of these safeguards are used for all records covered by this system notice. The particular safeguards used are selected as appropriate for the type of records covered by such individual study.

For computerized records, safeguards are in accordance with HHS/ADP System Security Manual, Part 6. The safeguards described for nonautomated records are in accordance with Chapter 45–13 in the General Administration Manual, and the supplementary PHS chapter.

**RETENTION AND DISPOSAL:**

Record copy maintained in accordance with retention schedules. Source documents for computer disposed of when no longer needed in the study, as determined by the system manager, and as provided in the signed consent form, as appropriate. Disposal methods include burning or shredding paper materials and erasing computer tapes.

**SYSTEM MANAGER(S) AND ADDRESS:**

Program Management Officer (PMO), Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH), 944 Chestnut Ridge Road, Morgantown, West Virginia 26505.

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about herself/himself upon written request, with notarized signature if request is made by mail, or with suitable identification (i.e., driver's license, passport) if request is made in

person. All individuals requesting records are informed that anyone who knowingly and willfully requests access to a record pertaining to an individual under false pretenses is committing a criminal offense under the Act and subject to a maximum fine of $5,000.

To determine if a record exists, write: Director, Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH), 944 Chestnut Ridge Road, Morgantown, West Virginia 26505.

An individual who requests notification of or access to medical records shall, at the time the request is made, (1) provide a written notarized request designating a responsible representative who is willing to review the record and inform the subject individual of its contents at the representative's discretion, (2) supply the name of the study, if known, (3) provide the approximate date and place of the study, if known, and (4) provide the approximate date and place of treatment of questionnaire administration.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under notification procedures above, and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Information is obtained directly from the individual, from employee records, from death certificates, and from industry and trade union records.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**Appendix I—Potential Sources for Determination of Vital Status**

*Military Records*

Appropriate State Motor Vehicle Registration Departments
Appropriate State Drivers License Departments
Appropriate State Government Divisions of:
Assistance Payments (Welfare), Social Services, Medical Services;
Food Stamp Program, Child Support, Board of Corrections, Aging;
Indian Affairs, Workman's Compensation, Disability Insurance
Veteran's Administration Files
Appropriate employee union or association records
Appropriate company pension or employment records
Company group insurance records
Appropriate State Vital Statistics Offices
Life Insurance Companies
Railroad Retirement Board
Area Nursing Homes
Area Indian Trading Posts
Mailing List Correction Cards (U.S. Postal Service)
Letters and telephone conversations with relatives
Letters and telephone conversations with former employees of the same establishement as cohort member
Appropriate local newspaper (obituaries)
Social Security Administration
Internal Revenue Service

**09-20-0154**

**SYSTEM NAME:**

Medical and Laboratory Studies. HHS/CDC/NIOSH.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH), 944 Chestnut Ridge Road, Morgantown, West Virginia 26505.

Also, occasionally data may be located at the facilities of collaborating researchers where analyses are performed, data collected and reports written. A list of these facilities is available upon request to the system manager. Data may be located only at those facilities that have an adequate data security program and the collaborating researchers must return the data to NIOSH or destroy individual identifiers at the conclusion of the project.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals who have had physical examinations at DRDS or who have had biochemical tests done on various samples submitted to DRDS.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Analysis of biochemical data, occupational and medical histories, and results of medical tests. The specific types of records collected and maintained are determined by the needs of the individual study.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Federal Mine Safety and Health Act of 1977, Section 501 (30 U.S.C. 951), Occupational Safety and Health Act, Section 20 (29 U.S.C. 669). Occupational Safety and Health Act, Section 22(d) (29 U.S.C. 671(d)).

**PURPOSE(S):**

The purpose of this system is to perform medical and epidemiological research, statistical analysis, and to identify early indicators of occupationally related diseases (biochemical indices); data is given to other NIOSH units for biochemical and epidemiological studies.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Data may be sent to State vital statistics divisions to obtain death certificates, and to missing person location agencies to find those individuals who cannot otherwise be located.

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, *provided*, such disclosure is compatible with the purpose for which the records were collected. For example, records may be released to the Department of Justice in defending claims against the U.S. when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual.

Records subject to the Privacy Act are disclosed to private firms for data entry, computer systems analysis and computer programming services. The contractors promptly return all data entry records, and all computer work is done on Government-owned computers. The contractors are required to maintain Privacy Act safeguards.

Test data which indicates the existence of cancer may be provided to the State Cancer Registry where the State has a legally constituted cancer registry program which provides for the confidentiality of information.

Certain communicable diseases may be reported to State and/or local Health Departments where the State has a legally constituted reporting program for communicable diseases and which provides for the confidentiality of the information.

In the event of litigation initiated at the request of NIOSH, the Institute may disclose such records as it deems desirable or necessary to the Department of Justice to enable the Department to effectively represent the Institute, provided such disclosure is compatible with the purpose for which the records were collected. The only types of litigative proceedings that NIOSH is authorized to request are (1) enforcement of a subpoena issued to an employer to provide relevant information, or (2) contempt citation against an employer for failure to comply with a warrant obtained by the Institute.

Disclosure may be made to NIOSH collaborating researchers (NIOSH contractors, grantees, or other Federal or State scientists) in order to accomplish the research purpose for which the records are collected. The collaborating researchers must agree in writing to comply with the confidentiality provisions of the Privacy Act and NIOSH must have determined that the researchers' data security procedures will protect confidentiality.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Computer tape, cards, and printouts, microfiche, X-rays, and manual files.

**RETRIEVABILITY:**

Name and case number are the indices used to retrieve records from this system.

**SAFEGUARDS:**

24-hour guard service in buildings, locked buildings, locked rooms, personnel screening, locked computer room and tape vaults, password protection of computerized records, limited access to only authorized personnel. Two or more of these safeguards are used for all records covered by this system notice. The particular safeguards used are selected as appropriate for the type of records covered by such individual study. For computerized records, safeguards are in accordance with HHS/ADP System Security Manual, Part 6. The safeguards described for nonautomated records are in accordance with Chapter 45–13 in the General Administration Manual, and the supplementary PHS chapter.

**RETENTION AND DISPOSAL:**

Record copy maintained in accordance with retention schedules. Source documents for computer disposed of when no longer needed in the study, as determined by the system manager, as provided in the signed consent form as appropriate. Disposal methods include erasing computer tapes and burning or shredding paper materials.

**SYSTEM MANAGER(S) AND ADDRESS:**

Project Management Officer, Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH), 944 Chestnut Ridge Road, Morgantown, West Virginia 26505.

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about herself/himself upon written request, with notarized signature if request is made by mail, or with suitable identification (i.e., driver's license, passport) if request is made in person. All individuals requesting records are informed that anyone who knowingly and willfully requests access to a record pertaining to an individual under false pretenses, is committing a criminal offense under the Act and subject to a maximum fine of $5,000.

To determine if a record exists, write to: Director, Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH), 944 Chestnut Ridge Road, Morgantown, West Virginia 26505. An individual who requests notification of or access to medical records shall, at the time the request is made, (1) provide a written notarized request designating a responsible representative who is willing to review the record and inform the subject individual of its contents at the representative's discretion, (2) supply the name of the study, if known, (3) provide the approximate date and place of the study, if known, and (4) provide the approximate date and place of treatment or questionnaire administration.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under notification procedures above, and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Information is obtained directly from the individual.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-20-0155**

**SYSTEM NAME:**

Morbidity Studies in Metal and Non-Metal Mining Activities. HHS/CDC/NIOSH.

**SECURITY CLASSIFICATION:**

None

**SYSTEM LOCATION:**

Division of Respiratory Disease Studies (DRDS), National Institute For Occupational Safety and Health (NIOSH), 944 Chestnut Ridge Road, Morgantown, West Virginia 26505.

Also, occasionally data may be located at the facilities of collaborating researchers where analyses are performed, data collected and reports written. A list of these facilities is available upon request to the system manager. Data may be located only at those facilities that have an adequate data security program and the collaborating researcher must return the data to NIOSH or destroy individual identifiers at the conclusion of the project.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Persons working, or having worked at mining operations other than coal mining operations and exposed or potentially exposed to substances which are known or suspected respiratory irritants or carcinogens. Also included are those individuals in the general population who have been selected as a control group.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Previous and current employment records, medical and occupational histories, demographic data, X-rays, smoking histories, results of medical tests such as pulmonary function data and spirometry test results, permission forms, industrial environmental data, and questionnaires. The specific types of records collected and maintained are determined by the research needs of the specific study.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Occupational Safety and Health Act, Section 20 (29 U.S.C. 669); Public Health Service Act, Section 301 (42 U.S.C. 241).

**PURPOSE(S):**

The purpose of this system is to investigate occupationally related diseases and to determine the cause and prevention of such diseases.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Data may be sent to State Vital Statistics Divisions to obtain death certificates, and to Missing Person Location Agencies to find those individuals who cannot otherwise be located.

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected. For example, records may be released to the Department of Justice in defending claims against the U.S. when the claim is based upon and individual's mental or physical conditions and is alleged to have arisen because of activities of the Public Health Service in connection with such individual.

Records subject to the Privacy Act are disclosed to private firms for data entry, computer systems analysis and computer programming services. The contractors promptly return all data entry records, and all computer work is done on Government-owned computers. The contractors are required to maintain Privacy Act safeguards.

Test data which indicates the existence of cancer may be provided to the State Cancer Registry where the State has a legally constituted cancer registry program which provides for the confidentiality of information.

Certain communicable diseases may be reported to State and/or local Health Departments where the State has a legally constituted reporting program for communicable diseases and which provides for the confidentiality of the information.

In the event of litigation initiated at the request of NIOSH, the Institute may disclose such records as it deems desiralbe or necessary to the Department of Justice to enable the Department to effectively represent the Institute, provided such disclosure is compatible with the purpose for which the records were collected. The only types of litigative proceedings that NIOSH is authorized to request are (1) enforcement of a subpoena issued to an employer to provide relevant information, or (2) contempt citation against an employer for failure to comply with a warrant obtained by the Institute.

Disclosure may be made to NIOSH collaborating researchers (NIOSH contractors, grantees, or other Federal or State scientists) in order to accomplish the research purpose for which the records are collected. The collaborating researchers must agree in writing to comply with the confidentiality provisions of the Privacy Act and NIOSH must have determined that the researchers' data security procedures will protect confidentiality.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DESPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Computer tape, cards, and printouts, microfiche, X-rays, and manual files.

**RETRIEVABILITY:**

Plant name, study, name, and/or assigned numerical identifiers are some of the indices used to retrieve records from this system. Social Security numbers, supplied on a voluntary basis, may occasionally be used for data retrieval.

**SAFEGUARDS:**

24-hour guard service in buildings, locked buildings, locked rooms, personnel screening, locked computer room and tape vaults, password protection of computerized records, limited access to only authorized personnel. Two or more of these safeguards are used for all records covered by this system notice. The particular safeguards used are selected as appropriate for the type of records covered by such individual study.

For computerized records, safeguards are in accordance with HHS/ADP System Security Manual, Part 6. The safeguards described for nonautomated records are in accordance with Chapter 45–13 in the General Administration Manual, and the supplementary PHS chapter.

**RETENTION AND DISPOSAL:**

Record copy maintained in accordance with retention schedules. Source documents for computer disposed of when no longer needed in the study, and as determined by the system manager, as provided in the signed consent form as appropriate. Disposal methods include erasing computer tapes and burning or shredding paper material.

**SYSTEM MANAGER(S) AND ADDRESS:**

Program Management Officer, Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH), 944 Chestnut Ridge Road, Morgantown, West Virginia 26505.

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about herself/himself upon written request, with notarized signature if request is made by mail, or with suitable identification (i.e., driver's license, passport) if request is made in person. All individuals requesting records are informed that anyone who knowingly and willfully requests access to a record pertaining to an individual under false pretenses is committing a criminal offense under the Act and subject to a maximum fine of $5,000. To determine if a record exists write to: Director, Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH), 944 Chestnut Ridge Road, Morgantown, West Virginia 26505.

An individual who requests notification of or access to medical records shall, at the time the request is made, (1) provide a written notarized request designating a responsible representative who is willing to review the record and inform the subject individual of its contents at the representative's discretion, (2) supply the name of the study, if known, (3) provide the approximate date and place of the study, if known, and (4) provide the approximate date and place of treatment or questionnaire administration.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under notification procedures above, and reasonably identify the record, specify the information being contested, and state the corrective

action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Vital status information is obtained from Federal, State and local governments and other available sources. Information is obtained from the individual and from employer records.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-20-0156**

**SYSTEM NAME:**

Cytotechnologist Proficiency Answer Sheets and Test Results (Medicare). HHS/CDC/LPO.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Laboratory Program Office, Building 3, Room B-15, Centers for Disease Control, 1600 Clifton Road, NE, Atlanta, Georgia 30333,
Federal Records Center, 1557 St. Joseph Avenue, East Point Georgia 30344, and
Professional Examination Service, 475 Riverside Drive, New York, New York 10115.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Cytotechnologists.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Answer Sheets, Examination scores.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Social Security Act, Sections 1123 (42 U.S.C. 1320a-2).

**PURPOSE(S):**

To maintain a record of examination scores in order to provide proficiency cards and test results to examinees.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense: *Provided,* Such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Computer tapes and computer-generated listings filed by discipline, by State, in file folders.

**RETRIEVABILITY:**

Listings and answer sheets are retrieved by examination, State, examinee's name and address, and examination number.

**SAFEGUARDS:**

Files are maintained in a combination lock file cabinet in a secured building. 24-hour guard service in buildings, locked buildings, locked rooms, personnel screening, locked computer rooms and tape vaults, password protection of computerized records, limited access to only authorized personnel. Two or more of these safeguards are used for all records covered by this system notice. For computerized records, safeguards are in accordance with HHS/ADP System Security Manual, Part 6. The safeguards described for nonautomated records are in accordance with Chapter 45-13 in the General Administration Manual, and the supplementary PHS chapter.

**RETENTION AND DISPOSAL:**

Lists are to be retained through FY 1985. They will then be filed at Federal Records Center for a period of three years. If at the expiration of that time the records are no longer of use, FRC will be authorized to destroy by paper recycling process or shredding.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, Laboratory Program Office, Building 3, Room B-15, Centers for Disease Control, 1600 Clifton Road NE, Atlanta, Georgia 30333.

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about himself or herself by contacting the System Manger at the address above. Requesters in person must provide driver's license or other positive identification. Individuals who do not appear in person must either (1) submit a notarized request to verify their identity or (2) must certify that they are the individuals they claim to be and that they understand that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Privacy Act subject to a $5,000 fine.

Finally, all of the following information should be provided when requesting notification: (1) Full name; (2) approximate date(s) of the examination(s); (3) name of the examination and location at which examination was administered.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-20-0157**

**SYSTEM NAME:**

Clinical Laboratory Technologists Proficiency Answer Sheets and Test Results (Medicare). HHS/CDC/LPO.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Laboratory Program Office, Building 3, Room B-15, Centers for Disease Control, 1600 Clifton Road NE, Atlanta, Georgia 30333,
Federal Records Center 1557 St. Joseph Avenue, East Point, Georgia 30344, and
Professional Examination Service, 475 Riverside Drive, New York, New York 10115.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Clinical laboratory technologists.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Answer sheets. Examination scores.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Social Security Act, Section 1123 (42 U.S.C. 1320a-2).

**PURPOSE(S):**

To maintain a record of examination scores in order to provide proficiency cards and test results to examinees. When applicable, answer sheets are used to revalidate results.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any

employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense provided such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Computer tapes and computer-generated listings filed by discipline, by State, in file folders.

**RETRIEVABILITY:**

Listings and answer sheets are retrived by examination, State, examinee's name and address, and examination number.

**SAFEGUARDS:**

24-hour guard service in buildings, locked buildings, locked rooms, personnel screening, locked computer rooms and tape vaults, password protection of computerized records, limited access to only authorized personnel. Two or more of these safeguards are used for all records covered by this system notice. For computerized records, safeguards are in accordance with HHS/ADP System Security Manual, Part 6. The safeguards are described for nonautomated records are in accordance with Chapter 45–13 in the General Administration Manual, and the supplementary PHS chapter.

**RETENTION AND DISPOSAL:**

Lists are to be retained through FY 1985. They will then be filed at Federal Records Center for a period of three years. If at the expiration of that time the records are no longer of use, FRC will be authorized to destroy by paper recycling process or shredding.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, Laboratory Program Office, Building 3, Room B–15, Centers for Disease Control, 1600 Clifton Road, NE, Atlanta, Georgia 30333.

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about himself or herself by contacting the System Manager at the address above. Requesters in person must provide driver's license or other positive identification. Individuals who do not appear in person must either (1) submit a notarized request to verify their identity or (2) must certify that they are the individuals they claim to be and that they understand that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Privacy Act subject to a $5,000 fine.

Finally, all of the following information should be provided when requesting notification: (1) Full name; (2) approximate date(s) of the examination(s); (3) name of the examination, and location at which examination was administered.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the offical at the address specified under System Manager above, and reasonably identify the record and specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Scored examinations.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09–20–0158**

**SYSTEM NAME:**

Independent Laboratory Directors Proficiency Answer Sheets and Exam Results (Medicare). HHS/CDC/LPO.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Laboratory Progam Office, Building 3, Room B–15, Centers for Disease Control, 1600 Clifton Rd., NE, Atlanta, Georgia 30333

Federal Records Center, 1557 St., Joseph Avenue, East Point, Georgia 30344, and

Professional Examination Service, 475 Riverside Drive, New York, New York 10115.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Independent laboratory directors.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Answer sheets. Examination scores.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Social Security Act, Section 1123 (42 U.S.C. 1320a–2).

**PURPOSE(S):**

To maintain a record of examination scores in order to provide proficiency cards and test results to examinees. When applicable, answer sheets are used to revalidate results.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employed, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Computer tapes and computer-generated listings filed by discipline, by State, in file folders.

**RETRIEVABILITY:**

Listings and answer sheets are retrieved by examination, State, examinee's name and address, and examination number.

**SAFEGUARDS:**

24-hour guard service in buildings, locked buildings, locked rooms, personnel screening, locked computer rooms and tape vaults, password protection of computerized records, limited access to only authorized personnel. Two or more of these safeguards are used for all records covered by this system notice. For computerized records, safeguards are in accordance with HHS/ADP System Security Manual, Part 6. The safeguards described for nonautomated records are

in accordance with Chapter 45–13 in the General Administration Manual, and the supplementary PHS chapter.

**RETENTION AND DISPOSAL:**

Lists are to be retained through FY 1985. They will then be filed at Federal Records Center for a period of three years. If at the expiration of that time the records are no longer of use, FRC will be authorized to destroy by paper recycling process or shredding.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, Laboratory Program Office, Building 3, Room B–15, Centers for Disease Control, 1600 Clifton Road, NE, Atlanta, Georgia 30333.

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about himself or herself by contacting the System Manager at the address above. Requesters in person must provide driver's license or other positive identification. Individuals who do not appear in person must either (1) submit a notarized request to verify their identity or (2) must certify that they are the individuals they claim to be and that they understand that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Privacy Act subject to a $5,000 fine.

Finally, all of the following information should be provided when requesting notification: (1) Full name; (2) approximate date(s) of the examination(s); (3) name of the examination, and location at which examination was administered.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under System Manager above, and reasonably identify the record and specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Scored examinations.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None

**09–20–0159**

**SYSTEM NAME:**

Records of Subjects in Certification, Testing and Safety Studies of Personal Protective Devices for Hazardous Work Environments.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Safety Research (DSR), National Institute for Occupational Safety and Health (NIOSH), 944 Chestnut Ridge Road, Morgantown, West Virginia 26505.

Also, occasionally data may be located at the facilities of collaborating researchers where analyses are performed, data collected and reports written. A list of these facilities is available upon request to the system manager. Data may be located only at those facilities that have an adequate data security program and the collaborating researcher must return the data to NIOSH or destroy individual identifiers at the conclusion of the project.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals exposed to hazardous work environments and individuals selected as control groups are covered by this system. Additionally, the system pertains to individuals selected to test the interaction between people, personal protection or safety equipment, users of such equipment, and a hazardous environment. Some examples include individuals selected to: Perform respirator facepiece fit tests, evaluate hearing protectors, perform lifting and manual materials handling studies, perform strength test studies, and perform hand speed tests.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

The system contins such records as physical examinations, questionnaires, results of laboratory tests (physiological acceleration measures, and performance tests), workplace performance records, results of hearing tests, occupational histories, medical histories, demographic data, and related medical information. The specific types of records collected and maintained are determined by the needs of the individual study.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

The Public Health Service Act, Section 301 (42 U.S.C. 241); the Occupational Safety and Health Act, Section 20 (29 U.S.C. 669); and the Federal Mine Health and Safety Act of 1977, Section 501 (30 U.S.C. 951).

**PURPOSE(S):**

The purpose of this system is to permit acquisition of information related to certification of personal protective equipment, hazard-measuring devices, and safety research studies.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USERS:**

Disclosures my be made to a congressional office from the record of an individual in response to an inquiry from the congressional office, made at the request of that individual. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected. For example, records may be released to the Department of Justice in defending claims against the U.S. when the claim is based upon an individual's mental or physical condition and is alleged to have arisen because of activities of the Public Health Service in connection with such individual.

In the event of litigation initiated at the request of NIOSH, the Institute may disclose such records as it deems desirable or necessary to the Department of Justice to enable the Department to effectively represent the Institute, provided such disclosure is compatible with the purpose for which the records were collected. The only types of litigative proceedings that NIOSH is authorized to request are (1) enforcement of a subpoena issued to an employer to provide relevant information, or (2) contempt citation against an employer for failure to comply with a warrant obtained by the Institute.

Portions of records (name, Social Security number if known, date of birth, and last known address) may be disclosed to one or more sources selected from those listed in Appendix I. This may be done to determine if the individual has died so that a death certificate can be obtained. Knowing the cause of death enables NIOSH to evaluate whether excess occupationally-related mortality is occurring.

Records subject to the Privacy Act are disclosed to private firms for data entry, computer systems analysis, and computer programming services. The

contractors promptly return all data entry records, and all computer work is done on Government-owned computers. The contractors are required to maintain Privacy Act safeguards.

Disclosure may be made to NIOSH collaborating researchers (NIOSH contractors, grantees, or other Federal or State scientists) in order to accomplish the research purpose for which the records are collected. The collaborating researchers must agree in writing to comply with the confidentiality provisions of the Privacy Act and NIOSH must have determined that the researchers' data security procedures will protect confidentiality.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Manual files, computer tape, microfilm, computer cards, index audiogram files, audiograms, questionnaire forms.

**RETRIEVABILITY:**

Name, assigned number, plant name, and year tested are some of the indices used to retrieve records from these systems. Other retrieval methods are utilized as individual research dictates.

**SAFEGUARDS:**

Locked buildings, locked rooms, locked file cabinets, personnel screening, locked computer room and computer tape vaults, 24-hour guard service, limited access only to authorized personnel. The particular safeguards used are selected as appropriate for the type of records covered by an individual study. For computerized records, safeguards are in accordance with Part 6, ADP Systems Security, of the HHS/ADP Systems Manual.

For computerized records, safeguards are in accordance with HHS/ADP System Security Manual, Part 6. The safeguards described for nonautomated records are in accordance with Chapter 45-13 in the General Administration Manual, and the supplementary PHS chapter.

**RETENTION AND DISPOSAL:**

Records are maintained from three to twenty years in accordance with retention schedules. Personal identifiers are stripped from records, and records are destroyed when they are no longer needed. All paper records which are disposed of are shredded or burned and computer tapes are erased.

**SYSTEM MANAGER(S) AND ADDRESS:**

Program Management Officer, Division of Respiratory Diseases Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH), 944 Chestnut Ridge Road, Morgantown, West Virginia 26505.

**NOTIFICATION PROCEDURE:**

An individual may learn if a record exists about herself/himself upon written request, with notarized signature if request is made by mail, or with suitable identification (i.e., driver's license, passport) if request is made in person. All individuals requesting records are informed that anyone who knowingly and willfully requests access to a record pertaining to an individual under false pretenses is committing a criminal offense under the Act and subject to a maximum fine of $5,000.

To determine if a record exists, write to: Director, Division of Respiratory Disease Studies (DRDS), National Institute for Occupational Safety and Health (NIOSH), 944 Chestnut Ridge Road, Morgantown, West Virginia 26505.

An individual who requests notification of or access to medical records shall, at the time the request is made, (1) provide a written notarized request designating a responsible representative who is willing to review the record and inform the subject individual of its contents at the representative's discretion, (2) supply the name of the study, if known, (3) provide the approximate date and place of the study, if known, and (4) provide the approximate date and place of treatment or questionnaire administration.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under notification procedures above, and reasonably identify the record, specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Information is obtained from the individual and from employer records.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

[FR Doc. 83-31245 Filed 11-28-83; 8:45 am]
BILLING CODE 4160-18-M

## Public Health Service

## Health Resources and Services Administration

## Privacy Act of 1974; Annual Publication of Systems of Records

**AGENCY:** Public Health Service (PHS); Health Resources and Services Administration (HRSA), HHS.

**ACTION:** HRSA is publishing this document to meet the requirements of Pub. L. 97-375, the Congressional Reports Elimination Act. This new statute amends the Privacy Act (5 U.S.C. 552a, section 3(e)(4)) to limit republication to revised system notices only.

**SUMMARY:** This preamble summarizes significant changes to systems of individually identifiable records which have occurred since the 1982 annual publication. Notices of modified systems of records currently maintained by HRSA follow this preamble. The notices include modifications for the purpose of clarity, timeliness, and correctness, as of August 19, 1983. None of the modifications being made at this time meet the OMB criteria for a new or altered system report, or a period of public comment.

**SUPPLEMENTARY INFORMATION:**

### A General Information

Notices published below describe systems of records maintained by the Health Resources and Services Administration (HRSA).

The routine uses set forth in each notice describe permissible disclosures outside the Department of records in that system, which may be made without the consent of individuals who are the subject of those records. Additional disclosures without the consent of subject individuals are permitted by the Privacy Act itself in Section 3(b), as follows:

"(1) To those officers and employees of the agency which maintains the record who have a need for the record in the performance of their duties;

"(2) Required under section 552 of this title (the Freedom of Information Act);

"(3) For a routine use as (described in the routine use section of each specific system notice);

"(4) To the Bureau of the Census for purposes of planning or carrying out a

census or survey or related activity pursuant to the provisions of title 13;

"(5) To a recipient who has provided the agency with advance adequate written assurance that the record will be used solely as a statistical research or reporting record, and the record is to be transferred in a form that is not individually identifiable;

"(6) To the National Archives of the United States as a record which has sufficient historical or other value to warrant its continued preservation by the United States Government, or for evaluation by the Administrator of General Services or his designee to determine whether the record has such value;

"(7) To another agency or to an instrumentality of any government jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the agency which maintains the record specifying the particular portion desired and the law enforcement activity for which the record is sought;

"(8) To a person pursuant to a showing of compelling circumstances affecting the health or safety of an individual if, upon such disclosure, notification is transmitted to the last known address of such individual;

"(9) To either House of Congress, or, to the extent of matter within its jurisdiciton, any committee or subcommittee thereof, any joint committee of Congress or subcommittee of any such joint committee;

"(10) To the Comptroller General, or any of his authorized representatives, in the course of the performance of the duties of the General Accounting Office;

"(11) To an authorized individual pursuant to a order of a court of competent jurisdiction; or

"(12) To a consumer reporting agency in accordance with Section 3(d) of the Federal Claims Collection Act of 1966 (31 U.S.C. 3711(f)).''

Permissible disclosure [12] was added this year by the Debt Collection Act of 1982 (Pub. L. 97-365). Accordingly, we are adding the following statement to the six system notices listed below:

*"Disclosures Pursuant to 5 U.S.C. 522a(b)(12):* Disclosures may be made from this system to "consumer reporting agencies" as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) or the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)). The purposes of this disclosure are: (1) to provide an incentive for debtors to repay delinquent Federal Government debts by making these debts part of their credit records, and (2) to enable HRSA to improve the quality of loan and scholarship decisions by taking into account the financial reliability of applicants. Disclosure of records will be limited to the individual's name; Social Security number (SSN), and other information necessary to establish the identity of the individual, the amount, status, and history of the claim, and the agency or program under which the claim arose."

The system notices affected by this special disclosure are:

a. Accounts Receivable; HHS/HRSA/OA, 09-15-0022.

b. Medical Fellowships and Educational Loans, HHS/HRSA/OA, 09-15-0026.

c. Health Professions Preparatory Scholarship for Indians and Health Professions Scholarship Program Record System, HHS/HRSA/IHS, 09-15-0036.

d. Public Health Service Scholarship and National Health Service Corps Scholarship Program, HHS/HRSA/BHCDA, 09-15-0037.

e. Physican Shortage Area Scholarship Program, HHS/HRSA/BHCDA, 09-15-0042.

f. Cuban Loan Program, HHS/HRSA/OA, 09-15-0043.

g. Health Education Assistance Loan Program (HEAL) Loan Control Master File, HHS/HRSA/BHPr, 09-15-0044.

**B. Specific changes**

HRSA has modified the below listed system notices this year to enhance clarity and specificity, as well as to incorporate normal updating changes, such as system name, system locations, and U.S.C. citations. Revisions for clarity and specificity include, but are not limited to the following:

1. The "System Name," "System Location," and "System Manager(s) and Address" sections of system notices are modified to reflect the establishment of the Health Resources and Services Administration (HRSA). All references to the former organizations Health Resources Administration (HRA) and Health Services Administration (HSA) are deleted and replaced with HRSA.

2. Pursuant to HRSA reorganization, the former HRA system notices which last appeared in the **Federal Register** on October 13, 1982 (pp. 45409-45411), are renumbered as follows:

a. Cycle II Dentist Survey, HHS/HRSA/BHPr, 09-35-0005, is renumbered 09-15-0047.

b. Chattanooga Incremental Care Program, HHS/HRSA/BHPr, 09-35-0009, is renumbered 09-15-0048.

c. Indo-China Refugee Physicians and Medical Students, HHS/HRSA/BHPr, 09-35-0013, is renumbered 09-15-0049.

d. National Research Service Awards, HHS/HRSA/BHPr, 09-35-0014, is renumbered 09-15-0050.

e. Professional Nurse Traineeships, HHS/HRSA/BHPr, 09-35-0016, is renumbered 09-15-0051.

f. Consultants for Division of Disadvantaged Assistance, HHS/HRSA/BHPr, 09-35-0027, is renumbered 09-15-0053.

g. Health Professional Planning and Evaluation, HHS/HRSA/BHPr, 09-35-0044, is renumbered 09-15-0046.

h. Nurse Practitioner Traineeships, HHS/HRSA/BHPr, 09-35-0045, is renumbered 09-15-0052.

3. The first "Routine Use" of Privacy Act system of records 09-15-0019, "Health and Medical Records Systems," HHS/HRSA/IHS, was revised to clarify that records may be disclosed to third party reimbursement organizations of fiscal intermediaries for the purpose of billing or collecting third party reimbursement for health care provided to American Indians and Alaskan Natives.

Readers who notice any inadvertent errors or omissions in HRSA system notices are invited to bring them to my attention at the following address: Department of Health and Human Services, Public Health Service, Health Resources and Services Administration, Office of the Administrator, Office of Operations and Management, Room 14A-03, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Dated: August 23, 1983.

**James A. Walsh,**

*Associate Administrator for Operations and Management.*

**Table of Contents**

The following table of contents lists all currently active systems of records.

*15-0001 Division of Federal Employee Occupational Health, Health and Counseling Records HHS/HRSA/Bureau of Health Care Delivery and Assistance.

*09-15-0002 Record of Patients' Personal Valuables and Monies, HHS/HRSA/Bureau of Health Care Delivery and Assistance.

*09-15-0003 Contract Physicians and Consultants, HHS/HRSA/Bureau of Health Care Delivery and Assistance

*09-15-0004 Federal Employee Occupational Health Data System, HHS/HRSA/Bureau of Health Care Delivery and Assistance.

*09-15-0007 Patients Medical Records System PHS Hospitals/Clinics, HHS/HRSA/Bureau of Health Care Delivery and Assistance.

*09-15-0008 Emergency Non-PHS Treatment Authorization File, HHS/HRSA/Bureau of Health Care Delivery and Assistance.

*Indicates that the system notice is being republished below.

*09-15-0018 Unofficial Vital Records Systems, HHS/HRSA/Indian Health Service.
*09-15-0019 Health and Medical Records Systems, HHS/HRSA/Indian Health Service
*09-15-0022 Accounts Receivable, HHS/HRSA/Office of the Administrator
*09-15-0026 Medical Fellowships and Educational Loans, HHS/HRSA/Office of the Administrator.
*09-15-0027 National Health Service Corps (NHSC) and Indian Health Service (IHS) Pre-Application Recruitment and Provider File, HHS/HRSA/Bureau of Health Care Delivery and Assistance.
*09-15-0028 PHS Clinical Affiliation Trainee Records, HHS/HRSA/Bureau of Health Care Delivery and Assistance.
*09-15-0029 PHS Beneficiary-Contract Medical/Health Care Records, HHS/HRSA/Bureau of Health Care Delivery and Assistance.
*09-15-0036 Health Professions Preparatory Scholarship Program for Indians and Health Professions Scholarship Program Record System, HHS/HRSA/Indian Health Service.
*09-15-0037 Public Health Service Scholarship and National Health Service Corps Scholarship Program, HHS/HRSA/Bureau of Health Care Delivery and Assistance.
*09-15-0038 Disability Claims of the Nursing Student Loan Program HHS/HRSA/Bureau of Health Professions.
*09-15-0039 Disability Claims in the Health Professions Student Loan Program, HHS/HRSA/Bureau of Health Professions.
*09-15-0040 Health Professions Student Loan Repayment Program, HHS/HRSA/Bureau of Health Professions.
*09-15-0041 Health Professions Student Loan Cancellation, HHS/HRSA/Bureau of Health Professions.
*09-15-0042 Physician Shortage Area Scholarship Program HHS/HRSA/Bureau of Health Care Delivery and Assistance.
*09-15-0043 Cuban Loan Program, HHS/HRSA/Office of the Administrator.
*09-15-0044 Health Education Assistance Loan Program (HEAL) Loan Control Master File, HHS/HRSA/Bureau of Health Professions.
*09-15-0045 Health Resources and Services Administration Loan Repayment/Debt Management Records System HHS/HRSA/Office of the Administrator.
*09-15-0046 Health Professions Planning and Evaluation, HHS/HRSA/Bureau of Health Professions.
*09-15-0047 Cycle II Dentist Survey, HHS/HRSA/Bureau of Health Professions.
*09-15-0048 Chattanooga Incremental Care Program, HHS/HRSA/Bureau of Health Professions.
*09-15-0049 Indo-China Refugee Physicians and Medical Students, HHS/HRSA/Bureau of Health Professions.
*09-15-0050 National Research Service Awards, HHS/HRSA/Bureau of Health Professions.
*09-15-0051 Professional Nurse Traineeships, HHS/HRSA/Bureau of Health Professions.
*09-15-0052 Nurse Practitioner Traineeships, HHS/HRSA/Bureau of Health Professions.
*09-15-0053 Consultants for Division of Disadvantaged Assistance, HHS/HRSA/Bureau of Health Professions.

## 09-15-0001

### SYSTEM NAME:

Division of Federal Employee Occupational Health, Health and Counseling Records, HHS/HRSA/BHCDA.

### SECURITY CLASSIFICATION:

None.

### SYSTEM LOCATION:

A current list of health and counseling unit sites is available by writing to the System Manager at the address below.

Data are also occasionally located at medical laboratories, medical consultants, or computer processing firm sites. A list of sites where individually identifiable data is currently located is available upon request to the System Manager.

### CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Federal employees enrolled in PHS/Division of Federal Employee Occupational Health (DFEOH) Health Units and individuals examined/treated/counseled by DFEOH staff.

### CATEGORIES OF RECORDS IN THE SYSTEM:

Health records including examination, diagnostic, counseling treatment data, information for program eligibility, social data, laboratory findings, nutrition and dietetic files, nursing notes, mental health files, and immunization registers.

### AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Title V (5 U.S.C. 7901), Health Service to Employees, and OMB Circular No. A-72.

### PURPOSE(S):

Employees are provided occupational health services (on a voluntary basis). Data necessary to ensure:

1. Proper evaluation, diagnosis, treatment, and referral to maintain continuity of care.
2. A medical history of the total health care and medical treatment received by the individual.
3. Planning for further care of the patient.
4. A means of communication among members of the health care team who contribute to the patient's care.
5. A legal document of health care rendered.
6. A tool for evaluating quality of health care rendered.

### ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Certain records may be disclosed to medical laboratories, medical consultants, or computer processing firms under a service contract agreement. Recipients are required to maintain adequate safeguards with respect to such records.

In the event of a change in sponsorship of a PHS/DFEOH health care unit or in a case of mass transfer of employees covered by a PHS/DFEOH health care unit to one served by a nondepartmental organization, the health records will be transferred to the costodianship of the new organization.

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

Disclosure may be made to the U.S. Department of Labor, Office of Workers' Compensation Programs (OWCP), of those files of persons claiming compensation benefits due to personal injury while on the job.

### POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

#### STORAGE:

File folders.

#### RETRIEVABILITY:

Alphabetically by last name.

#### SAFEGUARDS:

1. Authorized Users: DFEOH Health Unit personnel, physicians, nurses, and other allied health professionals.
2. Physical Safeguards: All documents are secured during lunch hours and nonworking hours in locked file cabinets or locked storage areas.

3. Procedural Safeguards: All users of personal information in connection with the performance of their jobs protect information from the public view and from unauthorized personnel entering an unsupervised office. Access to records is strictly limited to those staff members trained in accordance with the DFEOH Manual of Operations. The contractor is required to maintain confidentiality safeguards with respect to these records. These safeguards are in accordance with DHHS Chapter 45–13 and supplementary Chapter PHS. hf:45–13 in the General Administration Manual.

**RETENTION AND DISPOSAL:**

Number of years held—Period of service or 6 years if inactive. How destroyed: shredded and disposed of if inactive more than 6 years.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, Division of Federal Employee Occupational Health, Bureau of Health Care Delivery and Assistance, Health Resources and Services Administration, Room 7A–39, 5600 Fishers Lane, Rockville, MD 20857.

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the System Manager at the address above. Individual must provide positive identification, such as driver's license, passport, voter registration card, union card, or a written certification verifying his or her identity. Individuals must provide treatment location and approximate date of treatment. Requesters should also reasonably specify the record contents being sought. An individual who requests access to a medical record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

**RECORD ACCESS PROCEDURE:**

Same as notification procedure.

**CONTESTING RECORD PROCEDURE:**

Contact the official at the address specified in the Notification Procedures above and reasonably indentify the record, specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Information is obtained from the Federal employee, the x-ray, laboratory, and EKG contractors, physican and nurse notes, OWCP and personnel office: or supplied by a member of the individual's family, or derived from information supplied by the individual. Information may also be supplied from sources to whom the employee has been rerferred for assistance, Department officials, or program counselors.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09–15–0002**

**SYSTEM NAME:**

Record of Patients' Personal Valuables and Monies HHS/HRSA/BHCDA.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Financial Management Branch—National Hansen's Disease Center, Carville, Louisiana 70721.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals admitted to the National Hansen's Disease Center (NHDC).

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Information regarding personal valuables such as watches or rings, and monies checked in by the patients for safe-keeping.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 321 of the Public Health Service Act, as amended (42 U.S.C. 248), Hospitals, Medical Examinations, and Medical Care.

**PURPOSE(S):**

The purpose of the system is to provide for the safekeeping of patients' valuables. Redcords may also be used by the HHS Audit Agency for audit purposes.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense: *Provided,* Such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Valuables and monies are sealed in an envelope and filed in a locked safe.

**RETRIEVABILITY:**

Name and hospital record number.

**SAFEGUARDS:**

1. Authorized users: NHDC personnel responsible for the security of valuables and monies, NHDC cashiers, nurses, and physicians.

2. Physical Safeguards: All documents are protected during lunch hours and nonworking hours in locked file cabinets or locked storage areas.

3. Procedural Safeguards: All users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised office. Access to records is strictly limited to those staff members trained in accordance with the HHS Ch. 45–13 and Ch PHS.hf.: 45–13 of the General Administration Manual.

**RETENTION AND DISPOSAL:**

Number of years held: Until audited by HHS Audit Agency. How destroyed: incinerator.

**SYSTEM MANAGER(S) AND ADDRESS:**

Chief, Financial Management Branch, National Hansen's Disease Center, Carville, Louisiana 70721.

**NOTIFICATION PROCEDURE:**

Write to the Financial Management Office at the National Hansen's Disease Center. Individual must provide positive identification such as driver's license, passport, voter registration card, union card, or a written certification verifying his or her identity. Requesters should also reasonably specify the record contents being sought.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures.

**CONTESTING RECORD PROCEDURES:**

Write to the official at the address specified in the notification procedures above, and reasonably identify the record, specify the information to be contested, and state the corrective

action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Patient and admission record.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-15-0003**

**SYSTEM NAME:**

Contract Physicians and Consultants. HHS/HRSA/BHCDA.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Bureau of Health Care Delivery and Assistance, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, Maryland 20857. National Hansen's Disease Center, Carville, Louisiana 70721.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Medical and allied health professionals (e.g., physicians, nurses, physical therapists, and dentists) who have contracted with the Bureau of Health Care Delivery and Assistance to provide services to beneficiaries.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Duplicate of original contract and personal data qualifications. Orginal contracts developed by the National Hansen's Disease Center.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 320 of the Public Health Service Act, as amended (43 US.C. 225), Receipt, Apprehension, Treatment and Release of Lepers; Section 321 of the Public Health Service Act, as amended (42 U.S.C. 248), Hospitals, Medical Examinations, and Medical Care; and Section 326 of the Public Health Service Act, as amended (42 U.S.C. 253), Services to Coast Guard, Coast and Geodetic Survey, and Public Health Service.

**PURPOSE(S):**

To monitor contract negotiations and compliance, to review credentials, and to collect statistical data required to manage the program.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event that a system of records maintained by this agency to carry out its function indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether state or local, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation or order issued pursuant thereto.

Where a contract between a component of the Department and a recognized labor organization provides that the agency will disclose personal records relevant to the organization's mission, records in this system of records may be disclosed to such organization.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File folders.

**RETRIEVABILITY:**

Name and contract number.

**SAFEGUARDS:**

1. Authorized Users: PHS Omit medical and financial management staff and contracting personnel.

2. Physical Safeguards: All documents are protected during lunch hours and nonworking hours in locked file cabinets or locked storage areas.

3. Procedural Safeguards: All users of personal information in connection with the performance of their jobs protect information from public and from unauthorized personnel entering an unsupervised office. Access to records is strictly limited to those staff members trained in accordance with HHS Ch 45-13 and Ch PHS.hf:45-13 of the General Administrative Manual.

**RETENTION AND DISPOSAL:**

Duplicate contracts: Held 1-3 years dependent upon renewal. Destroyed by shredding.

Original Contracts: 1. Transactions of more than $10,000: destroy 6 years and 3 months after final payment. 2. Transactions of $10,000 or less: destroy 3 years after final payment.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, Division of Beneficiary Medical Programs, Bureau of Health Care Delivery and Assistance, Health Resources Administration, Room 7-36, 5600 Fishers Lane, Rockville, Maryland 20857, and Director, National Hansen's Disease Center, Carville, LA 70721.

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the System Manager at the address above. The individual must provide positive identification, such as driver's license, passport, voter registration card, or written certification verifying his or her identity. Requesters should also reasonably specify the record contents being sought.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures.

**CONTESTING RECORD PROCEDURES:**

Write to the official at the address specified in the notification procedures above, and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Medical, allied health professionals and dentists.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-15-0004**

**SYSTEM NAME:**

Federal Employee Occupational Health Data System. HHS/HRSA/BHCDA.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Bureau of Health Care Delivery and Assistance, Division of Federal Employee Occupational Health, 5600 Fishers Lane, Rockville, MD 20857.

Data are also occasionally located at medical laboratories, medical consultants, or computer processing firm sites. A list of sites where individually indentifiable data is currently located is available upon request to the System Manager.

**CATEGORIES OF INDIVIDUALS COVERED BY SYSTEM:**

Federal employees enrolled in PHS Division of Federal Employee Occupational Health (DFEOH) Health Units.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Health record derived data organized and presented for analysis and program planning purposes.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Title V (5 U.S.C. 7901), Health Service to Employees, and OMB Circular No. A-72.

**PURPOSE(S):**

The system is designed to provide health record derived data for program analysis and planning purposes in a fashion to reduce the manual information processing workload of unit physicians, nurses, and other health professionals.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

U.S. Department of Labor, Office of Workers' Compensation Programs, (OWCP) may be given access to files of the those persons claiming compensation benefits due to personal injury while on the job.

Certain records may be disclosed to medical laboratories, medical consultants, or computer processing firms under service contract agreement. Recipients are required to maintain adequate safeguards with respect to such records.

In the event of a change in sponsorship of a PHS/DFEOH health care unit or in a case of mass transfer of employees covered by PHS/DFEOH health care unit to one served by a nondepartmental organization, the health records will be transferred to the custodianship of the new organization.

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Magnetic tape and disc.

**RETRIEVABILITY:**

Name and Social Security numbers, which are supplied on a voluntary basis, are used for retrieval.

**SAFEGUARDS:**

1. Authorized Users: DFEOH personnel, health unit physicians, nurses, and other allied health professionals.

2. Physical Safeguards: Magnetic tapes, discs, and other computer equipment and computerized data are stored in areas where fire and life safety codes are strictly enforced. Twenty-four hours, 7-day security guards perform random checks on the physical security of the data. All documents are protected during lunch hours and nonworking hours in locked file cabinets or locked storage areas.

3. Procedural Safeguards: A password is required to access the terminal and a data set name controls the release of data only to authorized users. All users of personal information in connection with the performance of their jobs protect information from public view and from unathorized personnel entering an unsupervised office. Access to records is strictly limited to those staff members trained in accordance with the DFEOH Manual of Operations. The contractor is required to maintain confidentiality safeguards with respect to these records. These safeguards are in accordance with DHHS Chapter 45-13 and supplemetary Chapter PHS. fh: 45-13 in the General Administration Manual.

**RETENTION AND DISPOSAL:**

Number of years held Permanently or until 5 years after record becomes inactive. Purged from computer and stored on computer tape for a period of 5 years after files become inactive.

**SYSTEMS MANAGER(S) AND ADDRESS:**

Director, Division of Federal Employee Occupational Health, Bureau of Health Care Delivery and Assistance, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, MD 20857.

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the System Manager at the address above. Individuals must provide positive identification, such as driver's license, passport, voter, registration card, union card, or a written certification verifying his or her identity. Individuals must provide treatment locations and approximate date of treatment. Requestors should also reasonably specify the record contents being sought. An individual who requests access to a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures.

**CONTESTING RECORD PROCEDURES:**

Write to the official at the address specified in the notification procedures above, and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Information is obtained from the Federal employee, the x-ray, laboratory, and EKG contractors, physician and nurse notes; OWCP and personnel office.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**90-15-0007**

**SYSTEM NAME:**

Patients Medical Record System PHS Hospitals-Clinics. HHS/HRSA/BHCDA.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

See appendices 1 and 2.

Data are also occasionally located at medical laboratories, medical consultants, or computer processing firm sites. A list of sites where individually identifiable data is currently located is available upon request to the System Manager.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals examined and/or treated at former Public Health Service Hospitals and Clinics and the National Hansen's Disease Center, Carville, Louisiana.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Medical examination, diagnostic and treatment data; information for proof of eligibility; social data such as address and birthdate; disease registers such as, Hansen's disease, tumor and surgical procedure registers; treatment logs, summaries and correspondence.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 320 of the Public Health Service Act, as amended (42 U.S.C. 255),

Receipt, Apprehension, Treatment and Release of Lepers; Section 321 of the Public Health Sevice Act, as amended (42 U.S.C. 248), Hospitals, Medical Examinations, and Medical Care; and Section 326 of the Public Health Service Act, as amended (42 U.S.C. 253), Service to Coast Guard, Coast and Geodetic Survey, and Public Health Service.

**PURPOSE(S):**

The Purposes of this system are:

1. To serve as a basis for planning patient care and for continuity in the evaluation of the patient's condition and treatment to furnish documentary evidence of the course of the patient's medical evaluation, treatment and change in condition during the hospital stay, ambulatory care or emergency visit, or while being followed in a facility-based home care program;

2. To document communications between the responsible practitioner and any other health professionals contribution to the patient's care and treatment to assist in protecting the legal interests of the patient, the hospital or clinic and responsible practioners;

3. To provide data for use in facility management, continuing education, Department initiatives, quality assurance activities and research at the National Hansen's Disease Center, Carville, Louisiana.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to:

(1) Any community health organization, government agency, private physican and/or company which has requested or arranged for an examination, treatment or care of an individual.

(2) Army, Navy, Air Force to report results of examination/treatment of their uniformed service personnel.

(3) Department of Transportation to report results of examination/treatment of their uniformed services personnel found to be suffering from conditions that render them hazardous to themselves or to others.

(4) Department of Commerce to report results of examination/treatment of uniformed services and other personnel of that agency.

(5) Immigration and Naturalization Service to report results of examination/treatment of aliens examined and treated for and in behalf of that agency.

(6) Bureau of Prisons (BP) to report results of examination and treatment of patients examined and/or treated for and on behalf of the BP.

(7) Federal, state or private health benefit plans for billing purposes.

(8) U.S. Department of Labor, Office of Workers' Compensation Programs for persons claiming compensation benefits due to personal injury while employed by the Government.

(9) Organizations such as Joint Commission on Accreditation of Hospitals for accreditation of hospitals and clinics, and American Medical Association for accreditation of resident training programs. Medical records are used to document quality of service by health care providers.

(10) Health professions students serving an affiliation at the institution and their parent education program; students provide patient care and use medical records in performance of their duties.

(11) Nonagency physicans providing continuing care to current and former PHS beneficiaries, laboratories performing tests for the continuing care of these patients, and successor organizations providing health care in former PHS hospitals and clinics.

(12) Veterans Administration to assist uniformed service personnel, retirees and veterans to obtain medical care or benefits.

(13) Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

(14) Disclosure may be made to a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. The contractor is required to maintain Privacy Act safeguards with respect to such records.

(15) A record may be disclosed for a research purpose, when the department: (a) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained: (b) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring: (c) has required the recipient to—(1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, and (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except—(A) in emergency circumstances affecting the health or safety of any individual, (B) for use in another research project, under these same conditions, and with written authorization of the Department, (C) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (D) when required by law; (d) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by the these provisions.

(16) To organizations deemed qualified by the Secretary to carry out quality assessment, medical audits or utilization review.

(17) Information regarding the commission of crimes or the reporting or occurrence of communicable diseases, tumors, child abuse, births, deaths, alcohol or drug abuse, etc. as may be required by health providers and facilities, by state law, or regulation of the department of health or other agency of the state or its subdivision in which the facility is located. Disclosure may be made to organizations as specified by the state law or regulation such as birth and deaths to vital statistics agencies and crimes to law enforcement agencies. Disclosure of the contents of records which pertain to patient identity, diagnosis, prognosis or treatment of alcohol or drug abuse is restricted under the provisions of the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations 42 CFR Part 2 as authorized by 21 U.S.C. 1175 and 42 U.S.C. 4582, as amended by Pub. L. 93-282. To the extent possible, identical restrictions are applied to the disclosure of the contents of records pertaining to individuals with other programs who are participating in employee counseling programs.

(18) In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desrable or necessary to the Department of Justice to enable that Department to present an effective

defense, provided such disclosure is compatible with purpose for which the records were collected.

(19) To organizations or individuals with agreements to provide services to such facilities for the purpose of photocopying or abstracting medical record data services.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File folders, magnetic tape, punch cards, microfilm.

**RETRIEVABILITY:**

Indexed by name, register number, number control register, disease and operation, uniformed services service number which is the social security number. Those records indexe by SSN are retrived in accordance with section 7(a)(2)(B) of the Privacy Act.

**SAFEGUARDS:**

1. Authorized Users: Health care practitioners, and other allied health personnel, medical and allied health students and administrative personnel for determination of eligibility for care and facility management; qualified research personnel with approved protocol; PHS Commissioned Personnel Operations Division; and PHS Claims Officer.

2. Physical Safeguards: Magnetic tapes, discs, other computer equipment and other forms of personal data are stored in areas where fire and life safety codes are strictly enforced. Twenty-four hour, 7-day security guards perform random checks on the physical security of the data. All documents are protected during lunch hours and nonworking hours in locked file cabinets or locked storage areas.

3. Procedural Safeguards: A password is requaired to access the terminal and a data set name controls the release of data only to authorized users. All users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised office. Access to records is strictly limited to those staff members trained in accordance with privacy act safeguards. The contractor is required to maintain confidentiality safeguards with respect to these records. These safeguards are in accordance with DHHS Chapter 45–13 and supplementary Chapter PHS.hf: 45–13 in the General Administration Manual, and Part 6 of the DHHS ADP Systems Manual. The Memorandums of Agreement between the successor organizations and the Public Health Service require the successor organizations to comply with the Privacy Act. PHS and HHS guidelines have been provided to each successor organization.

**RETENTION AND DISPOSAL:**

Number of years held (or successor organization) (since 1970)—5 years after last activity. Number of years then held at Federal Record Center (See appendix 2) before disposal—50 years for active duty uniformed service personnel, 25 years for all others. How destroyed: The disposal standard for these records may be obtained by writing to the System Manager at the address below.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, Division of Beneficiary Medical Programs, Bureau of Health Care Delivery and Assistance, Health Resources Administration, Room 7–36, 5600 Fishers Lane, Rockville, Maryland, 20857, and Director, National Hansen's Disease Center, Carville, LA 70721.

**NOTIFICATION PROCEDURE:**

To determine the existence of a record, write to the facility where treatment was rendered if listed in Appendix 1. (Note that the facility may now be operated under a different name by the successor organization.) If the facility is not listed, write to: Director, Public Health Service Data Center, 10000 Aerospace Road, Warehouse No. 1, Lanham, Maryland 20706. Requests for records at the Federal Records Centers must be processed through the System Manager or the Public Health Service Health Data Center, Lanham, Maryland. If requesting records by mail, a written certification verifying identity must be provided. If appearing in person at the National Hansen's Disease Center, Carville, Louisiana, positive identification such as a driver's license, passport, or voter's registration card must be provided. An individual who requests access to a medical/dental record shall designate in writing, at the time the request is made, a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion. Finally, a parent or guardian who requests notification of access to a child's/incompentent person's record shall designate a family physican or other health professional (other than a family member) to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child/incompetent person as well as his/her own indentity.

**RECORD ACCESS PROCEDURE:**

Same as notificaion procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURE:**

Contact the official at the address specified in the notification procedures above, and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Individual, health care personnel, other hospitals and physicians, employers, social agencies, maritime unions, shipping companies.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**Appendix 1**

*A. Public Health Service Facilities*

Director, National Hansen's Disease Center, Carville, Louisiana 70721.

Director, Public Health Service Health Data Center, 10000 Aerospace Road, Warehouse No. 1, Lanham, Maryland 20706.

*B. Successor Organizations*

Director, Wyman Park Health System, Inc., 3100 Wyman Park Drive, Baltimore, Maryland 21211.

Director, Brighton Marine Public Health Center, 77 Warren Street, Boston (Brighton), Massachusetts 02135.

Administrator, Lutheran Downtown Health Care Services, 1313 Superior Ave., Cleveland, Ohio 44114.

Director, Hospital of St. John, 2050 Space Park Drive, Nassau Bay, Texas 77058.

Director, New Orleans Adolescent Children's Hospital, 210 State Street, New Orleans, Louisiana 70118.

Officer-in-Charge, Lafayette River Branch Clinic, 6500 Hampton Boulevard, Norfolk, Virginia 23508.

Administrator, Coastal Health Services, 331 Veranda Street, Portland, Maine 04103.

Officer-in-Charge, U.S. Army St. Louis Outpatient Clinic, 1520 Market Street, St. Louis, Missouri 63103.

Director, Seattle Public Health Hospital, 1131 14th Avenue South, Seattle, Washington 98144.

Director, Bayley Seton Hospital, Bay Street and Vanderbilt Avenue, Staten Island, New York 10304.

**Appendix 2—Federal Records Centers**

*Areas Served*

Maine, Vermont, New Hampshire, Massachusetts, Connecticut, and Rhode Island:
Federal Archives & Records Center, GSA, 380 Trapelo Road, Waltham, Massachusetts 02154.

New York, New Jersey, Puerto Rico, the Virgin Island, and the Panama Canal Zone:

Federal Archives & Records Center, GSA, Military Ocean Terminal, Bldg. 22, Bayonne, NJ 07002.
Delaware and Pennsylvania east of Lancaster:
Federal Archives and Records Center, GSA, 5000 Wissahicko Avenue, Philadelphia, PA 19144.
Pennsylvania except areas east of Lancaster:
Federal Records Center, Defense Activities, Bldg. 308, Mechanicsburg, PA 17055.
District of Columbia, Maryland, Virginia, and West Virginia:
Washington National Records Center, GSA, Washington, DC 20409.
North Carolina, South Carolina, Tennessee, Mississippi, Alabama, Georgia, Florida and Kentucky:
Federal Archives & Records Center, GSA, 1557 St. Joseph Avenue, East Point, GA 30344.
Illinois, Wisconsin and Minnesota:
Federal Archives and Records Center, GSA, 7358 South Pulaski Road, Chicago, IL 60629.
Indiana, Michigan, and Ohio:
Federal Records Center, 3150 Bertwynn Drive, Dayton, Ohio 45439.
Kansas, Iowa, Nebraska, and Missouri (except greater St. Louis area):
Federal Archives and Records Center, 2306 East Bannister Road, Kansas City, MO 64131.
Greater St. Louis Area:
National Personnel Records Center, GSA (Civilian Personnel Records), 111 Winnebago Street, St. Louis, MO 63118.
Texas, Oklahoma, Arkansas, Louisiana, and New Mexico:
Federal Archives & Records Center, GSA, P.O. Box 6216, Ft. Worth, TX 76115.
Colorado, Wyoming, Utah, Montana, North Dakota, and South Dakota:
Federal Archives and Records Center, Bldg. 48, Denver Federal Center, P.O. Box 25307, Denver, CO 80225.
Nevada (except Clark County), California (except Southern California), and America Samoa:
Federal Archives & Records Center, GSA, 1000 Commodore Drive, San Bruno, CA 94066.
Clark County, Nevada; Southern California (Counties of San Luis Obispo, Kern, San Bernadino, Santa Barbara, Ventura, Los Angeles, Riverside, Orange, Imperial, Inyo, and San Diego), and Arizona:
Federal Archives & Records Center, GSA, 24000 Avila Road, Luguna Niguel, CA 92677.
Washington, Oregon, Idaho, Alaska, Hawaii, and Pacific Ocean Area (except American Samoa):
Federal Archives & Records Center, GSA, 6125 San Point Way, Seattle, WA 98115.

**09-15-0008**

**SYSTEM NAME:**

Emergency Non-PHS Treatment Authorization File, HHS/HRSA/BHCDA.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Bureau of Health Care Delivery and Assistance, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, MD 20857.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals who are eligible for emergency care paid by the Public Health Service at non-PHS medical facilities and who had such care.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Eligibility information and reasons for emergency care.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 320 of the Public Health Service Act, as amended (42 U.S.C. 255), Receipt, Apprehension, Treatment and Release of Lepers; Section 321 of the Public Health Service Act, as amended (42 U.S.C. 248), Hospitals, Medical Examinations, and Medical Care; and Section 326 of the Public Health Service Act, as amended (42 U.S.C. 253), Services to Coast Guard, Coast and Geodetic Survey, and Public Health Service.

**PURPOSES(S):**

To determine eligibility for medical care by PHS, to document expenditure of public funds; to review and evaluate the quality of medical care.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to insurance companies for third party reimbursement.

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendent is (a) the Department, any component of the Department or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Document files.

**RETRIEVABILITY:**

Name.

**SAFEGUARDS:**

1. Authorized Users: Administrative officials, physicans; or other health care professionals; financial management personnel, HRSA: HHS Audit Agency for audit purposes.

2. Physical Safeguards: All documents are protected during lunch hours and nonworking hours in locked file-cabinets and locked storage areas.

3. Procedural Safeguards: All users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised office. Access to records is strictly limited to those staff members trained in accordance with DHHS Chapter 45-13 and supplementary Chapter PHS.hf:45-13 in the General Administration Manual.

**RETENTION AND DISPOSAL:**

Number of years held. Until audited by HHS Audit Agency. Then destroyed by shredding or in incinerator.

**SYSTEM MANAGER(S) AND ADDRESS:**

Division of Beneficiary Medical Programs, Bureau of Health Care Delivery and Assistance, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, MD 20857, and Director, National Hansen's Disease Center, Carville, LA 70721.

**NOTIFICATION PROCEDURE:**

To determine the existence of a record, writ to the facility where treatment or service was rendered. Individual must provide positive identification, such as driver's license, passport, voter's registration card, union card, or a written certification verifying his or her identify. Requesters should also reasonably specify the record contents being sought.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified in the notification procedures above, and reasonably identify the record, specify the identification to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Individual or someone acting in his/her behalf, and providers of medical care.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-15-0018**

**SYSTEM NAME:**

Unofficial Vital Records Sytem. HHS/HRSA/IHS.

**SECURITY CLASSIFICATION:**

None

**SYSTEM LOCATION:**

Indian Health Service Area and Program Offices. See Appendix

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

American Indian and Alaskan Native birth records.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Birth information. The records include paper copies or microfilm images of State records or machine readable data prepared by the State from records collected under the laws of each State for births. The records contain the demographic characteristics of individuals associated with each event. In addition the birth records include information on the characteristics of each live birth, the health status of the infant, and socioeconomic characteristics of the parents.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 321 of the Public Health Service Act, as amended (42 U.S.C. 248), Hospitals, Medical Examinations, and Medical Care.

**PURPOSE(S):**

Used in health care program development, analysis, and evaluation. Birth record is an unofficial copy of the State record which is used internally for aggregate statistical and planning purposes.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office form the unofficial birth record of a subject individual in response to an inquiry from the congressional office made at the request of the subject individual. Such disclosure will be made in conjunction with notification that the birth record is an unofficial copy of the State Record, thus it must be verified by the State Health Department from which the record came.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File folders in file cases; microfilm reels, computer cards and tapes.

**RETRIEVABILITY:**

Indexed by date of event, mother's name, state, and county of occurence and residence.

**SAFEGUARDS:**

Stored in locked files and cabinets, located in secured areas. Only authorized individuals in the performance of their official duties are granted access to locked areas. Authorized individuals include maternal and child health personnel, health planners, statisticians, epidemiologists, demographers, and others concerned with problems of health, health care, and health hazards. Access to records is limited in accordance with implementation Guidelines: DHHS Chapter 45-13 and supplementary Chapter PHS. hf:45-13 of the General Administration Manual; and with the DHHS ADP Systems Manual Part 6, "ADP Systems Security."

**RETENTION AND DISPOSAL:**

Number of years held at IHS: Varies by IHS area from 1 year to permanently. How destroyed: Burned or shredded.

**SYSTEM MANAGER(S) AND ADDRESS:**

See Appendix.

**NOTIFICATION PROCEDURE:**

To determine if a records exists, write to the official at the appropriate address specified in the appendix. Supply date of birth, place of birth, father's name, and mother's maiden name.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures.

**CONTESTING RECORD PROCEDURES:**

Write to the official at the address specified in the appendix and reasonably identify the record, specify the information to be contested, and state the corrective action sought with supporting justification. The information contested may only be changed in the unofficial vital records system and the State must be notified separately to change the official documents.

**RECORD SOURCE CATEGORIES:**

Source documents are obtained from State vital statistics offices and other jurisdictions. Information sources include parent(s) as well as the medical care provider.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

Appendix

Director, Aberdeen Area Indian Health Service, Federal Building, 115 Fourth Avenue, S.E., Aberdeen, South Dakota 57401, Attn: Chief Maternal and Child Health Branch

Director, Alburquerque Area Indian Health Service, Room 4005, Federal Office Building, 500 Gold Avenue, SW., Albuquerque, New Mexico 87101, Attn: Chief, Program Analysis & Statistics Br.

Director, Alaska Area Native Health Service, P.O. Box 7-741, Anchorage, Alaska 99510, Attn: Chief, Office of Systems Development

Program Director, Bemidji Program Office, Indian Health Service, 203 Federal Building, Box 768, Bemidji, Minnesota 56601, Attn: Privacy Act Coordinator

Director, Billings Area Indian Health Service, P.O. Box 2143, Billings, Montana 59103, Attn: Area Program Planning & Statistics Office

Director, Navajo Area Indian Health Service, P.O. Box G, Window Rock, Arizona 86515, Attn: Chief, Maternal and Child Health Br.

Directpr, Oklahoma City Area Indian Health Service, 215 Dean A. McGee Street, NW., Oklahoma City, Oklahoma 73102-3477, Attn: Chief, Program Analysis & Statistics Br.

Director, Phoenix Area Indian Health Service, 3738 N. 16th Street, Suite A. Phoenix, Arizona 85016-5981, Attn: Director, Office of Program Planning

Director, Portland Area Indian Health Service, Room 476, Federal Building, 1220 Southwest Third Avenue, Portland, Oregon 97204-2892, Attn: Chief, Program Planning & Statistics

Program Director, United Southeastern Tribes, Indian Health Service, Oak Towers Building, 1101 Kermit Drive, Suite 810, Nashville, Tennessee 37217-2191, Attn: Privacy Act Coordinator

Director, Tucson Program Office, Indian Health Service, P.O. Box 11340, Tucson, Arizona 85734, Attn: Chief, Community Health Status Surveillance

Director, California Program Office, Indian Health Service, 2999 Fulton Avenue,

Sacramento, California 95821, Attn: Privacy Act Coordinator

**09-15-0019**

**SYSTEM NAME:**

Health and Medical Records Systems, HHS/HRSA/IHS.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Indian Health Service (IHS) hospitals, health centers, school health centers, health stations, field clinics, Service Units, Area and Program Offices (Appendix 1), and Regional Federal (Records Centers (Appendix 2). Automated records are stored at the Data Processing Service Center, IHS located in Albuquerque, NM (Appendix 1). Records may be located at hospitals and offices of health care providers who are under contract to IHS. A current list of contractor sites is available by writing to the appropriate System Manager (Area or Service Unit Director) at the address shown in Appendix 1.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals examined/treated by IHS staff and by contract health care providers.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Health and medical records containing: Examination, diagnostic and treatment data, proof of eligibility and social data; case records for special programs and/or disciplines such as: Contract care, dental, social service/mental health, nursing, laboratory test results, eye care, nutrition and dietetis, hearing aid users, and detoxification; follow-up registers of individuals with specific health conditions or of a particular health status such as: Tumors, selected communicable and noncommunicable diseases, hospital commitment, child abuse and neglect, immunizations provided and/or scheduled, self-destructive behavior, and handicapped children; logs or files of individuals provided health care or related services by staffs of specific hospital components such as: Surgery, emergency, delivery, x-ray/radiologic and laboratory; operation and/or disease indices for particular hospitals which, by operation or disease, lists each patient who has had the operation or disease.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 321 of the Public Health Service Act, as amended (42 U.S.C. 248), Hospitals, Medical Examinations, and Medical Care; Indian Self Determination and Education Assistance Act (25 U.S.C. 450); Snyder Act (25 U.S.C. 13); Health Care Improvement Act (25 U.S.C. 1601 et seq.); Construction of Community Hospitals Act (25 U.S.C. 2005–2005f); and the Indian Health Service Transfer Act (42 U.S.C. 2001–2004).

**PURPOSES:**

Records retrieved in individually identifiable form provide a description of the patient's illness, treatment administered, and the results achieved. Over time records serve as a medical history of the total health care and medical treatment received by the individual. These records of the patient's health status and of services received and recommended to assist in planning for further care of the patient; serves as a basis for planning future health programs; serves as a means of communication among members of the health care team who contribute to the patient's care; serves as a legal document of health care rendered; serves as a tool in evaluating quality of health care rendered; are used for continuing education by the Indian Health Service staff and for research purposes. For example, copies of individually identifiable records may be sent to the following two components of this Department for the purposes stated:

To the National Centers for Disease Control for their surveillance of various communicable diseases among persons residing within the United States;

To the National Institutes of Health for their review of the prevalence of particular diseases (i.e., malignant neoplasms, diabetes mellitus, arthritis, metabolism and digestive diseases) for various ethnic groups of the Nation.

A by-product of the information contained in this system of records is program health statistics which is used by IHS to evaluate the effect of the IHS health care delivery program. In addition, aggregate program statistics, which maintain the privacy of the subject individuals, may be provided by IHS upon request to the following components of the Department of Health and Human Services (HHS) for the purposes stated below. (Please note that this list is not all inclusive, as other entities of HHS may be provided aggregated statistics on a one-time need-to-know basis). Specifically, aggregated statistics may be provided;

To the National Center for Health Statistics, HHS, for its dissemination of aggregated health statistics for various ethnic groups;

To the Assistant Secretary for Population Affairs to keep a record of the number of sterilizations provided through the use of Federal funds;

To the Health Care Financing Administration for the documentation of health care provided by the Indian Health Service covered by the Medicare program for third party reimbursement;

To the Bureau of Support Services, Health Care Financing Administration to determine the prevalence of end stage renal disease among the American Indian and Alaskan Native population and to coordinate the care of American Indian and Alaskan Native patients with this condition.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Records in part or total may be disclosed to state, local or other authorized organizations which provide health services to American Indians and Alaskan Natives or third party reimbursement or fiscal intermediary functions for the purpose of planning for or providing such services, billing or collecting third party reimbursements and reporting results of medical examination, care and treatment.

2. Records in part or total may be disclosed to federal and non-federal school systems which serve American Indians and Alaskan Natives for the purpose of student health maintenance. Response to the request for disclosure will be based upon the subject matter being requested, the justification for its receipt, and the manner in which it will be used so as to protect its confidential nature. Disclosure will not be made unless the patient's right to privacy will be protected by the recipient of the information.

3. Records in part or total may be disclosed to organizations deemed qualified by the Secretary to carry out quality assessment, medical audits, or utilization review.

4. Records in part or total may be disclosed to authorized organizations or individuals for conduct of analytical and evaluation studies sponsored by the Indian Health Service.

5. Records in part or total may be disclosed to a congressional office in response to an inquiry from that office made at the request of the subject individual.

6. A record may be disclosed for a research purpose, when the Department: (a) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained;

(b) Has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable

form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring;

(c) Has required the recipient to—(1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, and (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use of disclosure of the record except—(A) in emergency circumstances affecting the health or safety of any individual, (B) for use in another research project, under these same conditions, and with written authorization of the Department, (C) for disclosure to a properly identified person for the purpose of an audit releted to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (D) when required by law;

(d) Has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

7. Information regarding the commission of crimes or the reporting of occurrences of communicable diseases, child abuse, births, deaths, alcohol or drug abuse, etc. may be disclosed by health providers and facilities to State and local agencies as required by State and local law.

8. Disclosure of the contents of records of individuals indicating alcohol or drug abuse which pertain to patient identity or the diagnosis, prognosis or treatment of alcohol or drug abuse is restricted under the provisions of the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations 42 CFR, Part 2, as authorized by 21 U.S.C. 1175 and 42 U.S.C. 4582, as amended by Pub. L. 93–282.

9. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File folders, ledgers, card files, microfiche, microfilm, computer cards and tapes, and automatic or open shelf files, automated tapes and disc files.

**RETRIEVABILITY:**

Indexed by name, record number, and Social Security Number (SSN) and cross-indexed. SSN is supplied on a voluntary basis.

**SAFEGUARDS:**

All personnel including IHS personnel, IHS contractors and subcontractors who are involved with this system are made aware of their responsibilities under the provisions of the Privacy Act and are required to maintain Privacy Act safeguards with respect to such records. Access is limited to authorized personnel in the performance of their duties. (Authorized personnel include medical records personnel, health care providers, management personnel, authorized contractors, researchers, medical audit personnel and health care team members.) Within each facility a list of personnel or categories of personnel having a demonstrable need for the records in the performance of their duties has been developed and is maintained. Procedures have been developed and implemented to review one-time requests for disclosure by personnel who may not be on the routine disclosure list. Proper chargeout procedures are followed for the removal of records from the area in which they are maintained. Persons who have a need to know are entrusted with records from this system of records and are instructed to safeguard the confidentiality of these records and to destroy all copies or to return such records when the need to know has expired. Instructions include the statutory penalties for noncompliance. Before an employee who will control disclosure of records can work with the records (i.e., employees who report to the system manager) the system manager or designee ensures that the employee has received training in the safeguards applicable to the records and is aware of the actions to take to restrict disclosure. Records are kept in locked metal filing cabinets or in a secured room at all times when not actually in use during working hours and at all times during nonworking hours. Record storage areas, including file cabinets in offices, are not left unattended or unlocked during office hours, including lunch hours. When copying records for authorized purposes, care is taken to ensure that any imperfect pages are not left in the reproduction room where they can be read, but are destroyed or obliterated. Implementation Guidelines: DHHS Chapter 45–13 and supplementary Chapter PHS. hf:45–13 of the General Administration Manual; and with the DHHS ADP Systems Manual Part 6, "ADP Systems Security." In this regard magnetic tapes, discs, other computer equipment and other forms of personal data are stored in areas where fire and life safety codes are strictly enforced. A password is required to access the terminal and a data set name controls the release of data to only authorized users.

**RETENTION AND DISPOSAL:**

Active records are maintained in the facility providing health services. For selected IHS health stations the record is stored in the facility to which the health station is administratively assigned. (See Appendix 1 for the mailing addresses of IHS facilities at which records in this system are stored and the mailing addresses for the system managers for this system.) Patient listings which may identify individuals are maintained in IHS Area and Program Offices permanently. Inactive records at the facility are held from three to seven years and then are transferred to the appropriate Federal Records Center. (See Appendix 2 for Federal Record Centers). Records are retained at the Federal Records Centers 50 years for active duty uniformed services personnel; 25 years for all others. How destroyed: According to practices in effect in each Regional Federal Record Center.

**SYSTEM MANAGER(S) AND ADDRESS:**

See Appendix 1. The IHS Office Directors and Service Unit Directors listed in Appendix 1 are System Managers. Other addresses listed in Appendix 1 are IHS facilities at which records are stored.

**NOTIFICATION PROCEDURE:**

Requests must be to the appropriate System Manager (IHS Program Office Director or Service Unit Director) list in Appendix 1. An individual who request notification of, or access to, a medical record shall at time the request is made designate in writing a responsible representative who will be willing to

review the record and inform the subject individual of its contents at the representative's discretion.

Requests in person:

A subject individual who appears in person at a specific location seeking access or disclosure of medical/dental records relating to him/her shall provide his/her name, current address, and at least one piece of tangible identification such as driver's license, passport, voter registration card, or union card. Identification papers with current photographs are preferred but not required. If a subject individual has no identification but is personally known to an agency employee, such employee shall make a written record verifying the subject individual's identity. Where the subject individual has no identification papers, the responsible agency official shall require that the subject individual certify in writing that he/she is the individual whom he/she claims to be and that he/she understands that the knowing and willful request or acquisition of records concerning an individual under false pretenses is a criminal offense subject to a $5,000 fine. In some situations additional identification may be requested. Some examples include the request for access to (1) records which contain sensitive information, (2) different records for persons with the same name, and (3) records which contain an apparent discrepancy between information contained in the record and that provided by the individual requesting access to the record. No verification of identity shall be required where the record is one which is required to be disclosed under the Freedom of Information Act.

Other names used:

Where an individual is seeking to obtain information about himself/herself which may be retrieved by a different name or identifier than his/her current name or identifier, he/she shall be required to produce evidence to verify that he/she is the person whose record he/she seeks.

Requests by mail:

Requests for information and/or access to records received by mail must contain information providing the identity of the writer and a reasonable description of the record desired. Written requests must contain the name and address of the requester, his/her date of birth and at least one piece of information which is also contained in the subject record, and his/her signature for comparison purposes. Where the written request does not contain sufficient information, the System Manager shall inform the requester in writing that additional, specified information is required to process the request.

Requests by telephone:

Since positive identification of the caller cannot be established, telephone requests are not honored.

Parents and legal guardians:

Parents of minor children and legal guardians of legally incompetent individuals shall verify their own identification in the manner described above, as well as their relationship to the individual whose record is sought. A copy of the child's birth certificate or court order establishing legal guardianship may be required when there is any doubt regarding the relationship of the individual to the patient. Minors or individuals who have been declared to be legally incompetent may have their rights under the Privacy Act invested in their parents or legal guardians.

Individuals acting in loco parentis to minors, parents, legal guardians, and custodians may act on behalf of the individual for purposes of giving consent for disclosures to others when it is determined that the subject individual is a minor who is unable to or cannot exercise with appropriate understanding, the right of consent by him or herself, IHS health professionals designated by parents or guardians, in accordance with 45 CFR 56.6(c) (2), to transmit information to them from their child's medical records, will disclose the requested information if the need for the information outweighs potentially conflicting program objectives (i.e., family planning, disease prevention, treatment or containment). Implied or expressed promises of confidentiality will be honored. State laws with respect to emancipated minors, will also be considered.

Signature:

Where an individual is unable to sign his/her name when required, he/she shall make his/her mark and have the mark verified in writing by two additional persons.

**RECORD ACCESS PROCEDURES**

Same as Notification Procedure.

**CONTESTING RECORD PROCEDURES:**

Write to the appropriate IHS Area Program Office Director or Service Unit Director at the address specified in Appendix 1 and reasonably identify the record, specify the information being contested, and state the corrective action sought with supporting justification.

**RECORD SOURCE CATEGORIES:**

Patients and/or family members, Indian Health Service health care personnel, contract health care providers, and State and local health organizations.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**Appendix 1**

Director, Aberdeen Area Indian Health Service, Federal Building, 115 Fourth Avenue, S.E., Aberdeen, South Dakota 57401, Attn.: Chief, Health Records Branch

Director, Rapid City Service Unit, Rapid City Indian Hospital, Rapid City, South Dakota 57701

Director, Cheyenne River Service Unit, Eagle Butte Indian Hospital, Eagle Butte, South Dakota 57625

Director, Fort Berthold Service Unit, Minni-Tohe Indian Health Center, New Town, North Dakota 58763

Director, Fort Totten Service Unit, Fort Totten Indian Health Center, Fort Totten, North Dakota 58335

Director, Pine Ridge Service Unit, Pine Ridge Indian Hospital, Pine Ridge, South Dakota 57770

Office in Charge, Wanblee Indian Health Center, Wanblee; South Dakota 57577

Director, Rosebud Service Unit, Rosebud Indian Hospital, Rosebud, South Dakota 57570

Director, Sisseton-Wahpeton Service Unit, Sisseton Indian Hospital, Sisseton, South Dakota 57262

Director, Flandreau Indian School Health Center, Flandreau, South Dakota 57028

Director, Wahpeton Indian School Health Center, Wahpeton, North Dakota 58075

Director, Standing Rock Service Unit, Fort Yates Indian Hospital, Fort Yates, North Dakota 58538

Director, McLaughlin Indian Health Center, McLaughlin, South Dakota 57642

Director, Turtle Mountain Service Unit, Belcourt Indian Hospital, Belcourt, North Dakota 58316

Director, Omaha-Winnebago Service Unit, Winneago Indian Hospital, Winnebago, Nebraska 68071

Director, Yankton-Wagner Service Unit, Wagner Indian Hospital, Wagner, South Dakota 57380

Director, Santee Indian School Health Station, Niobrara, Nebraska 68760

Director, Pierre Indian Learning Center, Star Route, 3 Pierre, South Dakota 57501

Director, Crow Creek Indian Health Center, P.O. Box 597, Ft. Thompson, South Dakota 57339

Director, Lower Brule Indian Health Center, Lower Brule, South Dakota 57548

Director, Bemidji Program Office, Indian Health Service, 203 Federal Building, Bemidji, Minnesota 56601, Attn.; Program Office Privacy Act Coordinator

Director, Kincheloe Indian Health Center, Kincheloe, Minnesota 49788

Director, Greater Leach Lake Service Unit, Cass Lake Indian Hospital, Cass Lake, Minnesota 56633

Director, Inger Indian Health Station, Inger Route, Deer River, Minnesota 56636

Director, Squaw Lake Indian Health Station, Squaw Lake, Minnesota 56681
Director, Ball Club Indian Health Station, Ball Club, Minnesota 56622
Director, Onigum Indian Health Station Star, Route, Walker, Minnesota 56484
Director, Lac Courte Oreille Service Unit, Indian Health Service, P.O. Box 733, Hayward, Wisconsin 54843
Director, Reserve Indian Health Station, c/o Director, Lac Courte Oreille Service Unit, Indian Health Service, P.O. Box 733, Hayward, Wisconsin 54843
Director, Odenah Indian Health Station, Odenah, Wisconsin 54861
Director, Nett Lake Indian Health Station, Nett Lake, Minnesota 55772
Director, Red Lake Service Unit, Red Lake Indian Hospital, Red Lake, Minnesota 56671
Director, Ponemah Indian Health Station, Ponemah, Minnesota 56666
Director, White Earth Service Unit, White Earth Indian Health Center, White Earth, Minnesota 56591
Director, Naytahwaush Indian School Health Station, Naytahwaush, Minnesota 56566
Director, Ponsford, Indian School Health Station, Ponsford, Minnesota 56575
Director, Rhinelander Indian Health Field Office, De Byle Building, Nine South Brown Street, Rhinelander, Wisconsin 56501
Director, Alaska Area Native Health Service, P.O. Box 7-741, Anchorage, Alaska 99510, Attn.: Chief, Health Records Branch
Director, Anchorage Service Unit, PHS Alaska Native Medical Center, P.O. Box 7-741, Anchorage, Alaska 99510
Director, Alaska Native Health Center, St. George Island, Alaska 99660
Director, Alaska Native Health Center, St. Paul Island, Alaska 99660
Director, Barrow Service Unit, Barrow Alaska Native Hospital, Barrow, Alaska 99723
Director, Bristol Bay Area Service Unit, Bristol Bay Area Alaska Native Hospital, Dillingham, Alaska 99576
Director, Interior Alaska Service Unit, Alaska Native Health Center, 1638 Cowles Street, Fairbanks, Alaska 99701
Director, PHS Alaska Native Health Center, Tanana, Alaska 99777
Director, Fort Yukon Alaska Native Health Center, Fort Yukon, Alaska 99740
Director, Southeast Area Regional Health Center, 3272 Hospital Drive, Juneau, Alaska 99801
Director, Kotzebue Service Unit, Kotzebue Alaska Native Hospital, Kotzebue, Alaska 99752
Director, Mt. Edgecumbe Service Unit, Mt. Edgecumbe Alaska Native Hospital, P.O. Box 4577, Sitka, Alaska 99835
Director, Juneau Alaska Native Health Center, Box 890, Juneau, Alaska 99802
Director, Ketchikan Alaska Native Health Center, 3289 Tongass Avenue, Ketchikan, Alaska 99901
Director, Annette Island Service Unit, Metlakatla Alaska Native Health Center, Box 428 Metlakatla, Alaska 99926
Director, Yukon-Kuskokwim-Delta Service Unit, Yukon-Kuskokwim-Delta Regional Hospital, Indian Health Service, Bethel, Alaska 99559
Director, Albuquerque Area Indian Health Service, Room 4005, Federal Office Building, 500 Gold Avenue, S.W., Albuquerque, New Mexico 87101, Attn.: Chief, Health Records Branch
Director, Albuquerque Service Unit, Albuquerque Indian Hospital, 801 Vassar Drive, N.E. Albuquerque, New Mexico 87106
Director, Isleta Indian Health Center, P.O. Box 429, Isleta, New Mexico 87022
Director, Jemez Indian Health Center, P.O. Box 256 Jemez Pueblo, New Mexico 87024
Chief, Dental Program, IHS Dental Training Center, Southwestern Indian Polytechnical Inst., 9168 Coors Road, N.W., P.O. Box 25927, Albuquerque, New Mexico 87125
Director, Indian School Health Center, Southwestern Indian Polytechnical Inst., 9168 Coors Road, N.W., P.O. Box 25927, Albuquerque, New Mexico 87125
Director, Sandia Indian Health Station, Sandia New Mexico 87047
Director, Santa Ana Indian Health Station, P.O. Box 580, Bernalillo, New Mexico 87004
Director, Zia Indian Health Station, General Delivery, San Ysidro, New Mexico 87053
Director, Mescalero Service Unit, Mescalero Indian Hospital, P.O. Box 210, Mescalero, New Mexico 88340
Director, Santa Fe Service Unit, Santa Fe Indian Hospital, 1700 Cerrillos Road, San Fe, New Mexico 87501
Director, Southern Colorado Service Unit P.O. Box 778, Ignacio, Colorado 81137
Director, Dulce Indian Health Center, Dulce, New Mexico 87528
Director, Ignacio Indian Health Center, Ignacio, Colorado 81137
Director, Taos Indian Health Center, Taos, New Mexico 87571
Director, Towaoc Indian Health Center, Towaoc, Colorado 81334
Director, Santa Clara Indian Health Station, P.O. Box 477, Espanola, New Mexico 87532
Director, Santo Domingo Indian Health Station, Santo Domingo, New Mexico 87052
Director, San Juan Indian Health Station, San Juan, New Mexico 87566
Director, Cochiti Indian Health Station, Cochiti, New Mexico 87041
Director, San Felipe Indian Health Station, General Delivery, San Felipe Pueblo, New Mexico 87001
Director, White Mesa Indian Health Station, General Delivery, Towaoc, Colorado 81334
Director, Zuni-Ramah Service Unit, Zuni Indian Hospital, Zuni, New Mexico 87327
Director, Acoma-Canoncito-Laguna Service Unit, Acoma-Canoncito-Laguna Indian Hospital, P.O. Box 130, San Fidel, New Mexico 87049
Director, Laguna Indian Health Center, P.O. Box 199, New Laguna, New Mexico 87038
Director, Canoncito Indian Health Center c/o Acoma-Canoncito-Laguna Indian Hospital, P.O. Box 130, San Fidel, New Mexico 87049
Director, Billings Area Indian Health Service, P.O. Box 2143, Billings, Montana 59103, Attn: Program Planning and Statistics Office
Director, PHS Indian School Health Center, P.O. Box 602, Brigham City, Utah 84302
Director, Blackfeet Service Unit, Browning Indian Hospital, Browning, Montana 59417
Director, Heart Butte Indian Health Station, Heart Butte, Montana 59448
Director, Crow Service Unit. Crow Indian Hospital, Crow Agency, Montana 59022
Director, Lodge Grass Indian Health Center Loge Grass, Montana 59050
Director, Pryor Indian Health Station. Pryor, Montana 59066
Director, Flathead Service Unit St. Ignatius Indian Health Center, St. Ignatius, Montana 59865
Director, Polson Indian Health Center, 320-B, 4th Avenue East, Polson, Montana 59860
Director, Fort Belknap Service Unit, Harlem Indian Hospital, Harlem, Montana 59526
Director, Hays Indian Health Station, Hays, Montana 59527
Director, Fort Peck Service Unit, Poplar Indian Health Center, Poplar, Montana 59255
Director, Wolf Point Indian Health Center, Wolf Point, Montana 59201
Director, Wind River Service Unit, Fort Washakie Indian Health Center, Fort Washakie, Wyoming 82514
Director, Arapahoe Indian Health Center, Arapahoe, Wyoming 82510
Director, Northern Cheyenne Service Unit, Lame Deer Indian Health Center, Lame Deer, Montana 59043
Director, Rocky Boy's Service Unit, Rocky Boy's Indian Health Center, Box Elder, Montana 59521
Director, Navajo Area Indian Health Service, P.O. Box G, Window Rock, Arizona 86515, Attn.: Chief, Health Records Branch
Director, Chinle Service Unit, Chinle Comprehensive Health Facility, P.O. Box P.H., Chinle, Arizona 86503
Director, Many Farms Indian Health Center, c/o Chinle, Comprehensive Health Facility P.O. Box P.H., Chinle Arizona 86503
Director, Many Farms Indian School Health Center c/o Chinle Comprehensive Health Facility, P.O. Box P.H., Chinle, Arizona 86503
Director, Pinon Indian Health Center, Pinon, Arizona 86510
Director, Rock Point Indian Health Center, c/o Chinle Comprehensive Health Facility, P.O. Box P.H., Chinle, Arizona 86503
Director, Crownpoint Service Unit, Crownpoint Indian Hospital, Crownpoint, New Mexico 87313
Director, Pueblo Pintado Clinic c/o Community Health Services, Crownpoint Indian Hospital, Crownpoint, New Mexico 87313
Director, Fort Defiance Service Unit, Fort Defiance Indian Hospital, Fort Defiance, Arizona 86504
Medical Officer in Charge, Toyei Clinic, Indian Health Center, Fort Defiance, Arizona 86504
Director, Lower Greasewood Indian Health Center, Lower Greasewood, Arizona 86505
Director, Gallup Service Unit, Gallup Indian Medical Center, Gallup, New Mexico 87301
Medical Officer in Charge, Tohatchi Indian Health Center, Gallup, New Mexico 87301
Director, Fort Wingate Indian Health Center, Fort Wingate, New Mexico 87316
Medical Officer in Charge, Fort Wingate Indian School Health Center, Fort Wingate, New Mexico 87316
Director, Kayenta Service Unit, Kayenta Indian Health Center, Kayenta, Arizona 86033

Director, Shonto Indian Health Center, Shonto, Arizona 86044
Director, Dennebotso Indian Health Center, c/o Kayenta Indian Health Center, Kayenta, Arizona 86033
Director, Shiprock Service Unit, Shiprock Indian Hospital, Shiprock, New Mexico 87420
Director, Tes Nos Pos Indian Health Center, P.O. Drawer D, Tes Nos Pos, Arizona 86514
Director, Sanostee Indian Health Clinic, c/o Shiprock Indian Hospital, Field Health, Shiprock, New Mexico 87420
Director, Todalena Indian Health Clinic, c/o Shiprock Indian Hospital, Field Health, Shiprock, New Mexico 87420
Director, Tuba City Service Unit, Tuba City Indian Hospital, Tuba City, Arizona 86045
Director, Dinnebeto Indian Health Clinic, c/o Community Health, Tuba City Hospital, Tuba City, Arizona 86045
Director, Winslow Service Unit, Winslow Indian Health Center, P.O. Box 40, Winslow, Arizona 86047
Director, Dilkon Indian Health Center, P.O. Box 40 Winslow, Arizona 86047
Director, Leupp Indian Health Center, c/o Winslow Indian Health Center, Community Health Services, Winslow, Arizona 86047
Director, Oklahoma City Area Indian Health Service, 215 Dean A. McGee Street, N.W., Oklahoma City, Oklahoma 73102–3477, Attn: Chief, Records Librarian Consultant
Director, Ada Service Unit, Ada Indian Hospital, 1001 North Country Club Drive, Box 1564, Ada, Oklahoma 74820
Director, Wewoka Indian Health Center, Wewoka, Oklahoma 74884
Director, Tishomingo Indian Health Center, Tishomingo, Oklahoma 73460
Director, Claremore Service Unit, Claremore Indian Hospital, Claremore, Oklahoma 74017
Director, Seneca Indian Health Station, Wyandotte, Oklahoma 74370
Director, Delaware District (Jay) Indian Health Center, Jay, Oklahoma 74346
Director, Okmulgee Indian Health Center, P.O. Box 1015, Okmulgee, Oklahoma 74447
Director, Miami Indian Health Center, P.O. Box 1498, Miami, Oklahoma 74354
Director, Locust Grove Indian Health Station, Locust Grove, Oklahoma 74352
Director, Seneca Indian School Health Station, Wyandotte, Oklahoma 74370
Director, Clinton Service Unit, Clinton Indian Hospital, Clinton, Oklahoma 73601
Director, Watonga Indian Health Center, P.O. Box 878, Watonga, Oklahoma 73772
Director, Concho Indian School Health Center, Concho, Oklahoma 73022
Director, Kansas Service Unit, Holton Indian Health Center, Holton, Kansas 66436
Facility Director, Lawrence (Haskell) Indian School Health Center, Lawrence, Kansas 66044
Director, Lawton Service Unit, Lawton Indian Hospital, Lawton, Oklahoma 73501
Director, Anadarko Indian Health Center, Anadarko, Oklahoma 73005
Director, Riverside Indian School Health Center, Anadarko, Oklahoma 73005
Director, Carnegie Indian Health Station, Carnegie, Oklahoma 73015
Director, Pawnee Service Unit, Pawnee Indian Health Center, Pawnee, Oklahoma 74058
Director, Pawhuska Indian Health Center, Pawhuska, Oklahoma 74056
Director, White Eagle Indian Health Center, Route 4, Ponca City, Oklahoma 74601
Director, Shawnee Service Unit, Shawnee Indian Health Center, Shawnee, Oklahoma 74801
Director, Tahlequah Service Unit, W. W. Hastings Indian Hospital, 1120 Grand, Tahlequah, Oklahoma 74464
Director, UPSHS Indian School Health Station, Sequoyah Institute, Tahlequah, Oklahoma 74464
Director, Talihina Service Unit, Talihina Indian Hospital, Talihina, Oklahoma 74571
Director, John Anderson Memorial Health Center, USPHS Indian Health Center, Broken Bow, Oklahoma 74728
Director, Hugo Indian Health Center, 109 E. Main, Hugo Oklahoma 74743
Director, McAlester Indian Health Center, McAlester, Oklahoma 74501
Director, Jones Academy Indian Health Station, Heartshorne, Oklahoma 74547
Director, Phoenix Area Indian Health Service, 3738 N. 16th Street, Suite A, Phoenix, Arizona 85016–5981, Attn. Chief, Health Records Branch
Director, Colorado River Service Unit, Parker Indian Hospital, Route, 1, P.O. Box 12, Parker, Arizona 85344
Director, Peach Springs Indian Health Center, Peach Springs, Arizona 86434
Director, Riverside Indian School Health Center, 8934 Magnolia, Riverside, California 92503
Director, Havasupai Indian Clinic, Supi, Arizona 86435
Director, Fort Yuma Service Unit, Winterhaven Indian Hospital, P.O. Box 1368, Yuma, Arizona 85364
Director, Keams Canyon Service Unit, Keams Canyon Indian Hospital, P.O. Box 98, Keams Canyon, Arizona 86034
Director, Second Mesa Indian Health Center, General Delivery, Second Mesa, Arizona 86043
Director, Owyhee Service Unit, Owyhee Indian Hospital, P.O. Box 212, Owyhee, Nevada 89832
Director, Phoenix Service Unit, Phoenix Indian Medical Center, 4212 North 16th St. Phoenix, Arizona 85016
Director, Fort McDowell Indian Health Station c/o Phoenix Indian Medical Center, 4212 North 16th Street, Phoenix, Arizona 85016
Director, Salt River Indian Health Center, Route 1, Box 115, Scottsdale, Arizona 85257
Director, Gila Crossing Indian Health Clinic, Route 1, Box 770, Laveen, Arizona 85339
Director, San Lucy Indian Health Station c/o Phoenix Indian Medical Center 4212 North 16th Street Phoenix, Arizona 85016
Director, Phoenix Indian School Health Center, c/o Phoenix Indian Medical Center, 4212 North 16th St., Phoenix, Arizona 85016
Director, Sacaton Service Unit, Sacaton Indian Hospital, Sacaton, Arizona 85247
Director, San Carlos Service Units, San Carlos Indian Hospital, San Carlos, Arizona 85550
Director, Bylass Indian Health Clinic, Bylass, Arizona 85530
Director, Schurz Service Unit, Schurz Indian Hospital, Schurz, Nevada 89427
Director, Stewart Indian Health Center, Stewart, Nevada 89437
Director, Fort McDermitt Indian Health Center, P.O. Box 475 McDermitt, Nevada 89421
Director, Unitah and Ouray Service Unit, Fort Duchesne Indian Health Center, P.O. Box 967, Roosevelt, Utah 84066
Director, Fort Duchesne Indian Dental Clinic, Roosevelt, Utah 84066
Director, Whiteriver Service Unit, Whiteriver Indian Hospital, Whiteriver, Arizona 85941
Director, Cibecue Indian Health Center, Cibecue, Arizona 85911
Director, Plortland Area Indian Health Service, Room 476, Federal Building 1220 Southwest Third Avenue, Portland Oregon 97204, Attn: Chief Health Records Branch
Director, Chemawa Indian School Health Center, 3750 Hazelgreen Road, N.E., Salem, Oregon 97303
Director, Colville Service Unit, Colville Indian Health Center, Nespelem, Washington 99155
Director, Inchellium Indian Health Center, Inchelium, Washington 99138
Director, Fort Hall Service Unit, Fort Hall Indian Health Center, P.O. Box 317, Fort Hall, Idaho 83203
Director, Blackfoot Indian Health Station, Blackfoot, Idaho 83221
Director, Northern Idaho Service Unit, Northern Idaho Indian Health Center, P.O. Drawer 367, Lapwai, Idaho 83540
Director, Kamiah Indian Health Station, Kamiah, Idaho 83536
Director, Coeur d'Alene Indian Health Station, Coeur d'Alene, Idaho 83814
Director, Warm Springs Service Unit, Warm Springs Indian Health Center, Warm Springs, Oregon 97761
Director, Puget Sound Service Unit, Kitsap Indian Health Center, 1212 South Judkins, Seattle, Washington 98144
Director, Muckleshoot Indian Dental Clinic, 14812 S.E. 368th Place, Auburn, Washington 98002
Director, Port Gamble Indian Health Station, Port Gamble, Washington 98364
Director, Yakima Service Unit, Yakima Indian Health Center, Route 1, Box 1104, Toppenish, Washington 98948
Director, White Swan Indian Health Station, White Swan, Washington 96952
Director, Umatilla Service Unit, Yellowhawk Indian Health Center, P.O. Box 159, Pendleton, Oregon 97801
Director, Taholah Service Unit, Taholah Indian Health Center P.O. Box 219, Taholah, Washington 98587
Director, Queets Indian Health Station, c/o Service Unit Director, Taholah Indian Health Center, P.O.Box 219, Taholah, Washington 98587
Director, Oakville Indian Health Station, Oakville, Washington 98568
Director, Neah Bay Service Unit, Neah Bay Indian Health Center, P.O. Box 418, Neah Bay, Washington 98357
Director, La Push Indian Health Station, La Push, Washington 98350
Director, Lower Elwha Indian Health Station, Port Angeles, Washington 98362
Director, Northwest Washington Service Unit, Lummi Indian Health Center, 2592

Kwina Road, Bellingham, Washington 98225
Swinomish Indian Dental Program, P.O. Box 64, La Conner, Washington 98257
Director, Burlington Indian Health Station, Burlington, Washington 98233
Director, Deming Indian Health Station, Deming, Washington 98244
Director, Wellpinit Service Unit, Wellpinit Indian Health Center, P.O. Box 391, Wellpinit, Washington 99040
Director, Kalispel Indian Health Station, c/o Wellpinit Service Unit Director, Wellpinit Indian Health Center, P.O. Box 391, Wellpinit, Washington 99040
Director, Tucson Program Office, Indian Health Service, P.O. Box 11340, Tucson, Arizona 85734, Attn.: Privacy Act Coordinator
Director, Sells Service Unit, Sells Indian Hospital, Sells, Arizona 85634
Director, Santa Rosa Indian Health Center, Star Route, Box 71, Sells, Arizona 85634
Director, San Xavier Indian Health Center, Tucson, Arizona 85734
Program Office Director, United Southeastern Tribes, Indian Health Service, Oak Towers Building, 1101 Kermit Drive. Suite 810, Nashville, Tennessee 37217-2191 Attn.: Privacy Act Coordinator
Director, Cherokee Service Unit, Cherokee Indian Hospital, Cherokee, North Carolina 28719
Director, Choctaw Service Unit, Choctaw Indian Hospital, Route 7, Box 50-R, Philadelphia, Mississippi 39350
Program Office Director, California Program Office, Indian Health Service, 2995 Fulton Avenue, Sacramento, California 95821, Attn.: Privacy Act Coordinator

**Appendix 2—Federal Archives and Records Centers**

*District of Columbia, Maryland, Except U.S. Court Records for Maryland*
Washington National Records Center, 4205 Suitland Road, Suitland, Maryland 20233
*GSA Region 1—Maine*
Federal Archives and Records Center, 380 Trapelo Road, Waltham, MA 02154
*GSA Region 2—New York*
Federal Archives and Records Center, Military Ocean Terminal, Bldg. 22, Bayonne, NJ 07002
*GSA Region 3—Pennsylvania*
Federal Records Center, Defense Activities, Bldg. 308, Mechanicsburg, PA 17055
*GSA Region 4—Mississippi and Flordia*
Federal Archives and Records Center, 1557 St. Joseph Avenue, East Point, GA 30344
*GSA Region 5—Wisconsin, Minnesota and U.S. Court Records for Michigan*
Federal Archives and Records Center, 7358 South Pulaski Rd., Chicago, Il 60629
*GSA Region 5—Michigan, Except U.S. Court Records*
Federal Records Center, 3150 Bertwynn Drive, Dayton, OH 45439
*GSA Region 6—Kansas, Iowa and Nebraska*
Federal Archives and Records Center, 2306 East Bannister Rd., Kansas City, MO 64131
*GSA Region 7—Oklahoma, Louisiana and New Mexico*
Federal Archives and Records Center, P.O. Box 6216, Ft. Worth, TX 76115
*GSA Region 8—Colorado, Wyoming, Utah, Montana, North Dakota and South Dakota*
Federal Archives and Records Center, Bldg. 48, Denver Federal Center, P.O. Box 25307, Denver, CO 80225
*GSA Region 9—California, Except Southern California, and Nevada, Except Clark County*
Federal Archives and Records Center, 1000 Commodore Drive, San Bruno, CA 94066
*GSA Region 9—Arizona: Clark County, Nevada, and Southern California (Counties of San Luis Obispo, Kern, San Bernardino, Santa Barbara, Ventura, Los Angeles, Riverside, Orange, Imperial, Inyo, and San Diego)*
Federal Archives and Records Center, 24000 Avila Road, Laguna Niguel, CA 92677
*GSA Region 10—Washington, Oregon, Idaho and Alaska*
Federal Archives and Records Center, 6125 Sand Point Way, Seattle, WA 98115

**09-15-0022**

**SYSTEM NAME:**

Accounts Receivable. HHS/HRSA/OA.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

1. Chief, Debt Management Branch, Division of Fiscal Services, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, Maryland 20857.

2. Director, National Hansen's Disease Center, Carville, Louisiana 70721.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Patients and PHS employees.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Billing to individuals.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 321 of the Public Health Service Act, as amended (42 U.S.C. 248), Hospitals, Medical Examinations, and Medical Care.

**PURPOSE(S):**

To bill and collect funds due the Federal Government. Records may be used by the HHS Audit Agency and HHS claims office for audit purposes.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSE OF SUCH USES:**

Information may be provided to any Government agency which had requested or arranged for treatment or care of an individual by the Bureau of Medical Services.

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

**DISCLOSURE TO CONSUMER REPORTING AGENCIES:**

*Disclosures pursuant to 5 U.S.C. 552a(b)(12):* Disclosures may be made from this system to "consumer reporting agencies" as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) or the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)). The purposes of this disclosure are: (1) to provide an incentive for debtors to repay delinquent Federal Government debts by making these debts part of their credit records, and (2) to enable HRSA to improve the quality of loan and scholarship decisions by taking into account the financial reliability of applicants. Disclosure of records will be limited to the individual's name, Social Security number (SSN), and other information necessary to establish the identity of the individual, the amount, status, and history of the claim, and the agency or program under which the claim arose.

**POLICIES AND PRACTICES FOR STORING RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File Folders.

**RETRIEVABILITY:**

Retrievable by name.

**SAFEGUARDS:**

1. Authorized Users: Billing clerks, cashiers, and HRSA financial management personnel.

2. Physical Safeguards: All documents are protected during lunch hours and nonworking hours in locked file cabinets and locked storage areas.

3. Procedural Safeguards: All users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised office. Access to records is

strictly limited to those staff members trained in accordance with HHS Ch 45–13 and Ch PHS.hf:45–13 of the General Administration Manual.

**RETENTION AND DISPOSAL:**

Number of years held: Until audited. How destroyed: Incinerator.

**SYSTEM MANAGER(S) AND ADDRESS:**

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

Director, National Hansen's Disease Center, Carville, Louisiana 70721.

**NOTIFICATION PROCEDURE:**

Contact the Division of Fiscal Services, HRSA, for records from the former PHS hospitals and clinics. For records pertaining to care at the National Hansen's Disease Center, contact the Chief, Financial Management Branch, National Hansen's Disease Center, Carville, Louisiana 70721. Individuals must provide positive identification, such as driver's license, passport, voter's registration card, union card, or a written certification verifying his or her identify.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Requesters should reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURE:**

Write to appropriate Financial Management Offices as listed in the Notification Procedure and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Form individual medical record.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09–15–0026**

**SYSTEM NAME:**

Medical Fellowships and Educational Loans, HHS/HRSA/OA.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Fiscal Service, Health Resources and Services Administration, Room 16–23 Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857, and Regional Federal Records Center.

Washington National Records Center, 4205 Suitland Road, Washington, D.C. 20409

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Applicants and recipients of fellowships, grants, and loans administered by the Health Resources and Services Administration.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Fellowship, Grants and Loan Applications. Promissory note signed by the individual receiving the loan.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 301 of the Public Health Service Act, as amended (42 U.S.C. 241), Research and Investigations.

**PURPOSE(S):**

To support the HSA's accounting system of obligations and payments.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim is successful is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

**DISCLOSURE TO CONSUMER REPORTING AGENCIES:**

*Disclosures pursuant to 5 U.S.C. 552a(b)(12):* Disclosures may be made from this system to "consumer reporting agencies" as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) or the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)). The purposes of this disclosure are: (1) to provide an incentive for debtors to repay delinquent Federal Government debts by making these debts part of their credit records, and (2) to enable HRSA to improve the quality of loan and scholarship decisions by taking into account the financial reliability of applicants. Disclosure of records will be limited to the individual's name, Social Security number (SSN), and other information necessary to establish the identity of the individual, the amount, status, and history of the claim, and the agency or program under which the claim arose.

**POLICIES AND PRACTICES FOR STORING RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File folders.

**RETRIEVABILITY:**

Retrievable by name.

**SAFEGUARDS:**

1. Authorized Users: Accounting clerks accountants and auditors that are performing the accounting function for this program.

2. Physical Safeguards: Files are kept in locked metal filing cabinets during lunch hours and nonworking hours. Twenty-four-hour, 7-day security guards perform random checks on the physical security of the data. Files are stored in areas where fire and life safety codes are strictly enforced.

3. Procedural Safeguards: All users of personal information in connection with the performance of their jobs protect information from the public view and from unauthorized personnel entering an unsupervised office. Access to records is strictly limited to those staff members trained in accordance with the Privacy Act and the following guidelines.

Implementation Guidelines: DHHS Chapter 45–13 and supplementary Chapter PHS. hf.45–13 of the General Administration Manual.

**RETENTION AND DISPOSAL:**

Number of years held: 2 yrs. 1 yr. Warehouse. Number of years held at Federal Records Center before disposal: 7 yrs How destroyed: in accordance with items 4.b and 4.c of Schedule 3.OSA General Records Schedules.

**SYSTEM MANAGER(S) AND ADDRESS:**

Chief, Accounting and Finance Branch, Division of Fiscal Services, Health Resources and Services Administration, 5600 Fishers Lane, Parklawn Bldg. Rm. 16–22. Rockville. MD 20857.

**NOTIFICAITON PROCEDURES:**

Requests must be made to the System Manager.

Requests in person: A subject individual who appears in person at a

specific location seeking access or disclosure of records relating to him/her shall provided his/her name, current address, and at least one piece of tangible identification such as driver's license, passport, voter registration card, or union card. Identification papers with current photographs are preferred but not required. If a subject individual has no identificaiton but is personally known to an agency employee, such employee shall make a written record verifying the subject individual's identity. Where the subject individual has no identification papers, the responsible agency official shall require that the subject individual certify in writing that he/she is the individual whom he/she claims to be and that he/she understands that the knowing and willful request or acquisition of records concerning an individual under false pretenses is a criminal offense subject to a $5,000 fine. In some situations additional identification may be requested. Some examples include the request for access to (1) records which contain sensitive information, (2) different records for persons with the same name, and (3) records which contain an apparent discrepancy between information contained in the records and that provided by the individual requesting access to the record. No verification of identity shall be required where the record is one which is required to be disclosed under the Freedom of Information Act.

Requests by mail: Request for information and/or access to records received by mail must contain information providing the identity of the writer and a reasonable description of the record desired. Written requests must contain the name and address of the requestor, his/her date of birth and at least one piece of information which is also contained in the subject record, and his/her signature for comparison purposes.

Requests by telephone: Since positive identification of the caller cannot be established, telephone requests are not honored.

**RECORD ACCESS PROCEDURES:**

Write to System Manager. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Write to the System Manager and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Individual applicants for loans supply the information.

**SYSTEM EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-15-0027**

**SYSTEM NAME:**

National Health Service Corps (NHSC) and Indian Health Service (IHS) Pre-Applicant Recruitment and Provider File. HHS/HRSA/BHCDA.

**SECURITY CLASSIFICATION**

None.

**SYSTEM LOCATION:**

National Health Service Corps, Parklawn Building, 5600 Fishers Lane Rockville, MD 20857, Washingtion National Records Center, 4205 Suitland Road, Suitland, MD 20832.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

NHSC volunteer or scholarship applicants who wish to be assigned to health manpower shortage areas and individuals who indicate an interest in an assignment at an Indian Health Service location.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Employment data, private practice data, preference for site-selection, personal and professional background information.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 333 of the Public Health Service Act, as amended (42 U.S.C. 254f), Assignment of Corps Personnel; and Section 338C of the Public Health Service Act, as amended (42 U.S.C. 294v), Private Practice.

**PURPOSE(S)**

Matching applicant for assignment to health manpower shortage areas and Indian Health Service locations most suited to their interest. Users: Used by Regional Offices, IHS Area Offices and Service Units to prenegotiate assignments. Used PHS-wide for recruitment programs.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department or any employee of the Department, in his or her official capacity; (b) the United States where the Department of determines that the claim, if successful, is likely to directly affect the operations of the Department or any of it components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the systems of records may be referred, as a routine use, to the Department of Justice, General Accounting Office, and to any Federal or State agency charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute or rule, regulation or order issued pursuant thereto.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Manual files, computer tape and disk, punched cards.

**RETRIEVABILITY:**

Applicant name and number.

**SAFEGUARDS:**

1. Authorized users: System manager, Director and staff of the Office of Data Management; and the Chief and staff of the Recruitment and Placement Branch, NHSC and IHS.

2. Physical Safeguards: Locked area and file cabinets. ADP remote stations and files are locked during non-standard working hours, with periodic checks made by building security force. Individual files are in locked cabinets inside a secured area.

3. Procedural Safeguards: Codes by which automatic files may be accessed are changed periodically. This procedure also includes deletion of access codes when employees leave. New employees are briefed and the guard office is notified of all staff members authorized to be in secured

area during non-standard working hours. This list is revised as employees are gained or lost. Backup files are maintained in an off-site facility with fire extinguishers and controlled entrances and exists. These safeguards are in compliance with Implementation Guidelines: DHHS Chapter 45–13, and supplementary Chapter PHS.hf:45–13 of the General Administration Manual; and with the DHHS ADP Systems Manual Part 6, "ADP Systems Security".

**RETENTION AND DISPOSAL:**

Maintained for three years; the historical tapes are sent to a Federal records center and the initial record is destroyed.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, National Health Service Corps, BHCDA/HRSA, Parklawn Building, Room 6–40, 5600 Fishers Lane, Rockville, MD 20857.

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the System Manager. The System Manager will then refer the requester to the appropriate Regional Office. Only Regional Offices disperse such records. The Regional Health Administrator will request individuals to provide positive identification, such as a driver's license, passport, voter's registration card, union card, or a written certification verifying his or her identity. Requesters should reasonably specify the record contents being sought.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Write to System Manager.

**CONTESTING RECORD PROCEDURES:**

Contact the official at the address specified under notification procedures above, and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Letters of inquiry, NHSC Site Selection Questionnaire; NHSC Private Practice Option Agreements; and Bureau of Health Professions scholarship source tape.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-15-0028**

**SYSTEM NAME:**

PHS Clinical Affiliation Trainee Records, HHS/HRSA/BHCDA.

**SYSTEM CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

National Hansen's Disease Center, Carville, Louisiana 70721

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Students in PHS training programs or serving clinical affiliation in National Hansen's Disease Center.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Transcripts of past education application for training, training program staff and clinical supervisor evaluations and progress reports, course grades and evidence of completion of training requirements.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 320 of the Public Health Service Act, as amended (42 U.S.C. 255), Receipt, Apprehension, Treatment and Release of Lepers; Section 321 of the Public Health Sevice Act, as amended (42 U.S.C. 248), Hospitals, Medical Examinations, and Medical Care; and Section 327A of the Public Health Service Act, as amended (42 U.S.C. 254), Sharing of Medical Care Facilities and Resources.

**PURPOSE(S):**

To provide communication between educational and supervisory staff for evaluation of trainees.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made:

To Educational Program staff of affiliated college/university to provide reports of student trainee's progress in training:

To representatives of medical/allied health training program accreditation of PHS Training Programs;

To prospective employers for professional reference;

To professional boards or associations to certify the students' progress in or completion of training as required for professional license, registration certification, etc.

To a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclosure such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File Folders.

**RETRIEVABILITY:**

Alphabetically by last name.

**SAFEGUARDS:**

1. Authorized Users: Director of Education at the National Hansen's Disease Center, work and staff supervisors and administrative personnel.

2. Physical Safeguards: All documents are protected during lunch hours and nonworking hours in locked file cabinets and locked storage areas.

3. Procedural Safeguards: All users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised office. Access to records is strictly limited to those staff members trained in accordance with HHS Ch 45–13 and Ch PHS.hf.45–13 of the General Administration Manual.

**RETENTION AND DISPOSAL:**

Number of years held: 10 years, then destroyed by shredding.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, National Hansen's Disease Center, Carville, LA 70721.

**NOTIFICATION PROCEDURE:**

The individual should contact the Director, National Hansen's Disease Center, and provide name, date of birth and approximate dates of training to allow positive identification of the record.

**RECORD ACCESS PROCEDURE:**

Same as notification procedures. Requesters should also reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the facility mentioned at the address specified in the notification procedures above, and reasonably identify the record, specify the

information to be contested, and state corrective action sought, with supporting justification

**RECORD SOURCE CATEGORIES:**

Individual, clinical supervisors, instructors, training program staff and administrative personnel of facility and affiliated college/university.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-15-0029**

**SYSTEM NAME:**

PHS Beneficiary-Contract Medical/Health Care Records. HHS/HRSA/BHCDA.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

1. Director, Division of Beneficiary Medical Programs, Bureau of Health Care Delivery and Assistance, Health Resources and Services Administration, Room 7-36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857
2. U.S. Public Health Service Health Data Center, 10000 Aerospace Road, Lanham, MD 20706
3. See Appendix for hospital and clinic locations.
4. See Appendix 2 of Patient Medical Records System PHS Hospital/Clinics, 09-15-0007, for location of Federal Records Centers.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals who are or were legally entitled to health care by the Public Health Service and who have received health care from health professionals or facilities under contract or agreement to the Public Health Service.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

May include any or all of the following: medical history, diagnostic (laboratory/X-ray, etc.) and treatment data, sociologic information, eligibility data including employment history, master's certificate, uniformed services information (employing services, service numbers, duty station etc.).

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 320 of the Public Health Service act, as amended (42 U.S.C. 255), Receipt, Apprehension, Treatment and Release of Lepers; Section 321 of the Public Health Service Act, as amended (42 U.S.C. 248), Hospitals Medical Examinations, and Medical Care; and Section 326 of the Public Health Act, as amended (42 U.S.C. 253), Services to Coast Guard, Coast and Geodetic Survey, and Public Health Service.

**PURPOSE(S):**

To serve as a basis for planning patient care and for continuity in the evaluation of the patient's condition and treatment; to furnish documentary evidence of the course of the patient's medical evaluation and treatment to document communications between the responsible practitioner and any other health professionals contributing to the patient's care and treatment; to verify patient eligibility; and to ensure quality assurance, and to monitor contract compliance.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made:

To medical laboratories and facilities, and non agency physicians. Recipients are required to maintain adequate safeguards with respect to such records.

To Department of Transportation and Department of Commerce to report results of examination and/or treatment of that agency's personnel;

To the Veterans Administration to assist uniformed services personnel, retirees and veterans to obtain medical care or benefits;

To a Federal agency, in response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the record is relevant and necessary to the requesting agency's decision on the matter.

To a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual:

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records are collected.

Information regarding the commission of crimes or the reporting of occurrences of communicable diseases, tumors, child abuse, births, deaths, alcohol or drug abuse, etc., may be disclosed as required by health providers and facilities by State Law or regulation of the department of health, or other agency of the state or its subdivision in which the facility is located. Disclosures will be made to organizations as specified by the State law or regulation, such as births and deaths to the vital statistics agency and crimes to law enforcement agencies. Disclosure of the contents of records which pertain to patient identify, diagnosis, prognosis or treatment of alcohol or drug abuse is restricted under the provisions of the Confidentiality of Alcohol and Drug Abuse Patient Records Regulation 42 CFR Part 2, as authorized by 21 U.S.C. 1175 and 42 U.S.C. 4582, as amended by Pub. L. 93-282.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File folders.

**RETRIEVABILITY:**

Name, uniformed service number which is the Social Security number, and/or Z number. Those records indexed by SSN are maintained and retrieved in accordance with sec. 7(a)(2)(B) of the Privacy Act.

**SAFEGUARDS:**

1. Authorized Users: supervisory contracting officials who review the contractor's records annually, doctors, dentists, nurses, allied health professionals and administrative staff in the contractor's office or System Manager's Staff.
2. Physical Safeguards: All documents are protected during lunch hours and nonworking hours in locked file cabinets and locked storage areas.
3. Procedural Safeguards: All users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised office. Access to records is strictly limited those staff members trained in accordance with HHS Ch 45-13; and Ch PHS.hf: 45-13 of the General Administration Manual.

**RETENTION AND DISPOSAL:**

Retained in the contracting professional's facility files until the contract is terminated. Then turned over to the Division of Beneficiary Medical Programs for transmittal to a new

contracting professional or storage at a Federal Records Center. When stored in a Federal Records Center, records are stored for 50 years, active duty uniformed service personnel, 25 years all others. Destruction at that time is in accordance with standard practices of the Federal Records Center.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, Division of Beneficiary Medical Programs, Bureau of Health Care Delivery and Assistance, Room 7-36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857; and Director, National Hansen's Disease Center, Carville, LA 70721.

**NOTIFICATION PROCEDURE:**

Inquiries should be addressed to the facility where care has been obtained. (See listing in Appendix). Individual must provide name, beneficiary category, date of birth, service number/Z number (if applicable) and name and location of source of contract care. Identification such as driver's license, passport, voter's registration card, union card, or a written certification verifying the individual's identity is required. An individual who requests access to a medical record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion. Requesters should also reasonably specify the record content being sought.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures.

**CONTESTING RECORDS PROCEDURES:**

Contact the official at the apporpriate address specified in the notification procedures above, and reasonably identify the record, specify the information to be contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Individual, employers, other medical care providers, families and social agencies.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**Appendix**

Director Division of Beneficiary Medical Programs, BHCDA, Room 7-36, 5600 Fishers Lane, Rockville, MD 20857
President, Wyman Park Health System, 3100 Wyman Park Drive, Baltimore, MD 21211
President, Brighton Marine Public Health Center, 77 Warren Street, Boston, MA 02135
Administrator, Hospital of St. John, 2050 Space Park Drive, Nassau Bay, TX 77058
President, Seattle Public Health Hospital, 1131 14th Avenue South, Seattle, WA 98144
President, Bayley Seton Hospital, Bay St. and Vanderbilt Ave., Staten Island, NY 10304
Administrator, Coastal Health Services, 331 Veranda Street, Portland, ME 04103
Administrator, Lutheran Medical Center, Downtown Health Care Services, New Post Office Bldg., West 3rd Street and Prospect Avenue, Cleveland, OH 44113
Administrator, St. Mary's Hospital, 404 8th Street, N Galveston, TX 77550
Director, St Joseph Ambulatory Care Center, 1919 La Branch, Houston, TX 77002
Director, St. Mary's Hospital Family Practice Center of Port Arthur, 3600 gates Boulevard, Port Arthur, TX 77040

**09-15-0036**

**SYSTEM NAME:**

Health Professions Preparatory Scholarship Program for Indians and Health Professions Scholarship Program Record System, HHS/HRSA/IHS.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Human Resources Management Branch, Indian Health Service, 5600 Fishers Lane, Room 6A-23, Rockville, Maryland 20857 and
Washington National Records Center, 4205 Suitland Road, Suitland, Maryland 20832

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Persons who have applied for and have been approved to receive, persons who are receiving, and persons who have received scholarship grant funds since January 1978 from the Health Professions Preparatory Scholarship Program for Indians and/or Health Professions Preparatory Scholarship Program for Indians and/or Health Professions Scholarship Program. Applicants for financial support awarded under the Health Professions Preparatory Scholarship Program for Indians must be American Indians or Alaskan Natives. Even though there is no racial requirement for the Health Professions Scholarship Program, priority selection is accorded to American Indian and Alaskan Native applicants, as stated in the legislation establishing this program.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Records inlcude grant applications of selected applicants only, and selection and performance records. In addition to the application forms for each of the two scholarship programs, these records also contain high school and college grade transcripts, evidence of acceptance in a school covered by the program, two faculty letters of recommendation or faculty evaluation forms, documentation of Indian eligibility (BIA Certification or State-Recognized Tribes Certification) for scholarship grant applicants who are claiming priority selection as American Indians or Alaskan Natives, verification from a school official that the course is required to meet an educational deficiency and that the program represents a full course load (for health Professions Preparatory Scholarship Program), signed contract (for Health Professions Scholarship Program), and a brief written explanation of the applicants' reasons for requesting the scholarship. Progress reports and vouchers of expenditures are included with the records after the scholarships have been awarded.

Information requested on a scholarship grant application form includes: Full name of applicant, mailing address, telephone number, place of birth, citizenship, school in which enrolled or accepted for enrollment as a full-time student, dates of attendance, expected date of graduation, length of program in years, tuition and fees charged, future specialty, present and previous residences (city, county, state), work experience, and career goals. In addition, the Social Security Number (SSN) is requested on the scholarship grant application (optional on the application but required prior to the award of a grant). IHS scholarship grant recipients have an active duty service obligation (25 U.S.C. 1613) and are entitled to employment in IHS during any nonacademic period of the year (25 U.S.C. 1614). In anticipation of these obligations and entitlements, the SSN is obtained from IHS scholarship grant recipients at the time of grant award for identification of "permanent" accounts for these individuals.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 103 of the Indian Health Care Improvement Act, 25 U.S.C. 1613, Health Professions Preparatory Scholarship Program for Indians.

Section 104 of the Indian Health Care Improvement Act, 42 U.S.C. 294y-1, Indian Health Scholarship Program.

Executive Order 9397, dated November 22, 1943, authorizing Federal agencies to collect SSNs from Federal employees for identification of "permanent" accounts.

**PURPOSE OF THE SYSTEM:**

The purpose of this system of records is to select candidates for the Indian Health Service scholarship program, to

monitor the scholarship-related activities of candidates selected, and to evaluate the effectiveness of the program. Scholarship-related activities are defined as enrollment and attendance in IHS-funded courses, the receipt by the student of a monthly stipend and the expenditure of funds by the student for the purchase of supplies (including books), equipment, tuition, fees and other reimbursable and justified expenses authorized by IHS.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Records may be disclosed to a congressional office in response to an injury from that office made at the request of the subject individual.

2. Records may be disclosed to authorized persons employed by the grantee institution (the institution which the recipient of a scholarship grant is attending) as needed for the administration of a scholarship grant award.

3. Records may be disclosed to other Federal agencies that also provide scholarship funding at the request of these Federal agencies in conjunction with a matching program conducted by these Federal agencies to detect or curtail fraud and abuse in Federal scholarship programs, and to collect delinquent loans or benefit payments owed to the Federal Government.

4. Name, tribal affiliation if applicable, and school of scholarship recipients will be published in the **Federal Register** as required by the terms of the legislation establishing the IHS scholarship grant program.

**DISCLOSURE TO CONSUMER REPORTING AGENCIES:**

Disclosures pursuant to 5 U.S.C. 552a(b)(12): Disclosures may be made from this system to "consumer reporting agencies" as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) or the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)). The purposes of this disclosure are: (1) to provide an incentive for debtors to repay delinquent Federal Government debts by making these debts part of their credit records, and (2) to enable HRSA to improve the quality of loan and scholarship decisions by taking into account the financial reliability of applicants. Disclosure of records will be limited to the individual's name, Social Security number (SSN), and other information necessary to establish the identity of the individual, the amount, status, and history of the claim, and the agency or program under which the claim arose.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Records are maintained in folders, ledgers, and on electronic word processing diskettes.

**RETRIEVABILITY:**

Records which identify individual persons are indexed by name or identification number of scholarship grant applicant or recipient.

**SAFEGUARDS:**

1. Paper records are stored in locked file cabinets. The records storage area is secured during off-duty hours. This area is not left unattended during office hours. including lunch hours. Records are not removed from the area in which they are maintained in the absence of proper charge-out procedures.

2. All IHS personnel who make use of records contained in this system are made aware of their responsibilities under the provisions of the Privacy Act and are required to maintain Privacy Act safeguards with respect to such records.

3. When copying records for authorized purposes, care is taken to ensure that any imperfect pages are not left in the reproduction room where they can be read, but are destroyed or obliterated.

4. Access is limited only to authorized personnel in the performance of their duties. Authorized personnel includes the system manager, his/her staff and staff of the Grants Management Office, IHS.

5. Word processing diskettes are stored in areas where fire and life safety codes are strictly enforced. Twenty-four hour, seven-day security guards perform random checks on the physical security of the data. Word processing diskettes are off-loaded and stored in locked cabinets when not in use. A data set name controls the release of data to only authorized users.

Implementation Guidelines: DHHS Chapter 45–13 and supplementary Chapter PHS. hf:45–13 of the General Administration Manual; and with the DHHS ADP Systems Manual Part 6, "ADP Systems Security and PHS Grants Administration Manual chapter PHS.i.1–602, "Information on Individuals Obtained in Grant Applications."

**RETENTION AND DISPOSAL:**

Records in this system are retained by the Indian Health Service for one year after the final award payment has been made by IHS and are then retired to a Federal Records Center. Records are shredded or burned by the Federal Records Center four years after they are received.

**SYSTEM MANAGER AND ADDRESS:**

Chief, Human Resources Development Branch, Indian Health Service, 5600 Fishers Lane, Room 6A–23, Rockville, Maryland 20857.

**NOTIFICATION PROCEDURE:**

Requests by mail or in person: To substantiate the identity of subject individual seeking access to his/her scholarship grant application and/or performance record the requester must provide his/her name, signature, and Grant Identification Number; and to identify the record sought must provide dates of attendance, school(s) of attendance, and field or speciality or courses taken.

In addition, the requester is informed that provision of the SSN may assist in the verification of the identity of the person as well as the identification of his/her record. The requester is informed that provisions of his/her SSN is voluntary and that the individual will not be refused access to his/her record for failure to disclose his/her SSN.

**RECORD ACCESS PROCEDURES:**

Same as notification procedures. Requesters should also provide a reasonable description of the record being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the system manager, provide a reasonable description of the record, specify the infromation you want to contest, and state the corrective action sought with supporting justification.

**RECORD SOURCE CATEGORIES:**

Individuals whose records are contained in the system, third parties who provide reference concerning the subject individuals, and schools that individuals in the system attend or have attended.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09–15–0037**

**SYSTEM NAME:**

Public Health Service Scholarship and National Health Service Corps Scholarship Program HHS/HRSA/BHCDA.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Health Services Scholarships, Bureau of Health Care

Delivery and Assistance, 5600 Fishers Lane, Rockville, MD 20857.

Division of Computer Research and Technology, NIH Building 12, 9000 Rockville Pike, Bethesda, Maryland 20205.

Washington National Records Center, 4205 Suitland Road, Suitland, MD 20832.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Applicants for and recipients of Public Health Service and National Health Service Corps Scholarships.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Application and associated forms; recipient records contain progress reports, payroll forms, deferment and placement data, and social security numbers.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 338 of the Public Health Service Act, as amended (42 U.S.C. 294t), National Health Service Corps Scholardship Program.

**PURPOSE(S):**

To select and monitor scholarship recipients. After the award is made, the Health Services Administration and the Department's Central Payroll use the records for the following purposes: payment tracking; deferment of service obligation; default, placement, and claims determination.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

1. Names, disciplines, current mailing addresses, and dates of graduation of scholarship recipients are made available to designated coordinators at each school of medicine, osteopathy, and dentistry participating in the Scholarship Program for the purpose of guiding and informing these recipients about the nature of their forthcoming professional service obligation in health manpower shortage areas.

2. Name of scholarship recipient, professional school he or she is attending and the date of graduation are made available to health professions associations and other interested health professions groups which have responsibility for coordinating funds paid to students from Federal and other sources.

3. A record may be disclosed for a research purpose, when the Department:

(A) Has determined that the use of disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained;

(B) Has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring;

(C) Has required the recipients to—(1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use of disclosure of the record, (2) remove or destory the information that identifies the individual at the earlist time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except:

(a) In emergency circumstances affecting the health or safety of any individual, (b) for use in another research project under these same conditions and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of conducting an audit related to the research project if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law;

(D) Has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

4. Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

5. In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclosure such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

6. In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to any Federal or State agency charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute or rule, regulation or order issued pursuant thereto. Authorized recipients include, but are not limited to, the Department of Justice, Department of Education, Department of the Treasury, Department of the Army, Department of the Navy, Department of the Air Force, Department of Agriculture, General Accounting Office, and the Veterans Administration.

**DISCLOSURE TO CONSUMER REPORTING AGENCIES:**

*Disclosures pursuant to 5 U.S.C. 522a(b)(12):* Disclosures may be made from this system to "consumer reporting agencies" as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) or the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)). The purposes of this disclosure are: (1) to provide an incentive for debtors to repay delinquent Federal Government debts by making these debts part of their credit records, and (2) to enable HRSA to improve the quality of loan and scholarship decisions by taking into account the financial reliability of applicants. Disclosure of records will be limited to the individual's name, Social Security number (SSN), and other information necessary to establish the identity of the individual, the amount, status, and history of the claim, and the agency or program under which the claim arose.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File folders and magnetic tape.

**RETRIEVABILITY:**

Name, award number, university, or Social Security Number.

**SAFEGUARDS:**

1. Authorized Users:

Administrative and staff personnel of the Division of Health Services Scholarships, Office of Financing Services, and the National Health Service Corps, Bureau of Health Care Delivery and Assistance, who have responsibility for implementing the NHSC Scholarship Program.

2. Physical Safeguards:

Magnetic tapes, discs, other computer equipment, and other forms of personal data are stored in areas where fire and life safety codes are strictly enforced. Twenty-four hour, 7-day security guards perform random checks on the physical security of the data. All nonautomated documents are protected during lunch hours and nonworking hours is locked file cabinets or locked storage areas.

3. Procedural Safeguards:

A password is required to access the terminal and a data set name controls the release of data to only authorized users. All users of personal information in connection with the performance of their jobs (see Authorized Users, above) protect information from public view and from unauthorized personnel entering an unsupervised office.

The foregoing safeguards are in accordance with DHHS Chapter 45–13 and supplementary Chapter PHS. hf:45–13 "Safeguarding Records Contained in Systems of Records," of the General Administration Manual; and with the DHHS ADP Systems Manual Part 6, "ADP System Security".

**RETENTION AND DISPOSAL:**

Applications of individuals not selected for participation in the Scholarship program are retained for 6 months, then destroyed by shredding. Applications, contracts, and other records of selectees to the Program are retained through the completion or other disposition of the Scholarship service obligation, then sent to the Federal Records Center for an additional 7-year retention period and destroyed in accordance with Federal Records Center disposal standards.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, Division of Health Services Scholarships, BHCDA, 5600 Fishers Lane, Rockville, MD 20857.

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the System Manager and provide reasonably specific information on the record contents being sought.

**RECORD ACCESS PROCEDURES:**

Same as Notification Procedures.

**CONTESTING RECORD PROCEDURES:**

Contact the System Manager Giving a reasonable description of the record, specify the information you want to contest, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Dean or Registar of the educational institution attended; internship and/or residency training site supervisor; personnel records of the PHS Commissioned Personnel Operations Division, Office of Personnel Management/OASH.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-15-0038**

**SYSTEM NAME:**

Disability Claims of the Nursing Student Loan Program HHS/HRSA/BHPr.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Student Assistance, Bureau of Health Professions, Health Resources and Services Administration, Room 8–23, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Washington National Records Center, 4205 Suitland Road, Suitland, MD 20832.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Applicants for cancellation of nursing student loans due to disability.

**CATEGORIES OR RECORDS IN THE SYSTEM:**

Letter requests claiming disability, correspondence, payment determinations and medical records or reports.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 836 of the Public Health Service Act, as amended (42 U.S.C. 297b), Nursing Student Loan Provisions.

**PURPOSE(S):**

To determine the eligibility of applicants who request loan cancellation due to total and permanent disability.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of the individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the General Accounting Office, Office of Management and Budget, Department of Justice, and other appropriate Federal and States agencies charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute or rule, regulation or order issued pursuant thereto.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File folders.

**RETRIEVABILITY:**

Name of individual.

**SAFEGUARDS:**

1. Authorized Users: Access by administrative personnel for determination of eligibility.

2. Physical Safeguards: File folders, medical records, reports and other forms of personal data are stored in areas where fire and life safety codes are strictly enforced. All documents are protected during lunch hours and nonworking hours in locked file cabinets or locked storage areas.

3. Procedural Safeguards: All users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised office.

Access to records is strictly limited to those staff members trained in accordance with the Privacy Act. Implementation Guidelines: DHHS Chapter 45–13 and supplementary Chapter PHS, Hf: 45–13 of the General Administration Manual; and with the DHHS ADP Systems Manual Part 6, "ADP Systems Security".

**RETENTION AND DISPOSAL:**

Records will be retained for 5 years after retirement of loans; 1 year on site and 4 years at the Federal Records Center. Records are disposed of in accordance with the Records Control Schedule of the Health Resources and Services Administration. Contact the System Manager for the disposal standards.

**SYSTEM MANAGER(S) AND ADDRESS:**

Chief, Student and Institutional Assistance Branch/Division of Student Assistance, BHPr/HRSA, Parklawn Building, Room 8–44, 5600 Fishers Lane, Rockville, MD 20857.

**NOTIFICATION PROCEDURE:**

Request must be made to the System Manager. An individual who requests notification of, or access to, a medical record shall at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

Requests in person: A subject individual who appears in person at a specific location seeking access or disclosure of records relating to him/her shall provide his/her name, current address, and at least one piece of tangible identification such as driver's license, passport, voter registration card, or union card. Identification papers with current photographs are preferred but not required. Additional identification may be requested when there is a request for access to records which contain an apparent discrepancy between information contained in the record and that provided by the individual requesting access to the record. No verification of identity shall be required where the record is one which is required to be disclosed under the Freedom of Information Act.

Requests by mail: Requests for information and/or access to records received by mail must contain information providing the identity of the writer and a reasonable description of the record desired. Written requests must contain the name and address of the requester, his/her date of birth and at least one piece of information which is also contained in the subject record, and his/her signature for comparison purposes.

Requests by telephone: Since positive identification of the caller cannot be established, telephone requests are not honored.

**RECORD ACCESS PROCEDURES:**

Contact the Systems Manager and give a reasonable description of the record. An individual who requests access of a medical record shall at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

**CONTESTING RECORDS PROCEDURES:**

Contact the System Manager and reasonaby identify the record, specify the information being contested, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Individual claimants.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THAT ACT:**

None.

**09–15–0039**

**SYSTEM NAME:**

Disability Claims in the Health Professions Student Loan Program. HHS/HRSA/BHPr.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Student Assistance, Bureau of Health Professions, Health Resources and Services Administration, Room 8–23, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Washington National Records Center, 4205 Suitland Road, Suitland, MD. 20832.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Applicants for cancellation of health professions student loans due to disability. These health professions are included: Medicine, dentistry, esteopathy, optometry, pharmacy, podiatry, veterinary medicine.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Letter requests claiming disability, correspondence, payment determinations and medical records or reports.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 741(d) of the Public Health Service Act, as amended (42 U.S.C. 294n), Student Loan Professions.

**PURPOSE(S):**

To determine the eligibility of applicants who request loan cancellation due to total and permanent disability.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclosure such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosrue is compatible with the purpose for which the records were collected.

In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the General Accounting Office, Office of Management and Budget, Department of Justice, and other appropriate Federal and State agencies charged with the responsibility of investigating or prosecuting such violation or charge with enforcing or implementing the statute or rule, regulation or order issued pursuant thereto.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File folders. Medical records and reports are temporarily held during medical evaluation and then returned to and retained by health professions schools upon final determination of claim validity.

**RETRIEVABILITY:**

Name of individual.

**SAFEGUARDS:**

1. Authorized Users: Access by administrative personnel for determination of eligibility.

2. Physical Safeguards: File folders, medical records, reports and other forms of personal data are stored in areas where fire and life safety codes are strictly enforced. All documents are protected during lunch hours and nonworking hours in locked file cabinets or locked storage areas.

3. Procedural Safeguards: All users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised office.

Access to records is strictly limited to those staff members trained in accordance with the Privacy Act. Implementation Guidelines: DHHS Chapter 45–13 and supplementary Chapter PHS hf: 45–13 of the General Administration Manual; and with the DHHS ADP Systems Manual Part 6, "ADP Systems Security".

**RETENTION AND DISPOSAL:**

Records will be retained for 5 years after retirement of loans; 1 year on site and 4 years at the Federal Records Center. Records are disposed of in accordance with the Records Control Schedule of the Health Resources and Services Administration. Contact the Systems Manager for the disposal standard.

**SYSTEM MANAGER(S) AND ADDRESS:**

Chief, Student, and Institutional Assistance Branch/Division of Student Assistance, BHPr/HRSA, Room 8–44, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

**NOTIFICATION PROCEDURE:**

Requests must be made to the System Manager. An individual who requests notification of, or access to, a medical record shall at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

Requests in person: A subject individual who appears in person at a specific location seeking access or disclosure of records relating to him/her shall provide his/her name, current address, and at least one piece of tangible identification such as driver's license, passport, voter registration card, or union card. Identification papers with current photographs are preferred but not required. Additional identification may be requested when there is a request for access to records which contain an apparent discrepancy between information contained in the record and that provided by the individual requesting access to the record. No verification of identity shall be required where the record is one which is required to be disclosed under the Freedom of Information Act.

Request by mail: Requests for information and/or access to records received by mail must contain information providing the identity of the writer and a reasonable description of the record desired. Written requests must contain the name and address of the requester, his/her date of birth and at least one piece of information which is also contained in the subject record, and his/her signature for comparison purposes.

Requests by telephone: Since positive identification of the caller cannot be established, telephone requests are not honored.

**RECORD ACCESS PROCEDURE:**

Contact the System Manager and give a reasonable description of the record. An individual who requests access of a medical/dental record shall at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individuals of its contents at the representative's discretion.

**CONTESTING RECORD PROCEDURES:**

Contact the System Manager giving a reasonable description of the record, specify the information you want to contest, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Individuals claimants.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09–15–0040**

**SYSTEM NAME:**

Health Professions Student Loan Repayment Program. HHS/HRSA/BHPr.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Student Assistance, Bureau of Health Professions, Health Resources and Services Administration, Room 8–23 Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Division of Computer Research and Technology, NIH Building 12, 9000 Rockville Pike, Bethesda, MD 20205.

Washington National Records Center, 4205 Suitland Road, Suitland, MD 20832.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Applicants for repayment of health professions student loans—medicine, dentist, osieopathy optometry., pharmacy, podiatry, veterinary medicine.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Application and associated forms, correspondence.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 741(f) of the Public Health Service Act, as amended (42 U.S.C. 294n), Student Loan Provisions.

**PURPOSE(S):**

Data is utilized by Loan Repayment Program Staff to identify the borrowers participating in the program, to determine eligibility of loan applicants to determine current status of loan repayment agreements, to calculate amounts received under agreements, and to compile and generate managerial and statistical reports.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendent is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or a regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the General Accounting Office, Office of Management and Budget, Department of Justice, and other appropriate Federal and State agencies charged with the responsibility of investigating or prosecuting such

violation or charged with enforcing or implementing the statute or rule, regulation or order issued pursuant thereto.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File folders and magnetic tapes.

**RETRIVABILITY:**

Name of individual.

**SAFEGUARDS:**

1. Authorized Users: Access by administrative personnel for determination of eligibility.

2. Physical safeguards: File folders, magnetic tapes, computer equipment and other forms of personal data are stored in areas where fire and life safety codes are strictly enforced. All documents are protected during lunch hours and nonworking hours in locked files cabinets or locked storage areas.

3. Procedural Safeguards: A password is required to access the terminal and a data set name controls the release of data to only authorized users. All users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering and unsupervised office.

Access to records is strictly limited to those staff members trained in accordance with the Privacy Act. Implementation Guidelines: DHHS Chapter 45–13 and supplementary Chapter PHS. hf: 45–13 of the General Administration Manual; and with the DHHS ADP Systems Manual Part 6, "ADP Systems Security".

**RETENTION AND DISPOSAL:**

Records will be retained for 5 years alter completion of the service obligation or repayment of the loan; 1 year on site and 4 years at the National Records Center. Records on magnetic tape are retained for 5 years and then they are destroyed. Records are disposed of in accordance with the Records Control Schedule of the Health Resources and Services Administration Contact the System Manager for the disposal standard.

**SYSTEM MANAGER(S) AND ADDRESS:**

Chief, Student and Institutional Assistance Branch/Division of Student Assistance, BHPr/HRSA, Room 8–44, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

**NOTIFICATION PROCEDURE:**

Requests must be made to the System Manager.

Requests in person: A subject individual who appears in person at a specific location seeking access or disclosure of records relating to him/her shall provide his/her name, current address, and at least one piece of tangible identification such as driver's license, passport, voter registration card, or union card. Identification papers with current photographs are preferred but not required. Additional identification may be requested when there is a request for access to records which contain an apparent discrepancy between information contained in the record and that provided by the individual requesting access to the record. No verification of identity shall be required where the record is one which is required to be disclosed under the Freedom of Information Act.

Requests by mail: Requests for information and/or access to records received by mail must contain information providing the identity of the writer and a reasonable description of the record desired. Written requests must contain the name and address of the requester, his/her date of birth and at least one piece of information which is also contained in the subject record, and his/her signature for comparison purposes.

Requests by telephone: Since positive identification of the caller cannot be established, telephone requests are not honored.

**RECORD ACCESS PROCEDURE:**

Contact the System Manager and give a reasonable description of the record.

**CONTESTING RECORD PROCEDURES:**

Contact the System Manager giving a reasonable description of the record, specify the information you want to contest, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Applicant, applicant's health professions school and lending institutions.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09–15–0041**

**SYSTEM NAME:**

Health Professions Student Loan Cancellation. HHS/HRSA/BHPr.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Student Assistance, Bureau of Health Professions, Health Resources and Services Administration, Room 8–23, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Applicants for health professions student loan cancellation.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Application and associated forms, correspondence.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 741(f) of the Public Health Service Act, as amended (42 U.S.C. 294n), Student Loan Provisions.

**PURPOSE(S):**

To identify students participating in the cancellation program. To compile and generate managerial and statistical reports for program evaluation.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of ligitation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system or records may be referred, as a routine use, to the General Accounting Office, Office of Management and Budget, Department of Justice, and other appropriate Federal and State agencies charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or

implementing the statue or rule, regulation or order issued pursuant thereto.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File folders.

**RETRIEVABILITY:**

Name of individual.

**SAFEGUARDS:**

1. Authorized Users: Access by administrative personnel for determination of eligibility.

2. Physical Safeguards: File folders are stored in areas where fire and life safety codes are strictly enforced. All documents are protected during lunch hours and nonworking hours in locked file cabinets or locked storage areas.

3. Procedural Safeguards: All users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised office.

Access to records is strictly limited to those staff members trained in accordance with the Privacy Act. Implementation Guidelines: DHHS Chapter 45–13 and supplementary Chapter PHS. hf: 45–13 of the General Administration Manual; and with the DHHS ADP Systems Manual Part 6, "ADP Systems Security".

**RETENTION AND DISPOSAL:**

Records will be retained for 5 years after retirement of the completion of the request of cancellation of the loan. Records are disposed of in accordance with the Records Control Schedule of the Health Resources and Services Administration. Contact the System Manager for the disposal standard.

**SYSTEM MANAGER(S) AND ADDRESS:**

Chief, Student, and Institutional Assistance Branch/Division of Student Assistance, BHPr/HRSA, Room 8–44, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

**NOTIFICATION PROCEDURE:**

Requests must be made to the Systems Manager.

Requests in person: A subject individual who appears in person at a specific location seeking access or disclosure of records relating to him/her shall provide his/her name, current address, and at least one piece of tangible identification such as a driver's license, passport, voter registration card, or union card. Identification papers with current photographs are preferred but not required. Additional identification may be requested when there is a request for access to records which contain an apparent discrepancy between information contained in the record and that provided by the individual requesting access to the record. No verification of identity shall be required where the record is one which is required to be disclosed under the Freedom of Information Act.

Requests by mail: Requests for information and/or access to records received by mail must contain information providing the identity of the writer and a reasonable description of the record desired. Written requests must contain the name and address of the requester, his/her date of birth and at least one piece of information which is also contained in the subject record, and his/her signature for comparis purposes.

Requests by telephone: Since positive identification of the caller cannot be established, telephone requests are not honored.

**RECORD ACCESS PROCEDURE:**

Contact the System Manager and give a reasonable description of the record.

**CONTESTING RECORD PROCEDURE:**

Contact the System Manager giving a reasonable description of the record, specify the information you want to contest, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Applicant, school and State Health Authority.

**SYSTEM EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09–15–0042**

**SYSTEM NAME:**

Physician Shortage Area Scholarship Program, HHS/HRSA/BHCDA.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Health Services Scholarships, Bureau of Health Care Delivery and Assistance, 5600 Fishers Lane, Rockville, MD 20857.

Division of Computer Research and Technology, NIH Building 12, 9000 Rockville Pike, Bethesda, MD 20205.

Washington National Records Center, 4205 Suitland Road, Suitland, MD 20832.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Applicants for and recipients of Physician Shortage Area grants in the field of medicine and osteopathy.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Grant applications, awards, and correspondence.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 409(b) of the Health Professions Educational Assistance Act of 1976, (42 U.S.C. 259g).

**PURPOSE(S):**

To select award recipients, to monitor their payments, and continued eligibility and their placement in health manpower shortage areas in fulfillment of their service obligations.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim if successful, is likely to directly affect the operations of the Department, or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the Department of Justice, Department of Education, Department of the Treasury, Department of the Army, Department of the Navy, Department of the Air Force, Department of Agriculture, General Accounting Office, Veterans Administration, and to any Federal or State agency charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute or rule, regulation or order issued pursuant thereto.

**DISCLOSURE TO CONSUMER REPORTING AGENCIES:**

*Disclosures pursuant to 5 U.S.C. 552a(b)(12):* Disclosures may be made from this system to "consumer reporting agencies" as defined in the Fair Credit Reporting Act (15 U.S.C. 1581a(f)) or the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)). The purposes of this disclosure are: (1) to provide an incentive for debtors to repay delinquent Federal Government debts by making these debts part of their credit records, and (2) to enable HRSA to improve the quality of loan and scholarship decisions by taking into account the financial reliability of applicants. Disclosure of records will be limited to the individual's name, Social Security number (SSN), and other information necessary to establish the identity of the individual, the amount, status, and history of the claim, and the agency or program under which the claim arose.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File folders and magnetic tape.

**RETRIEVABILITY:**

Name or program ID number.

**SAFEGUARDS:**

1. Authorized Users:

Administrative and staff personnel of the Division of Health Services Scholarships and other components of the Bureau of Health Care Delivery and Assistance who have responsibility for implementing the NHSC Scholarship Program.

2. Physical Safeguards:

Magnetic tapes, disks, other computer equipment, and other forms of personal data are stored in areas where fire and life safety codes are strictly enforced. Twenty-four hour, 7-day security guards perform random checks on the physical security of the data. All documents are protected during lunch hours and nonworking hours in locked file cabinets or locked storage areas.

3. Procedural Safeguards:

A password is required to access the terminal and a data set name controls the release of data to only authorized users. All users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised office. Access to records is strictly limited to those staff members trained in accordance with the Privacy Act.

Implementation Guidelines: DHHS Chapter 45-13 and supplementary Chapter PHS. hf:45-13 of the General Administration Manual; and with the DHHS ADP Systems Manual Part 6, "ADP Systems Security".

**RETENTION AND DISPOSAL:**

Applications, contracts and other records of selectees to the program are retained through the completion or other dispositin of the scholarship service obligation. The records are then sent to the Federal Records Center for a seven year retention period and then disposed of in accordance with the Health Resources and Services Administration Records Control Schedule.

**SYSTEM MANAGER(S) AND ADDRESS:**

Director, Division of Health Services Scholarships, BHCDA, 5600 Fishers Lane, Rockville, MD 20857.

**NOTIFICATION PROCEDURE:**

To determine if a record exists, write to the Systems Manager. Individual must provide positive identification, such as driver's license, passport, voter's registration card, union card, or a written certification verifying his or her identity. Requestors should also reasonably specify the record contents being sought.

**RECORD ACCESS PROCEDURE:**

Same as Notification Procedures.

**CONTESTING RECORD PROCEDURES:**

Contact the System Manager giving a reasonable description of the record, specify the information you want to contest, and state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Applicant and applicant's health professions school.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-15-0043**

**SYSTEM NAME:**

Cuban Loan Program HHS/HRSA/OA.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Debt Management Branch, Division of Fiscal Services, OA/HRSA, Room 16A-08, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Washington National Records Center. 4205 Suitland Road, Suitland, MD 20832.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Applicants and recipients of Cuban Loan for medical students.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Applications, and associated forms, correspondence.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Migration and Refugee Assistance Act of 1962 (8 U.S.C. 1255).

**PURPOSE(S):**

The purposes of this record system are to:

(a) Maintain, by borrower, all information relative to the application for and/or awarding of a medical school loan to an individual who qualifies under the Migration and Refugee Assistance Act;

(b) Provide proof of the notice of award, amount of original indebtedness and repayment schedule; and

(c) Support all repayment claims and/or necessary collection actions until the loan obligation is satisfied.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the Department of Justice or other Federal and State agencies, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute or rule,

regulation or order issued pursuant thereto.

**DISCLOSURE TO CONSUMER REPORTING AGENCIES:**

Disclosures pursuant to 5 U.S.C. 552a(b)(12): Disclosures may be made from this system to "consumer reporting agencies" as defined the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) or the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)). The purposes of this disclosure are: (1) to provide an incentive for debtors to repay delinquent Federal Government debts by making these debts part of their credit records, and (2) to enable HRSA to improve the quality of loan and scholarship decisions by taking into account the financial reliability of applicants. Disclosure of records will be limited to the individual's name, Social Security number (SSN), and other information necessary to establish the identity of the individual, the amount, status, and history of the claim, and the agency or program under which the claim arose.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Files of individual borrowers are maintained in a standard upright file cabinet. All original promissory notes are kept in a fire-proof file safe.

**RETRIEVABILITY:**

All record files are maintained and indexed alphabetically by last name and can be retrieved accordingly.

**SAFEGUARDS:**

1. Authorized Users: Access to Borrower's Files is limited to only those individuals within the Department having a substantiated need for information. These individuals must have available proof of employment.

2. Physical Safeguards: All folders are kept in standard up-right locking file cabinets which are locked during non-duty hours. Original Promissory Notes are maintained in a fire-proof file safe. Twenty-four hour, seven days a week, security guards perform random checks on the physical security of the data.

3. Procedural Safeguards: All users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised office. Access to records is strictly limited to those staff members trained in accordance with the Privacy Act. Implementation Guidelines: DHHS Chapter 45–13 and supplementary Chapter PHS. hf:45–13 of the General Administration Manual;: and with the DHHS ASP Systems manual Part 6, "ADP Systems Security".

**RETENTION AND DISPOSAL:**

Records will remain onsite until all financial obligations have been satisfied. Records will then be forwarded to the Federal Records Center for 10 years.

Records are disposed of in accordance with the Records Control Schedule of the Health Resources and Services Administration. Contact the System Manager for the disposal standard.

**SYSTEM MANAGER(S) AND ADDRESS:**

Chief, Debt Management Branch, Division of Fiscal Services, OA/HRSA, Room 16A–08, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

**NOTIFICATION PROCEDURE:**

To determine if a record exists, an individual must either come to the office or write to the Systems Manager. Individuals in either case, must provide positive identification, such as a driver's license, passport, voters registration, union card, or a written certification verifying his or her identity. The person should then be able to reasonably specify the contents of the record being sought.

**RECORD ACCESS PROCEDURE:**

Contact the System Manager and give a reasonable description of the record.

**CONTESTING RECORD PROCEDURES:**

To contest the contents of a record, an individual must contact the Systems Manager, identify him or herself and give a reasonable description of the record. He or she must then specify the information being contested and state the corrective action being sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Applicant and applicant's health professions school.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09–15–0044**

**SYSTEM NAME:**

Health Education Assistance Loan Program (HEAL) Loan Control Master File. HHS/HRSA/BHPr.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Student Assistance, Bureau of Health Professions, Health Resources and Services Administration, Room 8–23, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. COMNT, 5185 MacArthur Blvd., NW., Washington, D.C.

Data are also occasionally located at contractor sites as data is collected and reports written. A list of contractor sites where individually identifiable data is currently located is available upon request to the System Manager.

Washington National Records Center, 4205 Suitland Road, Suitland, MD 20832.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Applicants for and recipients of health education assistance loans.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Contains name, social security number or other identifying number, birthdate, demographic background, educational status, loan location, status, and financial information about the individuals for whom the record is maintained. Contains lender and school indentification.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 727 of the Public Health Service Act, as amended (42 U.S.C. 294), Statement of Purpose and Appropriations Authorized; Section 728 of the Public Health Service Act, as amended (42 U.S.C. 294a), Scope and Duration of Federal Loan Insurance Program; and Section 739 of the Public Health Service Act, as amended (42 U.S.C. 2941), Eligibility of Institutions.

**PURPOSE(S):**

Data are utilized by HEAL Program staff to identify students participating in the HEAL Program; to determine eligibility of loan applicants; to determine loan status of borrower; to compute insurance premium for Federal insurance; to compile and generate managerial and statistical reports; and to update file and correct errors.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to Federal, State, or local agencies, to private parties such as relatives, present and former employers, business and personal associates, to educational and financial institutions, to collection agencies, and to agency contractors. Such disclosures are made in order to verify the identity of the applicant, to determine program eligibility and benefits, to enforce the conditions or terms of the loan, to counsel the borrower in repayment efforts, to investigate possible fraud and abuse, to

verify compliance with program regulations and to locate delinquent borrowers in preclaims assistance. Information may be provided to an educational or lending institution against which a complaint has been made.

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department or any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the General Accounting Office, Office of Management and Budget, Department of Justice, and other appropriate Federal and State agencies charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute or rule, regulation or order issued pursuant thereto.

**DISCLOSURE TO CONSUMER REPORTING AGENCIES:**

*Disclosures pursuant to 5 U.S.C. 552(a)(b)(12):* Disclosures may be made from this system to "consumer reporting agencies" as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) or the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)). The purposes of this disclosure are: (1) to provide an incentive for debtors to repay delinquent Federal Government debts by making these debts part of their credit records, and (2) to enable HRSA to improve the quality of loan and scholarship decisions by taking into account the financial reliability of applicants. Disclosure of records will be limited to the individual's name, Social Security number (SSN), and other information necessary to establish the identity of the individual, the amount, status, and history of the claim, and the agency or program under which the claim arose.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Storage media includes magnetic tape and disk packs. Under an existing contract with Office of Education, all subcontractors will maintain automated data in accordance with the provisions of the Education Department ADP systems security standards.

**RETRIEVABILITY:**

Social Security Number or other identifying number.

**SAFEGUARDS:**

1. Authorized Users: Access by administrative personnel for determination of eligibility.

2. Physical Safeguards: Magnetic tapes, disk packs, computer equipment and other forms of personal data are stored in areas where fire and life safety codes are strictly enforced. All documents are protected during lunch hours and nonworking hours in locked file cabinets or locked storage areas.

3. Procedural Safeguards: A password is required to access the terminal and a data set name controls the release of data to only authorized users. All users of personal information in connection with the performance of their jobs protect information from public view and from unauthorized personnel entering an unsupervised office.

Access to records is strictly limited to those staff members trained in accordance with the Privacy Act. The contractor is required to maintain confidentiality safeguards with respect to these records. Implementation Guidelines: DHHS Chapter 45-13 and supplementary Chapter PHS, hf: 45-13 of the General Administration Manual; and with the DHHS ADP Systems Manual Part 6. "ADP Systems Security".

**RETENTION AND DISPOSAL:**

Records will be retained for 5 years after the loan is repaid; 1 year on site and 4 years Federal Records Center. After 5 years, computer tapes are erased and all paperwork is destroyed.

**SYSTEM MANAGER(S) AND ADDRESS:**

Chief, HEAL Branch/Division of Student Assistance, BHPr/HRSA, Room 8-38, Parklawn Building, 560 Fishers Lane, Rockville, MD 20857.

**NOTIFICATION PROCEDURE:**

Requests must be made to the Systems Manager. An individual who requests notification of, or access to, a medical record shall at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

Requests in person: A subject individual who appears in person at a specific location seeking access or disclosure of records relating to him/her shall provide his/her name, current address, and at least one piece of tangible identification such as driver's license, passport, voter registration card, or union card. Identification papers with current photographs are preferred but not required. Additional identification may be requested when there is a request for access to records which contain an apparent discrepancy between information contained in the record and that provided by the individual requesting access to the record. No verification of identity shall be required where the record is one which is required to be disclosed under the Freedom of Information Act.

Requests by mail: Requests for information and/or access to records received by mail must contain information providing the identity of the writer and a reasonable description of the record desired.

Written requests must contain the name and address of the requester, his/her date of birth and at least one piece of information which is also contained in the subject record, and his/her signature for comparison purposes.

Requests by telephone: Since positive indentification of the caller cannot be established, telephone requests are not honored.

Signature: Where an individual is unable to sign his/her name when required he/she shall make his/her mark and have the mark verified in writing by two additional persons.

**RECORD ACCESS PROCEDURES:**

An individual who is interested in seeing his or her record should contact the system manager, provide the information listed in notification procedure, and reasonably specify the record contents being sought.

**CONTESTING RECORD PROCEDURES:**

Contact the System Manager and reasonably identify the record, specify the information being contested, and

state the corrective action sought, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Individual loan recipients, HEAL schools, lenders and holders of HEAL loans and their agents.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-15-0046**

**SYSTEM NAME:**

Health Professions Planning and Evaluation. HHS/HRSA/OA.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Grants and Procurement Management, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, MD 20857. In addition, data are at contractor and field work sites as studies are developed, data collected, and reports written. You may request a list of locations where individually identifiable data are currently located from the System Manager. Washington National Records Center, 4205 Suitland Road, Suitland, Md. 20832.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Health professionals and students in the various health professions. Physicians, dentists, pharmacists, optometrists, podiatrists, veterinarians, public health personnel, audiologists, speech pathologists, health care administration personnel, nurses, allied health personnel, medical technologists, chiropractors, clinical psychologists, and other health personnel may be included.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Name, address, health profession, education history, academic grades, employment history, nationality, race, ethnicity, economic background, and sex. The specific data items collected and maintained are determined by the needs of the individual project.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Public Health Service Act, Section 708[42 U.S.C. 292h], Health Professions Data, Section 787[42 U.S.C. 295g-7], Educational Assistance to Individuals from Disadvantaged Backgrounds, Section 798[42 U.S.C. 295h-7], Educational Assistance to Disadvantaged Individuals in Allied Health Training, and Section 820[42 U.S.C. 296k], Special Project Grants and Contracts.

**PURPOSE(S):**

The Health Resources and Services Administration uses various records in this system to identify problems in the health care training and delivery systems to plan programs to correct those problems, and to evaluate the effectiveness of the resultant programs. The agency assesses the current supply of health professionals and predicts the supply needs of the future. The agency determines nationwide requirements as well as the needs of specific areas.

The agency also collects data on the educational system which supplies health professionals and on specific health education programs. The data are used to develop and test new methods of training and utilizing health professionals.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

A record may be disclosed for a research purpose, when the Department:

(a) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained:

(b) Has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in indevidually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring:

(c) Has required the recipient to—(1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the pupose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information, and (3) make no further use or disclosure of the record except—(A) in emergency circumstancres affecting the health or safety of any individual, (B) for use in another research project, under these same conditions, and with written authorization of the Department, (C) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (D) when required by law: and

(d) Has secured a written statement attesting to the recipient's understanding of, and willingness to abide by these provisions.

Disclosure may be made to HHS contractors and their staff, in order to accomplish any of the purposes of the system of records. The recipients are required to protect such records from improper disclosure and to maintain Privacy Act Safeguards

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File folders, magnetic tape, card files, microfilm, microfiche, and disk storage. The needs of each project determine the types of storage actually used.

**RETRIEVABILITY:**

By name. In some instances an assigned number may be used to retrieve records.

**SAFEGUARDS:**

Locked building, locked rooms, locked file cabinets, personnel screening, locked computer rooms and computer tape vault, guard service, password protection of automated records and limited access to only authorized personnel may be used. Particular safeguards are selected as appropriate to the type of records included in each project. Authorized personnel are generally limited to contractor personnel directly involved in data collection, compilation, and analysis. [Safeguards are in accordance with Part 6 ADP Systems Security of the Department's ADP Systems Manual, with Chapter 45-13, Safeguarding Records Contained in Systems of Records, of the Department's General Administration Manual, and with supplementary Chapter PHS.hf: 45-13.]

**RETENTION AND DISPOSAL:**

The contractor removes personal identifiers and destroys the records when they are no longer needed, as appropriate to the specific project. [Records may be retired to a Federal Records Center and subsequently disposed of in accordance with the Records control Schedule of the Health Resources and Services Administration]. You may obtain a copy of the disposal standard for a particular project by writing to the System Manager.

**SYSTEM MANAGER(S) AND ADDRESS:**

Contracting Officer, Division of Grants and Procurement Management, HRSA, Room 13A-03, Parklawn

Building, 5600 Fishers Lane, Rockville, MD 20857.

**NOTIFICATION PROCEDURE:**

To determine if you are the subject of a record, contact the System Manager and provide suitable identification and, if possible, information about the specific project.

**RECORD ACCESS PROCEDURES:**

To obtain access to your record, contact the System Manager and provide suitable identification, a reasonable description of the record and, if possible, information about the specific project.

**CONTESTING RECORD PROCEDURES:**

To correct your record, contact the System Manager and provide (a) suitable identification, (b) a reasonable description of the record, (c) the specific information you want corrected, and (d) a precise description of the correction, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Subject individuals, state and local health departments, other health providers, health professions schools, and health professions associations may provide information depending on the individual project involved.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-15-0047**

**SYSTEM NAME:**

Cycle II Dentist Survey. HHS/HRSA/BHPr.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Computer Research and Technology, NIH Building 12, 9000 Rockville Pike, Bethesda, MD 20205.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

All U.S. dentists since 1974.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Name; practice location; practice characteristics; and professional history.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 301 of the Public Health Service Act, as amended (42 U.S.C. 241), Research and Investigation.

**PURPOSE(S):**

To study the supply and distribution of dentists in each state.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Magnetic tape.

**RETRIEVABILITY:**

Name within state.

**SAFEGUARDS:**

Locked file cabinets, personnel screening, and password protection of automated records. Access is restricted to personnel in the professional practices development program area. (Safeguards are in accordance with Part 6, ADP Systems Security of the Department's ADP Systems Manual, with Chapter 45-13, Safeguarding Records Contained in Systems of Records, of the Department's General Administration Manual, and with supplementary Chapter PHS.hf: 45-13.)

**RETENTION AND DISPOSAL:**

Records are held for 10 years and then are disposed of in accordance with the Records Control Schedule of the Health Resources and Services Administration. Contact the System Manager for the disposal standard.

**SYSTEM MANAGER(S) AND ADDRESS:**

Chief, Health Professions Analysis Branch, Division of Associated and Dental Health Professions, BHPr/HRSA, Room 8C-02, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

**NOTIFICATION PROCEDURE:**

To determine if you are the subject of a record, contact the System Manager and provide suitable identification.

**RECORD ACCESS PROCEDURE:**

To obtain access to your record, contact the System Manager and provide suitable identification and a reasonable description of the record.

**CONTESTING RECORD PROCEDURE;**

To correct your record, contact the System Manager and provide (a) suitable identification, (b) a reasonable description of the record, (c) the specific information you want corrected, and (d) a precise description of the correction, with supporting justification.

**RECORD SOURCE CATEGORIES:**

American Association of Dental Examiners.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-15-0048**

**SYSTEM NAME:**

Chattanooga Incremental Care Program. HHS/HRSA/BHPr.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Computer Research and Technology, NIH Building 12, 9000 Rockville Pike, Bethesda MD 20205.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Elementary school children ages 4-14 who were treated in the Chattanooga Dental Care Program from 1972-1976.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Patients' dental records.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 301 of the Public Health Service Act, as amended (42 U.S.C. 241), Research and Investigation.

**PURPOSE(S):**

To study dental health patterns of children in a dental care program.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to and inquiry from the congressional office made at the request of that individual.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Magnetic tape.

**RETRIEVABILITY:**

I.D. Number assigned by program.

**SAFEGUARDS:**

Locked file cabinets, personnel screening, and password protection of automated records. Access is restricted to personnel in the professional practices development program area. [Safeguards are in accordance with Part 6, ADP Systems Security, of the Department's ADP Systems Manual, with Chapter 45-13, Safeguarding Records Contained in Systems of Records, of the Department's General Administration Manual, and with supplementary Chapter PHS.hf: 45-13.]

**RETENTION AND DISPOSAL:**

Records are held for 6 years and then are disposed of in accordance with the Records Control Schedule of the Health Resources and Services Administration. Contact the System Manager for the disposal standard.

**SYSTEM MANAGER(S) AND ADDRESS:**

Chief, Health Professions Analysis Branch, Division of Associated and Dental Health Professions, BHPr/HRSA, Room 8C-02, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

**NOTIFICATION PROCEDURE:**

To determine if you are the subject of a record, contact the System Manager and provide suitable identification. An individual who requests notification of a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion. A parent or guardian who requests notification of a child's medical/dental record shall designate a family physician or other health professional [other than a family member] to whom the record, if any, will be sent. The parent or guardian must verify relationship to the child as well as his/her own identity.

**RECORD ACCESS PROCEDURE:**

To obtain access to your record, contact the System Manager and provide suitable identification and a reasonable description of the record.

**CONTESTING RECORD PROCEDURES:**

To correct your record, contact the System Manager and provide (a) suitable identification, (b) a reasonable description of the record, (c) the specific information you want corrected, and (d) a precise description of the correction, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Tennessee Department of Public Health.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-15-0049**

**SYSTEM NAME:**

Indo-China Refugee Physicians and Medical Students. HHS/HRSA/BHPr.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Washington National Records Center, 4105 Suitland Road, Washington, DC 20405.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Indo-China physicians and medical students who applied for certification by the Educational Commission for Foreign Medical Graduates or the National Board of Medical Examiners under the Indo-China Rfugee Physicians and Medical Students Program.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Medical school attended, specialty or specialty preference, age, sex, and marital status.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

The Indo-China Refugee Migration and Refugee Assistance Act of 1975 (22 U.S.C. 2601).

**PURPOSE OF THE SYSTEM:**

To establish credentials and eligibility for training of Indo-China refugee physicians and medical students.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

To persons responsible for admitting candidates to training courses for the ECFMG and the National Board of Medical Examiners examinations.

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of the individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department to Justice to enable that Department of present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File folders.

**RETRIEVABILITY:**

Name of individual.

**SAFEGUARDS:**

Restricted access in the Federal Records Center.

**RETENTION AND DISPOSAL:**

Records are held for 10 years and then are disposed of in accordance with the Records Control Schedule of the Health Resources and Services Administration. Contact the System Manager for the disposal standard.

**SYSTEM MANAGER(S) AND ADDRESS:**

Chief, International Medical Education Programs Branch, Division of Medicine, BHPr/HRSA, Room 4C-13, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

**NOTIFICATION PROCEDURE:**

To determine if you are the subject of a record, contact the System Manager and provide suitable identification.

**RECORD ACCESS PROCEDURE:**

To obtain access to your record, contact the System Manager and provide suitable identification and a reasonable description of the record.

**CONTESTING RECORD PROCEDURE:**

To correct your record, contact the System Manager and provide (a) suitable identification, (b) a reasonable description of the record, (c) the specific information you want corrected, and (d) a precise description of the correction, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Questionnaires completed by Indo-China physicians and medical students.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09-15-0050**

**SYSTEM NAME:**

National Research Service Awards. HHS/HRSA/BHPr.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Office of Program Support Room 8C-22, Division of Nursing, HRSA, Room 5C-26, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Division of Computer Research and Technology, NIH Building 12, 9000 Rockville Pike, Bethesda, MD 20205.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Applicants for the recipients of National Research Service Award fellowships.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Biographical data, education and employment history, reference reports, research background, progress of residency training, and transcripts.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 472 of the Public Health Service Act, as amended (42 U.S.C. 2891–1), National Research Service Awards.

**PURPOSE(S):**

To select and monitor recipients of fellowship support.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

In the event that a system of records maintained by this Agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by statute or regulation issued under the statute, the relevant records in the system of records may be referred, as a routine use, to the Department of Justice, for the purpose of investigation and possible prosecution of such violation.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File folders and magnetic tape.

**RETRIEVABILITY:**

Name of individual or application number.

**SAFEGUARDS:**

Files are locked during non-business hours, personnel screening, locked computer room and tape vault, guard service, and password protection of automated records. Access is restricted to grants management and program personnel responsible for managing the National Research Service Awards program. (Safeguards are in accordance with Part 6, ADP Systems Security, of the Department's ADP Systems Manual, Chapter 45–13, Safeguarding Records Contained in Systems of Records, of the Department's General Administration Manual, and with supplementary Chapter PHS.hf: 45–13.)

**RETENTION AND DISPOSAL:**

Records are held for one year and then are disposed of in accordance with the Records Control Schedule of the Health Resources and Services Administration. Contact the System Manager for the disposal standard.

**SYSTEM MANAGER(S) AND ADDRESS:**

Grants Management Officer, Office of Program Support, HRSA, Room 8C–22, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

**NOTIFICATION PROCEDURE:**

To determine if you are the subject of a record, contact the System Manager and provide suitable identification.

**RECORD ACCESS PROCEDURES:**

To obtain access to your record, contact the System Manager and provide suitable identification and a reasonable description of the record.

**CONTESTING RECORD PROCEDURE:**

To correct your record, contact the System Manager and provide (a) suitable identification, (b) a reasonable description of the record, (c) the specific information you want corrected, and (d) a precise description of the correction, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Applicants; references (supplied by applicant); sponsoring faculty member.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09–15–0051**

**SYSTEM NAME:**

Professional Nurse Traineeships. HHS/HRSA/BHPr.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Office of Program Support Room 8C–22, Division of Nursing, HRSA, Room 5C–26, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Division of Computer Research and Technology, MIH Building 12, 9000 Rockville Pike, Bethesda, MD 20205.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Registered nurses who have received Professional Nurse Traineeships.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

U.S. citizenship verification, nursing licensure verification, education and employment history, and post-traineeship employment.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 830 of the Public Health Service Act, as amended (42 U.S.C. 297), Professional Nurse Traineeships.

**PURPOSE OF THE SYSTEM:**

To select and monitor recipients of traineeships. Also used for statistical reports and program evaluation.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

The length of allowable support for a particular applicant may be disclosed to participating schools.

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

In the event of litigation where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

In the event that a system of records maintained by the agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by statute or regulation issued under the statue, the relevant

records in the system of records may be referred, as a routine use, to the Department of Justice for the purpose of investigation and possible prosecution of such violation.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File folders and magnetic tape.

**RETRIEVABILITY:**

Name or I.D. number of individual.

**SAFEGUARDS:**

Flies are locked during non-business hours, personnel screening, locked computer room and tape vault, guard service, and password protection of automated records. Access is restricted to grants management and program personnel responsible for managing the professional nurse traineeship program. (Safeguards are in accordance with Part 6, ADP Systems Security, of the Department's ADP Systems Manual, with Chapter 45–13, Safeguarding Records Contained in Systems of Records, of the Department's General Administration Manual, and with supplementary Chapter PHS.hf: 45–13.)

**RETENTION AND DISPOSAL:**

Records are held for 6 years and then are disposed of in accordance with the Records Control Schedule of the Health Resources and Services Administration. Contact the System Manager for the disposal standard.

**SYSTEM MANAGER(S) AND ADDRESS:**

Grants Management Officer, Office of Program Support, BHPr, HRSA, Room 8C–22, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

**NOTIFICATION PROCEDURE:**

To determine if you are the subject of a record, contact the System Manager and provide suitable identification.

**RECORD ACCESS PROCEDURE:**

To obtain access to your record, contact the System Manager and provide suitable identification and a reasonable description of the record.

**CONTESTING RECORD PROCEDURE:**

To correct your record, contact the System Manager and provide (a) suitable identification, (b) a reasonable description of the record, (c) the specific information you want corrected, and (d) a precise description of that correction, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Applicants and participating schools.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09–15–0052**

**SYSTEM NAME:**

Nurse Practitioner Traineeships. HHS/HRSA/BHPr.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Office of Program Support, Room 8C–22, Division of Nursing, Room 5C–26, BHPr, HRSA, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Washington National Records Center, 4205 Suitland Road, Suitland, MD 20832.

Health Resources and Services Administration, Debt Management Branch, DFS/OA/HRSA, Parklawn Building, Room 16–08, 5600 Fishers Lane, Rockville, MD 20857.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals selected to receive nurse practitioner traineeships by schools participating in the program.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

A trainee's case file contains a "Traineeship Award Agreement," "Verification of Address Card," and related correspondence with the individual and school(s) attended. Personal information includes name, current address, home address and address of the primary medical care practice location. Social security medical records or reports may be included when a trainee has requested suspension or cancellation of the payment or practice obligation because of medical disability. After determination of the claim, medical records will be returned to the subject individual or authorized representative.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 822(b) of the Public Health Service Act, as amended (42 U.S.C. 296m), Nurse Practitioner Traineeships.

**PURPOSE(S):**

The purpose of the system is to carry out the Department's reponsibilities for the Nurse Practitioner Traineeship Program. The Health Resources and Services Administration uses the records to: (1) Determine eligibility of trainees selected by participating schools, (2) determine that the nature, location and duration of practice meets the service commitment of nurses who completed their training, and (3) recover funds from trainees who do not fulfill their practice commitment.

The records in the system are also used by the Health Resources and Service Administration, Accounting and Finance Branch, to monitor the contractual obligations of trainees found to be in default. If the trainee does not fulfill the service commitment, the trainee must repay the traineeship support received, plus interest, to the U.S. Treasury.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of the individual.

In the event of litigation, where the defendant is (a) the Department, any component of the Department, or any employee of the Department in his or her official capacity; (b) the United States where the Department determines that the claim, if successful, is likely to directly affect the operations of the Department or any of its components; or (c) any Department employee in his or her individual capacity where the Justice Department has agreed to represent such employee, the Department may disclose such records as it deems desirable or necessary to the Department of Justice to enable that Department to present an effective defense, provided such disclosure is compatible with the purpose for which the records were collected.

Disclosure may be made to organizations considered qualified by the Secretary to conduct studies to evaluate the program.

In the event that a system of records maintained by this agency to carry out its functions indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by statute or regulation issued under the statute, the relevant records in the system of records may be referred, as a routine use, to the Department of Justice for the purpose of investigation and possible prosecution of such violation.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File folders, magnetic tape, and disk storage.

**RETRIEVABILITY:**

By name of individual.

**SAFEGUARDS:**

Locked file cabinets, personnel screening, locked computer rooms and

computer tape vault, guard service, and password protection of automated files. Access is restricted to personnel responsible for managing the nurse practitioner traineeship program. (Safeguards are in accordance with Chapter 45–13, Safeguarding Records Contained in Systems of Records, of the Department's General Administration Manual, with supplementary Chapter PHS.hf: 45–13, and with Part 6, ADP Systems Security, of the Department's ADP Systems Manual.)

**RETENTION AND DISPOSAL:**

Case files are retired to a Federal Records Center three years after all activity is terminated, usually when the practice or payment obligation has been fulfilled or cancelled. Records are disposed of in accordance with the Records Control Schedule of the Health Resources and Services Administration. You may obtain a copy of the disposal standard by writing to the System Manager.

**SYSTEM MANAGER(S) AND ADDRESS:**

Grants Management Officer, Office of Program Support, BHPr/HRSA, Room 8C–22, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

**NOTIFICATION PROCEDURE:**

To determine if you are the subject of a record, contact the System Manager and provide suitable identification. An individual who requests notification of a medical/dental record shall, at the time the request is made, designate in writing a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion.

**RECORD ACCESS PROCEDURE:**

To obtain access to your record, contact the System Manager and provide suitable identification and a reasonable description of the record.

**CONTESTING RECORD PROCEDURES:**

To correct your record, contact the System Manager and provide (a) suitable identification, (b) a reasonable description of the record, (c) the specific information you want corrected, and (d) a precise description of the correction, with supporting justification.

**RECORD SOURCE CATEGORIES:**

Individuals in the system and participating institutions.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:**

None.

**09–15–0053**

**SYSTEM NAME:**

Consultants for Office of Health Resources Opportunity, Division of Disadvantaged Assistance, HHS/HRSA/BHPr.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

Division of Disadvantaged Assistance, Bureau of Health Professions, Health Resources and Services Administration, Room 8A–09, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Private citizens employed as consultants by the Division of Disadvantaged Assistance (DDA).

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Name, address, phone number, academic history, period of appointment, duties performed for DDA.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Section 301 of the Public Health Service Act, as amended (42 U.S.C. 241), Research and Investigation.

**PURPOSE OF THE SYSTEM:**

To identify and locate consultants with experience in projects concerning health disadvantaged assistance.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

File folders.

**RETRIEVABILITY:**

Name of individual.

**SAFEGUARDS:**

Locked file cabinets with access by authorized personnel only and general building security. (Safeguards are in accordance with Chapter 45–13, Safeguarding Records Contained in Systems of Records, of the Department's General Administration Manual, and with supplementary Chapter PHS.hf:45–13.)

**RETENTION AND DISPOSAL:**

Records are held for two years and then are disposed of in accordance with the Records Control Schedule of the Health Resources and Service Administration. Contact the System Manager for the disposal standards.

**SYSTEM MANAGER(S) AND ADDRESS:**

Administrative Officer, Division of Disadvantaged Assistance, BHPr, HRSA, Room 8A–09, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

**NOTIFICATION PROCEDURE:**

To determine if you are the subject of a record, contact the System Manager and provide suitable identification.

**RECORD ACCESS PROCEDURES:**

To obtain access to your record, contact the System Manager and provide suitable identification and a reasonable description of the record.

**CONTESTING RECORD PROCEDURES:**

To correct your record, contact the System Manager and provide (a) suitable identification, (b) a reasonable description of the record, (c) the specific information you want corrected, and (d) a precise description of the correction, with supporting justification.

**RECORD SOURCE CATEGORIES**

Subject individuals, peer referrals, previous employers.

**SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT**

None.

[FR Doc. 83–31246 Filed 11–28–83; 8:45 am]
BILLING CODE 4160–01–M

## Food and Drug Administration

## Privacy Act of 1974; Annual Publication of Systems of Records

**AGENCY:** Public Health Service (PHS); Food and Drug Administration (FDA), HHS.

**ACTION:** Annual republication of notices of systems of records.

**SUMMARY:** FDA is publishing this document to meet requirements of Pub. L. 97–375, the Congressional Reports Elimination Act. This new statute amends the Privacy Act (5 U.S.C. 552a, section 3(e)(4)) to limit republication to revised system notices only. FDA has reviewed each of its system notices and has revised many of its system notices this year to enhance specificity and clarify the effects of reorganization. These revisions are minor and have no affect on the public's need-to-know.

Therefore, FDA is not republishing any of its system notices at this time.

A copy of the revised FDA system notices is available from the FDA Privacy Act Coordinator (HFW-30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

**SUPPLEMENTARY INFORMATION:**

1. The routine uses set forth in each notice describe permissible disclosures outside the Department of records in that system which may be made without the consent of individuals who are the subjects of those records. Additional disclosures without consent of subject individuals are permitted by the Privacy Act in Section 3(b) as follows:

"(1) To those officers and employees of the agency which maintains the record who have a need for the record in the performance of their duties;

"(2) Required under section 552 of this title (the Freedom of Information Act);

"(3) For a routine use as (described in the routine use section of each specific system notice);

"(4) To the Bureau of Census for purposes of planning or carrying out a census or survey or related activity pursuant to the provisions of Title 13;

"(5) To a recipient who has provided the agency with advance adequate written assurance that the record will be used solely as a statistical research or reporting record, and the record is to be transferred in a form that is not individually identifiable;

"(6) To the National Archives of the United States as a record which has sufficient historical or other value to warrant its continued preservation by the United States Government, or for evaluation of the Administrator of General Services or his designee to determine whether the record has such value;

"(7) To another agency or to an instrumentality of any government jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the agency which maintains the record specifying the particular portion desired and the law enforcement activity for which the record is sought;

"(8) To a person pursuant to a showing of compelling circumstances affecting the health or safety of an individual if, upon such disclosure, notification is transmitted to the last known address of such indivdual;

"(9) To either House of Congress, or, to the extent of matter within its jurisdiction, any committee or subcommittee thereof, any joint committee of Congress or subcommittee of any such joint committee;

"(10) To the Comptroller General, or any of his authorized representatives in the course of the performance of the duties of the General Accounting Office;

"(11) Pursuant to the order of a court of competent jurisdiction;" or

"(12) To a consumer reporting agency in accordance with section 3(d) of the Federal Claims Collection Act of 1966 (31 U.S.C. 952(d))."

Permissible disclosure [12] was added this year by Pub. L. 97-365, the Debt Collection Act of 1982, to allow disclosure of information to consumer reporting agencies to provide an incentive for debtors to repay delinquent Federal Government debts by making these debts part of their credit records. This "Special Disclosure" statement does not apply to any FDA system of records.

2. The Office of General Counsel has determined that the paragraph, "[W]here the appropriate official of the Department, pursuant to the Department's Freedom of Information regulation, determines that it is in the public interest to disclose a record which is otherwise exempt from mandatory disclosure, disclosure may be made from this system of records." Under the "Routine Uses * * *" section of system numbers 09-10-0002 and 09-10-0010 this routine use has been deleted since it is irrelevant in most cases and may even be counterproductive.

3. An addition to the "Routine Uses" section of system numbers 09-10-0008 and 09-10-0009 has been made to permit the FDA to disclose information to contractors to accomplish the purpose for which the records are collected. This addition was published in the **Federal Register**, Vol. 47, No. 237, Thursday, December 9, 1982.

**Gerald H. Deighton,**

*Acting Associate Commissioner for Legislation and Information.*

**Table of Contents**

The following table of contents lists all currently active systems of records

09-10-0002 Regulated Industry Employee Enforcement Records. HHS/FDA/ACMO, FR, Vol. 47, No. 198, Oct. 13, 1982, p. 45412-45414.

09-10-0003 FDA Credential Holder File. HHS/FDA/EDRO, FR, Vol. 47, No. 198, Oct. 13, 1982, p. 45415.

09-10-0004 Communications (Oral and Written) With the Public. HHS/FDA/ACMO, FR, Vol. 47, No. 198, Oct. 13, 1982, p. 45415-45416.

09-10-0005 State Food and Drug Official File. HHS/FDA/EDRO, FR, Vol. 47, No. 198, Oct. 13, 1982, p. 45416-45417.

09-10-0007 Science Advisor Research Associate Program (SARAP). HHS/FDA/EDRO, FR, Vol. 47, No. 198, Oct. 13, 1982, p. 45417-45418.

09-10-0008 Radiation Protection Program Personnel Monitoring System. HHS/FDA/NCDRH, FR, Vol. 47, No. 237, Dec. 9, 1982, p. 55425-55426.

09-10-0009 Special Studies and Surveys on FDA-Regulated Products. HHS/FDA/ACMO, FR, Vol. 47, No. 237, Dec. 9, 1982, p. 55426-55427.

09-10-0010 Bioresearch Monitoring Information System. HHS/FDA, FR, Vol. 47, No. 198, Oct. 13, 1982, p. 45419-45420.

09-10-0011 Certified Retort Operators. HHS/FDA/BF, FR, Vol. 47, No. 198, Oct. 13, 1982, p. 45420-45421.

09-10-0012 Association of Official Analytical Chemists (AOAC) Member File. HHS/FDA/AOAC, FR, Vol. 47, No. 198, Oct. 13, 1982, p. 45421-45422.

09-10-0013 Employee Conduct Investigative Records. HHS/FDA/ACMO, FR, Vol. 47, No. 198, Oct. 13, 1982, p. 45422-45423.

09-10-0015 Blood Donors for Tissue Typing Sera and Cell Analysis and Related Research. HHS/FDA/NCDB/OB, FR, Vol. 47, No. 198, Oct. 13, 1982, p. 45423.

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# Part III

# Environmental Protection Agency

## Toxic Substances Control; Good Laboratory Practice Standards; Final Rule

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 792**

**[FRL 2437-2; OPTS-46004B]**

## Toxic Substances Control; Good Laboratory Practice Standards

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This action promulgates Good Laboratory Practice (GLP) Regulations applicable to persons conducting chemical studies required by rules promulgated under section 4(a) of the Toxic Substances Control Act (TSCA). It is also EPA's policy that persons comply with these regulations when submitting data in response to orders or regulations issued under section 5 of TSCA, and when submitting data to the Agency voluntarily. These regulations are intended to assure the high quality of laboratory test data required to evaluate the health and environmental effects, and fate of chemical substances and mixtures subject to the provisions of TSCA. This action is based on the results of investigations by the Food and Drug Administration (FDA) and EPA which showed that some studies submitted in support of the safety of regulated products had not been conducted in accordance with acceptable practice, and that, accordingly, data from such studies have not always been of adequate quality and integrity.

**EFFECTIVE DATE:** December 29, 1983.

**FOR FURTHER INFORMATION CONTACT:** Jack McCarthy, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Rm. E-543, 401 M St., SW., Washington, D.C. 20460, Toll-free: (800-424-9065), In Washington, D.C.: (544-1404), Outside the USA: (Operator—202-554-1404).

**SUPPLEMENTARY INFORMATION:** Following is an index to the remainder of this preamble:

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## I. Introduction

### *A. Legal Authority*

These standards are promulgated under the authority of section 4 of the Toxic Substances Control Act ("TSCA", 90 Stat. 2006, 15 U.S.C. 2603). Section 4(a) of TSCA authorizes the Administrator of the Environmental Protection Agency to require, by rule, that manufacturers (including importers) and processors of identified chemical substances and mixtures test such chemicals if certain specific findings are made. Section 4(b)(1) specifies that each test rule shall include: (1) Identification of the chemical(s) to be tested, (2) standards for the development of test data, and (3) specification of the period within which testing must be completed. "Standards for the development of test data" are defined in section 3(12) of TSCA to mean a prescription of—

> (A) the—
> (i) health and environmental effects, and
> (ii) information relating to toxicity, persistence, and other characteristics which affect health and the environment,
> for which test data for a chemical substance or mixture are to be developed and any analysis that is to be performed on such data, and
> (B) to the extent necessary to assure that data respecting such effects and characteristics are reliable and adequate—
> (i) the manner in which such data are to be developed,
> (ii) the specification of any test protocol or methodology to be employed in the development of such data, and
> (iii) such other requirements as are necessary to provide such assurance.

The definitions in sections 3(12)(B)(i) and 3(12)(B)(iii) are applicable to the standards contained in the rule promulgated by this notice. In summary, the specific authority to issue the GLP Standards promulgated by this notice is provided by section 4(b)(1) of TSCA, which is further explained by the definitions in sections 3(12)(B)(i) and 3(12)(B)(iii). On the basis of EPA and FDA experience and sound administrative policy, as described more completely below, EPA has determined that enforceable GLPs common to all section 4(a) test rules are necessary to assure that adequate and reliable data are developed.

In addition, the Agency also requires sponsors to utilize these GLP Standards when conducting testing under negotiated testing agreements and will include provisions to adhere to these GLP regulations in these agreements. Also, it is the Agency's policy that all data developed as a result of regulations or orders under section 5 of TSCA should be in accordance with the provisions of this part. If the data developed under negotiated testing agreements or under section 5 of TSCA are not generated in accordance with the provisions of this part, the Agency may elect to consider such data insufficient to evaluate the health effects, environmental effects, and fate of the chemical.

### *B. Relationship of GLPs to Chemical Testing*

GLP standards delineate the proper general procedures for conducting laboratory testing. These GLP Standards are concerned with the organizational process and the conditions under which laboratory studies are planned, performed, monitored, recorded, and reported.

For purposes of this regulation, GLPs are distinguished from test protocols, which deal: (1) With the proper experimental design, conduct, and evaluation of tests for particular effects, and (2) with the proper methods for evaluating chemicals for their different physical, chemical, and persistence characteristics. Test protocols describe procedures such as the proper route of administration, the duration of exposure to test systems by the chemical, the appropriate number of test organisms to

use for a particular type of study, and the appropriate evaluations to conduct during the study.

EPA takes the position that testing facilities should be held to a high standard with respect to laboratory procedures. The Agency's approach still provides for flexibility in the design of methodology and protocols used in individual studies. Accordingly, EPA is promulgating GLPs as enforceable regulations but will allow some flexibility in deciding which methodology to use for a particular test. The general framework of this system and EPA's reasons for choosing it are explained in the next section of this preamble, entitled "Historical Background."

*C. Historical Background*

EPA's decision to develop enforceable GLP Standards under TSCA was based on EPA's own experience and that of the FDA in dealing with the integrity of data submitted to them in support of the health and safety of regulated products and pesticides. Inspections by FDA of several pharmaceutical firms and contract laboratories led to the discovery of unacceptable laboratory practices that, in turn, called into question the validity of the test data, including fraudulent submission by those sources. Inspection of laboratories conducting tests on pesticides and data audits of studies on pesticides confirmed FDA's earlier findings. Aware of FDA's findings, EPA responded by forming a toxicology data audit program within the Agency's Office of Pesticide Programs (OPP) and the Office of General Enforcement (currently the Compliance Monitoring Staff in the Office of Pesticides and Toxic Substances (OPTS)) and by entering into an interagency agreement with FDA to establish a coordinated quality assurance program. In addition, EPA began training inspectors to audit both toxicological and ecological effects data and to conduct followup investigations.

As a result of finding unacceptable laboratory practices in use, the FDA had proposed GLP Regulations for non-clinical laboratory studies, published in the **Federal Register** of November 19, 1976 (41 FR 51206), and issued final regulations that were published in the **Federal Register** of December 22, 1978 (43 FR 59986). Thereupon, EPA proposed Good Laboratory Practice (GLP) Standards for Health Effects (Health Effects GLPs) under TSCA which were published in the **Federal Register** of May 9, 1979 (44 FR 27362). The GLP Standards for Health Effects proposed under TSCA were similar in most respects to the final FDA GLP regulations, although EPA proposed a number of more stringent provisions (see GLP Preamble, 44 FR 27362, et seq).

In another **Federal Register** notice, published along with the GLP Standards for Health Effects, EPA proposed several test protocols (test standards) for assessing specific effects (e.g., oncogenicity and other chronic effects; 44 FR 27334, May 9, 1979). These might be considered GLP standards (e.g. stringent requirements for reporting data to EPA).

EPA's policy in May, 1979, was fundamentally different from its current approach to testing protocols. At that time, EPA proposed the same approach for testing protocols as it did for GLPs, intending to publish both as enforceable regulations.

EPA proposed GLP standards for environmental effects testing and chemical fate testing in the **Federal Register** of November 21, 1980 (44 FR 77357).

Thus, when EPA announced in the **Federal Register** of March 26, 1982 (47 FR 13012) its current policy for developing standards to be used to test chemicals, the Agency had in place GLP proposals for health and environmental testing and proposals for test protocols. All were proposed to be enforceable regulations.

Under the approach announced on March 26, 1982, the Agency would retain enforceable GLP standards. The abuses uncovered by FDA remain the underlying rationale for this decision. EPA decided to allow more flexibility for test protocol development in order to enable the Agency as well as sponsors and testing facilities to take into account new developments in design procedures.

Under the approach to test protocol development announced in March 1982, EPA has published test protocols as general guidelines, which are now available from the National Technical Information Service (NTIS) in Springfield, Virginia. To the extent, however, that EPA determines that protocol requirements are necessary for any particular chemical tests the Agency will establish such requirements in an administrative rulemaking proceeding.

Today's rule promulgates the GLPs proposed under TSCA on May 9, 1979, and on November 21, 1980 and is consistent with the March 1982 policy statement. A number of changes in the proposed GLP regulations have been made as a result of EPA evaluation of public comments and other information available to the Agency.

*D. Summary of GLPs*

The GLP regulation is organized as follows:

Subpart A—General Provisions
Subpart B—Organization and Personnel
Subpart C—Facilities
Subpart D—Equipment
Subpart E—Testing Facilities and Operation
Subpart F—Test and Control Substance
Subpart G—Protocol for and Conduct of a Study
Subparts H and I—[Reserved]
Subpart J—Records and Reports
Subpart K—[Reserved]
Subpart L—Environmental Testing Provisions

Subparts A through J apply to both human health and environmental testing. However, there are some GLP provisions related to environmental testing that are not covered in these subparts. Subpart L, therefore, covers matters that are uniquely applicable to tests designed to determine the potential environmental effects and fate of chemicals.

Subpart A explains that these GLPs apply to testing required by regulations promulgated under section 4(a) of TSCA and that EPA, as a matter of policy, expects that these GLP regulations will be followed for other test data submitted to EPA for the purpose of evaluating health and environmental effects as well as the fate of chemicals. Subpart A also contains a number of definitions applicable to these GLP regulations.

The most significant sections in Subpart A deal with requirements to ensure that testing facilities satisfy requirements of regulations promulgated under section 4(a) of TSCA. These requirements are described below.

If the sponsor of a study uses a consulting laboratory, contractor, or grantee to conduct testing under a contractural agreement, § 792.10 requires the sponsor to notify the laboratory that the study must be conducted in accordance with these GLP standards. Thus, the sponsor will be liable for failure to notify the laboratory and the laboratory will not be able to claim lack of knowledge that GLP standards were applicable as an excuse for non-compliance.

Any person submitting test data under a section 4 regulation must submit a statement attesting to compliance with the regulations or describing the deviations between the study and the GLP standards.

Section 792.15 requires testing facilities to permit an authorized employee or a duty designated representative of EPA or FDA to inspect at reasonable times and in a reasonable manner. EPA will not consider reliable for purposes of showing that a chemical does not present a risk of injury to health or the environment data developed by a testing facility or

sponsor that refuses to permit inspection.

Section 792.17 explains that failure to comply with the GLP regulations, submission of false or misleading information under the regulations, and denial to EPA representatives of entry to inspect will be violations of TSCA. Such violations may subject persons to civil or criminal penalties under section 16 of TSCA or criminal prosecution under 18 U.S.C. 2 or 1001.

Finally, under § 792.17, EPA may determine that data from a study not conducted in accordance with GLP standards are not reliable for purposes of showing that a chemical does not present a risk of injury to health or the environment. If a person submits data to EPA under a section 4 test rule requirement, EPA may require the sponsor to perform the test again under the theory that the sponsor has not fulfilled its obligations under the section 4 test rule. In addition, when studies other than those submitted under section 4 test rules (e.g. studies under negotiated testing agreements) are not conducted in accordance with the provisions of these regulations, the Agency may deem those studies unreliable.

EPA's reasons for adopting these provisions to ensure compliance are explained in the preamble to the proposed GLPs (44 FR 27362; May 9, 1979). No persuasive reasons against adopting these approaches were presented in comments submitted to the Agency on the rule, nor is there any other information available to the Agency that suggests it should not adopt these provisions. Later in this preamble, EPA responds in more detail to comments submitted on these issues and other issues relating to compliance with the rule.

Subparts B through J of the GLP standards discuss specific organizational procedures of the testing facility such as personnel requirements, procedures for development of testing protocols, and reporting requirements. In Unit IV of this preamble, EPA discusses the significant issues, if any, in each of these areas raised by public comments on the proposed rule.

Subpart L contains modification to subparts A through J that apply to environmental studies. Environmental studies include ecological effects and chemical fate studies. Ecological effects studies are those performed for development of information on non-human toxicity and potential ecological impact of chemicals and their degradation products. Chemical fate studies are those performed to characterize physical, chemical, and persistence properties of a substance in order to evaluate the transport and transformation of the substance in the environment.

Section 792.228 modifies applicable provisions of subparts B through J to ensure that adequate and reliable data will be developed in ecological effects testing. In general, this section establishes additional laboratory practices provisions that will be applicable to testing of plants, microbial organisms, aquatic organisms, amphibians, reptiles and birds, where appropriate. Section 792.232 provides that certain more stringent provisions of subparts B through J need not apply to chemical fate testing due to the nature of the tests. This section is discussed in more detail later in this preamble.

### *E. Organization of This Notice*

The remainder of this preamble is divided into five additional units. Unit II lists the sections added to the Code of Federal Regulations (CFR) by this action and the comparable sections in the proposed rule. Unit III describes the approach to GLP taken by U.S. regulatory agencies and the applicability of these regulations under the Toxic Substances Control Act (TSCA). Unit IV summarizes the public comments received on the proposed GLP Standards, the Agency's response to those comments and what changes, if any, were made to the GLP Standards in response to the public comments. Unit V contains the Agency's determinations concerning various regulatory assessments required by statute or executive order. Finally, Unit VI provides information on public participation and the public record.

## II. Amendments to Federal Register Proposals

In the proposal published in the **Federal Register** of May 9, 1979, the GLP Standards were designated as a new § 772.110–1 (Health Effects) of Subpart B of Part 772, while in the proposal published in the **Federal Register** of November 21, 1980, the GLP Standards were designated as new § 772.110–2 (Ecological Effects Testing) and § 772.110–3 (Chemical Fate Testing) of Subpart B, Part 772. As a part of the Toxic Substances Control Act Data Reimbursement Advance Notice of Proposed Rulemaking (ANPR) published in the **Federal Register** of September 19, 1979 (44 FR 54284), proposed materials codified at 40 CFR Parts 770, 771, 772 and 773 were redesignated under 40 CFR Parts 790 through 799. This final rule incorporates the GLP Standards into Part 792 (40 CFR Part 792). The following redesignation table correlates the new sections with those proposed and, in most instances, reference to the new sections will be used hereinafter.

| Old Section | New Section |
|---|---|
| 772.110–1(a)(1) | 792.1 |
| 772.110–1(a)(2) | 792.10 |
| 772.110–1(a)(3) | 792.3 |
| | 792.12 |
| | 792.17 |
| 772.110–1(b)(1) | 792.105 |
| 772.110–1(b)(2) | 792.107 |
| 772.110–1(b)(3) | 792.113 |
| 772.110–1(c)(1) | 792.29 |
| 772.110–1(c)(2) | 792.31 |
| 772.110–1(c)(3) | 792.33 |
| 772.110–1(c)(4) | 792.35 |
| 772.110–1(d)(1) | 792.41 |
| 772.110–1(d)(2) | 792.43 |
| 772.110–1(d)(3) | 792.45 |
| 772.110–1(d)(4) | 792.47 |
| 772.110–1(d)(5) | 792.49 |
| 772.110–1(d)(6) | 792.51 |
| 772.110–1(d)(7) | 792.53 |
| 772.110–1(e)(1) | 792.61 |
| 772.110–1(e)(2) | 792.63 |
| 772.110–1(f)(1) | 792.81 |
| 772.110–1(f)(2) | 792.83 |
| 772.110–1(f)(3) | 792.90 |
| 772.110–1(g)(1) | 792.120 |
| 772.110–1(g)(2) | 792.130 |
| 772.110–1(h) [Reserved] | Subpart H-[Reserved] |
| 772.110–1(i) [Reserved] | Subpart I-[Reserved] |
| 772.110–1(j)(1) | 792.185 |
| 772.110–1(j)(2) | 792.190 |
| 772.110–1(j)(3) | 792.195 |
| 772.110–1(k)(1) | 792.15 |
| 772.110–1(k)(2) | 792.15 |
| Appendix A | |
| | Subpart K-[Reserved] |
| 772.110–2(a)(1) | 792.1 |
| 772.110–2(a)(2) | 792.10 |
| 772.110–2(a)(3) | 792.3 |
| | 792.206 |
| 772.110–2(b)(1) | 792.105 |
| 772.110–2(b)(2) | 792.107 |
| 772.110–2(b)(3) | 792.113 |
| 772.110–2(c)(1) | 792.29 |
| 772.110–2(c)(2) | 792.31 |
| 772.110–2(c)(3) | 792.33 |
| 772.110–2(c)(4) | 792.35 |
| 772.110–2(d)(1) | 792.41 |
| 772.110–2(d)(2) | 792.47 |
| 772.110–2(d)(3) | 792.51 |
| 772.110–2(d)(4) | 792.53 |
| 772.110–2(e)(1) | 792.61 |
| 772.110–2(e)(2) | 792.63 |
| 772.110–2(f)(1) | 792.81 |
| 772.110–2(f)(2) | 792.83 |
| 772.110–2(g)(1) | 792.120 |
| 772.110–2(g)(2) | 792.130 |
| 772.110–2(h)(1) | 792.185 |
| 772.110–2(h)(2) | 792.190 |
| 772.110–2(h)(3) | 792.195 |
| 772.110–2(i) | 792.15 |
| 772.110–3(a) | 792.1 |
| 772.110–3(b) | 792.29 |
| 772.110–3(c) | 792.49 |
| 772–110–4(a) | 792.1 |
| 772.110–4(b) | 792.29 |
| 772.110–4(c)(1) | 792.41 |
| | 792.43 |
| | 792.228 |
| | 792.45 |
| | 792.228 |
| | 792.47 |
| 772.110–4(c)(3) | 792.49 |
| 772.110–4(d)(1) | 792.81 |
| | 792.228 |
| 772.110–4(d)(2) | 792.90 |
| | 792.228 |
| | 792.105 |
| | 792.228 |
| | 792.113 |
| | 792.228 |
| 772.110–4(e)(1) | 792.120 |
| 772.110–4(e)(2) | 792.130 |
| 770.5 | 792.12 |
| | 792.17 |

## III. Approach to Good Laboratory Practice Standards

1. *Consistency with the FDA.* On the basis of the Agency's needs and responsibilities under TSCA, the general purpose of GLP Standards, the arguments set forth by the FDA for its approach to GLP standards, the reasons presented in public comments for consistency, and the need to reduce any unnecessary burden on the regulated public, EPA finds no basis for promulgating TSCA GLP Standards that differ significantly from those of FDA except to the extent necessary for effective implementation of TSCA in accordance with the two Agencyies different statutory responsibilities. Accordingly, the EPA GLP regulations under TSCA differ from the FDA GLP requirements in that the EPA GLP regulations: (1) Incorporate GLP provisions for ecological effects and chemical fate testing; (2) require a signed statement by the sponsor and the study director that the study was conducted in compliance with the provisions of this part; (3) establish different mehods for assuring compliance in accordance with enforcement authority under TSCA and the consequences of non-compliance with this part; (4) establish different retention requirements for records and supporting material; (5) establish different retrieval of records and data requirements consistent with provisions of TSCA; and (6) do not establish provisions for disqualifying testing facilities. In the FDA regulation, one option provides for the disqualification of a testing laboratory (see 21 CFR 58.20 through 58.219) if a study was not conducted in accordance with GLPs. Since EPA has never formally proposed for comment a system for disqualifying testing facilities similar to FDA's, this regulation does not include a scheme for disqualification. EPA will consider proposing a scheme of disqualification similar to FDA's in the future.

2. *Consistency with OPP.* At the same time that the Agency was developing generic GLP Standards under TSCA, it was also developing GLP guidelines under section 3(c)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136). Although no separate GLP Guidelines were initially developed under FIFRA, GLP related standards were being incorporated into the general provisions section and the test specific sections of the individual pesticide test guidelines for evaluating hazards to humans and domestic animals (43 FR 37336; August 22, 1978). The Office of Pesticide Programs, after the GLP Standards proposal under TSCA, consolidated its GLP Standards provisions for health effects testing under FIFRA into one proposal published in the **Federal Register** of April 18, 1980 (45 FR 26373). This proposal was substantially similar to those proposed under TSCA. As a part of this final rulemaking procedure, the Agency has made every effort to harmonize the TSCA and FIFRA GLP Regulations except in those areas where there are different statutory needs and requirements. The FIFRA GLP are being published elsewhere in today's **Federal Register**.

3. *Consistency with Organization for Economic Cooperation and Development (OECD).* Since 1977, the EPA has been a full and regular partner in extensive international consultations concerning harmonization of chemical programs held under the auspices of the 24-nation Organization for Economic Cooperation and Development (OECD). During this time, U.S. experts, along with those of other OECD member countries, worked to develop agreed-upon guidelines for good laboratory practice. The principal objective of the guidelines effort was to assure, to the extent practicable under the laws of the OECD member countries, that data developed to meet one country's requirements would be acceptable to other countries. EPA placed a high priority on these activities because of benefits for international chemical trade and for more effective health and environmental protection. The United States strongly endorsed the work of the OECD Expert Group on GLP at meetings of high level national regulatory officials in May, 1980, and in November, 1982, at which the United States indicated its firm commitment to domestic implementation of the OECD GLP Guidelines. In May, 1981, the United States, along with the other OECD member countries, voted to adopt a formal decision on mutual acceptance of data. This decision binds member countries, to the extent practicable under the laws of OECD member countries, to accept data generated according to the OECD Test Guidelines and Principles of Good Laboratory Practice for assessment purposes.

The OECD Principles of Good Laboratory Practice (GLP) are comparable with the final FDA GLP Regulations but differ from those of the FDA in two areas. First, the OECD GLP Guidelines have been expanded to cover laboratories conducting chemical fate and environmental effects testing. Second, the OECD Principles are published as guidelines and do not contain any legally enforceable provisions. At this time, EPA has decided to publish a single TSCA GLP Standard covering testing for health effects, environmental effects, and chemical fate testing under TSCA. This is being done because EPA has determined that publication of a single GLP Standard containing general provisions that are applicable to all areas of testing will eliminate confusion and be consistent with the approach and scope taken by OECD.

EPA's decision is to promulgate its GLP Standards as regulations containing provisions which are to be enforced as requirements. EPA, in accordance with the OECD recommendation of the OECD Expert Group on Good Laboratory Practice, is developing a national GLP compliance program which is intended to ensure adherence to the Principles of GLP. EPA has already entered into an interagency agreement with FDA to conduct laboratory inspections and study audits for health effects testing. EPA inspectors and scientists may accompany FDA inspectors, Based upon available resources, EPA may conduct its own laboratory inspections and study audits or follow-up investigations. Comparable programs for conducting laboratory inspections and study audits for environmental effects and chemical fate testing will be carried out by the EPA. Although these final GLP regulations may not reflect the exact language of the Organization for Economic Cooperation and Development (OECD) GLP guidance document, the Agency believes that the OECD GLP Priciples are embodied in the final EPA GLP regulations. As indicated previously, the language of this final GLP regulation has been harmonized to the extent possible with the language of the FDA GLP regulations. This approach by EPA is considered the first phase of more closely harmonizing U.S. regulatory agencies' language and policies with respect to GLP regulations and GLP compliance programs. The statutory requirement under section 4(b)(2)(B) of TSCA provides for the annual review of standards. Under this mandate,the Agency will develop a process by which the TSCA GLP regulations will be brought into even closer harmony with the OECD Principles of Good Laboratory Practice. Furthermore, as a part of this process, the Agency is committed to working with the FDA to coordinate the mutual development of GLP regulations.

The Agency believes that the FDA and EPA GLP regulations and GLP compliance programs will provide the assurance to other nations that high quality test data are being developed in

this country and that they should be acceptable to other nations. Reducing the overall cost of testing by preventing duplicative testing should reduce the likelihood of non-tariff barriers to international chemical trade.

4. *Enforceability of these Regulations.* These GLP Standards are modeled after the final FDA GLP Regulations because EPA has the same concern about the quality and integrity of reported test data that FDA has. After an analysis of alternatives, EPA agreed with FDA that the best way to deal with this concern was via promulgation of GLP Standards that regulate test procedures.

EPA determined that implementation of GLP Standards as regulations containing enforceable provisions is justified on the basis of the need to assure the highest quality and integrity of the test data submitted to it under TSCA. The Agency agrees with FDA's position on the need to publish enforceable regulations instead of guidelines. Good Laboratory Practice is the major element in ensuring the reliability and adequacy of test data.

The Agency has determined that it will receive reliable and adequate data by promulgating GLP Standards comparable, in most respects, to those of FDA. Generally, EPA has adopted FDA provisions because they have been in use by laboratories for a number of years and the laboratories have become familiar with them. In addition, FDA provisions have already been subjected to considerable public comment, and the EPA sees no need to revisit all the issues in this rulemaking proceeding. If, at a later time, EPA or FDA finds that the GLP provisions should be modified, the public can be assured that the two Agencies will work together to bring about such changes. As test-specific rules are promulgated, more detailed descriptions may be necessary and will be presented for comment at the time of proposal.

5. *Applicability to negotiated testing agreements.* In appropriate circumstances, EPA has entered into negotiated testing agreements, in lieu of section 4 test rules, when the Agency determines that it can obtain needed data more quickly for high priority chemicals (see 47 FR 13012). This approach requires that industry provide to the Agency an acceptable testing plan including schedules, test methodology, data reporting components, and a commitment to carry out the testing plan according to EPA GLP Standards. Under such negotiated agreements, the Agency reserves the right to conduct inspection when the Agency determines that such inspections are appropriate. The Agency reserves the right to require testing through section 4 rulemaking including the incorporation of these GLP Standards should industry fail to meet its testing obligations including all aspects relating to GLP compliance.

6. *Applicability to section 5 of TSCA.* The Agency has instituted a policy that test data developed under section 5 and submitted to the Administrator should be developed under the provisions of this part.

7. *Applicability to ongoing industry testing.* On a case-by-case basis, the Agency may decide that testing under section 4 is not warranted because of ongoing and planned testing by industry which is expected to provide information from which the effects of concern can be reasonably determined or predicted. In these specific cases, the Agency expects that these studies will be conducted in accordance with the provisions of this part. In addition, the Agency, at its discretion, may select all or some of these studies for inspection and/or study audit. This policy is necessary to assure that the data are reliable and adequate and provide a basis for EPA's decision whether to initiate rulemaking under section 4 or to control the chemical under section 6 of TSCA.

## IV. Issues/Responses to Public Comments

EPA proposed and requested comment on several issues related to testing and to GLP compliance under proposed Part 770—Test Rules for Chemical Substances and Mixtures published in the **Federal Register** of May 9, 1979 (44 FR 27347) and proposed Part 772—Standards for Development of Test Data in the **Federal Register** of May 9, 1979 (44 FR 27369) and of November 21, 1980 (45 FR 77332). Comments and responses that follow refer to the proposals cited above and the decisions reflecting them are promulgated in Part 792, Subpart A—General Provisions.

### *A. General Provisions*

i. Clarification/objections to definitions:

1. *Comment.* The definition of "raw data" should not include contractual and economic correspondence because this type of information is not generally relevant to the assessment of a study. Furthermore, FDA does not include such information within its definition of raw data.

*Response.* EPA has not included contractual and financial correspondence in the definition of raw data in its final rule. The Agency believes that in the normal course of their business, testing facilities will retain contractual and financial information. Thus, regulation in this case seems unwarranted.

EPA may, nevertheless, inspect these records during the course of laboratory inspections on a case-by-case basis. While EPA agrees that such records will not need to be reviewed on a routine basis, there may be situations where review will be necessary to determine compliance (in fact, TSCA section 11, "Inspections and Subpoenas," contemplates this need). Therefore, EPA expects that such documents will be retained and reserves the right to inspect them as appropriate.

An example of EPA's use of contractual and financial information was demonstrated in the case of one testing facility in which the scope of their GLP problem was not apparent until records were reviewed which indicated that the testing facility had contracted to do more studies than they could possibly have done based on its resources. Even though such documents will not be reviewed routinely, they may be inspected and copied on a need-to-know basis and will be treated as TSCA Confidential Business Information (CBI), where appropriate.

2. *Comment.* EPA has expanded the definition of "raw data" to include "correspondence relating to the planning, conduct, and interpretation of the study." This requirement is unwarranted because it would require laboratories to retain and provide EPA with informal memoranda and other documents which reflect the preliminary observations and analyses of laboratory personnel.

The purpose of retaining raw data is to permit reconstruction and independent evaluation of study results by Agency scientists. The exposure of informal memoranda of test personnel to Agency scrutiny will serve only to inhibit the independent and candid evaluation of test data by industry scientists while testing is in progress.

*Response.* The Agency has reviewed these comments and believes that, on a case-by-case basis, it should have access to any notes or correspondence that would aid in the date assessment process. The Agency has removed correspondence relating to the planning, conduct and interpretation of the study from the definition of "raw data." However, it has included a requirement in § 792.190 that "correspondence and other documents relating to the conduct of a study and the interpretation and evaluation of data, other than those documents contained in the final report" be retained. As discussed below, this requirement is included because these documents may be needed by the

Agency for assessment and compliance monitoring purposes.

Under both TSCA and FIFRA, the availability of correspondence relating to the interpretation and evaluation of data is often helpful in the assessment process and for a quality control check on the testing facility's reporting system. The Agency believes that open discussion of scientific views are an intimate part of the assessment process. This policy has been exemplified within public institutions which utilize both internal and external peer review mechanisms to assess the scientific aspects of any study. Furthermore, EPA's experience in the data audit program under FIFRA indicates that documents relating to interpretation and evaluation of data are not only useful in the review of data but also reveal problems with a study which may not otherwise have been detected. In one case, a laboratory operated by a registrant/sponsor contracted with an outside laboratory to conduct the pathology interpretation. The report submitted to the Agency did not accurately reflect the contract pathologist's findings. The submitter had disagreed with the findings and changed them. The Agency believes that correspondence, particularly from consulting scientists such as pathologists and toxicologists, should be treated in the same manner as reports from contributing scientists within the testing facility. EPA has taken the position, as has FDA, that contributing scientists' reports should be appended to the final report.

The Agency has detemined that correspondence and other documents relating to the the conduct of a TSCA study be retained and made available for inspection. EPA considers documents concerning initiation or termination of a study, as well as changes in the study schedule, to be related to the conduct of a study within the meaning of § 792.190. EPA believes that this requirement is necessary to assure that testing schedules imposed by TSCA section 4 test rules and negotiated testing agreements are being met. If an established testing schedule is not being met, correspondence between the testing facility and sponsor can also reveal the reasons for an unauthorized delay.

As TSCA tests are conducted at EPA's initiative and schedule, adherenct to test schedules is an integral part of compliance with TSCA. For TSCA section 4 test rules, failure to test in accordance with specific schedules is a violation subject to a TSCA section 16 civil penalty. For TSCA negotiated testing agreements, failure to meet testing schedules can result in rescission of the negotiated testing agreement and promulgation of a TSCA section 4 test rule. The Agency therefore needs information about whether testing schedules are met and the reasons for delay in order: (1) To assess penalties for noncompliance with TSCA section 4 test rule schedules or, alternatively, (2) to promulgate a TSCA section 4 test rule in lieu of negotiated testing agreements where there is not a good cause for delay.

The FIFRA GLP regulation does not require retention of documents related to the conduct of a study because, in contrast to TSCA, not all testing is conducted at EPA's initiative and schedule. In the instance of FIFRA section 3(c)(2)(B) data call-in letters, where EPA does initiate and schedule testing, the Agency does not need information about the particular reason for delay to remedy noncompliance. If appropriate steps to secure the required data are not taken in a timely manner, the Agency suspends the pesticide registration.

ii. Authority to audit and inspect:

1. *Comment.* FDA does not have authority to audit data or inspect laboratories on behalf of EPA.

*Response.* The EPA disagrees with this comment. An Interagency Memorandum of Agreement, published in the **Federal Register** of April 24, 1979 (44 FR 24233) and renewed annually, provides for the data auditing and inspection of laboratories by FDA of selected health-related toxicity test reports and laboratory records to enable EPA to determine: (1) Whether testing was properly performed, and (2) whether test reports fully and accurately reflect test procedures. This agreement allows FDA to inspect and audit testing done for EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.) and the Toxic Substances Control Act (15 U.S.C. 2601). The agreement enables EPA and FDA to make the most efficient use of resources to achieve consistent regulatory policy, thereby improving the protection of the public and environment. The agreement cites 31 U.S.C. 686 (The Economy Act); 7 U.S.C. 136t and 15 U.S.C. 2625 as legal authority.

Sections 10 and 11 of TSCA constitute additional authority for FDA to audit data or inspect laboratories on behalf of EPA. TSCA section 10(a) mandates that [t]he Administrator shall, in consultation and cooperation with the Secretary of Health, Education and Welfare * * * conduct such * * * monitoring as is necessary to carry out the purpose of this Act. The Administrator may enter into contracts and may make grants for * * * monitoring under this subsection." The EPA believes the term "monitoring" under section 10(a) includes "compliance monitoring," such as investigations conducted by FDA pursuant to the Interagency Memorandum of Agreement, to ensure compliance with TSCA and applicable regulations.

Section 11(a) permits "any duly designated representative of the Administrator" to inspect facilities where chemicals are held. The term "representative of the Administrator" is not restricted to officers and employees of EPA.

2. *Comment.* FDA should handle all GLP inspections using inspectors who possess knowledge of and authority under FIFRA, TSCA, and the Federal Food, Drug, and Cosmetics Act. EPA should accept the FDA's schedule for inspection of laboratories on a routine basis and not impose additional routine GLP inspections.

*Response.* EPA disagrees with these comments. FDA cannot adequately conduct all GLP investigations for both Agencies because: (1) FDA does not have sufficient resources and (2) it does not have personnel with the training or experience to adequately inspect facilities conducting environmental effects and chemical fate testing. In addition, the Interagency Memorandum of Agreement with FDA does not provided for FDA inspection of facilities which only conduct environmental testing. Therefore, EPA inspectors will inspect facilities conducting environmental effects and chemical fate testing. Furthermore, under the Memorandum of Agreement, EPA inspectors and scientists may accompany FDA inspectors. EPA will conduct as many inspections as it deems necessary to assure that test data developed pursuant to a test rule or negotiated testing agreement under section 4 of TSCA, or data developed pursuant to section 5 of TSCA, are reliable and adequate. The Agency will not arbitrarily determine the number of inspections it must conduct in fulfillment of its TSCA responsibilities by limiting itself to FDA's inspection schedule. EPA will, however, continue to conduct inspections in coordination with FDA so as to avoid imposing duplicative inspections and to use inspectional resources efficiently.

3. *Comment.* EPA has no authority under TSCA to inspect laboratories. At best, the Agency could inspect laboratories owned by the sponsor who is subject to a testing rule, but has no

right under TSCA to inspect independent testing laboratories conducting tests under contract.

*Response.* The Agency disagrees with these comments. Although the comments suggested that the Agency differentiate between the types of testing laboratories, e.g., independent, contracting, sponsor's laboratories, etc., the Agency does not make this distinction either within this preamble or the final regulation. The responses that follow in this document will address responsibilities of testing laboratories. (See § 792.3 for the definition of a "testing facility".)

EPA considers a testing laboratory to be a place where chemicals are stored or held, and therefore, subject to inspections under section 11 of TSCA. Under TSCA section 11(a) "* * * any duly designated representative of the Administrator, may inspect any establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce * * *." Section 11(b)(2)(E) of TSCA also expressly indicates that the scope of inspection extends to "research data" required by TSCA or a rule promulgated thereunder. Furthermore, section 15 of TSCA states: "It shall be unlawful for any person to (3) fail or refuse to * * * (C) permit access to or copying of records, as required by this Act or a rule thereunder; or (4) fail or refuse to permit entry as required by section 11."

In addition, as noted in the preamble to the Good Laboratory Practice Standards for Health Effects (44 FR 27367), EPA's authority to inspect any laboratory, including any contract testing facility, derives from section 4(b)(1) of TSCA, which directs EPA to promulgate "standards for the development of test data." These standards are defined in section 3(12)(B) of TSCA to include those requirements necessary to assure that data developed under testing rules are reliable and adequate, and "such other requirements as are necessary to provide such assurance." The Agency remains convinced that laboratory inspections are necessary to provide this assurance. Without this opportunity to properly assess the quality of facilities and procedures used in developing health and environmental data, EPA would be restricted to reviewing written records. A mere paper representation is, of course, no substitute for the careful physical scrutiny which occurs during laboratory inspections.

iii. Penalties:

*Comment.* Penalties should be applied to cases of intentional, rather than inadvertent, misconduct.

*Response.* Unlike section 16(b) of TSCA, which applies to criminal violations, sections 15 and 16(a) are not limited to knowing or willful acts. EPA is authorized to assess civil penalties for both intentional misconduct and negligent or other inadvertent misconduct. Furthermore, in determining the amount of a civil penalty under section 16(a)(2)(B), EPA will take into account the seriousness of the violation and the degree of culpability of the violator as well as all the other factors listed in section 16(a)(2)(B).

iv. Foreign inspections:

*Comment.* Several commenters expressed concern about the Agency's approach toward inspection of foreign laboratories. Areas of concern ranged from the necessity of inspecting foreign laboratories to assure compliance with internationally recognized guidelines to EPA's authority to inspect in other countries.

*Response.* EPA, in developing these TSCA Good Laboratory Practice regulations, has also been an active participant in developing international GLP guidelines under the auspices of the OECD. The United States has been the lead country for this OECD Good Laboratory Practice project. EPA experts are currently participating in OECD efforts to: (1) Establish an international mechanism for recognizing the comparability of GLP compliance programs of each OECD Member country, and (2) develop a comparable inspection program that would be acceptable to other OECD Member countries which will ascertain proper study conduct and assure the quality of resulting test data. EPA, as well as FDA, has inspected and will continue to inspect foreign laboratories which conduct studies submitted to the Agency and will hold those testing facilities accountable to the same GLP requirements as United States laboratories. As part of its work to implement the OECD Principles of Good Laboratory Practice intended to assure the mutual acceptance of test data, EPA will help devise an internationally acceptable approach toward inspection of foreign laboratories.

v. Unannounced inspections:

*Comment.* Inspections should not be performed unannounced in order to ensure the integrity of the inspection process. Other comments suggested that EPA should inform sponsors and permit their presence at any inspection of an independent testing facility conducting section 4 testing for the sponsor. Testing facilities should be able to obtain approval of the sponsor before an unannounced inspection is conducted or, alternatively, EPA should get approval directly from the sponsor.

*Response.* The Agency maintains that the possibility of unannounced inspections both motivates compliance and efficiently uses resources. Furthermore, EPA and FDA, as a matter of policy, have conducted unannounced inspections and have found them to enhance compliance. While EPA reserves the right to perform unannounced inspections, it will generally notify laboratories up to two days prior to inspection in order to minimize inconvenience by assuring the availability of appropriate personnel and records. Once EPA notifies a laboratory, it will not change the date of inspection unless the laboratory demonstrates unusual circumstances and good cause.

While the Agency does not object to the presence of sponsors of section 4 testing or negotiated testing agreements during an inspection of a testing facility conducting studies for that sponsor, the Agency generally will neither: (1) Notify sponsors separately, nor (2) arrange for sponsors to accompany the inspector for two reasons. First, the sponsor and the testing facility are jointly responsible for proper conduct of the test. Only one notification therefore need be made. If time permits, the testing facility may itself inform the sponsor. Second, considerations of administrative efficiency realistically may prevent EPA from notifying sponsors separately and arranging for their presence at an inspection. As more testing is conducted under TSCA section 4 test rules, through negotiated testing agreements, or under section 5, each test facility will be testing for an increasing number of sponsors. The Agency may perform a GLP inspection of a facility which is conducting tests for more than one sponsor. It is impracticable to notify each sponsor of a GLP inspection, which may not focus on a single study but rather on laboratory operations in general. EPA will, however, notify the sponsor in the rare event that the testing laboratory refuses entry to inspectors.

The Agency does not believe that it needs to get approval for an inspection directly from the sponsor. Furthermore, the Agency disagrees with the assertion that testing laboratories need to obtain approval of the sponsor immediately before the Agency conducts an unannounced inspection. Because EPA has determined that regular GLP inspections are essential to assure the quality and integrity of test data

ubmitted to the Agency, sponsors annot help but be aware that aboratories conducting testing for them nder TSCA section 4 test rules, egotiated testing agreements, or section will be subject to periodic GLP nspections. EPA expects that sponsors vill generally give their approval to the esting laboratory well before testing ommences so as to ensure compliance vith the GLP Standards. Sponsors may ndeed wish to assure that EPA's right to nspect a testing facility is included in ny contract because sponsors are ltimately responsible for test data they ubmit to the Agency.

vi. Inspection of Quality Assurance Jnit records:

*Comment.* EPA should exclude from GLP inspections Quality Assurance Unit QAU) records of findings and problems, r actions recommended and taken.

*Response.* The Agency requested ublic comment on this issue in its roposed Good Laboratory Practice Standards for Health Effects on May 9, 979 (44 FR 27365). The Agency oncluded that QAU records of findings nd problems, or actions recommended nd taken be excluded from routine GLP nspections. The Agency recognizes the eed to maintain a degree of onfidentiality if QAU inspections are to e complete and candid. The Agency ppreciates the concern that routine ccess by EPA to QAU records of this ype may diminish the usefulness of the QAU.

Section 792.35(d) requires testing acility management, upon request of a uly designated representative of EPA, o certify in writing that inspections are eing performed and recommended ction is being or has been taken. Any erson who submits a false certification f compliance is liable to prosecution nder 18 U.S.C. 1001. While EPA will not nspect QAU records during a routine udit, the Agency reserves its right of ccess to such records under special ircumstances, particularly in litigation.

vii. Refusal of entry:

1. *Comment.* What will EPA do when laboratory refuses entry to inspectors?

*Response.* The Agency expects that aboratories will generally consent to nspection in order to assure adequacy nd reliability of data. On April 11, 1979, EPA issued a Memorandum on "Conduct of Inspections After the *Barlow's* Decision" which outlines rocedures the Agency will follow in the are instance where entry is refused, 41:2451, Environmental Reporter, June 8, 1979). Where an inspector is refused ntry, EPA will determine whether to eek a warrant through the U.S. Attorney.

Section 15 of TSCA further provides that "[i]t shall be unlawful for any person to (3) fail or refuse to (C) permit access to or copying of records, as required by this Act or a rule thereunder; or (4) fail or refuse to permit entry or inspection as required by section 11." Refusal to allow entry for inspectional purposes will not, however, result in imposition of civil or criminal penalties under section 16 of TSCA where: (1) The refusal is based on the inspector's lack of a warrant, and (2) no right of warrantless entry exists.

Refusal to allow entry to inspectors may also result in issuance of a subpoena under section 11(c) of TSCA. Section 11(c) provides that "in carrying out this Act, the Administrator may by subpoena require the attendance and testimony of witnesses and the production of reports, papers, documents, answers to questions and other information that the Administrator deems necessary." In contrast to inspections, subpoenas are, however, far more burdensome for both the laboratory and Agency, and constitute a substantially less effective means of ascertaining adequacy and reliability of test data. Finally, by the terms of section 4, denial of inspection will result in EPA's not considering a study valid for purposes of showing that a chemical does not present adverse effects (see § 792.15). EPA's exercise of its responsibility to consider the weight to be given a study in the evaluation of a chemical is separate from any enforcement authority held by the Agency, such as imposition of civil or criminal penalties under section 16 of TSCA.

2. *Comment.* The Agency should not presume invalid any data submitted from a testing facility which refuses to permit inspections. Such invalidation: (1) Exceeds Agency authority where inspection is unlawful, and (2) is needlessly punitive because there may be valid justification for refusing inspection and the data may otherwise be acceptable. If laboratories refuse lawful inspections, then EPA should seek legal action such as section 16 civil and criminal penalties in lieu of automatically presuming a properly conducted study invalid. In addition, EPA should not utilize studies conducted by laboratories refusing inspection only for purposes of showing adverse effects while rejecting such studies that show no adverse effects. This policy is a double standard. If negative results are rejected, positive results should be rejected as well. [See May 9, 1979 proposal, §§ 770.5(c)(3), 770.5(d), 772.110-1(k)(2), 44 FR 27334 through 27362].

*Response.* EPA will conduct only lawful inspections, in accordance with section 11 of TSCA and relevant judicial decisions construing the Fourth Amendment of the U.S. Constitution. The Agency will not conduct inspections which exceed its authority.

In circumstances where the testing facility refuses entry to EPA or FDA inspectors, the Agency "will not consider reliable for purposes of showing that a chemical substance or mixture does not present a risk of injury to health or the environment, any data developed by a testing facility or sponsor that refuses to permit inspection" (see § 792.16(b)). Section 4(b)(1) of TSCA authorizes EPA to promulgate standards for development of test data. The Agency believes that it cannot rely upon test data for purposes of indicating that a chemical does not present an adverse health or environmental effect if the Agency is prohibited from inspecting a testing facility and its operating procedures to assure itself that data were developed in accordance with the applicable standards. The Agency believes that it is within its discretion to question the validity of any study when it has not had the opportunity to conduct on-site inspections. The Agency would be simply exercising its statutory responsibilities to assure itself that data submitted to the Agency was of the highest quality.

The Agency maintains that it may, at its discretion, rely upon studies conducted by laboratories refusing inspection for purposes of showing a chemical causes adverse effects. This policy is not a double standard, but rather enables the Agency to apply its expertise to information that it concludes is sufficient and reliable to adequately assess the potential risk a chemical may pose to human health or the environment. When FDA issued its final GLP regulations (43 FR 59990), it also rejected this double standard argument:

> A positive finding of toxicity in the test system in a study not conducted in compliance with the good laboratory practice regulations, may provide a reasonable lower bound on the true toxicity of the substance. The Agency must be free to conclude that scientifically valid results from such a study, while admittedly imprecise as to incidence or severity of the untoward effect, cannot be overlooked in arriving at a decision concerning the toxic potential of the product.

viii. Liability:

*Comment.* Conflicting comments were received on who should be liable for violations of GLPs. Comments questioned EPA's legal authority to

impose section 16 penalties for section 15 violations upon testing facilities suggesting that only sponsors be penalized. A distinction should be made between the sponsor and the testing laboratory in regard to accountability for infractions.

*Response.* After assessing both its own and FDA's experience with unreliable test data, EPA has determined that an enforceable set of GLP standards is necessary to assure adequacy and reliability of test data submitted to the Agency (see generally, 44 FR 27363–27364, May 9, 1979). The essence of an enforceable GLP program is EPA's ability to impose civil and criminal penalties on responsible parties for violations of regulatory requirements. The Agency has authority to proceed against both the sponsor of a test and the testing facility for failure to comply with these GLP Standards under sections 15 and 16 of TSCA; both the sponsor and testing facility are "persons" within the meaning of these sections.

Furthermore, the purpose of sections 4 and 3(12) is to assure adequacy and reliability of all test data received by EPA concerning health and environmental studies for which: (1) There is an insufficiency of data and experience, and (2) which are relevant to the Agency's assessment needs. Regardless of who performs the testing and submits the test data, EPA's need for adequate and reliable test data to support decisions affecting public health and the environment remains the same. In fact, section 3(12) of TSCA is not by its terms limited to manufacturers or processors; rather section 3(12) concerns any development of test data, without reference to who developed the data.

Although the sponsor who submits studies to EPA bears responsibility for the work performed for it by any testing facility, that fact in no way relieves the testing facility performing the work for the sponsor from responsibility for the portion of the study it has performed and those activities for which it is responsible. In order to make this clear in the regulations, EPA has included a requirement in § 792.10 that the sponsor "shall notify the consulting laboratory, contractor, or grantee that the service is, or is part of, a study that shall be conducted in compliance" with these GLP regulations. This will assure that all parties developing data are aware of their responsibilities under the regulation.

ix. Deviations from the test requirements:

*Comment.* The requirement to report all deviations from test requirements is excessive and should be deleted (see § 772.113–1(k)(1)(ii) of the Test Standards proposed on May 9, 1979), [44 FR 27351]. It is not necessary to justify deviations which result in the test exceeding the requirements.

*Response.* The Agency agrees. The requirement in the final regulation is "a description of all circumstances that may have affected the quality or integrity of the data" (§ 792.185(a)(9)). This language refers to circumstances that would adversely affect the validity of the study.

x. Incorporation by reference:

*Comment.* Many comments objected to the incorporation by reference in an Appendix of other laws, recommendations, and guidelines stating: (1) Many have no legal or regulatory standing, (2) they are redundant and/or fall within the purview of other agencies, (3) for some guidelines there is no provision for public review when they are amended as required by the Administrative Procedure Act, 5 U.S.C. 553, (4) the economic impact was not considered, (5) it promotes confusion and is inconsistent with the FDA GLPs, (6) it would be restrictive of improvements in equipment technologies, (7) radioactive materials are already highly regulated, and (8) the GLPs should be complete in themselves.

*Response.* The Agency is in general agreement with some of the comments; however, it believes that reference to other guidance or regulatory documents is appropriate under some circumstances. In order to be consistent with FDA, the Agency has deleted these requirements from the GLP regulation but will expect testing facilities to be familiar with and utilize appropriate references such as those cited in its earlier GLP proposals.

xi. Penalties associated with minor violations:

*Comment.* Some comments concerned questions about EPA actions regarding minor violations of GLPs.

*Response.* The TSCA Penalty Policy takes into account the gravity of the violation. Minor infractions will be treated differently from major infractions.

*B. Organization and Personnel*

In the TSCA rulemaking proceedings, several comments expressed approval of EPA's requirements for personnel qualifications in the proposed Test Standards published in the **Federal Register** of May 9, 1979 [44 FR 27334; §§ 772.113–1(e)] and of July 26, 1979 [44 FR 44054, § 772.100–2(b)], and in the proposed GLP Standards of November 21, 1980 [45 FR 77353; §§ 772.110–3(b) and 772.110–4(b)], (now § 792.29). Numerous comments, however, stated that these EPA personnel requirements were unnecessary or too restrictive. Still others agreed that EPA should specify who is qualified to perform the requisite studies but suggested different qualifications from those proposed by EPA.

*Comment.* EPA's personnel requirements are too stringent. EPA's detailed and stringent requirements for personnel, proposed §§ 772.113–1(e), 772.100–2(b), 772.110–3(b) and 772.110–4(b), will have a negative effect on the testing industry because: (1) There is a limited availability of qualified personnel, (2) certification of personnel does not ensure the quality of work provided, (3) some qualified foreign scientific personnel may be excluded, (4) the requirements may eliminate qualified but not certified personnel and stifle professional judgment, and (5) such requirements are management's responsibility.

*Response.* On the basis of the reasoning stated in the comments, the Agency has decided not to specify exactly what scientific disciplines, education, training or expertise should be used in any specific study. The Agency has, therefore, adopted the FDA approach to personnel in which these factors, which vary from study to study, are left to the discretion of responsible study directors and management. The Agency has adopted this approach in the following sections of the GLP regulations: §§ 792.29, 792.31, and 792.33. The Study Director and testing facility management will be responsible for the type and number of personnel and for the quality and integrity of the data these personnel will collect, analyze, document, and report. The Agency urges, however, that management and Study Directors exercise great care in considering personnel qualifications for a particular study.

*C. Facilities*

i. Bedding used in animal cages or pens:

*Comment.* EPA should delete any bedding requirments in the proposed §§ 772.110–1(f)(3)(viii) and 772.110–4(d)(2)(ix).

*Response.* The Agency does not see the need to delete the requirement that "bedding used in animal cages or pens shall not interfere with the purpose of the study * * *" (now § 792.90(i)). This requirement is identical to the one in the FDA GLP's and has undergone considerable public comment and evaluation prior to its final publication (43 FR 59986).

ii. Dietary requirements and dietary contaminant analysis:

*Comment.* The dietary and contaminant requirements in the proposed §§ 772.110–1(f)(3)(vii) and 772.110–4(d)(2)(viii) are too restrictive and any effect caused by contaminants or dietary constituents would be expressed in the concurrent control groups.

*Response.* After careful review of the comments and the published literature, the Agency has determined that feed and water used for animal studies shall be analyzed periodically to ensure that contaminants known to be capable of interfering with the study and likely to be present in feed or water are not present at concentrations that would compromise the assessment of the study (§ 792.90(g)). The Agency has decided not to require a specific diet in these GLP regulations. However, on a case-by-case basis, for long-term chronic or reproductive testing on specific chemicals, food and/or water consumption data must include source of diet or nutrients, contaminants found in the diet or nutrients, and their concentrations. EPA, as well as FDA, expects that if any of the above parameters are in deviation from acceptable control levels, they will be reported to the Agency as they would be a basis of concern in the assessment process. The Agency requires that study reports include descriptions of the test system and circumstances that may have affected the quality and integrity of the data (43 FR 59986).

Although the Agency is not specifying how or what contaminant will be tested, it does require that the ones normally present should be quantitatively determined (§ 792.120(a) (9)). Although toxic effects, if any, may be produced and expressed in the concurrent control group, the combination of the contaminant and test substance may involve chemical or biological interaction inducing antagonistic or potentiating effects not suggested by control findings. This information will assist the Agency in determining the impact of dietary nutrients and contaminants in the assessment of the chemical on the biologic test system.

*D. Equipment*

No substantive comments were received on this Subpart.

*E. Testing Facilities Operations*

No substantive comments were received on this Subpart.

*F. Test and Control Substances*

i. A flexible approach to stability and homogeneity determinations for test and control substances:

1. *Comment.* EPA should adopt a more flexible approach for stability determination of test and control substances under §§ 772.110–1(b)(1) and 772.110–2(b)(1) (now § 792.105) and analysis of such substances incorporated into a feed vehicle under §§ 772.110–1(b)(3) and 772.110–2(b)(3) (now § 792.113). These comments noted that FDA, in its GLP regulations, left determination of appropriate analytic procedures to the discretion of the Study Director (21 CFR 58.105), while EPA had proposed particular requirements for stability and homogeneity determinations in proposed test standards published along with GLPs under § 772.113–1(g) (44 FR 27351).

*Response.* The Agency had proposed more stringent requirements for stability and homogeneity for test and control substances in the proposed Test Standards for Chronic Health Effects (§ 772.113–1(g) (44 FR 27351) and has subsequently dropped this provision from its test guidelines. The Agency agrees that a more flexible approach should be accepted and has adopted, in this final rule, the approach taken by FDA in its final regulations, i.e., detailed analytical procedures for homogeneity and stability of test and control substances and dietary admixtures are up to the discretion of the Study Director of the test facility (under § 792.105(b); proposed §§ 772.110–1(b)(1) and 772.110–2(b)(1)).

2. *Comment.* EPA should not require a battery of stability studies as proposed in § 772.113–1(g) (44 FR 27351), including degradation product analysis, for every substance. For example, if there is considerable evidence that the test substance is stable, there is no need to test for degradation products because degradation can be expected to be minimal and toxic effects of degradation products will be measured during the test of the substance.

*Response.* The Agency, in its GLP Standards does not require a battery of stability studies. However, consistent with FDA's requirement, the stability of each test or control substance must be determined by the testing facility or sponsor prior to the study under § 792.105 (proposed §§ 772.110–1(b)(1) and 772.110–2(b)(1)); or if the stability cannot be determined prior to a study, periodic analysis of each batch shall be performed under § 792.105(b) (proposed §§ 772.110–1(b)(1)).

ii. Numerical requirements for stability and homogeneity of the test and control substances:

*Comment.* The requirements that the tester ensure that the administered substance contains at least 90 percent of the designated test substance concentration specified in the sponsor-approved protocol or that the initial mean concentration of the test substance must not vary more than five percent from the designated concentration are unduly restrictive and unrealistic under the proposed §§ 772.100–2(b)(3) and 772.113–1(g) (FR 44 27351). Reasons given for this position are: (1) When low levels of the test substance are used, analytic procedures may not be available which are sufficiently sensitive to verify the variances; (2) five percent may be impossible to achieve; (3) depending on differences in dose levels and route of administration ± 20 percent variation may occur. Similar considerations apply to the requirement that the variability for the test substance in an administered mixture must not exceecd ± 10 percent of the mean sample concentration among random samples of the mixture under proposed § 772.113–1(g) (44 FR 27351). As an alternative means of assuring homogeneity and uniformity of test substance concentration, several comments recommended that EPA should adopt FDA's approach which requires showing that the administered substance conforms to protocols as closely as possible by relying on mixing records and stability and dose preparation data. EPA should require the development and validation of a procedure for preparing a homogeneous dietary admixture and for determining stability of the test substance at the initiation of the study, under proposed § 772.110–1(b)(3). This procedure should be applied during the course of the study to the preparation of fresh treated diet. Random samples should be analyzed for homogeneity and concentration.

*Response.* The Agency has not included in this rulemaking the numerical requirements for stability and homogenity that were proposed in the Test Standards under § 772.113–1(g). However, the sponsor is responsible for providing data that would assure these chemical characteristics (§ 792.105). When evaluating a particular test, the Agency may examine test facility records to determine whether appropriate test substance stability and homogeneity have been achieved in accordance with the study plan. With respect to the development and validation of a procedure for preparing dietary admixtures, EPA believes that

this should be done by every testing facility as a part of their preparation and documentation of Standard Operating Procedures.

iii. Concurrent stability testing:

*Comment.* EPA should permit concurrent stability testing at the discretion of the Study Director. This would also assure test substance integrity. Proposed § 772.110–1(b)(1)(ii) (now § 792.105) requires establishment of stability before conducting testing and only allows concurrent stability testing if the test substance or mixture is too unstable for pre-study stability determination. In the case of exceptionally stable chemicals, stability testing may be extremely lengthy and may delay the start of testing and that, if there is good reason to believe satisfactory stability exists, a study confirming stability after initiation of the toxicity study is an efficient procedure. Other comments agree with the EPA proposal that stability testing should be conducted before testing. In fact, it was stated that EPA need not establish a mandatory requirement because it is illogical to assume that anyone would begin testing prior to stability evaluation.

*Response.* The Agency concludes that characterization of the stability of test or control substance should be determined before the initiation of the study in order to provide a means of controlling variations from batch to batch as well as to make certain that the test substance meets the specifications of the study plan. A thorough understanding of the nature of the test substance is a basic requirement for assuring the absence of contaminants that may interfere with the outcome of the study. FDA's regulations have the same provisions (see FDA regulations, 43 FR 60017).

iv. Acute phase testing without homogeneity and stability testing of the test material:

*Comment.* In certain studies, e.g., acute studies, the important parameter to measure is the absolute amount of material administered to the test animal. In these instances homogeneity of the test substance is not a crucial parameter under proposed §§ 772.110–1(b)(1) and 772.110–2(b)(1) (now § 792.105). Acute phase testing should be allowed prior to completion of stability testing for "known" stable chemicals.

*Response.* The Agency agrees that an important parameter to measure in an acute study is the total dose administered to the test animal. However, the investigator can be assured of appropriate dosing only if the homogeneity or uniformity of the test substance delivered in a vehicle is established. Otherwise the calculated dosage may be incorrect. Regarding the acute testing of test substances of "known" stability, stability of each test or control substance must be established prior to testing since there is no guarantee of the degree of degradation of any given batch of test chemical unless analysis is performed. Stability must be established for all test and control substances, unless those substances are too unstable to make it feasible, in which case periodic analysis of each batch is required under §§ 792.105 and 792.113 (formerly §§ 772.110–1(b)(1), 772.110–2(b)(1), and § 772.110–1(b)(3); also see FDA GLP regulations, §§ 58.105 and 58.113, 43 FR 60017–60018).

v. Responsibility for determining the homogeneity and stability of test mixtures:

*Comment.* It is the sponsor's obligation adequately to determine, document and report homogeneity and stability of mixtures. Some "testers" may not have technical capabilities to perform analytical studies in-house.

*Response.* The EPA believes that it is the obligation of the sponsor to ensure that all tests required by regulations have been completed. Testing facility management, if it is under contract to a sponsor, must assure that all tests under its responsibility have been done (see § 792.31(d) (formerly §§ 772.110–1(c)(2) and 772.110–2(c)(2)). In those cases where a testing facility is unable to perform the characterization testing, the sponsor must perform the required testing or have it performed by another facility and notify the original testing facility management of the results.

vi. Ideal vehicle:

*Comment.* EPA's requirement for composition of vehicles is an unrealistic requirement (see § 772.113–1(g), 44 FR 27351) of the proposed Test Standards. All vehicles will affect the metabolism and pharmacokinetics of a test substance to some degree and, therefore, it is not productive to try to create a perfect vehicle that will have no effect. Adoption of the EPA requirement would necessitate extensive and costly research on the effects of each vehicle on the distribution, metabolism or retention of a test substance or mixture. This would result in unnecessary cost and would discourage innovation. The sponsor or tester should be allowed to select the appropriate vehicle with the least non-desirable properties.

*Response.* The Agency concludes that the sponsor has every incentive to choose a proper vehicle with the least non-desirable properties. Therefore, the specific requirements section on vehicles that were proposed in the Test Standards under § 772.113–1(g) is not justified and is not included in the final EPA GLP rule.

vii. Retention of storage containers:

*Comment.* Proposed § 772.110–1(b)(1)(iii) (now § 792.107), which requires that storage containers be assigned to a particular test substance for the duration of the study is unnecessary and burdensome because: (1) It is burdensome to retain each container for the duration of the study once it has been emptied and, (2) it is more appropriate to retain the chemical in the original container submitted, rather than transfer it to a designated storage container although this may be advisable in some cases. Therefore, it was requested that the last sentence of § 772.110–1(b)(iii) (now § 792.107) be deleted.

*Response.* The intent of the storage container requirement of § 792.107 of this final rule is to ensure the purity of the test or control substance and prevent contamination with other chemicals. Storage containers may consist of the original container or a designated container or a combination of both. Standard laboratory practices for cleaning labware and preventing cross-contamination should be used for the short term storage of test chemicals, i.e., reagents and solutions. The Agency advises that any container that has been emptied during the course of a study must be disposed of in accordance with applicable regulations.

viii. Retention time for reserve samples of test or control carrier/substance mixture:

*Comment.* Since FDA has deleted their requirements for retention of reserve samples of each test or control carrier/substance mixture, having found such samples of uncertain value, EPA should do likewise to be consistent with the FDA GLP regulation (see proposed § 772.110–1(b)(3)(ii)). Reasons given include:

a. Provided adequate analysis is performed during the original study, additional requirements add nothing to quality or integrity of study or its support data.

b. Degradation of samples and the instability of carriers, e.g., feed mixtures, with time precludes accurately representing the original dose administered months or years before.

c. Other provisions of the GLP cover the purpose of this requirement adequately, e.g., Standard Operating Procedures (SOP's and Quality Assurance Unit (QAU).

d. Sheer number of retention samples is quite substantial and costly.

e. Time and effort to store, label, etc., samples would be unreasonable.

f. Re-examination of reserve samples would be extremely rare.

g. Maintenance of reserve samples may be a potential health hazard.

*Response.* The Agency has determined, based on these comments, that the requirement for retention of reserve samples of test or control substance carrier mixtures is unnecessary and has deleted it from the final TSCA GLP Standards.

*G. Protocol for and Conduct of a Study*

i. Detailed study plan:

*Comment.* Detailed study plans and status reports for routine chemical fate testing under proposed §§ 772.110–1(g)(1), 772.110–2(g)(1); and 772.110–4(e)(1) are cumbersome and unnecessary.

*Response.* The Agency agrees that this requirement for routine chemical fate testing is unnecessary for some testing such as pH, UV spectra, etc.; however, other tests such as persistence or degradation require a documented study plan. Consequently, those requirements that are applicable to chemical fate testing are listed in § 792.232 of the final rule.

ii. Study plan need:

1. *Comment.* Comments on the need for a study plan varied between those claiming there is no need for study plan submission in advance of the study or for Agency review of a study plan (under proposed §§ 772.113–1(f), 44 FR 27351) to those suggesting that review of the study plan should result in Agency approval or rejection.

*Response.* The Agency believes that the early development of a comprehensive study plan is necessary in order to conduct a systematic testing program resulting in the submittal of data in a timely manner. For example, under present policy, the Agency proposes the study plan for section 4(a) chemical-specific test rules under which it has the sole responsibility for detailing the testing schedule and the testing methodologies. When a negotiated testing agreement is indicated, the Agency works with the sponsor(s) to develop a timely study plan including testing schedules and appropriate chemical-specific test methodologies.

2. *Comment.* What is the difference between a "study plan" and "protocols?"

*Response.* A study plan is a comprehensive plan of the proposed study laying out such items as schedules, rationale, information concerning the sponsor and/or testing facility, the reporting needs and the protocol; the protocol is a subset of the study plan describing the experimental design and study conduct. The final GLP regulation addresses only the issues relating to the contents of the protocol.

*H. and I.—[Reserved]*

*J. Records and Reports*

i. Extent of reporting:

*Comment.* EPA should not require any more detailed reporting than FDA and should leave the contents of the final report to the discretion of the test sponsor.

*Response.* The general language in the GLP reporting section is now exactly the same as the final FDA GLP regulation. EPA agrees that the GLP reporting should be general. However, more specific reporting may be needed on a case-by-case basis in individual chemical-specific test rules, in negotiated testing agreements, or under section 5 testing. EPA may require that the final report contain additional information for some types of testing (e.g., chronic or reproductive studies) such as information concerning a description of the food and/or food consumption data including source of diet or nutrients, contaminants found in diet or nutrients, and their concentrations as well as water consumption data and, if suspect, water contaminants and their concentrations.

ii. Interim reports:

*Comment.* The EPA requirement of quarterly summary reports (as proposed in the Test Standards of May 9, 1979 in § 772.113–1(j)(2), 44 FR 27351) is valuable since it allows the Agency to take prompt regulatory action where necessary. However, many other comments stated that EPA's requirement may often be burdensome and impractical. Specific objections included: (1) The interim quarterly reports could be interpreted out of context, (2) if there are no scheduled sacrifices on a quarterly basis, there are little data available to report, and (3) cumulative incidence reporting is meaningless until termination of an experiment. Alternatives were suggested including notification of only significant findings, deletion of the requirement, and submission of an interim report at a six-month interval.

*Response.* In general EPA agrees with the comment suggesting that interim quarterly reports are inappropriate for all types of testing and has deleted them from the GLP requirements. However, on a case-by-case basis, the Agency may require interim reports for specific studies in chemical-specific test rules and in negotiated testing agreements. The deletion of this reporting requirement does not, however, relieve sponsors of the responsibility of reporting interim results when they indicate that the tested chemical presents a substantial risk as defined by section 8(e) of TSCA (also see the TSCA 8(e) reporting policy of March 16, 1978, 43 FR 11110).

iii. Route of administration:

*Comment.* If the route of administration is specified by test rules, a rationale for selection of route is not needed in a study report.

*Response.* The Agency agrees with the comment. Thus, the final report would require only a description of what the route of administration actually was and not a rationale for its selection because this will generally be specified in a chemical-specific test rule.

iv. Submission of raw data:

*Comment.* There were several objections to the EPA's requirements for submission on raw data (which includes individual animal data) in the final report (under the May 9, 1979 proposed § 772.113–1(k), 44 FR 27351). Objections included: (1) FDA found it impractical and required only a recapitulation of the data, (2) with respect to individual animal data, group data may be more meaningful than all raw data, (3) lists of cleaning and pest control agents should not be required, since they are already covered in the GLPs, (4) FDA inspections of data should apply, (5) loss of records and breach of confidentiality during shipping and/or storage of data may occur, (6) cost will be significant, and (7) submission of the raw data will be justified only in a few exceptional cases, e.g., where a testing laboratory goes out of business and the sponsor either cannot be identified or does not have appropriate storage facilities.

*Response.* The Agency agrees that it is not practical to submit all raw data in the final report, in all cases. Therefore, this requirement has been modified in § 792.185. However, specific data elements, in addition to the general reporting requirements found in this GLP Standard may be required in the testing of specific chemicals. The Agency needs only those data that are necessary to enable the Agency to perform adequate assessments. However, all raw data shall be retained for at least 10 years from the effective date of the applicalble final chemical-specific test rule or for at least 10 years from the publication date of the acceptance of a chemical-specific negotiated testing agreement (see final § 792.195(b)). With regard to an unidentified sponsor, where the testing facility goes out of business, or when raw data and documentation is transferred for any other reason, the

GLP Standard requires that the Agency be notified in writing under § 792.195(g) (proposed §§ 772.110–1(j)(3) and 772.110–2(h)(3)). This notification must include the new location and the responsible individual(s)

V. Data and calculations for each batch tested:

*Comment.* There is no need to report data and calculations for each batch of chemical tested (see TSCA Proposal: § 772.113–1(k)(v), 44 FR 27351). It should not be necessary for every solution administered to be analyzed.

*Response.* The Agency has detemined that information on each batch tested or analyses of every test solution administered is no longer required for submission in the final report. However, each batch must be appropriately defined, and documented before the initiation of the study (§ 792.105(a)).

vi. Rationale for selection of vehicles and reporting of contaminants in vehicles:

1. *Comment.* If a vehicle is in common use, then there should be no need to require a lengthy justification for why a vehicle is selected.

*Response.* The final GLP's do not require reporting the justification for the use of a vehicle but do require that control substances (which usually are used as vehicles for the test material) must be "* * * identified by name, chemical abstracts number or code number, strength, purity, and composition or other appropriate characteristics" under § 792.185(a)(4) (formerly §§ 772.110–1(j)(1)(i)(D) and 772.110–2(h)(1)(i)(D)).

2. *Comment.* It is inappropriate to require testing and reporting contaminants in vehicles because any effect caused by contaminants will be expressed as background in the vehicle control group.

*Response.* The Agency does not agree that testing and reporting contaminants in vehicles are unnecessary. Although toxic effects, if any, may be produced and expressed in the vehicle control group, the combination of the contaminant and the test substance may involve chemical or biological interaction including antagonistic or potentiating effects not suggested by control findings. Therefore, the tester must be aware of the composition of the test vehicles in order to properly assess its impact on the study (see final § 792.113).

vii. Fire resistant barriers:

*Comment.* EPA's requirement that tissue blocks must be separated for specimen slides by a fire resistant barrier in proposed § 772.110–1(j)(2)(ii) is superfluous and unnecessary because the cost of such barriers is expensive with little benefit since the chance of fire is so remote. It is the responsibility of the sponsor to provide the Agency with adequate support for the safety of data or rerun the test. The fire barrier requirement is vague and impossible to enforce because there are varying degrees of fire resistance and, therefore, no way to specify the resistance needed to protect the records adequately.

*Response.* On the basis of these comments and in order to be consistent with FDA, the Agency concludes that a fire resistant barrier is desirable but is unnecessary as a routine requirement if the testing facility provides a fire resistant archive facility. The Agency has deleted the requirement from the final GLP regulation.

viii. Statistical analysis of data:

*Comment.* Comments addressing EPA's general requirements for statistical analysis in proposed § 772.113–1(k)(1)(ix), 44 FR 27352, varied in that some agreed with the Agency's general approach to statistical methodology whereas others suggested that the EPA might in the future suggest more sophisticated statistical standards or that requirements for statistical analysis be deleted and replaced with a statement that statistical analysis be applied when appropriate. A suggestion was made that the investigators should be allowed to select a statistical package best suited to their experimental design. One comment also stated that EPA should provide professional statistical advice to cover special situations such as early deaths.

*Response.* The Agency has revised its requirements and has, in general, left the selection of statistical methods and analysis to the scientific discretion of the testing facility in § 792.185(a)(3) (formerly §§ 772.110–1(j)(1) and 772.110–2(h)(1)). However, EPA, as appropriate, may separately analyze data by different methods.

ix. Dissolution of business or ownership/transfer of records:

*Comment.* EPA proposed in § 772.110–1(j)(3)(vii) that if a testing facility or an archive contracting facility goes out of business, all records must be transferred to the archives of the sponsor of the study and EPA must be notified in writing about such transfer and the specific new location of the records. If a testing facility or archive contracting facility holding records of TSCA studies "changes ownership or management," the Agency and the sponsor must also concur with the disposition of the archives. Many comments stated that the EPA notification requirement was unnecessary because transfer of archives to the sponsor is automatic when contractor facilities go out of business and, in any event, it is sufficient to hold the sponsor responsible. A number of comments disagreed with EPA's need to concur in disposition of archives, stating that notification consistent with FDA's requirements is sufficient. In addition, EPA should delete or clarify the requirement to notify the Agency when a facility "changes ownership or management," because such a term is vague and will lead to uncertainty and inadvertent violation of the regulations.

*Response.* The Agency has decided to retain the notification requirement to be consistent with FDA in order to be able to locate the appropriate data if needed for regulatory purposes (see final § 792.195(g)). The notification and concurrence requirement for EPA and the sponsor when management or ownership changes has been deleted.

x. Retention time for records:

*Comment.* The following comments were submitted on the proposed TSCA GLP required 10 year retention time for documentation records, raw data and specimens under the proposed § 772.110–1(j)(3)(ii) (now § 792.195(b)):

1. The retention of raw data, specimens and other records should be for no more than 10 years.

2. EPA, in reference to the proposed § 772.110–1(j)(3), should be consistent with FDA on the maximum length of time required for retention of records (the FDA requirement is two to five years).

3. Different types of records should be maintained for different periods of time. For example: Test or control substances should be maintained according to their rate of degradation and records such as equipment calibration should be maintained for an intermediate time period.

4. Definite time limits on retention of raw data, specimens, and test substances should be established.

5. EPA should not establish a minimum length of time "original data" should be retained.

6. EPA should consider retention of data on a case-by-case basis to determine when records, test samples, etc. should be terminated.

7. EPA could reduce the cost burden if it permitted discard of data after such data have been subjected to EPA audit and validated.

*Response to comments 1 through 6.* The Agency concludes that "documentation records, raw data, and specimens pertaining to a study and required to be developed or collected by this part shall be retained in the archive(s) of the testing facility or sponsor for at least 10 years from the

effective date of the applicable final chemical-specific test rule under § 792.195(b) (formerly §§ 772.110–1(j)(3) and 772.110–2(h)(3)). The Agency also expects that all chemical-specific negotiated testing agreements will contain a provision requiring that the "raw data" from such an agreement be retained for at least ten years from the date of publication in the **Federal Register** of acceptance of the agreement. The Agency believes that this time period will permit sufficient time for the testing to be conducted and for the Agency to reveiw the results, to perform appropriate risk assessments, and, when necessary, institute appropriate regulatory control responses. This conclusion is based upon tests involving long-term studies which may take at least five years from the effective date of the final test rule or negotiated testing agreement to perform and to submit the final test data to the Agency. Assessment of study results may require an additional 1–2 years of internal and external peer review. In those cases, where the Agency decides to institute regulatory controls after testing, rulemaking proceedings and legal challenges may result in an additional 2–3 years before final resolution of issues. All studies, both short and long term, are relevant to assessing the potential risk of the test substance and, therefore, must be retained during this 10-year period. In those regulatory cases where the Agency's action may be challenged, it is imperative that all records, raw data, and specimens be available to support the Agency's decision(s). Section 792.195(c) (formerly §§ 772.110–1(j)(3) and 772.110–2(h)(3)) takes into account the retention of those specimens that may have a finite stability which may be less than 10 years by permitting the tester to retain those specimens only for the time that their quality and stability afford evaluation. In addition, in the case of section 5 testing, the sponsor determines the appropriate time to submit data to the Agency. Under these circumstances, the Agency believes that it is appropriate that documentation records, raw data, and specimens pertaining to the study be retained for a least 5 years following the date on which the results were submitted to the Agency. The Agency believes that this will provide sufficient time to review the results and to implement any appropriate regulatory decisions. In effect, EPA's data retention requirements are comparable to FDA's general requirement that data be retained for five years after the results are submitted to the Agency (see 21 CFR 58.195(b)(2)).

*Response to Comment 7.* The Agency agrees that some reduction in the cost burden could be realized if, under certain conditions as described in § 792.195(h), a sponsor or testing facility were permitted to discard data after such data have been subjected to an EPA audit. In these cases, data may be discarded only after EPA has notified the sponsor or testing facility in writing that its retention is no longer required by the Agency.

*K.—[Reserved]*

*L. Environmental Testing Provisions*

i. Applicability to chemical fate testing:

*Comment.* There is no need to apply GLPs to chemical fate testing.

*Response.* While it is true that some aspects of GLPs do not apply to chemical fate testing, many of the principles of GLP do apply to such testing (§ 792.232). Inapplicable would be sections and/or paragraphs that deal with animal handling, diet analyses, etc.

It is just as important to assure that chemical fate test data meet the same Agency requirements of adequacy and reliability that apply to other types of testing. Therefore, those sections and/or paragraphs of this GLP Standard that are deemed applicable to chemical fate testing are listed in § 792.232. Thus, appropriately designed and maintained facilities that allow for the proper administration and execution of laboratory studies are just as important in chemical fate testing as in testing for health and environmental effects. Similarly, the selection of appropriately trained and instructed personnel to conduct laboratory studies is an essential feature of any testing program. This universality of applicability would also include the maintenance and storage of records, maintenance and calibration of equipment, development of standard operating procedures for routine laboratory functions, and the retention of data for the time specified in the rule.

Many of the GLP provisions will not always be applicable to physical chemical fate testing but can be applied, if necessary, for testing on specific chemicals. For chemical fate testing, EPA may modify these GLP provisions based on functional activities of the laboratory. For example, it is not always reasonable to require the formation of a totally independent Quality Assurance Unit (QAU) for each chemical fate study. In the case of a small analytical chemistry laboratory, this may not be possible since the total number of employees would not warrant the formation of a QAU comprised of personnel that are entirely separate from and independent of those conducting a particular study. Thus, in a rule requiring chemical fate testing, EPA may establish a provision that the QAU may consist of the Study Director or other personnel involved in the study. Some of the other GLP requirements that are waived for chemical fate testing involve testing facility management. An example of this is the designation of a Study Director for each study wherein a study would involve a routine physical measurement on a single test substance. Although supervisory responsibility must be assigned for all laboratory work, it is not necessary to make such an assignment for each pH or density measurement on a particular chemical substance. Similarly, certain aspects of developing and keeping records would also be inappropriate to apply to all chemical fate testing. It would not be cost effective to require a detailed study plan for each routine physical chemical test. In those cases, supervisory responsibility would likely cover a series of routine functions rather than each study as defined in the GLP. Whenever this occurs, appropriate modifications in other GLP requirements related to the development and maintenance of records may have to be made with the Agency's approval. Finally, it is obvious that all sections and/or paragraphs of the GLP that refer to animal or plant testing would not apply to physical/chemical testing.

## V. Regulatory Assessment Requirements

### *A. Economic Analysis*

The GLP regulation delineates the organization, processes, and conditions under which laboratory studies are to be planned, performed, monitored, recorded, and reported under TSCA. These requirements may require additional personnel and facilities and therefore, may impose additional costs on laboratories performing testing. Some of these costs can be considered "up front" or "start up" costs; the demands of the marketplace may be such that a laboratory would have had to institute the prescribed procedures and processes before being able to solicit clients for their testing services. These GLP requirements may impose minimal additional costs on laboratories performing health effects testing as they are assumed to be meeting the FDA GLP standards (which are almost identical to the ones being promulgated by the EPA).

To evaluate the costs of the EPA GLP regulations, an EPA contractor, Borriston Laboratories, Inc., reviewed regulations in terms of facilities and

personnel requirements and estimated the additional costs for a laboratory and aggregate costs for the affected laboratories.

Based on their own experience as a testing laboratory, Borriston projected the additional technical and non-technical capabilities required to comply with the GLP regulation. Technical capabilities would include such items as additional technical personnel (needed for quality assurance, technical recordkeeping, verification of data, etc.), additional equipment, and supplies. Non-technical capabilities would include non-technical personnel (e.g., data clerk), storage and facility construction (if additional floor space for paper and test samples is needed), and utilities.

To estimate the additional costs of meeting these GLP requirements, Borriston used data from a 1981 telephone survey (conducted by EPA) of 285 commercial testing laboratories (inhouse and contract). The survey provided data on: the number of laboratories and the types of testing being performed; the size of the laboratories measured by square feet and number of employees; and the estimated dollar volume of testing per year. The survey found that of the 285 laboratories, 185 performed environmental effects and chemical fate testing. These 185 laboratories also included some that performed health effects testing as well. Testing (or industry sales) for environmental effects and chemical fate totalled $120 million in 1980.

Borriston grouped the various requirements into five costs categories: personnel (both technical and non-technical), equipment, supplies, storage construction, and utilities.

*Personnel.* For 185 laboratories, additional technical personnel costs amount to $8,700,000. Additional costs for non-technical personnel amount to $2,080,000.

*Equipment.* Borriston estimates that additional equipment may cost one-half of 1 percent of testing volume ($120 million) or $600,000.

*Supplies.* Additional supplies (paper, chemicals for standardization, controls, etc.) may cost one-half of 1 percent of testing volume or $600,000.

*Storage and facility construction.* The phone survey indicated that the average testing laboratory has 28,100 square feet. Borriston estimates that an additional 4 percent or 1,200 square feet will be needed. At $20 per square foot, this would amount to $24,000 in construction costs. Amortizing this cost over 30 years at 15 percent amounts to $3,700 in annual costs, or $684,000 for 185 firms. Costs for shelving and other types of storage containers are estimated to run one-half of 1 percent of the testing volume or $600,000.

*Utilities.* The additional space may mean added utility costs of $8,000 per laboratory per year. For 185 laboratories, this amounts to $1,480,000.

The total annual cost of the EPA GLP regulation is estimated to be approximately $80,000 per laboratory (or $15 million for 185 laboratories). These costs are likely to be considered either as direct or indirect overhead costs which will be allocated (amortized) over the tests that are performed.

This estimate may both overestimate and, to a lesser degree, underestimate the actual costs. The number of laboratories (185) used to calculate total industry costs include 70 laboratories that perform health effects testing as well as environmental effects and chemical fate testing. These 70 laboratories can be assumed to be meeting the FDA GLP regulations, and are likely to incur only minimal additional costs to comply with the EPA GLP regulations. Over-estimation of costs may also occur because the other laboratories may, for business reasons, have adopted all or portions of the FDA GLP requirements. On the other hand, there may be non-commercial (e.g., uniersity and government) testing laboratories that may now have to meet these additional requirements and will, therefore, incur the additional investment costs.

The estimated additional annual costs ($80,000) per laboratory is about 3 percent of the estimated $2.3 million of sales (dollar value of testing) of the average laboratory in 1980. The Agency does not expect that these additional costs will pose a significant economic impact on the commercial testing industry (or on the users of testing services).

Considering the entire commercial testing industry, it is clear that the demand for its services is substantially inelastic with regard to price. In part, this is because there are few substitutes for the services of the industry. While chemical producers can develop testing capabilities internally (and often do), in-house laboratories are also subject to GLP costs. Also, test costs are usually a very small fraction of the total cost of developing and maintaining a chemical in the marketplace. In most cases, even a large proportional increase in test costs will mean small increases in product costs on a percentage basis.

Thus, it can be concluded that a cost increase of about three percent of total revenues as a result of adoption of GLP requirements can be passed along to consumers and will have little effect on the industry as a whole. It is recognized however, that this conclusion might not hold for all individual commercial laboratories and there may be instances where competitors are placed at a relative disadvantage. Because the absolute level of costs is moderate, these instances should not be numerous.

The cost analysis is contained in the report, "Analysis of the Cost of EPA's Good Laboratory Practice Standards", Borriston Laboratories, Inc. 1982. Results of the industry survey are presented in the report, "Chemical Testing Industry: Profile of Toxicological Testing," 1981, EPA 560/4-81/003. Both documents are available in the Public Record for this rulemaking process.

*B. Classification of Rule*

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. The regulation for these Good Laboratory Practice Standards is not major because it does not meet any of the criteria set forth in section 1(b) of the Order.

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

*C. Regulatory Flexibility Act*

Under the Regulatory Flexibility Act (RFA) (15 U.S.C. 601, Pub. L. 96-354, September 19, 1980), EPA is certifying that this regulation will not have a significant impact on a substantial number of small entities.

These GLP regulations, when promulgated, may impose some costs on testing laboratories. As discussed in Unit V.A., these costs are not expected to pose any significant economic impact on testing laboratories or their customers.

*D. Paperwork Reduction Act*

The Paperwork Reduction Act of 1980 (PRA) (44 U.S.C. 3501 et seq.) authorizes the Director of OMB to review certain information collection requests by Federal agencies. The GLP Standards promulgated in this notice do not in themselves result in the recording or submission of information. Only when they are incorporated into test rules does the requirement for recording and reporting of information take effect. Because this regulation does not have impact until the GLP Standards are incorporated into chemical-specific test rules and, since the test rules are separate regulations requiring an analysis under the PRA, EPA believes

that the GLP Standards contained in this notice do not constitute information collection requests as defined in the PRA.

Although this rule does not contain any information collection requirements subject to the review and clearance functions of the PRA, each information collection element is necessary and will have practical utility to the EPA and government as a whole.

*E. Environmental Impact Statement*

EPA is not required to prepare an environmental impact statement under the National Environmental Policy Act (NEPA), 41 U.S.C. 4321 et seq. for test rules, and has determined that voluntary preparation of an environmental impact statement is not appropriate for regulations issued under section 4 of TSCA. See the preamble to the Agency's rules for compliance with NEPA published in the **Federal Register** of November 6, 1979 (44 FR 64174).

## VI. Public Participation and Records Requirements

*A. Public Participation*

Public participation has significantly influenced the development of the GLP Standards. During the development of the proposed Standards, numerous meetings and discussions were held with non-EPA scientists and scientists from other Federal agencies. Preliminary drafts of the proposed Standards were reviewed by industry and environmental groups.

The public comment period for receiving written comments on the Health Effects GLP Standards proposal extended from the May 9, 1979, proposal date until October 16, 1979. The public comment period for reviewing written comments on the environmental GLP proposals extended from the November 21, 1980, proposal date to January 21, 1981. In an effort to solicit additional public comment on the Health Effects GLP Standards, a public meeting was held in Chicago, October 15–16, 1979. A total of 72 submissions were received from the public in response to the two TSCA GLP proposals of May 9, 1979 (44 FR 27369) and November 21, 1980 (44 FR 77357).

*B. Public Record*

EPA has established a Public Record for this rulemaking (docket numbers OPTS–46003 and OPTS–46007). Documents in the record were identified in the proposed rules that were used as a basis for this rulemaking. These records include basic information considered by the Agency in developing this final rule. The Agency has supplemented the record with the following information:

(1) **Federal Register** Notices pertaining or pertinent to the this rule.

(2) Support documents.

(3) Minutes, summaries, or transcripts relating to public meetings held to develop the GLP Standards and Test Guidelines.

(4) Copies of all public comments received on the TSCA proposed Health Effects testing and GLP Standards.

(5) Copies of all public comments received on the TSCA proposed GLPs for physical, chemical, persistence, and ecological effects testing.

All publicly available published documents, including FDA's GLP Preamble (43 FR 59986) and the FIFRA GLP Preamble published elsewhere in today's **Federal Register** are incorporated in the rulemaking record. EPA also incorporates in the rulemaking record the public records in the FDA and FIFRA GLP regulations.

The administrative record for this action is available for public inspection in Rm. E–107 at the address noted above from 8:00 a.m. to 4:00 p.m. Monday through Friday, excluding legal holidays.

**List of Subjects in 40 CFR Part 792**

Good laboratory practice, Environmental protection, Hazardous materials, Chemicals.

Dated: October 31, 1983.

**William D. Ruckelshaus,**

*Administrator.*

Therefore, 40 CFR is amended by adding Part 792 to read as follows:

## PART 792—GOOD LABORATORY PRACTICE STANDARDS


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**Authority:** Sec. 4, 90 Stat. 2006; Pub. L. 94–469 (15 U.S.C. 2603).

### Subpart A—General Provisions

**§ 792.1 Scope.**

(a) This part prescribes good laboratory practices for conducting studies relating to health effects, environmental effects, and chemical fate testing. This part is intended to assure the quality and integrity of data submitted pursuant to section 4(a) of the Toxic Substances Control Act (TSCA) (Pub. L. 94–469, 90 Stat. 2006, 15 U.S.C., 2603 et seq.).

(b) This part applies to any study described by paragraph (a) of this section which any person conducts, initiates, or supports on or after December 29, 1983.

(c) It is the Agency's policy that all data developed under section 5 of TSCA should be in accordance with the provisions of this part. It is also EPA policy to incorporate this part into all chemical-specific negotiated testing agreements. If data are not developed in accordance with the provisions of this part, the Agency will consider such data insufficient to evaluate the health and environmental effects of the chemical

substances unless the submitter provides additional information demonstrating that the data are reliable and adequate.

**§ 792.3 Definitions.**

As used in this part the following terms shall have the meanings specified:

(a) [Reserved]

(b) "Batch" means a specific quantity or lot of a test or control substance that has been characterized according to § 792.105(a).

(c) "Control substance" means any chemical substance or mixture or any other material other than a test substance that is administered to the test system in the course of a study for the purpose of establishing a basis for comparison with the test substance.

(d) "EPA" means the U.S. Environmental Protection Agency.

(e) "FDA" means the U.S. Food and Drug Administration.

(f) [Reserved]

(g) [Reserved]

(h) "Person" includes an individual, partnership, corporation, association, scientific or academic establishment, government agency, or organizational unit thereof, and any other legal entity.

(i) "Quality assurance unit" means any person or organizational element, except the study director, designated by testing facility management to perform the duties relating to quality assurance of the studies.

(j) "Raw data" means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. "Raw data" may include photographs, microfilm or mocrofiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments.

(k) "Specimen" means any material derived from a test system for examination or analysis.

(l) "Sponsor" means:

(1) A person who initiates and supports, by provision of financial or other resources, a study;

(2) A person who submits a study to the EPA in response to a section 4(a) test rule and/or a person who submits a study under a negotiated testing agreement or section 5 rule/order to the extent the agreement or rule/order references this part; or

(3) A testing facility, if it both initiates and actually conducts the study.

(m) "Study" means any *in vivo* or *in vitro* experiment in which a test substance is studied prospectively in a test system under conditions to determine or help predict its fate, toxicity, metabolism, or other characteristics in humans, other animals and plants. The term does not include studies utilizing human subjects or clinical studies. The term does not include basic exploratory studies carried out to determine whether a test substance has any potential utility.

(n) "Study director" means the individual responsible for the overall conduct of a study.

(o) "Test substance or mixture" means a substance or mixture administered or added to a test system in a study, which substance or mixture is used to develop data to meet the requirements of a TSCA section 4(a) test rule and/or is developed under a negotiated testing agreement or section 5 rule/order to the extent the agreement or rule/order references this part.

(p) "Test system" means any animal, plant, microorganism, or subparts thereof, to which the test or control substance is administered or added for study. "Test system" also includes appropriate groups or components of the system not treated with the test or control substances.

(q) "Testing facility" means a person who actually conducts a study, i.e., actually uses the test substance in a test system. "Testing facility" encompasses only those operational units that are being or have been used to conduct studies.

(r) "TSCA" means the Toxic Substances Control Act (15 U.S.C., 2601 et seq.)

**§ 792.10 Applicability to studies performed under grants and contracts.**

When a sponsor or other person utilizes the services of a consulting laboratory, contractor, or grantee to perform all or a part of a study to which this part applies, it shall notify the consulting laboratory, contractor, or grantee that the service is, or is part of, a study that must be conducted in compliance with the provisions of this part.

**§ 792.12 Statement of compliance or non-compliance.**

Any person who submits to EPA a test required by a rule promulgated under section 4 of TSCA shall include in the submission a true and correct statement, signed by the sponsor and the study director, of one of the following types:

(a) A statement that the study was conducted in accordance with this part; or

(b) A statement describing in detail all differences between the practices used in the study and those required by this part; or

(c) A statement that the person was not a sponsor of the study, did not conduct the study, and does not know whether the study was conducted in accordance with this part.

**§ 792.15 Inspection of a testing facility.**

(a) A testing facility shall permit an authorized employee or duly designated representative of EPA or FDA, at reasonable times and in a reasonable manner, to inspect the facility and to inspect (and in the case of records also to copy) all records and specimens required to be maintained regarding studies to which this part applies. The records inspection and copying requirements shall not apply to quality assurance unit records of findings and problems, or to actions recommended and taken, except that EPA may seek production of these records in litigation or formal adjudicatory hearings.

(b) EPA will not consider reliable for purposes of showing that a chemical substance or mixture does not present a risk of injury to health or the environment any data developed by a testing facility or sponsor that refuses to permit inspection in accordance with this part. The determination that a study will not be considered reliable does not, however, relieve the sponsor of a required test of any obligation under any applicable statute or regulation to submit the results of the study to EPA.

(c) Since a testing facility is a place where chemicals are stored or held, it is subject to inspection under section 11 of TSCA.

**§ 792.17 Effects of non-compliance.**

(a) The sponsor or any other person who is conducting or has conducted a test to fulfill the requirements of a test rule promulgated under section 4 of TSCA will be in violation of section 15 of TSCA if:

(1) The test is not being or was not conducted in accordance with any requirement of this part;

(2) Data or information submitted to EPA under this part (including the statement required by § 792.12) include information or data that are false or misleading, contain significant omissions, or otherwise do not fulfill the requirements of this part; or

(3) Entry in accordance with § 792.15 for the purpose of auditing test data or inspecting test facilities is denied. Persons who violate the provisions of this part may be subject to civil or criminal penalties under section 16 of TSCA, legal action in United States district court under section 17 of TSCA, or criminal prosecution under 18 U.S.C. 2 or 1001.

(b) EPA, at its discretion, may not consider reliable for purposes of showing that a chemical substance or mixture does not present a risk of injury to health or the environment any study which was not conducted in accordance with this part. EPA, at its discretion, may rely upon such studies for purposes of showing adverse effects. The determination that a study will not be considered reliable does not, however, relieve the sponsor of a required test of the obligation under any applicable statute or regulation to submit the results of the study to EPA.

(c) If data submitted to fulfill a requirement of a test rule under section 4 of TSCA is not developed in accordance with this part, EPA may determine that the sponsor has not fulfilled its obligations under section 4 of TSCA and may require the sponsor to develop data in accordance with the requirements of this part in order to satisfy such obligations.

## Subpart B—Organization and Personnel

### § 792.29 Personnel.

(a) Each individual engaged in the conduct of or responsible for the supervision of a study shall have education, training, and experience, or combination thereof, to enable that individual to perform the assigned functions.

(b) Each testing facility shall maintain a current summary of training and experience and job description for each individual engaged in or superivising the conduct of a study.

(c) There shall be a sufficient number of personnel for the timely and proper conduct of the study according to the protocol.

(d) Personnel shall take necessary personal sanitation and health precautions designed to avoid contamination of test and control substances and test systems.

(e) Personnel engaged in a study shall wear clothing appropriate for the duties they perform. Such clothing shall be changed as often as necessary to prevent microbiological, radiological, or chemical contamination of test systems and test and control substances.

(f) Any individual found at any time to have an illness that may adversely affect the quality and integrity of the study shall be excluded from direct contact with test systems, test and control substances and any other operation or function that may adversely affect the study until the condition is corrected. All personnel shall be instructed to report to their immediate supervisors any health or medical conditions that may reasonably be considered to have an adverse effect on a study.

### § 792.31 Testing facility management.

For each study, testing facility management shall:

(a) Designate a study director as described in § 792.33 before the study is initiated.

(b) Replace the study director promptly if it becomes necessary to do so during the conduct of a study, and document and maintain such action as raw data.

(c) Assure that there is a quality assurance unit as described in § 792.35.

(d) Assure that test and control substances or mixtures have been appropriately tested for identity, strength, purity, stability, and uniformity, as applicable.

(e) Assure that personnel, resources, facilities, equipment, materials and methodologies are available as scheduled.

(f) Assure that personnel clearly understand the functions they are to perform.

(g) Assure that any deviations from these regulations reported by the quality assurance unit are communicated to the study director and corrective actions are taken and documented.

### § 792.33 Study director.

For each study, a scientist or other professional of appropriate education, training, and experience, or combination thereof, shall be identified as the study director. The study director has overall responsibility for the technical conduct of the study, as well as for the interpretation, analysis, documentation, and reporting of results, and represents the single point of study control. The study director shall assure that:

(a) The protocol, including any change, is approved as provided by § 792.120 and is followed.

(b) All experimental data, including observations of unanticipated responses of the test system are accurately recorded and verified.

(c) Unforeseen circumstances that may affect the quality and integrity of the study are noted when they occur, and corrective action is taken and documented.

(d) Test systems are as specified in the protocol.

(e) All applicable good laboratory practice regulations are followed.

(f) All raw data, documentation, protocols, specimens, and final reports are transferred to the archives during or at the close of the study.

### § 792.35 Quality assurance unit.

(a) A testing facility shall have a quality assurance unit composed of one or more individuals who shall be responsible for monitoring each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the regulations in this part. For any given study the quality assurance unit shall be entirely separate from and independent of the personnel engaged in the direction and conduct of that study.

(b) The quality assurance unit shall:

(1) Maintain a copy of a master schedule sheet of all studies conducted at the testing facility indexed by test substance and containing the test system, nature of study, date study was initiated, current status of each study, name of the sponsor, name of the study director, and status of the final report.

(2) Maintain copies of all protocols pertaining to all studies for which the unit is responsible.

(3) Inspect each phase of a study periodically and maintain written and properly signed records of each periodic inspection showing the date of the inspection, the study inspected, the phase or segment of the study inspected, the person performing the inspection, findings and problems, action recommended and taken to resolve existing problems, and any scheduled date for re-inspection. For studies lasting more than six months, inspections shall be conducted every three months. For studies lasting less than six months, inspections shall be conducted at intervals adequate to assure the integrity of the study. Any significant problems which are likely to affect study integrity found during the course of an inspection shall be brought to the attention of the study director and management immediately.

(4) Periodically submit to management and the study director written status reports on each study, noting any problems and the corrective actions taken.

(5) Determine that no deviations from approved protocols or standard operating procedures were made

without proper authorization and documentation.

(6) Review the final study report to assure that such report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study.

(7) Prepare and sign a statement to be included with the final study report which shall specify the dates inspections were made and findings reported to management and to the study director.

(c) The responsibilities and procedures applicable to the quality assurance unit, the records maintained by the quality assurance unit, and the method of indexing such records shall be in writing and shall be maintained. These items including inspection dates, the study inspected, the phase or segment of the study inspected, and the name of the individual performing the inspection shall be made available for inspection to authorized employees or duly designated representatives of EPA or FDA.

(d) An authorized employee or a duly designated representative of EPA or FDA shall have access to the written procedures established for the inspection and may request testing facility management to certify that inspections are being implemented, performed, documented and followed-up in accordance with this paragraph.

(e) All records maintained by the quality assurance unit shall be kept in one location at the testing facility.

## Subpart C—Facilities

### § 792.41 General.

Each testing facility shall be of suitable size, construction, and location to facilitate the proper conduct of studies. It shall be designed so that there is a degree of separation that will prevent any function or activity from having an adverse effect on the study.

### § 792.43 Animal care facilities.

(a) A testing facility shall have a sufficient number of animal rooms or areas, as needed, to assure proper: (1) separation of species or test systems, (2) isolation of individual projects, (3) quarantine of animals, and (4) routine or specialized housing of animals.

(b) A testing facility shall have a number of animal rooms or areas separate from those described in paragraph (a) of this section to ensure isolation of studies being done with test systems or test and control substances known to be biohazardous, including volatile substances, aerosols, radioactive materials, and infectious agents.

(c) Separate areas shall be provided for the diagnosis, treatment, and control of laboratory animal diseases. These areas shall provide effective isolation for the housing of animals either known or suspected of being diseased, or of being carriers of disease, from other animals.

(d) When animals are housed, facilities shall exist for the collection and disposal of all animal waste and refuse or for safe sanitary storage of waste before removal from the testing facility. Disposal facilities shall be so provided and operated as to minimize vermin infestation, odors, disease hazards, and environmental contamination.

(e) Animal facilities shall be designed, constructed, and located so as to minimize disturbances that interfere with the study.

### § 792.45 Animal supply facilities.

There shall be storage areas, as needed, for feed, bedding, supplies, and equipment. Storage areas for feed and bedding shall be separated from areas housing the test systems and shall be protected against infestation or contamination. Refrigeration shall be provided for perishable supplies or feed.

### § 792.47 Facilities for handing test and control substances.

(a) As necessary to prevent contamination or mixups, there shall be separate areas for:

(1) Receipt and storage of the test and control substances.

(2) Mixing of the test and control substances with a carrier, e.g., feed.

(3) Storage of the test and control substance mixtures.

(b) Storage areas for the test and/or control substance and test and control mixtures shall be separate from areas housing the test systems and shall be adequate to preserve the identity, strength, purity, and stability of the substances and mixtures.

### § 792.49 Laboratory operation areas.

(a) Separate laboratory space shall be provided, as needed, for the performance of the routine procedures required by studies, including specialized areas for performing activities such as aseptic surgery, intensive care, necropsy, histology, radiography, and handling of biohazardous materials.

(b) Separate space shall be provided for cleaning, sterilizing, and maintaining equipment and supplies used during the course of the study.

### § 792.51 Specimen and data storage facilities.

Space shall be provided for archives, limited to access by authorized personnel only, for the storage and retrieval of all raw data and specimens from completed studies.

### § 792.53 Administrative and personnel facilities.

(a) There shall be space provided for the administration, supervision, and direction of the testing facility.

(b) Separate space shall be provided for locker, shower, toilet, and washing facilities, as needed.

## Subpart D—Equipment

### § 792.61 Equipment design.

Automatic, mechanical, or electronic equipment used in the generation, measurement, or assessment of data and equipment used for facility environmental control shall be of appropriate design and adequate capacity to function according to the protocol and shall be suitably located for operation, inspection, cleaning, and maintenance.

### § 792.63 Maintenance and calibration of equipment.

(a) Equipment shall be adequately inspected, cleaned, and maintained. Equipment used for the generation, measurement, or assessment of data shall be adequately tested, calibrated, and/or standardized.

(b) The written standard operating procedures required under § 792.81(b)(11) shall set forth in sufficient detail the methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, calibration, and/or standardization of equipment, and shall specify remedial action to be taken in the event of failure or malfunction of equipment. The written standard operating procedures shall designate the person responsible for the performance of each operation, and copies of the standard operating procedures shall be made available to laboratory personnel.

(c) Written records shall be maintained of all inspection, maintenance, testing, calibrating, and/or standardizing operations. These records, containing the date of the operation, shall describe whether the maintenance operations were routine and followed the written standard operating procedures. Written records shall be kept of nonroutine repairs performed on equipment as a result of failure and malfunction. Such records shall document the nature of the defect, how and when the defect was discovered,

and any remedial action taken in response to the defect.

## Subpart E—Testing Facilities Operation

### § 792.81 Standard operating procedures.

(a) A testing facility shall have standard operating procedures in writing, setting forth study methods that management is satisfied are adquate to insure the quality and integrity of the data generated in the course of a study. All deviations in a study from standard operating procedures shall be authorized by the study director and shall be documented in the raw data. Significant changes in established standard operating procedures shall be properly authorized in writing by management.

(b) Standard operating procedures shall be established for, but not limited to, the following:

(1) Animal room preparation.

(2) Animal care.

(3) Receipt, indentification, storage, handling, mixing, and method of sampling of the test and control substances.

(4) Test system observations.

(5) Laboratory test.

(6) Handling of animals found moribund or dead during study.

(7) Necropsy of animals or postmortem examination of animals.

(8) Collection and indentification of specimens.

(9) Histopathology.

(10) Data handling, storage, and retrieval.

(11) Maintenance and calibration of equipment.

(12) Transfer, proper placement, and identification of animals.

(c) Each laboratory area shall have immediately available laboratory manuals and standard operating procedures relative to the laboratory procedures being performed, e.g., toxicology, histology, clinical chemistry, hematology, teratology, necropsy. Published literature may be used as a supplement to standard operating procedures.

(d) A historical file of standard operating procedures, and all revisions thereof, including the dates of such revisions, shall be maintained.

### § 792.83 Reagents and solutions.

All reagents and solutions in the laboratory areas shall be labeled to indicate identity, titer or concentration, storage requirements, and expiration date. Deteriorated or outdated reagents and solutions shall not used.

### § 792.90 Animal care.

(a) There shall be standard operating procedures for the housing, feeding, handling, and care of animals.

(b) All newly received animals from outside sources shall be placed in quarantine until their health status has been evaluated. This evaluation shall be in accordance with acceptable veterinary medical practice.

(c) At the initiation of a study, animals shall be free of any disease or condition that might interfere with the purpose or conduct of the study. If, during the course of the study, the animals contract such a disease or condition, the diseased animals shall be isolated. If necessary, these animals may be treated for disease or signs of disease provided that such treatment does not interfere with the study. The diagnosis, authorization of treatment, description of treatment and each date of treatment shall be documented and shall be retained.

(d) Warm-blooded animals, excluding suckling rodents, used in laboratory procedures that require manipulations and observations over an extended period of time or in studies that require the animals to be removed from and returned to their home cages for any reason (e.g., cage cleaning, treatment, etc.), shall receive appropriate identification (e.g., tattoo, toe clip, color code, ear tag, ear punch, etc.). All information needed to specifically identify each animal within an animal-housing unit shall appear on the outside of that unit.

(e) Animals of different species shall be housed in separate rooms when necessary. Animals of the same species, but used in different studies, should not ordinarily be housed in the same room when inadvertent exposure to control or test substances or animal mixup could affect the outcome of either study. If such mixed housing is necessary, adequate differentiation by space and identification shall be made.

(f) Animal cages, racks and accessory equipment shall be cleaned and sanitized at appropriate intervals.

(g) Feed and water used for the animals shall be analyzed periodically to ensure that contaminants known to be capable of interfering with the study and reasonably expected to be present in such feed or water are not present at levels above those specified in the protocol. Documentation of such analyses shall be maintained as raw data.

(h) Bedding used in animal cages or pens shall not interfere with the purpose or conduct of the study and shall be changed as often as necessary to keep the animals dry and clean.

(i) If any pest control materials are used, the use shall be documented. Cleaning and pest control materials that interfere with the study shall not be used.

## Subpart F—Test and Control Substances

### § 792.105 Test and control substance characterization.

(a) The indentity, strength, purity, and composition or other characteristics which will appropriately define the test or control substance shall be determined for each batch and shall be documented before the initiation of the study. Methods of synthesis, fabrication, or derivation of the test and control substances shall be documented by the sponsor or the testing facility.

(b) The stability of each test or control substance shall be determined by the testing facility or by the sponsor before initiation of a study. If the stability of the test or control substances cannot be determined before initiation of a study, standard operating procedures shall be established and followed to provide for periodic reanalysis of each batch.

(c) Each storage container for a test or control substance shall be labeled by name, chemical abstract number (CAS) or code number, batch number, expiration date, if any, and, where appropriate, storage conditions necessary to maintain the identity, strength, purity, and composition of the test or control substance. Storage containers shall be assigned to a particular test substance for the duration of the study.

(d) For studies of more than 4 weeks' duration, reserve samples from each batch of test and control substances shall be retained for the period of time provided by § 792.195.

(e) The stability of test and contol substances under the test conditions shall be known for all studies.

### § 792.107 Test and control substance handling.

Procedures shall be established for a system for the handling of the test and control substances to ensure that:

(a) There is proper storage.

(b) Distribution is made in a manner designed to preclude the possibility of contamination, deterioration, or damage.

(c) Proper identification is maintained throughout the distribution process.

(d) The receipt and distribution of each batch is documented. Such documentation shall include the date and quantity of each batch distributed or returned.

**§ 792.113 Mixtures of substances with carriers.**

(a) For each test or control substance that is mixed with a carrier, tests by appropriate analytical methods shall be conducted:

(1) To determine the uniformity of the mixture and to determine, periodically, the concentration of the test or control substance in the mixture.

(2) To determine the stability of the test and control substances in the mixture. If the stability cannot be determined before initiation of the study, standard operating procedures shall be established and followed to provide for periodic re-analysis of the test and control substances in the mixture.

(b) Where any of the components of the test or control substance carrier mixture has an expiration date, that date shall be clearly shown on the container. If more than one component has an expiration date, the earliest date shall be shown.

## Subpart G—Protocol for and Conduct of a Study

**§ 792.120 Protocol.**

(a) Each study shall have an approved written protocol that clearly indicates the objectives and all methods for the conduct of the study. The protocol shall contain but shall not necessarily be limited to the following information:

(1) A descriptive title and statement of the purpose of the study.

(2) Identification of the test and control substance by name, chemical abstract (CAS) number or code number.

(3) The name and address of the sponsor and the name and address of the testing facility at which the study is being conducted.

(4) The proposed starting and completion dates.

(5) Justification for selection of the test system.

(6) Where applicable, the number, body weight range, sex, source of supply, species, strain, substrain, and age of the test system.

(7) The procedure for identification of the test system.

(8) A description of the experimental design, including the methods for the control of bias.

(9) A description and/or identification of the diet used in the study as well as solvents, emulsifiers and/or other materials used to solubilize or suspend the test or control substances before mixing with the carrier. The description shall include specifications for acceptable levels of contaminants that are reasonably expected to be present in the dietary materials and are known to be capable of interfering with the purpose or conduct of the study if present at levels greater than established by the specifications.

(10) The route of administration and the reason for its choice.

(11) Each dosage level, expressed in milligrams per kilogram of body weight or other appropriate units, of the test or control substance to be administered and the method and frequency of administration.

(12) Method by which the degree of absorption of the test and control substances by the test system will be determined if necessary to achieve the objectives of the study.

(13) The type and frequency of test, analyses, and measurements to be made.

(14) The records to be maintained.

(15) The date of approval of the protocol by the sponsor and the signature of the study director.

(16) A statement of the proposed statistical methods to be used.

(b) All changes in or revisions of an approved protocol and the reasons therefor shall be documented, signed by the study director, dated, and maintained with the protocol.

**§ 792.130 Conduct of a study.**

(a) The study shall be conducted in accordance with the protocol.

(b) The test systems shall be monitored in conformity with the protocol.

(c) Specimens shall be identified by test system, study, nature, and date of collection. This information shall be located on the specimen container or shall accompany the specimen in a manner that precludes error in the recording and storage of data.

(d) Records of gross findings for a specimen from postmortem observations shall be available to a pathologist when examining that specimen histopathologically.

(e) All data generated during the conduct of a study, except those that are generated as direct computer input, shall be recorded directly, promptly, and legibly in ink. All data entries shall be dated on the day of entry and signed or initialed by the person entering the data. Any change in entries shall be made so as not to obscure the original entry, shall indicate the reason for such change, and shall be dated and signed or identified at the time of the change. In computer driven data collection systems, the individual responsible for direct data input shall be identified at the time of data input. Any change in computer entries shall be made so as not to obscure the original entry, shall indicate the reason for change, and shall be dated and the responsible individual shall be identified.

## Subparts H and I—[Reserved]

## Subpart J—Records and Reports

**§ 792.185 Reporting of study results.**

(a) A final report shall be prepared for each study and shall include, but not necessarily be limited to, the following:

(1) Name and address of the facility performing the study and the dates on which the study was initiated and was completed, terminated, or discontinued.

(2) Objectives and procedures stated in the approved protocol, including any changes in the original protocol.

(3) Statistical methods employed for analyzing the data.

(4) The test and control substances identified by name, chemical abstracts (CAS) number or code number, strength, purity, and composition or other appropriate characteristics.

(5) Stability of the test and control substances under the conditions of administration.

(6) A description of the methods used.

(7) A description of the test system used. Where applicable, the final report shall include the number of animals or other test organisms used, sex, body weight range, source of supply, species, strain and substrain, age, and procedure used for identification.

(8) A description of the dosage, dosage regimen, route of administration, and duration.

(9) A description of all circumstances that may have affected the quality or integrity of the data.

(10) The name of the study director, the names of other scientists or professionals, and the names of all supervisory personnel, involved in the study.

(11) A description of the transformations, calculations, or operations performed on the data, a summary and analysis of the data, and a statement of the conclusions drawn from the analysis.

(12) The signed and dated reports of each of the individual scientists or other professionals involved in the study, including each person who, at the request or direction of the testing facility or sponsor, conducted an analysis or evaluation of data or specimens from the study after data generation was completed.

(13) The locations where all specimens, raw data, and the final report are to be stored.

(14) The statement prepared and signed by the quality assurance unit as described in § 792.35(b)(7).

(b) The final report shall be signed and dated by the study director.

(c) Corrections or additions to a final report shall be in the form of an amendment by the study director. The amendment shall clearly identify that part of the final report that is being added to or corrected and the reasons for the correction or addition, and shall be signed and dated by the person responsible.

(d) A copy of the final report and of any amendment to it shall be maintained by the sponsor and the testing facility.

**§ 792.190 Storage and retrieval of records and data.**

(a) All raw data, documentation, records, protocols, specimens, and final reports generated as a result of a study shall be retained. Correspondence and other documents relating to the conduct of a study and the interpretation and evaluation of data, other than those documents contained in the final report, also shall be retained.

(b) There shall be archives for orderly storage and expedient retrieval of all raw data, documentation, protocols, specimens, and interim and final reports. Conditions of storage shall minimize deterioration of the documents or specimens in accordance with the requirements for the time period of their retention and the nature of the documents or specimens. A testing facility may contract with commercial archives to provide a repository for all material to be retained. Raw data and specimens may be retained elsewhere provided that the archives have specific reference to those other locations.

(c) An individual shall be identified as responsible for the archives.

(d) Only authorized personnel shall enter the archives.

(e) Material retained or referred to in the archives shall be indexed by test substance, date of study, test system, and nature of study.

**§ 792.195 Retention of records.**

(a) Record retention requirements set forth in this section do not supersede the record retention requirements of any other regulations in this subchapter.

(b)(1) Except as provided in paragraph (c) of this section, documentation records, raw data, and specimens pertaining to a study and required to be retained by this part shall be retained in the archive(s) for a period of at least ten years following the effective data of the applicable final test rule.

(2) In the case of negotiated testing agreements, each agreement will contain a provision that, except as provided in paragraph (c) of this section, documentation records, raw data, and specimens pertaining to a study and required to be retained by this part shall be retained in the archive(s) for a period of at least ten years following the publication date of the acceptance of a negotiated test agreement.

(3) In the case of testing submitted under section 5, except for those items listed in paragraph (c) of this section, documentation records, raw data, and specimens pertaining to a study should be retained in the archive(s) for a period of at least five years following the date on which the results of the study are submitted to the Agency.

(c) Wet specimens, samples of test or control substances, and specially prepared material (e.g., histochemical, electron microscopic, blood mounts, teratological preparation, and uteri from dominant lethal mutagenesis tests), which are relatively fragile and differ markedly in stability and quality during storage, shall be retained only as long as the quality of the preparation affords evaluation. In no case shall retention be required for longer periods than those set forth in paragraph (b) of this section.

(d) The master schedule sheet, copies of protocols, and records of quality assurance inspections, as required by § 792.35(c) shall be maintained by the quality assurance unit as an easily accessible system of records for the period of time specified in paragraph (b) of this section.

(e) Summaries of training and experience and job descriptions required to be maintained by § 792.29(b) may be retained along with all other testing facility employment records for the length of time specified in paragraph (b) of this section.

(f) Records and reports of the maintenance and calibration and inspection of equipment, as required by § 792.63 (b) and (c), shall be retained for the length of time specified in paragraph (b) of this section.

(g) If a facility conducting testing or an archive contracting facility goes out of business, all raw data, documentation, and other material specified in this section shall be transferred to the archives of the sponsor of the study. The EPA shall be notified in writing of such a transfer.

(h) Specimens, samples, or other non-documentary materials need not be retained after EPA has notified in writing the sponsor or testing facility holding the materials that retention is no longer required by EPA. Such notification normally will be furnished upon request after EPA or FDA has completed an audit of the particular study to which the materials relate and EPA has concluded that the study was conducted in accordance with this part.

## Subpart K—[Reserved]

## Subpart L—Environmental Testing Provisions

**§ 792.225 Applicability of this subpart.**

This subpart contains modifications to Subparts A through J that apply to environmental studies.

**§ 792.226 Additional definitions applicable to environmental studies.**

(a) "Test system" includes, in addition to those systems listed in § 792.3(p), chemical or physical matrices (e.g., soil or water), or subparts thereof, to which the test or control substance or mixture is administered or added for study.

(b) "Carrier" means any material (e.g., feed, water, soil, nutrient media) with which the test substance is combined for administration to test organisms.

(c) "Chemical fate studies" means studies performed for the characterization of physical, chemical, and persistence factors that may be used to evaluate transport and transformation processes.

(d) "Ecological effects studies" means studies performed for the development of information on non-human toxicity and potential ecological impact of test substances and their degradation and activation products.

(e) "Environmental studies" refers to either ecological effects studies or chemical fate studies or both.

(f) "Reference substance" means any chemical substance or mixture or material other than a test substance that is administered to or used in analyzing the test system in the course of a study for the purposes of establishing a basis for comparison with the test substance. For purposes of this Subpart all references to "control substance" in Subparts B through J also include "reference substance" as defined herein.

(g) "Vehicle" means any agent which facilitates the mixture, dispersion, or solubilization of a test substance with a carrier.

**§ 792.228 Ecological effects testing.**

The following additions and modifications to Subparts B through J of this Part apply to ecological effects studies.

(a) *Use of the term "animals".* The term "animal(s)" is used in Subparts B through J and shall be construed as including, when appropriate, plant and microbial test organisms.

(b) *Test system facilities.* The following provisions apply to facilities

used for ecological effects studies (refer to § 792.43):

(1) In tests with plants or aquatic animals, proper separation of species can be accomplished within a room or area by housing them separately in different chambers or aquaria. Separation of species is unnecessary where the protocol specifies the simultaneous exposure of two or more species in the same chamber, aquarium or housing unit.

(2) Aquatic toxicity tests for individual projects need to be isolated only to the extent necessary to prevent cross-contamination of different chemicals used in different tests.

(3) Facilities shall have proper provisions for collection and disposal of contaminated water, soil or other spent materials.

(4) The facilities shall have provisions to regulate environmental conditions (e.g., temperature, humidity, photoperiod) as specified in the protocol.

(5) For marine test organisms, an adequate supply of clean sea water or artificial sea water (prepared from deionized or distilled water and sea salt mixture) shall be available. The ranges of composition shall be as specified in the protocol.

(6) For freshwater organisms, an adequate, supply of clean water of the appropriate hardness, pH, and temperature, and free of contaminants capable of interfering with the study, shall be available.

(7) For plants, an adequate supply of soil of the appropriate composition, as defined in the protocol, shall be available as needed.

(c) *Test system supply facilities for ecological effects testing* (refer to § 792.45).

(1) When appropriate, plant supply facilities shall be provided. These include:

(i) Storage areas, as needed, for nutrients and soils.

(ii) Facilities for holding, culturing, and maintaining algae and aquatic plants, as specified in the protocol.

(iii) Facilities, as specified in the protocol, for plant growth (e.g., greenhouses, growth chambers, light banks).

(2) Facilities for aquatic animal tests shall be provided. These include aquaria, holding tanks, ponds, and ancillary equipment as specified in the protocol.

(d) *Standard operating procedures.* When appropriate, standard operating procedures shall be established for preparation and maintenance of incubators, greenhouses, or growth chambers.

(e) *Test system care for ecological effects testing.* The following modifications to § 792.90 apply to ecological effects testing:

(1) The health status of test organisms shall be evaluated in accordance with acceptable scientific practice.

(2) Adult reptiles and adult terrestrial amphibians must receive appropriate identification of individuals. Suckling mammals and juvenile birds are excluded from the requirement for individual identification unless otherwise specified in the protocol.

(3) Plants, invertebrate animals, aquatic vertebrate animals, and organisms that may be used in multispecies tests need not be housed in separate rooms, provided that they are adequately segregated to avoid mix-up and cross contamination.

(4) Pens and enclosures, aquaria, holding tanks, ponds, growth chambers, and other holding, rearing and breeding areas are also to be cleaned and sanitized at appropriate intervals.

(5) Soil and water used in plant studies require periodic analysis of contaminants.

(6) All plant and animal test organisms shall be acclimatized, prior to the initiation of the study, to the environmental conditions of the test.

(f) *Mixtures of substances with carriers.* The following modifications apply to the requirements of § 792.113:

(1) Determination of the uniformity of the mixture and of the concentration of the test or control substance in the mixture during the test shall only be accomplished to the extent required by the protocol.

(2) Determination of the stability of test and control substances in the mixture shall be done under the environmental conditions specified in the protocol.

(3) If a vehicle is used to facilitate the mixing of a test substance with a carrier, assurance shall be provided that the vehicle does not interfere with the integrity of the test.

**§ 792.232 Provisions applying to chemical fate studies.**

All provisions contained in Part 792 apply to the chemical fate testing except the following:

§ 792.31 (c), (d), and (g)
§ 792.35 (b) and (c)
§ 792.43
§ 792.45
§ 792.47
§ 792.49
§ 792.81 (b)(1), (2), (6) through (9), and (12)
§ 792.90
§ 792.105 (a) through (d)
§ 792.113
§ 792.120(a) (5) through (13), and (16)
§ 792.185(a) (5) through (8), (10), (12), and (14)
§ 792.195 (c) and (d)
§ 792.228.

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# Part IV

# Environmental Protection Agency

## Pesticide Programs; Good Laboratory Practice Standards; Final Rule

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 160**

**[PH-FRL 2437-3; OPP-30023C]**

## Pesticide Programs; Good Laboratory Practice Standards

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This action promulgates Good Laboratory Practice (GLP) Standards applicable to the conduct of laboratory studies which are used to obtain data for hazard evaluation pursuant to the data requirements established under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). This action is based on investigatory findings by the U.S. Food and Drug Administration (FDA) and EPA that some studies submitted in support of the health safety of regulated products and pesticides have not been conducted in accordance with acceptable practice, and that accordingly data from such studies have not always been of the needed quality and integrity. Conformity with this rule will help assure the high quality of laboratory testing required to evaluate the health safety aspects of registered pesticides.

**EFFECTIVE DATE:** This rule cannot take effect until 60 days of continuous session of Congress after publication of the rule. See Unit VII of the preamble for details.

**FOR FURTHER INFORMATION CONTACT:**

By mail: R. Bruce Jaeger, Hazard Evaluation Division (TS-769), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, D.C. 20460.

Office location and telephone number: Rm. 816, CM#2, 1921 Jefferson Davis Highway, Arlington, VA, (703-557-3713).

**SUPPLEMENTARY INFORMATION:** OMB Control Nos.: 2000-0468 and 2000-0483.

### I. Introduction

*A. Legal Authority*

These standards are promulgated under the authority of secs. 3, 5, 6, 8, 18, 24(c), and 25(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq., secs. 408, 409, and 701 of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 301 et seq., and Reorganization Plan No. 3 of 1970.

*B. Background*

Good Laboratory Practice (GLP) standards were originally proposed by EPA in the **Federal Register** of April 18, 1980 (45 FR 26373). The need for GLP standards for pesticide testing was based on the Agency's own experience and that of the U.S. Food and Drug Administration (FDA) in dealing with the integrity of data submitted to them in support of the health and safety of regulated products and pesticides. Inspections by FDA and EPA of several laboratories led to the discovery of unacceptable practices that, in turn, called into question the validity of the data submitted by those sources.

Prior to the April 18, 1980, proposal, the Agency had not proposed specifically designated GLP standards; rather, such standards had been incorporated into the general provisions section and data reporting section of proposed 40 CFR Part 163, Subpart F, published in the **Federal Register** of August 22, 1978 (43 FR 37336). Subpart F contained proposed guidelines for pesticide registration applicants on what data were required by EPA to evaluate hazards to humans arising from the use of a pesticide product. Proposed Subpart B of 40 CFR Part 163, published in the **Federal Register** of July 10, 1978 (43 FR 29696), also contained GLP-like provisions which, as proposed, would have applied to tests described by proposed Subpart F. In the April 1980 proposal, EPA's Office of Pesticide Programs (OPP) consolidated its GLP standards for human and domestic animal hazard evaluation in order to be more nearly consistent with those published by the FDA at 21 CFR Part 58 and those proposed under the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 et seq., in the **Federal Register** of May 9, 1979 (44 FR 2736).

*C. Consistency With FDA GLP Regulation*

As stated in the preamble to the April 18, 1980, proposal (45 FR 26373), it is the Agency's policy to reduce the burden on the regulated public that might arise from conflicting requirements that could be promulgated under different authorities. Most commenters on that proposal emphasized the need for consistency with the FDA GLP regulations. Accordingly, the final rule promulgated here follows the format of the FDA GLP regulation, and with only a few exceptions uses wording identical to FDA's. The remaining differences are explained in this preamble. After analyzing the Agency's needs and responsibilities under TSCA, FIFRA, and FFDCA, the purpose of GLP standards, the arguments set forth by the FDA for its approach and individual GLP provisions, the reasons presented in public comments for consistency, and the need to reduce any unnecessary burden on the regulated public, EPA finds no legal or scientific reason for promulgating GLP standards that differ substantially from those of FDA, except as explained in this document.

*D. Consistency With OECD*

Since 1977 the EPA has been a full and regular partner in extensive international consultations and negotiations held under the auspices of the Organization for Economic Cooperation and Development (OECD). During this time U.S. experts, along with those of other OECD member countries, worked to develop agreed-upon standards for good laboratory practice. The principal objective of the guidelines effort is to assure, to the extent practical under the laws of the OECD member countries, that data developed to meet one country's requirements would be acceptable to other countries. EPA placed a high priority on these activities because of benefits both for international chemical trade and for more effective health and environmental protection. The United States strongly endorsed the work of the Export Group on Good Laboratory Practices at meetings of high level national regulatory officials in May, 1980, and November, 1982, and firmly committed the United States to domestic implementation.

The OECD principles of good laboratory practice were developed from the final FDA GLP standards but differ from those of the FDA, and therefore from those of the EPA, in two areas. First, the OECD GLP standards have been expanded to cover laboratories conducting chemical fate and environmental effects testing. Second, the OECD principles are published as guidelines and do not contain any legally enforceable provisions.

EPA, in accordance with the OECD recommendation, is developing a national monitoring program which will ensure compliance with the GLP principles. EPA has already entered into an interagency agreement with FDA to conduct laboratory inspections and study audits for health effects testing. In addition, the Agency began training EPA inspectors to audit both toxicological and ecological effects data and to conduct follow-up investigations.

## II. Content of the Final Rule and Summary of Significant Comments and Responses

In the proposal, the GLP standards were designated as two new sections, §§ 163.80–6 and 163.80–7, and an appendix to Subpart F of Part 163. This final rule incorporates the GLP standards into a new Part 160 (40 CFR Part 160). The following redesignation table correlates the new sections with those proposed, and in most instances, references to the new sections will be used hereinafter.

| Old section | New section |
|---|---|
| 163.80–6(a)(1) | 160.1 |
| 163.80–6(a)(2) | 160.10 |
| 163.80–6(a)(3) | 160.3 |
| 163.80–6(b)(1) | 160.105 |
| 163.80–6(b)(2) | 160.107 |
| 163.80–6(b)(3) | 160.113 |
| 163.80–6(c)(1) | 160.29 |
| 163.80–6(c)(2) | 160.31 |
| 163.80–6(c)(3) | 160.33 |
| 163.80–6(c)(4) | 160.35 |
| 163.80–6(d)(1) | 160.41 |
| 163.80–6(d)(2) | 160.43 |
| 163.80–6(d)(3) | 160.45 |
| 163.80–6(d)(4) | 160.47 |
| 163.80–6(d)(5) | 160.49 |
| 163.80–6(d)(6) | 160.51 |
| 163.80–6(d)(7) | 160.53 |
| 163.80–6(e)(1) | 160.61 |
| 163.80–6(e)(2) | 160.63 |
| 163.80–6(f)(1) | 160.81 |
| 163.80–6(f)(2) | 160.83 |
| 163.80–6(f)(3) | 160.90 |
| 163.80–6(g)(1) | 160.120 |
| 163.80–6(g)(2) | 160.130 |
| 163.80–7(a) | 160.185 |
| 163.80–7(b) | 160.190 |
| 163.80–7(c) | 160.195 |
| Appendix | 160.12 |
| | 160.15 |
| | 160.17 |

As noted earlier, the final rule follows closely the FDA GLP rule in format and wording.

Subparts B through G are essentially identical to their counterparts in FDA's 21 CFR Part 58. As explained below, the EPA regulation contains no counterpart to FDA's Subpart K. Subparts A and J differ in some respects from the FDA version, as explained below. To the extent that the EPA and FDA provisions are identical, readers are referred to the preamble to FDA's final rule, published in the **Federal Register** of December 22, 1978 (43 FR 59986), for the basis for adopting those provisions; EPA agrees with the FDA Commissioner's supporting rationale concerning those provisions.

What follows in this portion of the preamble is a discussion of the few variations from the FDA regulation and a discussion of significant comments EPA received, organized to parallel the regulation's subparts.

### *A. General Provisions*

1. *Scope, purpose, and applicability.* Section 160.1 of the regulation deals with the scope, purpose, and applicability of this part. It is fashioned after FDA's 21 CFR 58.1, although conforming changes have been made here, as elsewhere, to reflect the fact that this is an EPA regulation implementing statutes EPA administers (FIFRA and FFDCA). A paragraph has been added specifying the studies to which this part applies. FDA, in the preamble to 21 CFR Part 58, treated this issue in the same way (43 FR 59987); for the convenience of users of the regulation who might not have ready access to this preamble, EPA has chosen to include this information in the regulations itself.

2. *Definitions*— a. *Application for research or marketing permit.* EPA has made conforming changes to the definition of this term to reflect differences in the statutes EPA administers. With respect to the appropriateness of this term, EPA refers interested persons to the discussion of the subject in the FDA preamble (43 FR 59991).

The 1978 and 1980 proposals indicated that the proposed GLPs would apply to studies submitted to support applications for registration under FIFRA section 3. There are a number of other FIFRA and FFDCA provisions, regulations, and procedures, under which persons seeking authorization to sell or distribute a pesticide (or authorization for food bearing pesticide residues to be sold), or seeking to persuade EPA to leave in effect an existing authorization, may submit data. These include FIFRA section 5 (experimental use permits), FIFRA section 18 (emergency exemptions), FIFRA section 24(c) and 40 CFR 162.153 (registrations for special local needs), FIFRA section 3(c)(2)(B) (data submitted to maintain existing registrations in effect), 40 CFR 162.11 (data submitted, e.g., to persuade EPA that cancellation proceedings should not be initiated), FFDCA section 408 (tolerances for pesticide residues on raw agricultural commodities), and FFDCA section 409 (food additive regulations). It is significant that data originally submitted for any one of these purposes likely will be later used by EPA for another of these purposes, including registration or reregistration. In view of the statements by most commenters that one set of GLPs should govern similar kinds of testing, no matter what the original purpose for conducting a study, and in view of the likelihood that tests once submitted will be used for a variety of purposes, including registration, EPA has chosen to define "application for research or marketing permit" broadly.

b. *Control substance.* FDA requires the testing of devices and electronic products which are not properly described as "substances." For this reason, FDA chose to use the terms "control article" and "test article" (43 FR 59990). However, EPA has chosen to use the terms "control substance" and "test substance," because under FIFRA and FFDCA, these terms most accurately reflect what will be used in the tests governed by this part.

c. *Raw data.* Most of the commenters on the April 1980 proposal argued the proposed definition of "raw data" (proposed § 163.80–6(a)(3)) should be modified so that a testing facility is not required to retain "correspondence relating to the planning, conduct, and interpretation" of the study. A variety of reasons were cited, including: correspondence is not "raw data"; exchanges between sponsors and testing facilities on costs and scheduling of tests are irrelevant to the Government and may contain trade secret or proprietary information; constructive criticism of the planning, conduct, and interpretation of studies will decrease, or will be delivered only orally, if documents containing such criticism must be disclosed to the Government; EPA should follow FDA's decision not to require retention of such documents; early comments may be misleading in view of later-developed data; other portions of the proposal would require reporting of relevant information, including interpretations of data, and the "correspondence" requirement thus is redundant; and filing and maintaining the correspondence is expensive.

The Agency has removed correspondence from the definition of "raw data" and treated it as a separate item in § 160.190 concerning storage and retrieval of records and data. In response to the comments regarding the particular problems associated with retention of correspondence relating to the planning and conduct of studies, the Agency has determined to delete the retention requirement for that type of correspondence. The following language is now found in § 160.190: "Correspondence and other documents relating to interpretation and evaluation of data, other than those documents contained in the final report, also shall be retained."

The Agency believes that the availability of documents containing or concerning interpretations or evaluations of study data often will be helpful in assessing the meaning of

completed studies, in providing information on studies in progress, and in assessing compliance with other provisions of the GLP regulation. EPA recognizes that retention of this correspondence may in some cases impose additional expense on persons subject to the GLP regulations, and that to some extent a retention requirement may lessen the willingness of testing personnel and others to reduce their views to writing. Those costs must be balanced against the benefits EPA expects the requirement will produce. The Agency doubts that the added burdens of retention will be significant. All pesticide producers have been subject to an essentially identical requirement since 1980 (40 CFR 169.2(k)), and EPA has not received any serious objections to those regulations.

The requirement applies to documents concerning data interpretation and evaluation that are not contained in the final report; thus, the requirement is not redundant. However, a testing-facility may include a copy of all such documents in the final report if it wishes to avoid the separate retention requirement for correspondence.

EPA is aware that great caution would have to be used in any attempt to draw regulatory conclusions from preliminary findings in as yet incomplete studies, because early or interim conclusions might prove unwarranted once data from the completed study become available and are evaluated. The primary purpose of the retention requirement is not to aid EPA in taking regulatory positions on the commercial use of chemicals still under test, but rather to allow evaluation of the studies once completed and to help EPA assess compliance with the GLP regulations.

d. *Study*. The corresponding FDA definition is for the term "non-clinical laboratory study." EPA has chosen the simpler term "study", with certain conforming modifications which make clear that covered studies are those which are designed to determine or help predict a test substance's toxicity to or metabolic or other behavior in humans and domestic animals.

e. *Test substance*. The EPA definition of test substance differs substantially from the EPA definition of "test article," primarily because it has been EPA's experience that often when pesticides are tested, it is not the pesticide product in the form it will be marketed which is tested, but rather a related substance (e.g., a relatively pure form of the active ingredient, a typical formulation, a metabolite, or a radioactive isotope of the active ingredient). Although FDA may have intended that all these substances would be included in the term "test article," the EPA definition expressly includes them.

f. *Abbreviations*. Finally, EPA has added a list of definitions of various abbreviations used in this part.

3. *Notification to consulting laboratories, contractors, and grantees*. Section 160.10 of these regulations parallels FDA's 21 CFR 58.10, with slight wording changes to make it clear that the duty of a sponsor or other person to notify the laboratory which does work on a study includes cases where the entire study is contracted out as well as cases where only a portion of the study is performed by someone other than the sponsor.

4. *Statement of compliance or non-compliance*. FDA's good laboratory practice regulations apply to some two dozen different regulatory programs. When FDA promulgated 21 CFR Part 58, it also promulgated a series of short additions to each of various regulations governing submission of data under those programs (43 FR 60020). Each of them says in substance what § 160.12 (a) and (b) of this EPA regulation say: that any applicant for a research or marketing permit who claims that the application is supported by data from a study to which this part applies shall include with the application a true and correct statement either: (1) Stating that the study was conducted in accordance with the GLPs, or (2) describing in detail any lack of conformity. EPA also has decided to allow the applicant the option of stating that he did not conduct or sponsor the study and does not know whether it conforms to the GLPs. EPA will include cross-references to this § 160.12 in regulations describing required contents of applications for pesticide research or marketing permits under FIFRA or FFDCA, when other changes are made to those latter regulations.

5. *Effects of non-compliance and inspection of a testing facility*. Section 160.15(a) of these regulations, concerning inspection of a testing facility, is similar to FDA's 21 CFR 58.15(a), appropriately modified to permit an authorized employee or duly designated representative of EPA to inspect the facility. A sentence has also been added specifying conditions under which QAU records may be obtained, e.g., only in litigation or formal adjudicatory hearings. FDA, in the preamble to 21 CFR Part 58, treated this issue in the same way (43 FR 59998); for the convenience of users of the regulation who might not have ready access to this preamble, EPA has chosen to include this information in the regulation itself.

In § 160.15(b) and § 160.17 of this regulation, EPA has spelled out the various possible consequences of the failure of a sponsor or testing facility to comply with the regulation. This is done for the convenience of readers. There are three sanctions that may be imposed:

a. EPA will not consider in support of an application for a research or marketing permit any data developed by a testing facility that refuses to permit inspection required by this regulation. This parallels FDA's 21 CFR 58.15(b), and originally was proposed in a similar fashion by EPA in proposed 40 CFR 163.40–5(d) (43 FR 29708).

b. EPA may refuse to consider reliable for purposes of supporting an application for a research or marketing permit any data from a study which was not conducted in accordance with this part. This provision parallels the FDA provision which appears at 21 CFR 58.215(b), and originally was proposed by EPA in similar form at 40 CFR (43 FR 29707). EPA will implement the provision in the same manner as FDA (see 43 FR 59989). In the FDA regulation, this sanction is described as an alternative to the more severe sanction of disqualification of a testing facility (21 CFR 58.200 through 58.219). Since EPA has never formally proposed for comment a system for disqualifying testing facilities similar to FDA's, this regulation does not include a scheme for disqualification. EPA will consider proposing a scheme of disqualification similar to FDA's in the future.

c. If an applicant submits a statement regarding the conformity of a supporting study to this regulation's requirements which is false, EPA may propose to cancel or suspend a registration granted on the basis of the assumed truth of the statement, to deny an application for registration, or to modify or revoke a tolerance or food additive regulation granted on the basis of the assumed truth of the statement. EPA has included this statement for the benefit of readers; it merely reflects current EPA-administered statutory provisions. See, e.g., FIFRA section 3(c)(1)(D), requiring "a full description of the tests made"; FIFRA section 3(c)(2)(B), requiring registrants to take "appropriate steps" to generate needed data; FIFRA section 3(c)(5)(B), requiring that an application for registration contain "material required to be submitted;" FIFRA section 6(b), authorizing the Administrator to cancel the registration of a pesticide if "material required to be submitted does not comply with the provisions of this Act;" FIFRA sections 12(a)(2)(M) and 12(a)(2)(N), making it

unlawful knowingly to falsify all or part of any application for registration, or any report filed under FIFRA; FFDCA sections 408(d)(1)(C) and 409(b)(2)(E), requiring that petitioners supply "full reports of investigations made;" FFDCA section 701(a), authorizing the Administrator to promulgate regulations governing procedures for amendment or repeal of tolerance and food additive regulations. The Agency has also included in § 160.17 a statement pointing out that submission of false statements may also be punishable under criminal laws, including 18 U.S.C. 2 and 1001 and FIFRA sections 12(a)(2)(M), 12(a)(2)(N), and 14, and may form the basis for civil penalties under FIFRA section 14. For a similar discussion in the FDA GLP preample, see 43 FR 60011.

Readers should also be aware that registrants of pesticide products are required by FIFRA section 6(a)(2) to report to EPA certain information concerning adverse effects of their products. See the **Federal Register** of Aug. 23, 1978 (43 FR 37611) and July 12, 1979 (44 FR 40716) for further information on this requirement.

*B. Organization and Personnel*

Several commenters expressed approval of EPA's requirements for personnel qualifications proposed at § 163.80–3(b)(1) (43 FR 37352). Numerous commenters, however, stated that EPA's personnel requirements were unnecessary or too restrictive. Still others agreed that EPA should specify who is qualified to perform toxicological studies but suggested different qualifications than those proposed by EPA. The following discussion takes up the specific issues on this topic.

1. *Stringency of personnel requirements.* Numerous comments indicated that the EPA's proposed detailed and stringent requirements for personnel would have a negative effect on the toxicology testing industry because:

a. There is a limited availability of qualified personnel.

b. Certification of personnel does not ensure the quality of work provided.

c. Qualified foreign scientific personnel would be excluded.

d. The requirements would eliminate qualified but not certified personnel and stifle professional judgment.

e. Such requirements are management's responsibility.

f. EPA would become a personnel-certifying organization.

On the basis of the reasoning stated in the comments, the Agency has concluded that it is inappropriate to specify exactly what scientific disciplines, education, training, or expertise should be used in a specific toxicology study. Therefore the EPA has adopted the FDA approach to personnel in which these factors, which vary from study to study, are left to the discretion of responsible management and study directors in § 160.29. They will be responsible for personnel selection and for the quality and integrity of the data the selected personnel will collect, analyze, document, and report. The Agency urges, however, that management and study directors exercise great care in considering personnel qualifications for a particular study.

2. *Responsible pathologist.* Commenters stated that EPA should not require that the pathologist responsible for the planning and conduct of all pathology and interpretation of results be Board-certified or Board-eligible or have equivalent training and experience, as proposed in § 163.80–3(b)(1)(iii)(A) (43 FR 37352). They felt the Agency should be consistent with FDA's approach (21 CFR 58.29), permitting the management of the testing facility to judge individual qualifications based on detailed knowledge of the appropriate personnel. The reasons given by these commenters were:

a. Certification *per se* does not necessarily guarantee quality work.

b. The availability of qualified pathologists is the rate-determining factor in determining the pace at which chemicals will be tested, and the proposed standards for qualifications are overly stringent and would exacerbate the situation.

c. There are not a sufficient number of Board-certified pathologists to comply with EPA's requirements.

d. The EPA standards, if adopted in the present form, would decrease the number of highly qualified scientists likely to enter toxicology testing.

e. The requirement would automatically disqualify foreign-trained personnel and foreign laboratories.

f. It would be virtually impossible for laboratories in the United States to employ only people with American qualifications as listed.

g. EPA might waive certification requirements for foreign labs and foreign-trained personnel, placing domestic laboratories at a competitive disadvantage.

h. American qualifications are inappropriate to apply to other countries and/or are contrary to the EPA's stated interest in achieving international harmonization of standards.

i. The certification requirements would prevent the performance of EPA-regulated tests outside the United States.

j. The EPA requirement for specific American qualifications for personnel will create a serious barrier to international trade.

k. In emphasizing licensing or certification of study professionals EPA is eliminating many individuals with experience, reliable performance, and reputation qualified to perform toxicological and pathological evaluations.

l. EPA's personnel requirements for pathologists would eliminate many well qualified toxicology pathologists with many years of experience but with backgrounds other than those stated in the proposed EPA guidelines. Indeed, many pathologists have acceptable qualifications of competency based on peer review and recognition, athough they cannot be expected to possess training equivalent to Board certification.

m. Regardless of the qualifications of the personnel, the only true measurement of whether one receives a quality lab report is based on the quality of the samples submitted and the overall qualifications of the lab, not personnel qualifications.

n. The requirements will tend to stifle professional judgment both in obtaining high-quality personnel and in the performance of professional duties. One commenter stated that the term "board eligible" should not be used.

o. The rule should allow for substitution of pathologists and veterinarians with equivalent training and experience as allowed by the FIFRA guidelines.

p. Excessive requirements will decrease the numbers of available qualified pathologists, toxicologists and technicians, thereby substantially slowing down the entire chemical testing process and limiting the number of chemicals tested.

q. EPA should specify the certifying board or boards when referring to "board certification."

The EPA is persuaded by the comments that it should not specify the individual qualifications of the pathologist responsible for the planning and conduct of the pathology procedures. Therefore, these requirements were not included in the final rule.

3. *Suggested changes in the qualifications requirements for pathologists and technicians.* Several suggestions were received on the qualifications, specifications and criteria for pathologists, and technicians. These suggestions are detailed below.

a. *Pathologists.* For pathologists, the suggestions include the following:

(1) One commenter suggested the following definitions for qualified pathologists and support professionals:

(a) Veterinarian(s) certified by the American College of Veterinary Pathologists with a minimum of three years of experience in laboratory animal pathology.

(b) Physician(s) (M.D. or D.O.) certified by the American Board of Pathology with a minimum of three years of experience in laboratory animal pathology.

(c) Veterinarian(s) or physician(s) (M.D. or D.O.) with a minimum of three years of experience in animal histopathology.

(d) Veterinarian(s) or physician(s) (M.D. or D.O.) with training in pathology sufficient to perform necropsies.

(e) Non-medical doctorate (Ph.D.) with training in animal pathology.

The commenter further stated that overall supervision and responsibility for pathology evaluation of animal tissues from toxicologic tests be performed by the ACVP-certified pathologist(s).

(2) One commenter submitted the following standards which were felt to describe fully the standards of pathologists qualified to do evaluations:

(a) Minimum of three years industrial experience in animal pathology in association with a mentor experience or in industrial laboratory animal pathology.

(b) Recognized expertise in gross and histopathology data generation and interpretation.

(c) Veterinary, or (equivalent) laboratory animal, clinical medicine training and/or experience.

(3) Three commenters stated that only veterinary pathologists (trained specialists with the D.V.M. or V.M.D. degree) should be allowed responsibility for gross or microscopic evaluation of animals or animal tissues.

(4) One commenter stated that the following should be acceptable to perform the job of a veterinary pathologist in a study:

(a) Medical or veterinary graduates with post graduate experience in diagnostic medical or veterinary pathology and at least three years experience in gross, clinical and/or histopathology of the species of laboratory animal to be used.

(b) Graduates in a biological science with a post graduate doctorate in pathology (D.Sc., Ph.D.) or who have obtained, by examination, membership of the Royal College of Pathologists and who have at least three years experience in gross, clinical and/or histopathology of the species of laboratory animal to be used.

(c) Graduates who fulfill the requirements of categories (a) and (b) but who do not have three years experience with the species to be used, working under the direction of the responsible pathologist.

(5) One commenter requested that EPA offer guidelines or examples of what would suffice as "experience in pathology," and this should include some documented capability in identifying gross and microscopic pathology in the species being evaluated.

(6) One commenter stated that the EPA should offer guidelines or examples of the phrase "equivalent training" which should include some documented capability in identifying gross and microscopic pathology.

b. *Technicians.* There were a few suggested changes to EPA's qualification requirements for technicians.

(1) One commenter requested more definition for the term "certification" as used for laboratory technicans.

(2) EPA's reference to all such paraprofessionals (43 FR 37399, proposed § 163.80–3) as technicians is misleading, and eligibility should instead be based on their experience; to require that all histopathology examinations be performed by pathologists with clinical degrees will place a great burden on the available supply of pathologists who would supervise them closely anyway.

The Agency has reviewed the comments received on individual qualifications, specifications for pathologists, and technicians, and concludes that the Agency is not justified in specifying exactly what scientific disciplines, education, training, or expertise best suit a particular toxicology study. Therefore, the proposed personnel requirements have been withdrawn and the FDA GLP requirements have been adopted, i.e., personnel requirements are left to the discretion of responsible management and study directors in § 160.29. They are responsible for personnel selection and for the quality and integrity of the data these personnel will collect, analyze, document, and report. The Agency urges, however, that management and study directors carefully consider personnel qualifications as they relate to a particular study. The Agency is aware of instances in which the conduct of a study by inadequately trained personnel resulted in invalid data. Although the Agency recognizes the value of certification by professional peer groups, it has determined that the concept is inappropriate for these GLP standards.

4. *Personnel responsibilities.* There were a number of comments received concerning the EPA's designated responsibilities for test study personnel.

a. *Proposed requirements.* In succinct form, EPA's proposed requirements were as follows:

(1) Same pathologist must be responsible for both necropsy and histopathology.

(2) Same person (technician) should do all necropsies for a single test.

(3) A pathologist must personally or "directly" supervise necropsies, slide preparation, tissue trimming, i.e., must be in lab.

(4) Same person (e.g., lab technician or professional, as appropriate) should be responsible for one part of a study (no switching).

(5) Study director must be a toxicologist.

b. Many commenters objected to EPA's requirements that the same pathologist examine first-hand all animal and tissue necropsy/histopathology or directly supervise such effort, proposed in §§ 163.80–3(b)(10) (iii), (iv) (43 FR 37353). These objections were as follows:

(1) This is not possible due to the large workload which may be involved.

(2) This requirement does not take into account that pathologists are people, and provision should be made for circumstances which prevent achieving this goal, such as illness, job changes, time available, etc.

(3) Properly trained technicians or another qualified pathologist with perhaps alternative training in a special discipline (e.g., teratology) should be allowed to assume some of the duties of the primary pathologist.

(4) The requirement proposed in § 163.80–3(b)(10)(iv) would severely impose restraints on common toxicology practices of allowing one qualified pathologist to be available for necropsy and other qualified pathologists to perform the pathological evaluation.

(5) Such a requirement would destroy the contractual process for outside scientific evaluation.

(6) The requirements will require that technicians and/or pathologists be on duty weekends, resulting in increased cost.

(7) A pathologist should be responsible for the interpretation of pathologic specimens, not necessarily for personally performing all aspects of the necropsy/histopathology work.

(c) *One person responsible.* Many other commenters similarly objected to the EPA's requirement that one person (a pathologist) accomplish all necropsies or personally supervise them as

proposed in § 163.80–3(b)(1)(ii) and (10)(iv) (43 FR 37352). The commenters stated that the requirement was neither practical nor feasible since:

(1) Individual animals die at odd times.

(2) Illnesses or resignations occur.

(3) Reassignments of personnel occur.

(4) It is impossible for one person to necropsy a large number of animals (e.g., 200) in a reasonable time period.

(5 ) Other properly trained personnel are available.

(6) In most laboratories this task is a team activity.

(7) There is no scientific basis for the requirement.

(8) Flexibility in scheduling laboratory workloads is required.

(9) Dialogue between experts should be encouraged.

(10) A Board-certified pathologist may not be available.

On the basis of the objections presented, the Agency has decided that the proposed requirement is inappropriate and has not included it in the final rule. All responsibilities related to the specific duties of the scientific staff have been delegated to the testing facility management and study director in §§ 160.31 and 160.33. However, the Agency strongly urges that, where possible, one pathologist be assigned to interpret pathologic specimens in a given study, since this provides consistency in the evaluation process.

d. *Supervision of technicians.* A few comments were received concerning supervision of technicians. One commenter suggested that detailed proposals concerning the supervision of a study or technician during tissue-trimming procedures be left to the judgment of the responsible pathologist. One commenter stated that the technicians embedding the tissues and performing the microtomy must be supervised by a competent and qualified pathologist in order to ensure that the proper aspects of the tissue and any associated lesions will be presented to the pathologist responsible for performing the histopathology examinations (proposed §163.80–3(b)(1)(iii)(C) and (11)(iii)(B), 43 FR 37352).

The Agency has not included in the final rule the proposed detailed requirements on supervision of technicians. Specific supervisory duties of the scientific staff have been delegated to the testing facility management.

e. *Responsibility for maintaining the health status of test animals.* Commenters stated that veterinarians or other qualified scientists should be responsible for maintaining the health status of test animals prior to and during studies. They felt that technical employees or qualified professional scientists should be responsible for the daily observations and care of test animals.

The Agency advises that the final rule delegates to the study director the overall responsibility for the technical conduct of the study, including animal care (§ 160.31). It is up to his discretion as to how the health status of test animals are maintained. No other duty specifications have been included in the current standards.

f. *Parapathologists.* Commenters felt that EPA should allow the use of properly trained paraprofessionals to conduct routine examinations of test animals, e.g., gross necropsies, pathologic sample preparation, and sample examination under the close supervision of a qualified pathologist.

The Agency considers that the use of parapathologists to perform various diagnostic procedures (e.g. gross necropsies or microscopic examinations) is acceptable, providing the testing facility management or study director is assured of each individual's ability to perform the assigned function and that his performance will allow proper conduct of the study according to the protocol (§§ 160.31 and 160.33).

g. *One person responsible for each phase of a study.* Several commenters objected to EPA's requirements in proposed § 163.80–3(b)(1)(ii) (43 FR 37352) that one person should be responsible for each particular phase of a study and that during necropsy no switching of roles should occur during the conduct of work on a single test. The reasons stated were:

(1) The phrase is unclear: a pathologist could be in charge of all phases since he has training in biochemistry, hematology, pathology, and experience in toxicology.

(2) The request is impractical since the number of animals on a long-term rodent study dictates, in itself, the need for involvement of several individuals, especially during necropsy procedures.

(3) The requirement acts to define the structure of a company operation and should be changed to make a qualified and/or experienced person responsible for the entire study.

(4) The phrase "switching roles during a test" in § 163.80–3(b)(1)(ii) is unclear; if individuals are trained across several phases of tests, there is no reason why a similarly trained individual could not be substituted.

(5) Due to the improbability of meeting the requirement, it should be deleted.

The Agency agrees with the commenters and has instead used FDA's requirements and language for these sections.

h. *Duties of the study director.* Regarding the duties of the study director proposed in § 163.80–6(c)(3) (45 FR 26373), one commenter suggested deletion of wording indicating that the study director has only "technical" control of the study and not overall control. Another commenter states that EPA should change proposed § 163.80–6(c)(3)(ii) to read "all experimental data, including observations of unanticipated responses * * * verified."

The Agency has revised the requirements for the study director to be consistent with those of the FDA GLPs which reflect a more flexible and comprehensive approach (i.e., the study director shall be a scientist of appropriate education, training, and experience, or combination thereof, who has overall responsibility for the technical conduct of the study, as well as the interpretation, analysis, documentation, and reporting of results (including unanticipated responses) and represents the single point of study control in § 160.29.

i. *Quality assurance unit (QUA) relation to standard operating procedures.* Commenters stated that the quality assurance unit should not have to assure that all standard operating procedures (SOPs) are adhered to as proposed in § 163.80–6(c)(4)(i)(B) (45 FR 26373), since many of these will be too specialized for the average QA individual to review intelligently. Also, the SOPs are the responsibility of the study director.

Like the FDA GLPs, this final rule requires the QAU to maintain copies of all protocols for all studies for which the unit is responsible and to determine that no deviations from the approved protocols or standard operating procedures were made without proper authorization and documentation. EPA disagrees with the comment that the QAU will not be able to fulfill this requirement in an intelligent manner. Management must assure that the QAU personnel are responsible.

j. *Quality assurance unit inspection of acute phase studies.* Two commenters objected to or were unclear concerning the QA requirement to inspect each phase of a study periodically. They argued that it was impractical and costly to have QA inspection of each phase of an acute toxicology study. It was felt that a provision for systems audits backed up by an audit of the report was adequate. One commenter felt that the QAU should monitor each

study by the FDA approach of allowing the testing facility to inspect the in-life phases of a significant number of short-term studies providing that at least each in-life phase of such studies are scrutinized on a monthly basis.

Concerning the inspection of acute studies, the Agency is adopting the FDA approach of allowing inspection of studies lasting less than six months at intervals adequate to assure the integrity of the study, i.e., at the discretion of the QAU. Such an approach would be consistent with an inspection of in-life phases of a large number of short-term studies on a monthly basis.

k. *Signed statement of the quality assurance unit in the final report.* Commenters felt that any signed statement of the QAU with the final study report in accordance with proposed § 163.80–6(c)(4)(ii)(G) (45 FR 26373) should incorporate certainty that all the items in proposed § 163.80–6(c)(4)(i)(F) have been met.

The Agency has elected to preserve the wording on the statement of signature by the QAU to be included with the final study report in § 160.35 (b)(7). The Agency is convinced that the requirement to specify only the dates inspections were made and the dates findings were reported to management and the study director is adequate. Such a requirement implies that periodic QAU review of the methods, the standard operating procedures, and the reported results of the study have occured, that problems have been noted, and that any appropriate corrective actions have been taken as required under the stated functions of the QAU.

l. *Size of the quality assurance unit.* Commenters stated that EPA should allow a small organization to combine the duties of the study director and QAU, since a laboratory has a limited number of personnel and performs a limited number of studies.

The EPA regulations, at § 160.35, permit a study director for a particular study to serve as a part of the QAU, or as the QAU for a different study. However, for any given study, a separation must exist between individuals actually engaged in the conduct of a study and those who inspect and monitor its progress.

m. *Master schedule sheet.* Commenters felt that the requirement for a master schedule sheet is unnecessary because its completion is time-consuming, which decreases QAU time to spend on study inspections, reports, reviews, and planning, and because the use of it is inflexible, i.e., the requirement should not specify the items the master schedule sheet will contain, and will not allow laboratories to reflect their individual operations.

The Agency is convinced that use of a master schedule sheet is essential to the proper function of the QAU. Only through such a mechanism can management be assured that the facilities are adequate and that there are sufficient numbers of qualified personnel available to accomplish the protocols of all studies being conducted at a facility at any given time. In addition, the time required to maintain it is minimal and it is consistent with general good management practices.

n. *Central storage of quality assurance unit records.* Commenters felt it may not be practical to store all QAU records in one location, as required in proposed § 163.80–6(c)(4)(iv) (45 FR 26373). They argued that there must be provision for facilities with multiple record storage sites and that limitations in storage area must be taken into account.

Although the Agency recognizes the possible difficulties in establishing a single storage location, the Agency elects to retain the requirement, consistent with FDA's GLP requirements. A centralized storage location will be beneficial to the management in terms of an efficient, comprehensive system for analyzing and monitoring the progress of ongoing test studies. Such a system will allow management rapid and convenient review of the progress of the tests and prompt correction of deficiencies noted in the studies.

This will also allow proper review of quality assurance records by the Federal agency of concern. The Agency has no objection to an establishment microfilming its QAU records, then storing these as the official records in lieu of the original material, provided that the QAU certifies that the microfilmed records are complete and legible.

o. *Quality assurance unit.* Clarification was requested concerning the more flexible statement on quality assurance in proposed § 163.80–3(b)(12) (43 FR 37352) and the less flexible statement in proposed § 163.80–6(c)(4) (45 FR 26373). The first section cited above proposed that the testing facility is responsible for developing a quality assurance system using the FDA GLPs or an equivalent system of quality control. The latter section cited above stated that a testing facility must/shall have a quality assurance unit composed of one or more individuals to assure the facilities, equipment, etc., are in conformity with the standards set forth in EPA's guidelines/standards. The commenters felt these statements created confusion and compliance complexities.

The EPA, as a matter of policy, has adopted the FDA GLPs requirement for a quality assurance unit. This policy should assure consistency between the Federal agencies and reduce unnecessary confusion for testing facilities subject to both EPA and FDA testing requirements.

*C. Facilities*

1. *Separation of facilities to prevent adverse effects on study.* Several commenters requested clarification of proposed § 163.80–3(b)(5)(iii) (43 FR 37352) and § 163.80–6(d) (1) and (2) (45 FR 26373) regarding the requirement that test facilities be designed with a degree of separation that will prevent any function or activity from having an adverse effect on the study. For example, could a test room be used as a quarantine room if the previous animal residents are removed and the room sanitized? Other commenters indicated that it is not necessary nor feasible (from a space standpoint) to isolate all individual projects of an acute nature, but it is suitable for subchronic and chronic studies.

The Agency's intent in proposing that there be defined and, where required, separate or specialized, areas in a testing facility was to assure the adequacy of the facility for conducting laboratory studies. This intent is clearly stated in the second sentence of § 160.41, which reads: "It shall be designed so that there is a degree of separation that will prevent any function or activity from having an adverse effect on the study." The facility must be designed so that the quality and integrity of the study data are assured. The manner in which the separation is accomplished may be determined by testing facility management.

Adequate separation may be, in various situations, a function of such factors as intended use of the specific part of the facility, space, time, and controlled air. The broad variety of test systems, test and control substances, and the size and complexity of testing facilities preclude the establishment of specific criteria for each situation. For these reasons the Agency declines to include in the final rule either a definition or specific examples of methods for achieving adequate separation.

2. *Cross contamination.* EPA's effort to limit cross-contamination in proposed § 163.80–3(b)(5)(iii) (43 FR 37352) was lauded as a reasonable one since it allows discretion on the part of the testing facility regarding separation of

species or test systems and isolation of individual projects. However, one commenter objected to EPA's proposal, at § 163.80–6(d)(2)(i) (45 FR 26373), for separation of biohazardous substances from animal rooms, stating that the requirement was superfluous since test and possibly control materials must be regarded as biohazardous until proven safe.

The Agency agrees that the requirements to limit cross contamination between tests is a reasonable one. Informed judgment must always be used in all test studies to assure proper isolation of individual projects. The FDA, in publishing their GLPs, found that commenters urged the inclusion of language concerning isolation of studies with biohazardous substances as a safety precaution. (43 FR 59999, Dec. 22, 1978.) The EPA agrees with this and has adopted this approach in order to emphasize the importance of maintaining isolation of test systems which may present hazard problems beyond those normally expected.

3. *Separate areas for diagnosis, treatment, and control of laboratory animal disease.* Commenters stated that the requirement in proposed § 163.80–6(d)(2)(ii) (45 FR 26373) to provide separate areas for diagnosis, treatment, and control of laboratory animal disease is contrary to practice and increases the risk of spreading infection. The commenters further stated that management should be responsible for determining the most appropriate approach to achieve objectives and to save money.

The Agency disagrees with these comments. Although diseased animals may be killed, this is not always the case, and it may not always be possible immediately to kill diseased animals. Thus, a separate area should be available for such animals until this can be accomplished.

4. *Separate areas for feed, bedding, supplies, and equipment.* Commenters felt that the EPA requirement in proposed § 163.80–6(d)(3) (45 FR 26373) that there must be separate storage areas for feed, bedding, supplies, and equipment is not always necessary and should be left to the discretion of facility management. Other commenters stated that provided the other parts of the GLPs regarding separation of individual projects and proper storage of test materials are complied with (proposed §§ 163.80–3(b)(5)(iii), 163.80–6 (b), (d), and (f)(3)(v), the integrity of the study would not be compromised by storage of test materials in areas housing the test systems as required in proposed § 163.80–6(d)(4)(iii).

The Agency agrees that discretion should be allowed in the storage of feed, bedding, supplies, and equipment as proposed in § 163.80–6(d)(3). The section has been modified to be consistent with the FDA GLPs by adding the words "as needed" in § 160.45. With regard to the second issue, the Agency is concerned with preventing the cross-contamination of test systems and therefore retains its requirement that "* * * storage areas for the test and/or control substance * * * be separate from areas housing the test systems * * *" in § 160.47(b).

5. *Separate laboratory space for the performance of routine procedures.* One commenter stated that the EPA requirement in the proposed § 163.80–6(d)(5)(i) (45 FR 26373) for separate laboratory space for the performance of routine procedures (e.g., necropsy, aseptic surgery) is wasteful and inefficient, and that the wording should be changed from "must be" to "should be." One commenter agreed with the EPA requirement as long as it is recognized that one area may serve various functions at different times. The commenter suggested adding the wording, "as needed." Two commenters objected to EPA's requirement under proposed § 163.80–6(d)(5)(ii) for separate space for cleaning, sterilizing, etc., stating that the requirements, in most cases, were impractical and unnecessary or should be more flexible. The latter commenter suggested adding the phrase, "as needed."

The Agency agrees that the requirements should be more flexible. Because of the nature and scope of the types of studies subject to these regulations, it would be inappropriate to set specific uniform requirements for all studies. Therefore, the provisions are revised to make it clear that reasonable judgments by the testing facility regarding area and space requirements may be made on the basis that a particular function or activity will not adversely affect other studies in progress. Section 160.49(a) has been revised to read "Separate laboratory space shall be provided, as needed, * * *." This wording is consistent with the FDA GLPs.

6. *Separate space for locker, shower facilities.* Commenters felt that proposed § 163.80–6(d)(7)(ii) (45 FR 26373), which requires separate space for locker, shower facilities, etc., is unnecessary and inappropriately addressed in the GLPs.

The Agency has revised this requirement to read "Separate space shall be provided for locker, shower * * * facilities, as needed" in § 160.53(b). This requirement is identical to the one in FDA's GLPs.

7. *Documentation of the treatment of diseased animals.* One commenter requested deletion of the concept of "complete" documentation of the treatment of diseased animals as stated in the note on treatment of diseased animals at proposed § 163.80–6(f)(3)(iii) (45 FR 26373).

The Agency has since deleted the requirement. As a suggested procedure, discretion is left to the testing facility on the amount of documentation submitted to the EPA. However, the Agency urges that, as a minimum, the nature of the disease, quantity of medication given, and route of administration be clearly indicated. This will provide the needed information to evaluate whether the treatment compromised the assessment of the chemical under study.

*D. Equipment*

1. *Definition of equipment.* Two commenters requested that a more specific definition of equipment than in proposed §§ 163.80–3(b)(7) (43 FR 37352) and 163.80–6(e) (45 FR 26373) be included, so that the tester will know what equipment must be inspected, cleaned, and maintained. One of the commenters stated that EPA should use the FDA GLPs' definition of equipment.

The Agency now includes FDA's definition of equipment to be inspected, cleaned, and maintained: "* * * automatic, mechanical, or electronic equipment used in the generation, measurement, or assessment of data and equipment used for facility environmental control * * *" in § 160.61.

2. *Documenting equipment defects.* Documenting how an equipment defect is discovered in proposed § 163.80–7(b)(6) (45 FR 26373) was felt by commenters to be irrelevant since the other parts of this clause (recording its existence, nature, and time of discovery or occurrence) ensured adequate record to assess the impact of any defect on integrity of the study. Other commenters felt the requirements were inconsistent with the regulations of other Government agencies.

These requirements have been directly adopted from the FDA GLPs. Adequate documentation of the nature of equipment defects, time of occurrence, and any remedial action taken is important to assure the validity and integrity of data generation, measurement, and assessment, and to allow an accurate reconstruction of a study.

*E. Testing Facilities Operation*

Labeling of reagents and solutions. A commenter considered that the proposed requirement for the labeling of reagents and solutions in proposed § 163.80–6(f)(2) (45 FR 26373) could lead to problems in regard to labeling, titer, and/or concentration, and expiriation for certain items, e.g., sera in growth media or reagents with unknown stabilities. The commenter suggested amending the requirement with the phrase "if applicable."

The Agency advises that the requirement is directly adopted from the FDA GLPs. The uncertainties in the titer and/or concentration and expiration date for materials such as sera in growth media or reagents with unknown stabilities should simply be reflected in the wording presented on the label.

1. *Replacement, isolation, and medication of sick animals.* Objections were made to the proposed requirements for replacement or isolation and medication of sick animals as found in proposed §§ 163.80–6(f)(3)(iii) (43 FR 37352) and 163.80–3(b)(5)(iii) (45 FR 26373). For replacement of animals, one commenter said it would disrupt the statistical design of the experiment, two commenters stated that it should be determined by the duration of the study and the point in time at which the animal has become sick, and another commenter stated that replacements should be obtained from the same shipment as the rest of the animals. One commenter stated that isolation and medication of sick animals is sometimes justified with dogs, providing the procedures are documented thoroughly, but not with rodents.

Based on these comments and the basic consideration that the person conducting the study best knows how to deal with individual animals, the Agency concludes that it is beyond the scope and purpose of these GLPs to describe detailed requirements concerning the management of diseased animals. Section 160.90(c) is sufficiently explicit to exclude the use of diseased animals that would interfere with the purpose or conduct of a study. The regulation does not prohibit the treatment of diseased animals if such treatment does not interfere with the study. The diseased animals shall be removed from the study. See Unit III.1. of this Discussion regarding this note.

2. *Quarantined animals.* EPA's proposal for the quarantining of animals in proposed § 163.80–6(f)(3)(ii) (45 FR 26373) was questioned by several commenters. Some commenters stated that EPA should be more flexible in its requirements for evaluating the health status of the quarantined animals by not requiring documentation but by leaving the treatment of animals for disease control up to the discretion of the scientist or veterinary medical officer in charge of animal care. Another commenter asked if the requirement applied to LD50 studies.

EPA has adopted the FDA GLP requirements for quarantining newly received animals from outside sources and does not specify documentation. This allows flexibility on the part of the scientist in charge of handling sick animals. However, standard veterinary medical practice will usually include such documentation, as a matter of course, since careful evaluation is required to prevent unwarranted loss of animals and test data due to subsequent animal disease or other factors.

Regarding the issue of LD50 studies, the agency advises that "all newly received animals * * * shall be placed in quarantine until their health status has been evaluated" in § 160.90(b). This is regardless of the supply source, although the source can be a factor in determining the degree or depth of health evaluation required. The conditions under which animals are transported from their source can seldom be considered certain to preclude the possibility of exposure of the animals to disease.

3. *Identification of animals.* A commenter felt it is not enough to assign a unique identification number to an animal; rather, an identification should be permanently attached to the animal by tattoo, ear punch, or tag (proposed § 163.80–3(b)(5)(i), 43 FR 37352).

The Agency has accepted the FDA approach and is withdrawing the requirement for a unique method of identification for small rodents (sucklings) in the absence of a proven and acceptable technique. The provisions of proposed § 163.80–6(f)(3)(iv) (now § 160.90(d)) are deemed sufficient to identify the test animals appropriately. Because of the varied nature of the tests conducted and the test system used, the manner of identification is left to the discretion of the testing facility.

4. *Nesting materials in teratology studies.* Many commenters generally objected to the EPA proposals on bedding of animals as proposed in § 163.83–3(b)(9) (43 FR 37352), i.e., providing nesting materials to pregnant animals utilized in teratology requirements. They stated the proposed requirements were unnecessary and scientifically indefensible. Specific comments were varied in nature:

a. One commenter wanted to know what is a suitable material for rats and mice.

b. Several said that the requirement is inconsistent with the design of a sound study since natural parturition is not allowed.

c. Several persons stated that bedding materials should be optional since there is no evidence that its absence affects the teratology study and, in fact, may seriously interfere with the study by introducing an uncontrolled variable.

d. One commenter thought it inappropriate for an inhalation study.

e. Six commenters wanted to know when bedding is "absolutely essential."

f. Two commenters said the requirement goes beyond the scope and philosophy of the GLPs.

g. One commenter felt the decision should remain in the hands of the scientist in charge.

h. Several commenters suggested adding a qualifying statement or rewording EPA's proposed requirement.

The Agency concludes from the comments that specific requirements for nesting materials are unnecessary. Therefore, the proposal has been rescinded. The decision concerning the use of bedding is left to the discretion of the study director, i.e., "Bedding used in animal cages or pens shall not interfere with the purpose or conduct of the study and shall be changed as often as necessary to keep the animals dry and clean" in § 160.90(h). This requirement is consistent with the FDA GLPs.

5. *Bedding used in animal cages or pens.* A commenter felt that the statement "* * * Bedding used in animal cages or pens must not interfere with the purpose or conduct of the study * * *" and the "note" in proposed § 163.80–6(f)(3)(viii) (45 FR 26373) should be deleted or be of alternative wording which allows scientific discretion.

The Agency advises that the note in proposed § 163.80–6(f)(3)(viii) on bedding is a recommendation of the FIFRA Scientific Advisory Panel, and should be considered as guidance on this issue. See Unit III.3. of this Discussion. The Agency does not see the need to delete the requirement that "Bedding used in animal cages shall not interfere with the purpose of the study * * *" since this requirement is identical to the one in the FDA GLPs and has undergone considerable public comment and evaluation prior to its final publication by FDA.

6. *Cleaning and pest control materials.* Commenters considered proposed § 163.80–6(f)(3)(ix) (45 FR 26373), including the note on cleaning and pest control materials, is

unnecessary, too detailed, and should be deleted.

The Agency advised that this is an FDA requirement, excluding the note. The Agency is persuaded that the documentation on use of cleaning and pest control materials is necessary. Such information is vital to the proper assessment of the potential toxicity which may occur from a test chemical and possible interaction of any cleaning material or pesticide with that chemical or direct effects of such materials on the test animals. See Unit III.4. of this Discussion regarding the note.

7. *Caging of animals.* Commenters pointed out that adult hens should be housed in cages which are large enough to permit mobility and ease of observation of gait during subchronic neurotoxicity studies (proposed § 163.82-5(c)(5)) (43 FR 37374). Three commenters maintained that, in teratology studies, individual caging should be used since group housing produces stress during gestation and increases the probability of loss of specimens in proposed § 163.83-3(b)(9) (43 FR 37383).

The Agency notes that caging requirements are not specified in the subchronic neurotoxicity test or the teratology test section. However, the final rule, at § 160.43(a)(4), requires that a testing facility have animal rooms which assure proper specialized housing for animals. This allows discretion on the part of the tester as to the most appropriate manner for the housing of any given animal species, e.g., adult hens.

8. *Housing of different animal species.* Several commenters objected to the wording in proposed § 163.80-6(f)(3)(v) (45 FR 26373) regarding housing of different species. One person stated that the added requirement of informing EPA when different species are housed in the same room is unnecessary, since such a decision is based on scientific judgment and should already be documented. The same comments requested deletion of such requirements. Three commenters requested clarification of the phrase "submitted to the Agency" and one person stated that the phrase "under most circumstances" is internally inconsistent.

The Agency advises that EPA, in order to minimize differences between EPA and FDA requirements, has adopted the FDA GLP requirements for housing of different species, i.e., "animals of different species shall be housed in separate rooms when necessary" in § 160.90(e). See Unit III.2. of this Discussion regarding the additional suggested guidance which provides more flexibility and allows for considerable latitude in scientific judgment.

*F. Test and Control Substances*

1. *Flexibility of approach.* EPA received numerous general comments that it should adopt a more flexible approach, such as the one adopted by FDA, for stability determination of test and control substances and analysis of such substances incorporated into feed or another vehicle. These comments noted that FDA in its GLPs deliberately left determination of appropriate analytic procedures to the discretion of the study director (21 CFR 58.105), while EPA has specified particular requirements for stability and homogeneity determinations in its proposed GLPs at § 163.80-3(b)(2) (v) and (vi) (43 FR 37352).

Other comments stated EPA should not require the battery of stability studies, including degradation product analysis, for every substance. For example, if there is considerable evidence that the test substance is stable, there is no need to test for degradation products because degradation can be expected to be minimal and toxic effects of degradation products will be measured during the test of the substance.

The Agency agrees that a more flexible approach should be accepted and has adopted the FDA requirements, i.e., detailed analytical procedures for homogeneity and stability of test and control substances and dietary admixtures are up to the discretion of the study director of the testing facility under §§ 160.105 and 160.113. Also, the Agency no longer requires a battery of stability studies. However, the stability of each test or control substance must be determined by the testing facility or sponsor prior to the study; or, if the stability cannot be determined prior to a study, periodic re-analysis of each batch shall be performed under § 160.105(a).

2. *Numerical requirements for stability and homogeneity of the test and control substances.* Commenters argued that EPA's proposal to require the tester to ensure that the administered substance contains at least 90 percent of the designated test substance concentration specified in the sponsor-approved protocol or that the initial mean concentration of the test substance does not vary more than 5 percent from the designated concentration in proposed § 163.80-3(b)(2) (i) through (iv) (43 FR 37352) is unduly restrictive and unrealistic. Reasons given for this position were:

a. When low levels of the test substance are used, analytic procedures may not be available which are sufficiently sensitive to verify the variances.

b. Five percent may be impossible to achieve.

c. Depending on differences in dose levels and route of administration, ± 20 percent variation may occur.

d. Mixing procedures may have built-in limitations.

Similar considerations apply to the requirement that the variability for the test substance in an administered mixture must not exceed ± 10 percent of the mean sample concentration among random samples of the mixture.

As an alternative means of assuring homogeneity and uniformity of test substance concentration, several comments recommend that EPA adopt FDA's approach which requires showing that the administered substance conforms to protocols as closely as possible by relying on mixing records and stability and dose preparation data. Other comments suggest EPA require the development and validation of a procedure for preparing a homogeneous dietary admixture and determination of stability of the test substance at the initiation of the study (proposed § 163.80-3(b)(2) (iii), (v), and (vi); 43 FR 37352) and which should be applied during the course of the study to the preparation of fresh treated diet or to analyze random samples for homogeneity and concentration.

EPA is persuaded by these comments and has deleted the numerical requirements for stability and homogeneity. When evaluating a particular test, the Agency may examine test facility records to determine whether appropriate test substance stability and homogeneity have been achieved in accordance with the test protocol.

3. *Concurrent stability testing.* Commenters felt EPA should permit concurrent stability testing at the discretion of the study director. The comments note that in the case of exceptionally stable chemicals stability testing may be extremely lengthy and may delay start of testing and that, if there is good reason to believe satisfactory stability exists, a study confirming stability after initiation of the toxicity study is an efficient procedure. One comment argues that concurrent stability testing assures substance integrity.

Other comments agree with the EPA proposal that stability testing should be conducted before testing. One said that EPA need not establish a mandatory requirement because it is illogical to assume that anyone would begin testing prior to stability evaluation.

The agency concludes that characterization of the stability of test or control substance should be determined before the initiation of the study in order to provide a means of controlling variations from batch to batch as well as to make certain that the test substance meets the specifications of the protocol. A thorough understanding of the nature of the test substance is a basic requirement for assuring the absence of contaminants that may interfere with the outcome of the study.

4. *Monthly analysis of the stability of a test or control substance.* Proposed § 163.80–3(b)(2)(v) (43 FR 37352) required that stability of a test or control substance in feed or another vehicle should be determined prior to the start of a study but, alternatively, allows such stability to be determined by analyzing randomized samples of the diet or vehicle mixture at least monthly. A monthly analysis of the diet or vehicle mixture is required in any event to determine the homogeneity of the mixture and test substance concentrations and to ensure that proper mixing, formulation and storage procedures are being followed. Proposed § 163.80–3(b)(2)(vi) had a similar requirement for test or control substance incorporated into feed or another vehicle.

Several comments objected to the monthly analysis requirements to verify homogeneity stability as being costly and unnecessary. One stated that the time required to conduct the monthly analysis would be extensive, thus forcing testing facilities to change to less desirable procedures for preparing test substances. Some argued that the requirements had no scientific merit.

Still another comment indicated that quarterly analysis would be appropriate. Others felt that scientific judgment should be used because the desired frequency can be affected by the time span of the experiment, the batch variations or additive stability.

The monthly analysis requirement was originally included because of EPA's concern that the tester ensure that the appropriate concentration and purity of the test material be used. In light of the comments received and the EPA's adoption of the policy of allowing the tester maximum scientific discretion, where possible, EPA has decided not to include the monthly analysis requirement in its final regulations. The FDA approach, however, is retained.

5. *Analysis of new compounds.* Two commenters requested rewording of proposed § 163.80–6(c)(2)(iv) (45 FR 26373) which required that the test or control substances or mixtures be appropriately tested for identity, strength, purity, stability or uniformity. They stated that it must be accepted that in the early stages of research and development of new compounds, sophisticated analytical techniques for the characterization of test materials may not be available.

The Agency is aware that development of a sophisticated analytical techniques for the characterization of test materials may be required. However, the Agency is persuaded that thorough characterization of the substance under test is essential because the results of the test may be compromised by possible contamination. Only by knowing the identity and quantity of the components can one predict their effect on the study.

6. *Acute phase testing without homogeneity and stability testing of the test material.* One commenter stated that in certain studies, e.g., acute studies, the important parameter to measure is the absolute amount of material administered to the test animal, and that in these instances homogeneity of the test substance is not a crucial parameter. Other commenters suggested that acute phase testing be allowed prior to completion of stability testing for "known" stable chemicals.

The Agency agrees that an important parameter to measure in an acute study is the total dose administered to the test animal. However, the investigator can only be assured of appropriate dosing if the homogeneity or uniformity of the test substance delivered in a vehicle is established; otherwise, the calculated dosage may be incorrect. Regarding the acute testing of test substances of "known" stability, stability of each test or control substance must be established prior to testing, since there is no guarantee of the degree of degradation of any given batch of test chemical unless analysis is performed. To conclude, the homogeneity of a test substance administered without a carrier or vehicle is left to the discretion of the tester; however, uniformity (homogeneity) must be established prior to testing for a test substance carrier mixture under § 160.113. Stability must be established for all test and control substances, unless those substances are too unstable to make it feasible, in which case periodic reanalysis of each batch is required under § 160.105.

7. *Responsibility for determining the homogeneity and stability of test mixtures.* One commenter felt it is the sponsor's obligation to determine adequately, document, and report homogeneity and stability of mixtures. Another commenter stated that some testers may not have technical capabilities to perform analytical studies in-house and, therefore, the sponsor or another lab should be responsible for such analyses.

The EPA has adopted the FDA position in § 160.31(d) which states that testing facility management shall assure that such homogeneity and stability tests have been appropriately tested, either by the sponsor or by the test facility. In those cases where a testing facility is unable to perform the characterization test, the sponsor should perform the required testing and notify testing facility management that the characterization of the test or control article has been performed. The sponsor, nonetheless, bears the overall responsibility to assure GLP's are complied with.

8. *Retention of storage containers.* One commenter stated that the storage requirements under proposed § 163.80–6(b)(1)(i) (45 FR 26373) are unnecessary and burdensome, and requested that the last sentence of proposed § 163.80–6(b)(i) be deleted, because:

a. It is burdensome to retain each container for the duration of the study once it has been emptied.

b. It is more appropriate to retain the chemical in the original container submitted, rather than transfer it to a designated storage container, although this may be advisable in some cases.

Another commenter argued that proposed § 163.80–6(b)(1)(i) would create technical and/or logistical difficulties and should be replaced with a specification that storage containers must be chemically cleaned before and between each use.

The intent of the requirement was to ensure the purity of the test or control substance and prevent contamination with other chemicals. To be consistent with the FDA guidelines, the requirement has been deleted. However, the Agency advises that any container that has been emptied during the course of a study should be disposed of in accordance with the Resource Conservation and Recovery Act. Further, storage containers may consist of the original container or a designated container or a combination of both. Standard laboratory practices for cleaning labware and preventing cross-contamination should be used for the short term storage of test chemicals, i.e., the production of all reagents and solutions

9. *Labeling of test material storage containers.* Three comments were received regarding the proposed requirements for labeling and handling test material storage containers under

§ 163.80–6(b) (1)(i) through (2)(v) and (g)(1)(i)(B) (45 FR 26373). One commenter stated that the storage conditions necessary to preserve the identity, strength, purity, and composition of the test or control substance under § 163.80–6(b)(1)(i)(B) were too restrictive, and that this type of information is better retained in the test material inventory log or protocol for the study. The same commenter stated that the labeling information should be limited to chemical name, chemical abstract number, or code number, batch or lot number, and expiration date. He felt that § 163.80–6(g)(1)(i)(B) should be reworded to "Identification of the test or control substances by name or by chemical abstract (CAS) number, or by code number". Two commenters argued that EPA was requiring more detailed information on the storage container of the test or control substance under § 163.80–(b) (1)(i) through (2)(v) than that required by FDA's GLPs. They further stated that such additional requirements do not increase the quality assurance of the study and should be left to the discretion of the testing facility and study sponsor. One suggested that the phrase "where appropriate" be inserted before "the work storage conditions," and further stated that storage conditions need be specified only when it is necessary to protect stability. He also stated that § 163.80–6(b)(2) already required the testing facility to establish procedures for handling test and control substances.

The Agency agrees with the commenters and has revised the requirements on storage containers to be consistent with the FDA GLPs; the requirements now read as follows: "Each storage container * * * shall be labeled by name, Chemical Abstract number or code number, batch number, expiration date, if any, and where appropriate, storage conditions necessary to maintain the identity, strength, purity, and composition of the test or control substance" in § 160.105(c).

10. *Retention time for reserve samples of test or control carrier/substance mixture.* Numerous comments were received stating, in effect, that since FDA has deleted its requirement for retention of reserve samples of each test or control carrier/substance mixture, having found such samples of uncertain value, EPA should do likewise to be consistent with the FDA GLPs. Several commenters enumerated reasons why the FDA deleted its requirement:

a. Provided adequate analysis is performed during the original study, additional requirements add nothing to quality or integrity of a study or its support data.

b. Degradation of samples with time precludes accurately representing the original dose administered months or years before.

c. Other provisions of GLPs cover purpose of this requirement adequately, e.g., SOPs, QAU.

d. Sheer number of retention samples is quite substantial and costly.

e. Time and effort to store, label, etc., samples would be unreasonable.

f. Provided adequate analysis is performed, retention of dosing samples serves little purpose and is costly, e.g., stability characteristics of mixtures would call for them to be discarded in a few months.

g. Reexamination of reserve samples would be extremely rare.

h. Maintenance of reserve samples is a potential health hazard.

i. Instability of carriers themselves, such as feed mixtures, preclude long term storage under commonly available conditions.

One commenter asked clarification between the conflicting statements in proposed §§ 163.80–6(b)(1)(ii) and 163.80–7(c) (2) and (3) (45 FR 26373).

The Agency has determined from a review of the comments that the requirement for retention of reserve samples of test or control substance carrier mixtures is generally not worthwhile, and has not included it in the current GLPs.

11. *Retention of reserve samples of test and control substances.* Three commenters took issue with EPA over the length of time required for retention of reserve samples of test and control substances and carrier/substance mixtures. Two commenters argued that EPA should specify finite times, comparable to FDA, for their retention, i.e., two years following approval of registration or at least five years following the date on which results of studies were submitted to EPA for registration. One argued that if the requirement is not deleted, it should be left up to the testing facility to determine the length of time appropriate for sample retention based on known stability and the Agency's stated specified use of that sample. He also stated that random selection of mixtures at some small percentage of the total should be acceptable and the amount of sample should be specified. Another person proposed that, since information on long-term storage of test article mixtures with carriers is not readily available and of uncertain value, reserve samples of such mixtures be discarded whenever satisfactory, periodic analysis for that period has been obtained. It was also suggested that analytic values of less than 20 percent variance from expected values be considered "satisfactory."

The Agency had adopted requirements similar to those of FDA for retention of reserve samples (test substance or control substance carrier mixtures have been deleted) in that they shall be retained only as long as the quality of the sample affords evaluation. This time limit is thus variable, possibly extending the period in which the sponsor holds any research or marketing permit to which the study is pertinent. However, such samples need not be retained after EPA has notified the sponsor or testing facility holding the materials in writing that retention is no longer required by EPA. Regarding the Agency's use of the samples, they are considered essential as checks on recorded observations and, whenever feasible, samples should be retained for confirmation of findings. Since it is not possible to determine which batch of test chemical will need to be re-examined, all batches must be sampled. The regulation does allow flexibility in the quantity of sample taken; the specific amount of sample should be taken in accordance with the tester's best judgment.

12. *Contaminant analysis.* Three commenters requested the definition of the terms "carrier," "purity," and "contaminant."

The Agency finds that the terms "purity," "carrier," and "contaminant" do not require individual definitions since they are used in their ordinary sense. As a general rule, a regulation defines separately only those words which will be used in a sense which differs from that given in currently accepted dictionaries, or those words whose meaning will be limited by the regulation. The Agency has used this policy for these standards.

13. *Characterization of test substance impurities.* Three commenters maintained that while it is important to characterize the test substance appropriately, the identification of each and every impurity down to the limits of technical feasibility is unnecessary and would require massive analytical effort with minimal benefit. They stated that the provision at proposed § 163.80–3(b)(2)(iv) (45 FR 37352) of Subpart F should be modified to require appropriate characterization which may include some impurities in some instances.

The agency advises that the requirements for characterization of the test substance in the final rule now reads, "The identity, strength, purity and

composition or other characteristics which will appropriately define the test or control substance shall be determined for each batch and shall be documented before the initiation of the study" under § 160.105(a).

*G. Protocol for and Conduct of a Study*

1. *Detailed sponsor-approved protocol.* One person requested that proposed § 163.80–6(g)(1)(i) (45 FR 26373) be reworded to read "an approved protocol," since the requirement of a detailed sponsor-approved protocol is inappropriate for a commercial testing lab. He stated that this was because:

a. Some of the specific details are determined in preliminary dose rangefinding tests.

b. It may impose an undue delay between the preliminary testing and actual study with no assurance of additional reliability of the data.

c. The sponsor might have no authority to sign such a protocol and no functional control over the testing facilities or procedures.

The Agency recognizes that some of the requirements, now at § 160.120, may present some problems to the test facility or sponsor. Nevertheless, a detailed sponsor-approved protocol is essential to ensure that all operations needed to fulfill the objectives of a study are performed. The required list of information is necessary to ensure that deviations, should they occur, are readily apparent. It is unlikely that a sponsor, who is financing a test study, would have no authority regarding the development of a protocol or the functioning of a given test.

2. *Absorption of test and control substances.* One commenter questioned the rationale for the placement of a statement on the method by which the degree of absorption of test and control substances under proposed § 163.80–6(g)(1)(i)(L) (45 FR 26373) will be determined in a general GLP document. The commenter argued that, since these studies represent only a small fraction of the testing done, they should be discussed only under the guidelines for metabolism testing and not in the GLP protocol requirements.

The Agency recognizes that absorption studies may be conducted concurrently with or as part of a toxicity study, and points out that the details of the determination of degree of absorption will be laid out in the protocol. Inclusion of the requirement at § 160.120(a)(12) in the final rule is only to assure that a method is documented; it makes no statement regarding the detail of the method. The Agency disagrees with the statement that these studies should be discussed only under the guidelines for metabolism testing. The scope of the GLPs should be as broad as possible in order to ensure, as far as possible, the quality and integrity of test data submitted to the EPA. Therefore, the requirement is retained in the final rule.

3. *Co-signature of entered data.* Many commenters objected, in a general sense, to EPA's co-signature requirement under proposed § 163.80–6(g)(2)(v) (45 FR 26373) stating that it was burdensome, unnecessary, or impractical to have an additional employee present to observe every event being recorded. Some felt the requirement to be a duplication of effort, since the study director and QAU require validation of data entries. Other commenters stated that the requirement was not consistent with FDA GLPs and that alternative approaches should be considered, e.g., co-signature by a co-worker or supervisor within one week, or microfilmed copies (one under lock and key, and one user copy), or deletion or rewording of the co-signature requirement.

The Agency has reviewed the comments and agrees that the proposed requirement of entering data with a co-signature by a co-worker is burdensome and has withdrawn the requirement. The FIFRA GLPs as amended are now consistent with the FDA GLPs and require that all data entries be dated on the day of entry and be signed or initialed by the person entering the data in § 160.130(e). In computer-driven data collection systems, the individual responsible for direct data input shall be identified at the time of data input. The EPA does not object to the microfilming of laboratory records as long as the data are readily available with the service of a microfilm reader.

4. *Specimen identification.* One commenter took issue with EPA's requirement on specimen identification under proposed § 163.80–6(g)(2)(iii) (45 FR 26373). The commenter states that the method of identification proposed is not always practical (e.g., microscopic slides could not contain all the required information), and suggests that the use of appropriate accession numbers or code numbers is adequate for identifying specimens and for their retrieval.

The Agency considers that the use of accession or code numbers is acceptable as long as the information accompanies the specimen and precludes error in the recording and storage of data.

5. *Review of data entry and documentation.* Commenters felt that the responsibility for specifying the nature of review of data entry and documentation must rest with the study director (proposed § 163.80–6(c)(3)(ii); 45 FR 26373).

The Agency notes that, in the final standard at § 160.33, the study director has the overall responsibility for the technical conduct of the study, including assuring that all experimental data are accurately recorded and verified. Such a requirement would not be inconsistent with the study director specifying the actual nature of the review of data entry and documentation.

6. *"Working" data.* In relation to the acquisition of data by computer, a commenter felt that the concept of "working" data should be introduced in proposed § 163.80–6(g)(2)(v) (45 FR 26373). The commenter suggested changing the proposed regulations to permit changes and corrections to these data at the time of entry.

The Agency elects to leave the requirement basically as is. The Agency recognizes, however, the importance of documenting any changes in the computer entries to ensure the quality and integrity of test data.

7. *Exploratory studies.* A commenter pointed out that the GLPs contain no section which excludes exploratory studies such as found in the FDA GLPs.

The Agency considers that exploratory studies, as defined in the FDA GLPs, are excluded from coverage by the final rule's § 160.1.

*H–I—[Reserved]*

*J. Records and Reports*

1. *Final report.* Many commenters recommended that specific proposed reporting requirements under § 163.83–1(d) (43 FR 37377), for example, or the entire reporting section at § 163.80–4 (43 FR 37354) should be deleted and/or placed under the GLPs. Two commenters stated that the FIFRA proposal's approach of requiring that records be made available upon request under proposed § 163.40–5 (c) and (d) (43 FR 29696) should apply to TSCA. Format for the final report was of particular concern. Comments and objections are listed below:

a. Some wanted only general guidelines while others requested deletion of the section.

b. One commenter stated that the final report should be in two parts, i.e., general section with the protocol, summary, etc., and a specific section with data on individual animals.

c. Several commenters suggested that a detailed summary should be the report itself, while others favored a minimum contents requirement such as is contained in the FDA GLP regulations.

d. One commenter favored the EPA format.

e. One stated it was unreasonable to expect recording of data developed during testing to be precisely the same format as the final report.

f. One commenter felt that requirements for data tabulation should be deleted while several commenters stated that tabulation of reported data by sex and dose level was repetitive and confusing.

g. One felt that formatting would restrict evaluation and innovative interpretation of data.

h. One commenter stated that any format mandated by EPA should require the use of clear and concise English.

i. A commenter said EPA should allow flexibility in data formatting requirements for several years while computer programs are modified to conform to EPA's needs. The commenter further stated that development of new programs to handle excessive data requirements would be an economically wasteful task.

j. Many commenters felt that prescribed formats would make data reporting inflexible and that standardized formats are inappropriate and totally unacceptable. One commenter stated that EPA's refusal to review data if it is not in a proper approved format is unrealistic.

k. Another commenter stated it is incongruous to mandate to highly qualified staff strict reporting formats, and furthermore that these stifling requirements would make it difficult to recruit and motivate staff.

l. One thought the pathologist should be allowed discretion in the reporting of lesions.

m. A commenter felt that, in the last analysis, it is the judgment of the pathologist that is most important in how histopathologic data should be reported. Tables, graphs and other standardized formats for reporting would be only of limited usefulness due to many variables and, in fact, may tend to obscure important results. This would be especially true in the reporting of possibly pre-neoplastic lesions.

n. Multiple commenters stated that the reporting of individual animal data (as opposed to group data) including dates, days, and times of study commencement, killing of animals, performance of gross necropsy and histopathologic examination, in proposed § 163.80–4 (43 FR 29696) would be excessive, burdensome, unnecessary, and/or would serve only to increase the bulk of the final report. Several commenters felt that individual animal reports are excessive even in a tabular form. It was further stated that individual animal data are rarely required to clarify an equivocal effect. Such information is stored as raw data and is available for inspection. One person stated that group data (means and trends) is of more value than individual data. One commenter stated that mean organ weights provide sufficient data for proper evaluation. One person agreed with EPA except perhaps for the reporting of pre-neoplastic lesions. Another commenter suggested that in certain instances, e.g., dosing, data should be on a group basis.

The EPA has decided for the present to adopt in § 160.185 the final report format found in the FDA GLPs with certain minor modifications. The Agency is continuing to study the issue of standardizing the formating of certain types of data in order to make more efficient the process of reviewing study reports.

Section 160.185(a)(12) requires that all professionals "involved in the study" sign and date individual reports which form a part of the final report. The Agency has chosen to add to § 160.185(a)(12) a clause making it clear that any person who, at the request or direction of the testing facility or sponsor, analyzes or evaluates data or specimens from a complete study is a person "involved in the study." The reports of the individuals involved in the study must set forth fully and accurately "the findings of the individual scientists," as stated in the FDA GLP preamble (43 FR 60009), including their expert opinions. The fact that a person performs a peer review of another person's draft report does not by itself mean that the peer reviewer is a person "involved in the study." EPA also has added a new paragraph, §160.185(d), requiring explicitly what the FDA regulations appear to contemplate tacitly—that the sponsor be furnished a copy of the final report. Finally, the Agency has chosen to amend § 160.185(a) slightly to make it clear that a final report must be prepared even if a study is terminated or discontinued rather than, strictly speaking, "completed" (comparable language appears at § 160.195(b)(3) and in 21 CFR 58.195(b)(3)).

These changes, if complied with, will ensure that all expert assessments of data and specimens from all covered studies will be recorded, retained and forwarded to the sponsor. The final report will include any "dissenting opinions" obtained by the testing facility concerning the meaning of the data from the study. This approach is consistent with the Agency's interpretations of, and policy concerning, the reporting obligations of registrants under FIFRA section 6(a)(2). See 43 FR 37611, 37612 (Aug. 23, 1978); 44 FR 40716, 40717 (July 12, 1979). As the latter document states: "[I]f it is not the data, but the expert analysis, conclusions, or opinion itself with which the registrant disagrees, the registrant's remedy is not to withhold the information from EPA, but to submit with the section 6(a)(2) report his own analysis of the information's significance" (44 FR 40718).

2. *Reporting to EPA by the sponsor.* Several commenters argued that reporting to EPA should be by the sponsor, not by the tester, if he should be different from the sponsor. One person felt that the sponsor should present the rationale for species, strain, dose levels, and route of administration directly to the Agency, as indicated in proposed § 163.80–4 (43 FR 37354).

The Agency agrees that if the sponsor is different from the test facility, the sponsor is responsible to submit the test report on a given chemical. However, the testing facility is required to maintain a protocol which includes:

a. Where applicable, species and strain of animal.

b. The dosage level of chemical.

c. The rationale for the route of administration.

d. A description of the diet used in the study as well as solvents, emulsifiers, and/or other materials used to solubilize or suspend the test or control substances before mixing with the carrier under § 160.120(a)(9).

In addition, the stability of the test and control substances in any mixture (e.g., feed) must be determined under § 160.113. Ultimate responsibility for these requirements lies with the test sponsor.

3. *Submission of raw data.* There were a number of objections to the EPA's requirements for submission of raw data in the final report under proposed § 163.80–4 (43 FR 37354). Objections included:

a. FDA found it impractical and required only a recapitulation of the data.

b. Requirements on cleaning and pest control agents are listed in the GLPs and therefore such data are needless.

c. FDA inspections of data should apply.

d. Loss of records and breach of confidentiality during shipping and/or storage of data may occur.

e. Cost will be significant.

f. Submission of the raw data will be justified only in a few exceptional cases, e.g., where a testing laboratory goes out of business and the sponsor either cannot be identified or does not have appropriate storage facilities.

The Agency agrees that it is not practical and often costly to include all raw data, including information on cleaning and pest control agents, for example, in the final reports. Therefore, this requirement has been deleted and replaced with a much more modest requirement for reporting study results in § 160.185.

With regard to the submission of raw data in cases where a testing laboratory goes out of business, the final rule requires that the Agency be notified in writing of the transfer of all raw data, documentation and other materials from a facility going out of business to the archives of the sponsor of the study under § 160.195(g). This requirement is consistent with FDA's 21 CFR 58.195(g).

4. *Age of animals.* Commenters felt it would be impossible to record an accurate age for rodents as proposed in § 163.83–1(d) (43 FR 37377), since ages are stated as one- to three-week birth date intervals. Problems of variance in birth date within an experiment are generally negated by the randomization process used to distribute animals to appropriate test groups.

The Agency agrees with the commenters, and advises that the GLPs now state that, "Where applicable, the final report shall include * * * age (of animals) * * *" in § 160.185(a)(7).

5. *Deviations from the test standards.* A commenter felt the proposed requirement to report all deviations from test standards was excessive and should be deleted. One commenter wanted to know if it is mandatory to report and justify deviations which result in the test exceeding the standards under proposed §§ 163.80–4(b)(2)(i) and § 163.40–3 (43 FR 29696).

The Agency advises that the present GLP requirement is for "a description of all circumstances that may have affected the quality or integrity of the data" in § 160.185(a)(7). See also the discussion in this rule concerning § 160.17.

6. *Fire-resistant barriers.* One commenter considered that EPA's proposed requirement that tissue blocks must be separated from specimen slides by a fire-resistant barrier as proposed § 163.80–7(b)(2) (45 FR 26373) was superfluous and unnecessary. He stated that the cost of such barriers is expensive with little benefit since the chance of fire is so remote. Other comments indicated that the Agency should allow greater flexibility, i.e., allowing methods other then fire-resistant barriers for protecting the archives or merely providing that, in the event of a fire, it was the responsibility of the sponsor to provide the Agency with adequate support for the safety data or rerun of the test. Other comments indicated that the fire barrier requirement is vague and impossible to enforce because there are varying degrees of fire resistance and therefore no way to specify the resistance needed to protect the records adequately. One commenter supported the EPA requirement for fire resistant barriers. Several commenters requested that EPA be consistent with the FDA GLP's which do not have this requirement.

On the basis of these comments, the Agency concludes that the proposed requirement for a fire-resistant barrier is not appropriate and has not included it in the current standards.

7. *Microfilming of data.* EPA requested comment on the microfilming of data (45 FR 26375, April 18, 1980). The comments received were as follows:

a. The Agency should not specify the details of when a sponsor can reduce this data to microfilm but leave this decision to the sponsor or testing laboratory.

b. The Agency should consider the use of microfilming at some appropriate time during the retention of the data, e.g., three or five years.

c. Original data should be discarded after microfilming is completed.

d. A two-year retention period should be required before microfilming is used.

e. Retention of raw data for five years is appropriate, after which time the laboratory should have to retain only a micrographic copy.

f. When microfilming of appropriate data is a recognized company policy, the Agency should allow retention of the original records for three years before microfilming and discarding of the original data.

g. EPA should not enter into a discussion about microfilming but solely require that records be maintained. This is because the state of the art is in such a state of flux. One of these commenters states that the definition of raw data in proposed § 163.80–6(a)(3) (45 FR 26373) covers microfilming adequately without being necessarily limiting.

h. One commenter is not convinced that microfilm copies are at any time suitable substitutes for raw data, records, etc.

The Agency has reviewed the comments and agrees that it is unnecessary to specify the time required before raw data should or can be microfilmed. In addition, the definition for raw data allows an exact copy to be substituted for original data which includes microfilming.

8. *Employment records.* One commenter asked, "Does EPA mean to include all employment records within the scope of their rules?" in reference to proposed § 163.80–7(c)(5) (45 FR 26373).

The Agency advises that the requirement for retention of occupational records (i.e., training and job descriptions) has been revised to read "* * * may be retained along with all other testing facility employment records * * *" under § 160.195(f). This does not include pay records.

9. *"Non-fixed" samples.* One commenter stated that adoption of proposed § 163.80–7(c) (2) and (3) (45 FR 26373) would require that wet specimens, samples of test or control samples, etc., be kept for unnecessarily long periods. Another commenter stated that only specimens of relatively long stability should be retained. Retention of specimens should include only formalin-fixed tissues, histochemical preparations if permanently mounted, electron microscopic mounts, blood mounts, paraffin blocks, and tissue section mounts. Whole blood, plasma, sera, urine, and other "non-fixed" samples need not be retained for extended periods of time.

The Agency notes that FDA deleted the requirement for retention of "samples of test or control article carrier mixtures" but has retained the requirement for retention of test or control substances, per se. EPA has followed FDA's lead in this and has accordingly revised § 160.195 to be consistent with FDA on this point. The Agency is aware of the difficulties in the storage of "non-fixed" samples. Section 160.195(c) clearly states that fragile samples, e.g., whole blood, sera, etc., shall be retained only so long as the quality of the preparation affords evaluation.

10. *Out of business/change of ownership—transfer of records.* EPA proposed at § 163.80–7(c)(7)(i) (45 FR 26373) that if a testing facility goes out of business, all records must be transferred to the archives of the sponsor of the study and EPA must be notified in writing about such transfer and the specific new location of the test data must be provided. One commenter stated that it is automatic to have the material transferred to the sponsor if the contractor goes out of business. Another commenter felt there was no need to notify EPA if the archived materials were not moved to the sponsor's facilities after a facility changed ownership or management.

EPA also proposed at § 163.80–7(c)(7)(ii) (45 FR 26373) that if a testing facility changes ownership or management, the Agency and the sponsor must be notified. This same proposal applied to an archive-

contracting facility holding records of FIFRA tests that is changing ownership or management. Such records and other associated material were not to be disposed of without the concurrence of the Agency and the sponsor. Several commenters felt that the EPA was requesting too much detail. They argued that the sponsor should be responsible for the integrity of the records. Four persons stated that EPA should merely require notification, consistent with FDA requirements. Two persons argued that EPA notification is unnecessary. Three commenters argued that no adequate definition of changing management is provided, while one commenter suggested that the requirement be made more explicit or be deleted.

The Agency, after review of the comments, has revised the GLP requirements at § 160.195(g) to be generally consistent with FDA requirements, i.e., EPA requires that if a testing facility or an archive contracting facility goes out of business, the Agency must be notified in writing of the record transfer to the test sponsor.

11. *Proper functioning of the QAU in relation to need for long-term archiving of records.* Some commenters felt that the responsibility of the quality assurance unit (QAU) to verify raw data periodically during the conduct of a study should negate the need to archive most of the records and samples for the proposed period (proposed § 163.80-7(c)(2); 45 FR 26373).

The retention period for samples and specimens has been changed, as discussed elsewhere in this preamble. Furthermore, the responsibilities of the QAU to verify raw data does not eliminate the possible need by the Agency to reanalyze and review archived records and data after a study has been completed. The Agency does not negate the importance of the QAU. It considers, however, that the retention of samples and records increases the assurance of the quality and integrity of submitted testing data.

12. *Individual responsible for the archives.* One commenter stated that the requirement for the name and address of the individual responsible for the archives under proposed § 163.80-4 (b)(2)(ix) (43 FR 29696) is unnecessary since the submitting company bears the ultimate responsibility for the validity of the studies. The commenter further stated that giving the location of the archives is sufficient. Two commenters requested the deletion of the EPA requirement for the name and address of the individual responsible for the data archives.

Three commenters requested deletion of the requirement that only authorized personnel may enter the archives as proposed in § 163.80-7(b)(4) (45 FR 26373). They felt the requirement to log in and out the items held in the archives as proposed in § 163.80-7(b)(2) should be deleted, because such a process is cumbersome and also because the security methods for the archives is the responsibility of the test facility management or sponsor. One commenter supported the EPA requirement.

The Agency has adopted the FDA position that only the name of the individual responsible for the data archives is required in § 160.190(c). The Agency disagrees that such a requirement is unnecessary. The Agency is persuaded of the need for one individual to be accountable for the maintenance and security of the archives to prevent access by unauthorized personnel. Such access could lead to the loss of, or damage to, records and specimens required to be maintained by these regulations. This provision does not preclude delegation of duties to other individuals who may help maintain the archives.

The Agency has therefore retained the first sentence of proposed § 163.80-7(b)(4); it now appears at § 160.190(d) as a requirement. The Agency agrees that security methods for safekeeping of the data, i.e., logging in and out of items in the archives, should be the responsibility of the management or sponsor and has not included the latter proposal in the final rule.

13. *Retention time for records.* There were many objections to EPA's proposed requirements on retention time for documentation records, raw data, and specimens under § 163.80-7(c) (2) and (4) through (6) (45 FR 26373). The proposed GLPs required retention of records until each application with which they are associated is denied or until each registration is canceled. Objections included the following:

a. The retention of raw data, specimens, and other records should be for no more than 10 years.

b. EPA should be consistent with FDA on the maximum length of time required for retention of records (FDA requirement is two to five years).

c. EPA has not justified its requirements in proposed § 163.80-7(c)(2) for retention of raw data and test substances, since different types of records should be maintained for different periods of time. For example: test or control substances should be maintained according to their rate of degradation, and records such as equipment calibration should be maintained for an intermediate time period.

d. Definite time limits on retention of raw data specimens and test substances should be established.

e. EPA should not establish a minimum length of time that "original data" (translated to mean bulky data) be retained.

f. EPA should consider retention of data on a case-by-case basis to determine when records, test samples, etc., should be terminated.

g. EPA could reduce the cost burden if it permitted discarding of data after such data have been subjected to EPA audit and validated.

h. EPA should not demand more than is really necessary and of value to the Agency, since FIFRA requirements are different from the TSCA GLPs. Two commenters agreed with EPA proposed § 163.80-7(c)(2) that it is sensible to retain raw data, specimens, etc., for the period during which there is an active application or registration for the substance to which the records relate. Two said that only key records should be stored for the life of the product.

i. Indefinite retention of records creates excessive archival space requirements. In addition, reconstruction of archival facilities may be required which may result in damage or loss of raw data.

j. Several commenters stated that the requirements require additional space, attendent personnel, and increased costs.

On the basis of these comments, the Agency concludes that the indefinite storage of all specimens and test samples is inappropriate and unreasonable. The final rule at § 160.195 requires such items as wet specimens, samples of test or control substances and specially prepared material, and similar items of relatively short stability to be retained only for as long as the quality of the preparation affords evaluation. More stable specimens, including fixed tissue blocks and slides, are to be retained for the same period as documentary raw data, but EPA has added a new § 160.195(h) which allows disposal of these non-documentary materials with EPA's consent, which normally will be given after an audit of the study leads EPA to conclude that the study was properly conducted.

With respect to retention of documentary raw data and other similar written records connected with the registration support data, the Agency has concluded that such data should be retained for the life of the registration of the pesticide. Such retention affords

both the applicant and the Agency the opportunity to conduct further studies and investigations at any time during which the pesticide is being used and entering the environment. Applicants, testing firms, and record-retention establishments should note that the Agency has no objection to the practice of storing microfilmed records of such data in lieu of retaining the original records. However, once the records are microfilmed, a responsible person should attest to the completeness of the microfilmed file; following this, the original documents may be discarded. The Agency has carefully considered this practice and has determined that the benefits of responsible microfilming outweigh the advantages of retaining original records.

EPA advises sponsors and testing facilities, who may have invested substantial amounts in testing, that the continuing value of the data for purposes of supporting research and marketing permits, to other persons as well as the original investors, may depend on compliance with the record retention and availability provisions of the regulation. Sponsors who transfer rights in data for consideration, and potential buyers of such data rights, thus would be advised to be aware whether there has been continued compliance with these provisions.

14. *Miscellaneous comments.* Finally, many commenters objected to the 1980 proposal's incorporation by reference in an Appendix of other laws, recommendations, and guidelines, stating:

(a) They have no legal or regulatory standing.

(b) They are redundant and/or fall within the purview of other agencies.

c. There is no provision for public review as required by the Administrative Procedure Act.

d. The economic impact was not considered.

e. It promotes confusion and is inconsistent with the FDA GLPs.

f. There will be an adverse impact on "unqualified" testing laboratories.

g. It would be restrictive of improvements in equipment technologies.

h. Radioactive materials are already highly regulated.

i. The GLPs should be complete in themselves.

The Agency is in general agreement with the comments and concludes that these recommendations should not duplicate regulations and requirements subject to the purview of other agencies or not subjected to a formal public review process. Therefore, the Appendix as proposed in § 163.80–7 (45 FR 26373) has not been incorporated into the final rule.

## III. FIFRA Scientific Advisory Panel Recommendations

Formal recommendations were made by the FIFRA Scientific Advisory Panel, following their review of the draft FIFRA document on July 19 and 20, 1979, as published in the **Federal Register** of April 18, 1980 (45 FR 26385). Recommendations accepted by the Agency were placed in the proposed GLPs at § 163.80–6(f)(3) (iii), (v), (viii), and (ix). In order to minimize the differences among the FIFRA, TSCA and FDA GLPs, these recommendations were withdrawn from the GLP standards and are placed below as additional guidance for testing facilities.

1. *Treatment of test animals for disease.* Treatment of test animals for disease should be undertaken only if absolutely necessary to allow for the continuation of a study in which there has been a considerable investment of time and resources. In these cases, complete documentation of the treatment should be submitted to the Agency so that an evaluation can be made regarding the effect of the treatment on the toxicological assessment of the test substance. The nature of the disease, quantity of medication given, and route of administration should be clearly indicated.

2. *Housing of animals of different species.* Under most circumstances, animals of different species should always be housed in separate rooms. In those circumstances where they must be housed in the same room, a statement should be submitted to the Agency explaining the reasons for the housing pattern and documentation that the joint housing did not compromise the results of the test(s) involving the test substance under study.

3. *Use of bedding.* To the extent possible, use of bedding should be avoided entirely for most studies required by this part, and should be used only where absolutely essential to the proper conduct of a study.

4. *Use of cleaning and pest control materials.* If use of cleaning and pest control materials are necessary during the conduct of a study, such use should be subject to the following limitations: (1) Persistent chlorinated hydrocarbon pest control materials should never be used; (2) volatile organophosphate and carbamate pest control materials should be avoided to the extent possible; and (3) documentation should include descriptions of quarters, time of treatment, purpose, quantity used, chemical and trade name of material, and name of vehicle.

## IV. Regulatory Assessment Requirements

### *A. Classification of Rule*

Under Executive Order (E.O.) 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirement of a regulatory impact analysis. This regulation in itself is not major because it does not meet any of the criteria set forth in section 1(b) of the Order. The cost impact of these regulations is anticipated to be insignificant, in most instances, because many laboratories are already following most provisions of these GLP Standards as a result of the FDA GLP Regulations.

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by E.O. 12291.

### *B. Regulatory Impact Analysis*

This regulation does not impose any direct costs upon the testing community. Initial start-up costs for establishing a GLP program within many testing laboratories will have already been incurred during the early phase of implementation under the FDA GLP regulations.

An intial estimate of additional cost of $80,000 per laboratory is only about 3 percent of the estimated $2.3 million of sales (dollar value of testing) of the average laboratory in 1980. While the significant ecomomic impact is on the commercial testing industry as a whole, and not the users of testing services, there may be some impacts on the smaller laboratories, e.g., especially those with less than 10 employees which account for 28 percent of the laboratories in a survey, but which account for a very small portion of the total testing volume. See reports listed below.

The survey indicated that over 70 percent of small laboratories cited capital as being their main constraint on growth and expansion. This difficulty might have been tied to their size, but it might also have been tied to the 20 percent over-capacity noted for 1980. Given the available data, it cannot be determined exactly how these small laboratories will be affected by the additional costs of the EPA GLP Standards.

The cost analysis is contained in the report, analysis of the Cost of EPA's Good Laboratory Practice Standards, "Borriston Laboratories, Inc. 1982. Results of the industry survey are presented in Chemical Testing Industry:

Profile of Toxicological Testing," 1981. EPA 560/4-81-003. These documents and reports are available in the public record for this rulemaking proceeding.

*C. Regulatory Flexibility Act*

Under the Regulatory Flexibility Act (RFA) (15 U.S.C. 601, Pub. L. 96-354, September 19, 1980), EPA is certifying that this regulation will not have a significant impact on a substantial number of small entities. As discussed in Unit IV. A. above, no costs will be imposed by this regulation.

*D. Paperwork Reduction Act*

Information collection requirements contained in this regulation at § 160.185 have been approved by the Office of Management and Budget (OMB) under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq. and have been assigned OMB Control numbers: 2000-0468 and 2000-0483.

*E. Environmental Impact Statement*

EPA is not required to prepare an Environmental Impact Statement under the National Environmental Policy Act of 1969 (NEPA) (41 U.S.C. 4321 et seq.) for this rule since it will not significantly affect the quality of the human environment. See the preamble to the Agency's rules for compliance with NEPA published in the **Federal Register** of November 6, 1979 (44 FR 84174).

**V. Public Participation and Records Requirements**

*A. Public Participation*

Public participation has significantly influenced the development of the GLP standards. During the development of the proposed standards, numerous meetings and discussions were held with non-EPA scientists and with an Agency work group consisting of Agency scientists, other EPA officials and scientists from other Federal agencies. Preliminary drafts of the proposed standards were reviewed by industry, environmental groups and EPA's Science Advisory Board. In addition, other meetings were held on specific scientific issues and included scientific experts from the EPA and other Government agencies.

The public comment period for receiving written comments on the two TSCA GLP proposals (44 FR 27334; 44 FR 44054) extended from the May 9 and July 26, 1979 proposal dates until October 16, 1979. In an effort to solicit additional public comment, a public meeting was held in Chicago, October 15-16, 1979, and several meetings were held with the EPA Science Advisory Board. A total of 323 submissions were received from the public in response to the two FIFRA proposals, dated August 22, 1978 and April 18, 1980 (43 FR 37336; 45 FR 26373), and the two TSCA proposals. The comments came from industry (116), trade associations (16), U.S. Government agencies and scientists (34), foreign government bodies (10), private testing or consulting laboratories (44), individual scientists and concerned citizens (53), public interest organizations (10), and legal firms (2). Comments were also received on the July 10, 1978 FIFRA guidelines proposal (43 FR 29708).

*B. Public Record*

EPA has established a public record for this rule (docket number OPP 30023C) which is available for inspection in Rm. 236, Crystal Mall #2, 1921 Jefferson Davis Highway, VA from 8:00 a.m. to 4:00 p.m. Monday through Friday, excluding legal holidays. This record includes basic information considered by the Agency in developing this rule. The Agency has supplemented this record with additional information as it was received. The record includes the following categories of information:

(1) Minutes, summaries, or transcripts relating to public meetings held to develop or review this rule.

(2) All public comments received in connection with the proposal of Subpart F of the FIFRA guidelines relevant to the proposal of this part.

(3) Published documents (or copies thereof) cited in any document in this record, to the extent that they would not ordinarily be available through ordinary library loans.

(4) All public comments received in connection with the proposal of Subpart B of 40 CFR Part 163 (43 FR 29696 and 29706, July 10, 1978) relevant to the proposal of this part.

(5) All comments from the Scientific Advisory Panel and the U.S. Department of Agriculture.

**VI. Statutory Review**

In accordance with FIFRA sec. 25, copies of an earlier draft of this regulation were submitted in September 1981 to the FIFRA Scientific Advisory Panel, to the U.S. Department of Agriculture, and the Chairmen and ranking minority members of the Committee on Agriculture of the U.S. House of Representatives and the Committee on Agriculture and Forestry of the U.S. Senate. The Panel concurred unanimously in recommending promulgation of this rule. The specific comments of the Panel and those of the U.S. Department of Agriculture are available for review at the address given in unit V.B. above and in the pesticide branch office of each Regional Office of the Agency. All comments were considered and, to a large extent, used by the Agency in the development of this rule. No comments were received from the U.S. Congress.

**VII. Effective Date**

FIFRA sec. 25(e) requires EPA to submit final regulations to Congress for review before the regulation becomes effective. Copies of this rule have been transmitted to appropriate offices in both Houses of Congress.

This rule will not take effect before the end of 60 calendar days of continuous session of Congress after the date of publication of this rule. Since the actual length of this waiting period may be affected by Congressional action, it is not possible, at this time, to specify a date on which this regulation will become effective. Therefore, EPA, at the appropriate time, will issue a notice for publication in the **Federal Register** notifying the public of the actual effective date of this regulation.

**List of Subjects in 40 CFR Part 160**

Good laboratory practice, Environmental protection, Hazardous materials, Pesticides and pests, Recordkeeping and reporting requirements.

Dated: October 31, 1983.

**William D. Ruckelshaus,**

*Administrator.*

Therefore, 40 CFR is amended by adding Part 160 to read as follows:

## PART 160—GOOD LABORATORY PRACTICE STANDARDS

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**Subpart K—[Reserved]**

**Authority:** 7 U.S.C. 136 a, 136 c, 136 d, 136 f, 136 j, 136 t, 136 v, 136 w; 21 U.S.C. 346 a, 348, 371; Reorganization Plan No. 3 of 1970.

## Subpart A—General Provisions

### § 160.1 Scope.

(a) This part prescribes good laboratory practices for conducting studies that support or are intended to support applications for research or marketing permits for pesticide products regulated by the EPA. This part is intended to assure the quality and integrity of data submitted pursuant to sections 3, 5, 8, 18, and 24(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136a, 136c, 136f, 136q, and 136v(c)) and sections 408 and 409 of the Federal Food, Drug and Cosmetic Act (FFDCA) (21 U.S.C. 346a, 348).

(b) This part applies to any study described by paragraph (a) of this section which any person conducts, initiates, or supports on or after December 29, 1983,

### § 160.3 Definitions.

As used in this part the following terms shall have the meanings specified:

(a) "Application for research or marketing permit" includes:

(1) An application for registration, amended registration, or reregistration of a pesticide product under FIFRA sections 3 or 24(c).

(2) An application for an experimental use permit under FIFRA section 5.

(3) An application for an exemption under FIFRA section 18.

(4) A petition or other request for establishment or modification of a tolerance, for an exemption for the need for a tolerance, or for other clearance under FFDCA section 408.

(5) A petition or other request for establishment or modification of a food additive regulation or other clearance by EPA under FFDCA section 409.

(6) A submission of data in response to a notice issued by EPA under FIFRA section 3(c)(2)(B).

(7) Any other application, petition, or submission sent to EPA intended to persuade EPA to grant, modify, or leave unmodified a registration or other approval required as a condition of sale or distribution of a pesticide.

(b) "Batch" means a specific quantity or lot of a test or control substance that has been characterized according to § 160.105(a).

(c) "Control substance" means any chemical substance or mixture or any other material other than a test substance that is administered to the test system in the course of a study for the purpose of establishing a basis for comparison with the test substance.

(d) "EPA" means the U.S. Environmental Protection Agency.

(e) "FDA" means the U.S. Food and Drug Administration.

(f) "FFDCA" means the Federal Food, Drug and Cosmetic Act, as amended (21 U.S.C. 321 et seq.).

(g) "FIFRA" means the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 et seq.).

(h) "Person" includes an individual, partnership, corporation, association, scientific or academic establishment, government agency, or organizational unit thereof, and any other legal entity.

(i) "Quality assurance unit" means any person or organizational element, except the study director, designated by testing facility management to perform the duties relating to quality assurance of the studies.

(j) "Raw data" means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. "Raw data" may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments.

(k) "Specimen" means any material derived from a test system for examination or analysis.

(l) "Sponsor" means:

(1) A person who initiates and supports, by provision of financial or other resources, a study;

(2) A person who submits a study to the EPA in support of an application for a research or marketing permit; or

(3) A testing facility, if it both initiates and actually conducts the study.

(m) "Study" means any in vivo or in vitro experiment in which a test substance is studied prospectively in a test system under laboratory conditions to determine or help predict its toxicity, metabolism, or other characteristics in humans and domestic animals. The term does not include studies utilizing human subjects or clinical studies or field trials in animals. The term does not include basic exploratory studies carried out to determine whether a test substance has any potential utility or to determine physical or chemical characteristics of a test substance.

(n) "Study director" means the individual responsible for the overall conduct of a study.

(o) "Test substance or mixture" means a substance or mixture administered or added to a test system in a study, which substance or mixture:

(1) Is the subject of an application for a research or marketing permit supported by the study, or is the contemplated subject of such an application; or

(2) Is an ingredient, impurity, degradation product, metabolite, or radioactive isotope of a substance described by paragraph (o)(1) of this section, or some other substance related to a substance described by that paragraph, which is used in the study to assist in characterizing the toxicity, metabolism, or other characteristics of a substance described by that paragraph.

(p) "Test system" means any animal, plant, microorganism, or subparts thereof, to which the test or control substance is administered or added for study. "Test system" also includes appropriate groups or components of the system not treated with the test or control substances.

(q) "Testing facility" means a person who actually conducts a study, i.e., actually uses the test substance in a test system. "Testing facility" encompasses only those operational units that are being or have been used to conduct studies.

**§ 160.10 Applicability to studies performed under grants and contracts.**

When a sponsor or other person utilizes the services of a consulting laboratory, contractor, or grantee to perform all or a part of a study to which this part applies, it shall notify the consulting laboratory, contractor, or grantee that the service is, or is part of, a study that must be conducted in compliance with the provisions of this part.

**§ 160.12 Statement of compliance or non-compliance.**

Any person who submis to EPA an application for a research or marketing permit and who, in connection with the application, submits data from a study to which this part applies shall include in the application a true and correct statement, signed by the applicant, the sponsor, and the study director, of one of the following types:

(a) A statement that the study was conducted in accordance with this part; or

(b) A statement describing in detail all differences between the practices used in the study and those required by this part; or

(c) A statement that the person was not a sponsor of the study, did not conduct the study, and does not know whether the study was conducted in accordance with this part.

**§ 160.15 Inspection of a testing facility.**

(a) A testing facility shall permit an authorized employee or duly designated representative of EPA or FDA, at reasonable times and in a reasonable manner, to inspect the facility and to inspect (and in the case of records also to copy) all records and specimens required to be maintained regarding studies to which this part applies. The records inspection and copying requirements should not apply to quality assurance unit records of findings and problems, or to actions recommended and taken, except that EPA may seek production of these records in litigation or formal adjudicatory hearings.

(b) EPA will not consider reliable for purposes of supporting an application for a research or marketing permit any data developed by a testing facility or sponsor that refuses to permit inspection in accordance with this part. The determination that a study will not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any applicable statute or regulation to submit the results of the study to EPA.

**§ 160.17 Effects of non-compliance.**

(a) EPA may refuse to consider reliable for purposes of supporting an application for a research or marketing permit any data from a study which was not conducted in accordance with this part.

(b) Submission of a statement required by § 160.12 which is false may form the basis for cancellation, suspension, or modification of the research or marketing permit, or denial or disapproval of an application for such a permit, under FIFRA sections 3, 5, 6, 18, or 24 or FFDCA sections 408 or 409, or for criminal prosecution under 18 U.S.C. 2 or 1001 or FIFRA section 14, or for imposition of civil penalties under FIFRA section 14.

## Subpart B—Organization and Personnel

**§ 160.29 Personnel.**

(a) Each individual engaged in the conduct of or responsible for the supervision of a study shall have education, training, and experience, or combination thereof, to enable that individual to perform the assigned functions.

(b) Each testing facility shall maintain a current summary of training and experience and job description for each individual engaged in or supervising the conduct of a study.

(c) There shall be a sufficient number of personnel for the timely and proper conduct of the study according to the protocol.

(d) Personnel shall take necessary personal sanitation and health precautions designed to avoid contamination of test and control substances and test systems.

(e) Personnel engaged in a study shall wear clothing appropriate for the duties they perform. Such clothing shall be changed as often as necessary to prevent microbiological, radiological, or chemical contamination of test systems and test and control substances.

(f) Any individual found at any time to have an illness that may adversely affect the quality and integrity of the study shall be excluded from direct contact with test systems, test and control substances and any other operation or function that may adversely affect the study until the condition is corrected. All personnel shall be instructed to report to their immediate supervisors any health or medical conditions that may reasonably be considered to have an adverse effect on a study.

**§ 160.31 Testing facility management.**

For each study, testing facility management shall:

(a) Designate a study director as described in § 160.33 before the study is initiated.

(b) Replace the study director promptly if it becomes necessary to do so during the conduct of a study, and document and maintain such action as raw data.

(c) Assure that there is a quality assurance unit as described in § 160.35.

(d) Assure that test and control substances or mixtures have been appropriately tested for identity, strength, purity, stability, and uniformity, as applicable.

(e) Assure that personnel, resources, facilities, equipment, materials and methodologies are available as scheduled.

(f) Assure that personnel clearly understand the functions they are to perform.

(g) Assure that any deviations from these regulations reported by the quality assurance unit are communicated to the study director and corrective actions are taken and documented.

**§ 160.33 Study director.**

For each study, a scientist or other professional of appropriate education, training, and experience, or combination thereof, shall be identified as the study director. The study director has overall responsibility for the technical conduct of the study, as well as for the interpretation, analysis, documentation, and reporting of results, and represents the single point of study control. The study director shall assure that:

(a) The protocol, including any change, is approved as provided by § 160.120 and is followed.

(b) All experimental data, including observations of unanticipated responses of the test system are accurately recorded and verified.

(c) Unforeseen circumstances that may affect the quality and integrity of the study are noted when they occur, and corrective action is taken and documented.

(d) Test systems are as specified in the protocol.

(e) All applicable good laboratory practice regulations are followed.

(f) All raw data, documentation, protocols, specimens, and final reports are transferred to the archives during or at the close of the study.

**§ 160.35 Quality assurance unit.**

(a) A testing facility shall have a quality assurance unit composed of one or more individuals who shall be

responsible for monitoring each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the regulations in this part. For any given study the quality assurance unit shall be entirely separate from and independent of the personnel engaged in the direction and conduct of that study.

(b) the quality assurance unit shall:

(1) Maintain a copy of a master schedule sheet of all studies conducted at the testing facility indexed by test substance and containing the test system, nature of study, date study was initiated, current status of each study, name of the sponsor, name of the study director, and status of the final report.

(2) Maintain copies of all protocols pertaining to all studies for which the unit is responsible.

(3) Inspect each phase of a study periodically and maintain written and properly signed records of each periodic inspection showing the date of the inspection, the study inspected, the phase or segment of the study inspected, the person performing the inspection, findings and problems, action recommended and taken to resolve existing problems, and any scheduled date for re-inspection. For studies lasting more than six months, inspections shall be conducted every three months. For studies lasting less than six months, inspections shall be conducted at intervals adequate to assure the integrity of the study. Any significant problems which are likely to affect study integrity found during the course of an inspection shall be brought to the attention of the study director and management immediately.

(4) Periodically submit to management and the study director written status reports on each study, noting any problems and the corrective actions taken.

(5) Determine that no deviations from approved protocols or standard operating procedures were made without proper authorization and documentation.

(6) Review the final study report to assure that such report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study.

(7) Prepare and sign a statement to be included with the final study report which shall specify the dates inspections were made and findings reported to management and to the study director.

(c) The responsibilities and procedures applicable to the quality assurance unit, the records maintained by the quality assurance unit, and the method of indexing such records shall be in writing and shall be maintained. These items including inspection dates, the study inspected, the phase or segment of the study inspected, and the name of the individual performing the inspection shall be made available for inspection to authorized employees or duly designated representatives of EPA or FDA.

(d) An authorized employee or a duly designated representative of EPA or FDA shall have access to the written procedures established for the inspection and may request testing facility management to certify that inspections are being implemented, performed, documented and followed-up in accordance with this paragraph.

(e) All records maintained by the quality assurance unit shall be kept in one location at the testing facility.

## Subpart C—Facilities

### § 160.41 General.

Each testing facility shall be of suitable size, construction, and location to facilitate the proper conduct of studies. It shall be designed so that there is a degree of separation that will prevent any function or activity from having an adverse effect on the study.

### § 160.43 Animal care facilities.

(a) A testing facility shall have a sufficient number of animal rooms or areas, as needed, to assure proper: (1) separation of species or test systems, (2) isolation of individual projects, (3) quarantine of animals, and (4) routine or specialized housing of animals.

(b) A testing facility shall have a number of animal rooms or areas separate from those described in paragraph (a) of this section to ensure isolation of studies being done with test systems or test and control substances known to be biohazardous, including volatile substances, aerosols, radioactive materials, and infectious agents.

(c) Separate areas shall be provided for the diagnosis, treatment, and control of laboratory animal diseases. These areas shall provide effective isolation for the housing of animals either known or suspected of being diseased, or of being carriers of disease, from other animals.

(d) When animals are housed, facilities shall exist for the collection and disposal of all animal waste and refuse or for safe sanitary storage of waste before removal from the testing facility. Disposal facilities shall be so provided and operated as to minimize vermin infestation, odors, disease hazards, and environmental contamination.

(e) Animal facilities shall be designated, constructed, and located so as to minimize disturbances that interfere with the study.

### § 160.45 Animal supply facilities.

There shall be storage areas, as needed, for feed, bedding, supplies, and equipment. Storage areas for feed and bedding shall be separated from areas housing the test systems and shall be protected against infestation or contamination. Refrigeration shall be provided for perishable supplies or feed.

### § 160.47 Facilities for handling test and control substances.

(a) As necessary to prevent contamination or mixups, there shall be separate areas for:

(1) Receipt and storage of the test and control substances.

(2) Mixing of the test and control substances with a carrier, e.g., feed.

(3) Storage of the test and control substance mixtures.

(b) Storage areas for the test and/or control substance and test and control mixtures shall be separate from areas housing the test systems and shall be adequate to preserve the identity, strength, purity, and stability of the substances and mixtures.

### § 160.49 Laboratory operation areas.

(a) Separate laboratory space shall be provided, as needed, for the performance of the routine procedures required by studies, including specialized areas for performing activities such as aseptic surgery, intensive care, necropsy, histology, radiography, and handling of biohazardous materials.

(b) Separate space shall be provided for cleaning, sterilizing, and maintaining equipment and supplies used during the course of the study.

### § 160.51 Specimen and data storage facilities.

Space shall be provided for archives, limited to access by authorized personnel only, for the storage and retrieval of all raw data and specimens from completed studies.

### § 160.53 Administrative and personnel facilities.

(a) There shall be space provided for the administration, supervision, and direction of the testing facility.

(b) Separate space shall be provided for locker, shower, toilet, and washing facilities, as needed.

## Subpart D—Equipment

### § 160.61 Equipment design.

Automatic, mechanical, or electronic equipment used in the generation, measurement, or assessment of data and equipment used for facility environmental control shall be of appropriate design and adequate capacity to function according to the protocol and shall be suitably located for operation, inspection, cleaning, and maintenance.

### § 160.63 Maintenance and calibration of equipment.

(a) Equipment shall be adequately inspected, cleaned, and maintained. Equipment used for the generation, measurement, or assessment of data shall be adequately tested, calibrated, and/or standardized.

(b) The written standard operating procedures required under § 160.81(b)(11) shall set forth in sufficient detail the methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, calibration, and/or standardization of equipment, and shall specify remedial action to be taken in the event of failure or malfunction of equipment. The written standard operating procedures shall designate the person responsible for the performance of each operation, and copies of the standard operating procedures shall be made available to laboratory personnel.

(c) Written records shall be maintained of all inspection, maintenance, testing, calibrating, and/or standardizing operations. These records, containing the date of the operation, shall describe whether the maintenance operations were routine and followed the written standard operating procedures. Written records shall be kept of nonroutine repairs performed on equipment as a result of failure and malfunction. Such records shall document the nature of the defect, how and when the defect was discovered, and any remedial action taken in response to the defect.

## Subpart E—Testing Facilities Operation

### § 160.81 Standard operating procedures.

(a) A testing facility shall have standard operating procedures in writing setting forth study methods that management is satisfied are adequate to insure the quality and integrity of the data generated in the course of a study. All deviations in a study from standard operating procedures shall be authorized by the study director and shall be documented in the raw data. Significant changes in established standard operating procedures shall be properly authorized in writing by management.

(b) Standard operating procedures shall be established for, but not limited to, the following:

(1) Animal room preparation.

(2) Animal care.

(3) Receipt, identification, storage, handling, mixing, and method of sampling of the test and control substances.

(4) Test system observations.

(5) Laboratory tests.

(6) Handling of animals found moribund or dead during study.

(7) Necropsy of animals or postmortem examination of animals.

(8) Collection and identification of specimens.

(9) Histopathology.

(10) Data handling, storage, and retrieval.

(11) Maintenance and calibration of equipment.

(12) Transfer, proper placement, and identification of animals.

(c) Each laboratory area shall have immediately available laboratory manuals and standard operating procedures relative to the laboratory procedures being performed, e.g., toxicology, histology, clinical chemistry, hematology, teratology, necropsy. Published literature may be used as a supplement to standard operating procedures.

(d) A historical file of standard operating procedures, and all revisions thereof, including the dates of such revisions, shall be maintained.

### § 160.83 Reagents and solution.

All reagents and solutions in the laboratory areas shall be labeled to indicate identity, titer or concentration, storage requirements, and expiration date. Deteriorated or outdated reagents and solutions shall not be used.

### § 160.90 Animal care.

(a) There shall be standard operating procedures for the housing, feeding, handling, and care of animals.

(b) All newly received animals from outside sources shall be placed in quarantine until their health status has been evaluated. This evaluation shall be in accordance with acceptable veterinary medical practice.

(c) At the initiation of a study, animals shall be free of any disease or condition that might interfere with the purpose or conduct of the study. If, during the course of the study, the animals contract such a disease or condition, the diseased animals shall be isolated. If necessary, these animals may be treated for disease or signs of disease provided that such treatment does not interfere with the study. The diagnosis, authorization of treatment, description of treatment and each date of treatment shall be documented and shall be retained.

(d) Warm-blooded animals, excluding suckling rodents, used in laboratory procedures that require manipulations and observations over an extended period of time or in studies that require the animals to be removed from and returned to their home cages for any reason (e.g., cage cleaning, treatment, etc.), shall receive appropriate identification (e.g., tattoo, toe clip, color code, ear tag, ear punch, etc.). All information needed to specifically identify each animal within an animal-housing unit shall appear on the outside of that unit.

(e) Animals of different species shall be housed in separate rooms when necessary. Animals of the same species, but used in different studies, should not ordinarily be housed in the same room when inadvertent exposure to control or test substances or animal mixup could affect the outcome of either study. If such mixed housing is necessary, adequate differentiation by space and identification shall be made.

(f) Animal cages, racks and accessory equipment shall be cleaned and sanitized at appropriate intervals.

(g) Feed and water used for the animals shall be analyzed periodically to ensure that contaminants known to be capable of interfering with the study and reasonably expected to be present in such feed or water are not present at levels above those specified in the protocol. Documentation of such analyses shall be maintained as raw data.

(h) Bedding used in animal cages or pens shall not interfere with the purpose or conduct of the study and shall be changed as often as necessary to keep the animals dry and clean.

(i) If any pest control materials are used, the use shall be documented. Cleaning and pest control materials that interfere with the study shall not be used.

## Subpart F—Test and Control Substances

### § 160.105 Test and control substance characterization.

(a) The identity, strength, purity, and composition or other characteristics which will appropriately define the test or control substance shall be determined for each batch and shall be documented before the initiation of the study.

Methods of synthesis, fabrication, or derivation of the test and control substances shall be documented by the sponsor or the testing facility.

(b) The stability of each test or control substance shall be determined by the testing facility or by the sponsor before initiation of a study. If the stability of the test or control substances cannot be determined before initiation of a study, standard operating procedures shall be established and followed to provide for periodic reanalysis of each batch.

(c) Each storage container for a test or control substance shall be labeled by name, chemical abstract number (CAS) or code number, batch number, expiration date, if any, and, where appropriate, storage conditions necessary to maintain the identity, strength, purity, and composition of the test or control substance. Storage containers shall be assigned to a particular test substance for the duration of the study.

(d) For studies of more than 4 weeks' duration, reserve samples from each batch of test and control substances shall be retained for the period of time provided by § 160.195.

(e) The stability of test and control substances under the test conditions shall be known for all studies.

### § 160.107 Test and control substance handling.

Procedures shall be established for a system for the handling of the test and control substances to ensure that:

(a) There is proper storage.

(b) Distribution is made in a manner designed to preclude the possibility of contamination, deterioration, or damage.

(c) Proper identification is maintained throughout the distribution process.

(d) The receipt and distribution of each batch is documented. Such documentation shall include the date and quantity of each batch distributed or returned.

### § 160.113 Mixtures of substances with carriers.

(a) For each test or control substance that is mixed with a carrier, tests by appropriate analytical methods shall be conducted:

(1) To determine the uniformity of the mixture and to determine, periodically, the concentration of the test or control substance in the mixture.

(2) To determine the stability of the test and control substances in the mixture. If the stability cannot be determined before initiation of the study, standard operating procedures shall be established and followed to provide for periodic re-analysis of the test and control substances in the mixture.

(b) Where any of the components of the test or control substance carrier mixture has an expiration date, that date shall be clearly shown on the container. If more than one component has an expiration date, the earliest date shall be shown.

## Subpart G—Protocol for and Conduct of a Study

### § 160.120 Protocol.

(a) Each study shall have an approved written protocol that clearly indicates the objectives and all methods for the conduct of the study. The protocol shall contain but shall not necessarily be limited to the following information:

(1) A descriptive title and statement of the purpose of the study.

(2) Identification of the test and control substance by name, chemical abstract (CAS) number or code number.

(3) The name and address of the sponsor and the name and address of the testing facility at which the study is being conducted.

(4) The proposed starting and completion dates.

(5) Justification for selection of the test system.

(6) Where applicable, the number, body weight range, sex, source of supply, species, strain, substrain, and age of the test system.

(7) The procedure for identification of the test system.

(8) A description of the experimental design, including the methods for the control of bias.

(9) A description and/or identification of the diet used in the study as well as solvents, emulsifiers and/or other materials used to solubilize or suspend the test or control substances before mixing with the carrier. The description shall include specifications for acceptable levels of contaminants that are reasonably expected to be present in the dietary materials and are known to be capable of interfering with the purpose or conduct of the study if present at levels greater than established by the specifications.

(10) The route of administration and the reason for its choice.

(11) Each dosage level, expressed in milligrams per kilogram of body weight or other appropriate units, of the test or control substance to be administered and the method and frequency of administration.

(12) Method by which the degree of absorption of the test and control substances by the test system will be determined if necessary to achieve the objectives of the study.

(13) The type and frequency of tests, analyses, and measurements to be made.

(14) The records to be maintained.

(15) The date of approval of the protocol by the sponsor and the signature of the study director.

(16) A statement of the proposed statistical methods to be used.

(b) All changes in or revisions of an approved protocol and the reasons therefor shall be documented, signed by the study director, dated, and maintained with the protocol.

### § 160.130 Conduct of a study.

(a) The study shall be conducted in accordance with the protocol.

(b) The test systems shall be monitored in conformity with the protocol.

(c) Specimens shall be identified by test system, study, nature, and date of collection. This information shall be located on the specimen container or shall accompany the specimen in a manner that precludes error in the recording and storage of data.

(d) Records of gross findings for a specimen from postmortem observations shall be available to a pathologist when examining that specimen histopathologically.

(e) All data generated during the conduct of a study, except those that are generated as direct computer input, shall be recorded directly, promptly, and legibly in ink. All data entries shall be dated on the day of entry and signed or initialed by the person entering the data. Any change in entries shall be made so as not to obscure the original entry, shall indicate the reason for such change, and shall be dated and signed or identified at the time of the change. In computer driven data collection systems, the individual responsible for direct data input shall be identified at the time of data input. Any change in computer entries shall be made so as not to obscure the original entry, shall indicate the reason for change, and shall be dated and the responsible individual shall be identified.

## Subparts H and I—[Reserved]

## Subpart J—Records and Reports

### § 160.185 Reporting of study results.

(a) A final report shall be prepared for each study and shall include, but not necessarily be limited to, the following:

(1) Name and address of the facility performing the study and the dates on which the study was initiated and was completed, terminated, or discontinued.

(2) Objectives and procedures stated in the approved protocol, including any changes in the original protocol.

(3) Statistical methods employed for analyzing the data.

(4) The test and control substances identified by name, chemical abstracts (CAS) number or code number, strength, purity, and composition or other appropriate characteristics.

(5) Stability of the test and control substances under the conditions of administration.

(6) A description of the methods used.

(7) A description of the test system used. Where applicable, the final report shall include the number of animals used, sex, body weight range, source of supply, species, strain and substrain, age, and procedure used for identification.

(8) A description of the dosage, dosage regimen, route of administration, and duration.

(9) A description of all circumstances that may have affected the quality or integrity of the data.

(10) The name of the study director, the names of other scientists or professionals, and the names of all supervisory personnel, involved in the study.

(11) A description of the transformations, calculations, or operations performed on the data, a summary and analysis of the data, and a statement of the conclusions drawn from the analysis.

(12) The signed and dated reports of each of the individual scientists or other professionals involved in the study, including each person who, at the request or direction of the testing facility or sponsor, conducted an analysis or evaluation of data or specimens from the study after data generation was completed.

(13) The locations where all specimens, raw data, and the final report are to be stored.

(14) The statement prepared and signed by the quality assurance unit as described in § 160.35(b)(7).

(b) The final report shall be signed and dated by the study director.

(c) Corrections or additions to a final report shall be in the form of an amendment by the study director. The amendment shall clearly identify that part of the final report that is being added to or corrected and the reasons for the correction or addition, and shall be signed and dated by the person responsible.

(d) A copy of the final report and of any amendment to it shall be maintained by the sponsor and the testing facility.

(Approved by the Office of Management and Budget under control numbers 2000-0468 and 2000-0483)

**§ 160.190 Storage and retrieval of records and data.**

(a) All raw data, documentation, records, protocols, specimens, and final reports generated as a result of a study shall be retained. Correspondence and other documents relating to interpretation and evaluation of data, other than those documents contained in the final report, also shall be retained.

(b) There shall be archives for orderly storage and expedient retrieval of all raw data, documentation, protocols, specimens, and interim and final reports. Conditions of storage shall minimize deterioration of the documents or specimens in accordance with the requirements for the time period of their retention and the nature of the documents of specimens. A testing facility may contract with commercial archives to provide a repository for all material to be retained. Raw data and specimens may be retained elsewhere provided that the archives have specific reference to those other locations.

(c) An individual shall be identified as responsible for the archives.

(d) Only authorized personnel shall enter the archives.

(e) Material retained or referred to in the archives shall be indexed by test substance, date of study, test system, and nature of study.

**§ 160.195 Retention of records.**

(a) Record retention requirements set forth in this section do not supersede the record retention requirements of any other regulations in this subchapter.

(b) Except as provided in paragraph (c) of this section, documentation records, raw data, and specimens pertaining to a study and required to be retained by this part shall be retained in the archive(s) for whichever of the following periods is longest:

(1) In the case of any study used to support an application for a research or marketing permit approved by EPA, the period during which the sponsor holds any research or marketing permit to which the study is pertinent.

(2) A period of at least five years following the date on which the results of the study are submitted to the EPA in support of an application for a research or marketing permit.

(3) In other situations (e.g., where the study does not result in the submission of the study in support of an application for a research or marketing permit), a period of at least two years following the date on which the study is completed, terminated, or discontinued.

(c) Wet specimens, samples of test or control substances, and specially prepared material (e.g., histochemical, electron microscopic, blood mounts, teratological preparation, and uteri from dominant lethal mutagenesis test), which are relatively fragile and differ markedly in stability and quality during storage, shall be retained only as long as the quality of the preparation affords evaluation. In no case shall retention be required for longer periods than those set forth in paragraph (b) of this section.

(d) The master schedule sheet, copies of protocols, and records of quality assurance inspections, as required by § 160.35(c) shall be maintained by the quality assurance unit as an easily accessible system of records for the period of time specified in paragraph (b) of this section.

(e) Summaries of training and experience and job descriptions required to be maintained by § 160.29(b) may be retained along with all other testing facility employment records for the length of time specified in paragraph (b) of this section.

(f) Records and reports of the maintenance and calibration and inspection of equipment, as required by § 160.63 (b) and (c), shall be retained for the length of time specified in paragraph (b) of this section.

(g) If a facility conducting testing or an archive contracting facility goes out of business, all raw data, documentation, and other material specified in this section shall be transferred to the archives of the sponsor of the study. The EPA shall be notified in writing of such a transfer.

(h) Specimens, samples, or other non-documentary materials need not be retained after EPA has notified in writing the sponsor or testing facility holding the materials that retention is no longer required by EPA. Such notification normally will be furnished upon request after EPA or FDA has completed an audit of the particular study to which the materials relate and EPA has concluded that the study was conducted in accordance with this part.

## Subpart K—[Reserved]

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# Part V

# Environmental Protection Agency

## Certification of Pesticide Applicators Recordkeeping and Reporting Requirements; Final Rule

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 171**

**[OPP 40010A; PH-FRL 2402-7]**

## Certification of Pesticide Applicators Recordkeeping and Reporting Requirements

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** EPA by this rule will amend the existing regulations at 40 CFR Part 171 by imposing certain recordkeeping and reporting requirements upon pesticide dealers in States or on Indian Reservations where the Administrator conducts the applicator certification and training program, as authorized by section 4(a)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA or the Act). This rule will require persons who make restricted use pesticides available to users to provide a one-time written report to the Agency, certifying that they are maintaining records of the sale or distribution of restricted use pesticides. The rule will also prescribe conditions under which pesticide dealers can make restricted use pesticides available to uncertified persons for use by a certified applicator, and describe more precisely the location where records concerning application of restricted use pesticides must be maintained.

**EFFECTIVE DATE:** This rule will not take effect before the end of 60 calendar days of continuous session of Congress after the date of publication. EPA will issue the effective date of this rule in the **Federal Register.** See Supplementary Information for further details.

**FOR FURTHER INFORMATION CONTACT:** David Hannemann, Compliance Monitoring Staff (EN-342), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. 2624-D, 401 M St., SW., Washington, D.C. 20460, (202-382-7849).

**SUPPLEMENTARY INFORMATION:** Approval by OMB is pending.

### Background

Section 4(a)(1) of FIFRA, as amended by the Federal Insecticide, Fungicide, and Rodenticide Act (Pub. L. 96-539, 92 Stat. 819, 7 U.S.C. 136b(a)(1)), provides that the administrator may prescribe by regulation the maintenance of records and submission of reports concerning the commercial application, sale or distribution of restricted use pesticides in States or on Indian Reservations where the Administrator conducts a pesticide applicator certification program. Recordkeeping requirements for commercial applicators in such States were promulgated and may be found at 40 CFR 171.11(c)(7).

### Discussion

The Administrator proposed a rule which was published in the **Federal Register** of July 28, 1982, (47 FR 32551), requiring that persons who sell or distribute restricted use pesticides in States or on Indian Reservations where the Administrator conducts a certification program must: (1) Submit a one-time report certifying that the records required by the final rule are being kept, and (2) maintain records of all transactions in which restricted use pesticides are made available for use. At the present time, persons to whom such restricted use pesticides are made available for use must be certified. Commercial certified applicators must keep records of their use of restricted use pesticides in accordance with regulations at 40 CFR Part 171.

This rule does not apply to transactions between pesticide producers, registrants, wholesalers, and retail sellers which do not involve the sale or distribution to persons who will actually use or supervise the use of the restricted use pesticides.

Prior to the 1978 amendments to FIFRA, there were no requirements that records be kept and reports be made concerning the sale and distribution of restricted use pesticides. As a result, the Agency has no comprehensive inventory of dealers who sell or distribute restricted use pesticides.

This rule adds a new paragraph (b) to 40 CFR 171.2 defining the terms "restricted use pesticide retail dealer," "make available for use," "dealership," "uncertified person," and "principal place of business." It also adds a new paragraph (g) to 40 CFR 171.11 which requires dealer reporting, recordkeeping, and availability of records regarding making restricted use pesticides available to certified applicators and uncertified persons and lists potential remedies for failure to comply.

The one-time reporting requirements contained in this rule will identify all dealers of restricted use pesticides in States or on Indian Reservations where the Administrator conducts the applicator certification and training program. The Agency will then be able to use this information to establish a neutral administrative inspection scheme to monitor compliance by both certified applicators and uncertified persons obtaining restricted use pesticides for use by certified applicators.

### Comments Received

During the public comment period on the proposed rule, which was published in the **Federal Register** of July 28, 1982 (47 FR 32551), five comments were received. Several of the commenters supported the proposed rule in general but recommended changes to particular sections. Minor changes were made to the regulation in response to the comments received. No major changes were required.

One commenter indicated that the commercial certified applicator recordkeeping requirements at 40 CFR 171.11(c)(7) should be clarified to make both the individual applicator and the firm by which he is employed responsible for assuring that the records regarding the use of restricted use pesticides will be maintained. The Agency does not wish to impose a duplicative recordkeeping requirement on certified commercial applicators and the firms which employ them. The Agency's expectation in making the certified commercial applicators responsible for maintaining records of their use of restricted use pesticides and making the records readily available to EPA inspectors was that such records would be kept at the principal place of business of the person or firm that makes the arrangement with a property owner to have the pesticides applied to the property.

Because of the many different types of relationships that exist between certified commercial applicators and the firms that utilize their services, many readers were unclear as to their particular recordkeeping responsibilities. Accordingly, the Agency has amended § 171.11(c)(7) to require that records regarding the use of restricted use pesticides by a certified commercial applicator must be maintained at a self-employed commercial applicator's principal place of business and at the principal place of business of a firm that employs a certified commercial applicator or that contracts to have such an applicator apply a restricted use pesticide on the property of another.

The Agency finds that this amendment is appropriate because it will allow EPA to examine records at the place of business of the person or firm with whom the property owner dealt in arranging to have a pesticide applied. This will facilitate investigation of improprieties alleged to have occurred in particular applications of restricted use pesticides. Moreover, the record of a use of a restricted use pesticide is usually an invoice prepared

by the certified commercial applicator or his employing firm when a commitment or contract for application is made prior to the actual application. The employer's principal place of business is generally the central repository for such application records. Requiring the records to be kept at this location should not add a separate recordkeeping burden.

One commenter suggested that the term "make available for use" appeared to include the activities of common carriers transporting restricted use pesticides, thus making common carriers subject to the requirements of this section. The Agency disagrees with this comment. Restricted use pesticides are not "made available for use" by common carriers. Common carriers simply transport material between pesticide producers, registrants, wholesalers or retailers. Common carriers are not subject to the requirements of this section. No changes were made in the definition of the term "make available for use."

One commenter indicated that requiring the dealer to record information outlined in § 171.11(g) will require additional work since much of the information is already on the delivery record or billing invoice. The rule does not require the dealer to record separately on the delivery receipt or billing invoice any of the required information which appears on the delivery record or billing invoice as a routine record of the commercial transaction. If the information is already present on the delivery receipt or the billing invoice, the dealer need not duplicate such information. Indeed, the Agency feels that most of the information required to be maintained under this rule is already routinely kept as a part of the commercial sales records.

Several commenters indicated that it would be difficult for the dealers to provide the name and address of the person(s) to whom the restricted use pesticide is made available for use if the dealer delivers the restricted use pesticide to a field or an airstrip. The rule has been clarified to indicate that in such instances, the address which the dealer must keep on record is the address of the certified applicator's principal place of business, and not the delivery address.

Several commenters indicated that recording the name and EPA registration number (or the special local needs registration number) would impose an unwarranted burden, and that when preparing a delivery record or invoice, firms would be required to go into the warehouse to search out the appropriate registration number. The Agency believes that both the dealer and EPA need to know exactly which restricted use pesticides are being made available for use to individual users. Because substantially different restricted use pesticides have similar names, pesticide dealers cannot simply use a generic reference, such as parathion 8 lb., to identify the product made available for use. Only the registration number will identify a restricted use pesticide exactly. Furthermore, commercial applicator certifications are issued for specific limited use categories. It is essential that the dealer document that the certification of the applicator is appropriate for each specific restricted use pesticide product made available for use. This link between a specific product and a specific applicator can be made only with a reference to a registration number. This requirement has been retained.

Several commenters indicated that it is meaningless to require a record of the expiration date of an applicator's certification since the applicator's certification could expire after the restricted use pesticide was purchased, but before the product was used. An applicator who uses a restricted use pesticide after his certification has expired would be in violation of FIFRA. To eliminate the further availability of restricted use pesticides to applicators whose certifications have expired and to minimize the opportunity that such a violation could occur, the requirement has been retained.

Several commenters indicated that many restricted use pesticide dealers maintain files with the names, addresses, certification numbers, and certification expiration dates of applicators who purchase restricted use pesticides. They argue that requiring this information, particularly information regarding the certified applicator, on the sales record would unnecessarily dictate one method of recordkeeping for all dealers subject to this rule. The Agency disagrees. While the restricted use pesticide dealer is responsible for maintaining the information required by this rule, the Agency does not prescribe any particular method for keeping these records. The dealer may elect to maintain the required information regarding the certified commercial applicator in a file containing the name, address, certification number, certification category (if applicable) and expiration date of certified applicators who regularly purchase restricted use pesticides from them. The dealer may reference these records to verify the information presented at the time of each transaction and to update his own files.

The Agency believes that the best source of data regarding the name, address, certification number, certification category (if applicable) and expiration date of the certified applicator who purchases the restricted use pesticides is the applicator's current certification document or a facsimile of that document. The Agency has no preference, however, regarding the system used by the dealers to catalogue or maintain the information required by this rule. This requirement has been retained.

One commenter pointed out that restricted use pesticides, when delivered to an applicator's residence, business or application site, are frequently received by an individual who is not certified. In other circumstances, a certified applicator may send an associate, employee or spouse to obtain a restricted use pesticide for use by the certified applicator. In response to this comment, the Agency has divided the recordkeeping section of the rule into two parts. The first set of recordkeeping requirements applies to persons making restricted use pesticides available to certified applicators. The second set of recordkeeping requirements applies to the special situation when a dealer makes restricted use pesticides available to an uncertified person for use by a certified applicator.

FIFRA 12(a)(2) states that it is unlawful for any person:

> "(F) to make available for use, or to use, any registered pesticide classified for restricted use for some or all purposes other than in accordance with section 3(d) and any regulations thereunder; *Provided*, That is shall not be unlawful to sell, under regulations issued by the Administrator, a restricted use pesticide to a person who is not a certified applicator for application by a certified applicator;

EPA recognizes the need to ensure that restricted use pesticides are made available only to persons who are qualified to use them safely, without making it unduly burdensome for certified applicators to obtain restricted use pesticides. Therefore, the Agency has amended the rule to permit pesticide dealers to make restricted use pesticides available to uncertified persons for use by certified applicators only under the circumstances set forth therein.

This rule affects only pesticide dealers making restricted use pesticides available to uncertified persons in States or on Indian Reservations where the Administrator conducts the pesticide applicator certification and training program. States having State Plans

approved under FIFRA section 4 and wishing to adopt a similar procedure of making restricted use pesticides available to uncertified persons shall submit to the Administrator a Plan containing the minimum standards outlined in 40 CFR Part 171. Such a Plan should contain the information as outlined in Unit IX, (entitled "Purchase By Uncertified Persons For Use By Certified Applicators") of the preamble to the rule entitled "Optional Procedures for Classification of Pesticide Uses by Regulation; Pesticide Use Restrictions" published in the **Federal Register** February 9, 1978 (43 FR 5783).

**Further Information on Effective Date of This Rule**

On December 17, 1980, an Act to extend the Federal Insecticide, Fungicide, and Rodenticide Act (Pub. L. 96–539) became law. This bill amended several sections of FIFRA, including section 25 on rulemaking. Section 4 of the Extension Act adds a new paragraph, section 25(e), to FIFRA which requires EPA to submit final rules to Congress for review before the rule becomes effective. Copies of this rule have been transmitted to the appropriate committees in both Houses of Congress.

Under section 4 of the 1980 FIFRA Extension Act, this rule will not take effect before the end of 60 calendar days of continuous session of Congress after the date of publication of this rule. Since the actual length of this waiting period may be affected by Congressional action, it is not possible at this time to specify the date on which this rule will become effective. Therefore, at the appropriate time, EPA will announce in the **Federal Register** expiration of the legislative review period and the effective date of this rule.

**Compliance With the Regulatory Flexibility Act and Executive Order 12291**

I hereby certify that this rule will not have a significant economic impact on small business entities. This rule affects only a small number of businesses in States where the Administrator conducts the pesticide applicator certification and training program.

This rule was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

**Compliance With the Paperwork Reduction Act**

Under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq., the information provisions in this rule have been submitted for approval to the Office of Management and Budget (OMB) and have been assigned OMB Control Number 2000–0352.

(Secs. 3(d), 4(a)(1), and 25(a)(1), Pub. L. 95–396, 92 Stat. 819 (7 U.S.C. 136a, 136b, 136w))

**List of Subjects in 40 CFR Part 171**

Pesticides and pests, Intergovernmental relations, Indian lands, Recordkeeping and reporting requirements.

Dated: November 17, 1983.

**William D. Ruckelshaus,**

*Administrator.*

## PART 171—[AMENDED]

Therefore, Part 171, Subchapter E, Chapter I of 40 CFR is amended as follows:

1. In § 171.2, by redesignating paragraphs (a) through (bb) as paragraph (a)(1) through (28); by revising the introductory text of § 171.2 and designating it as the introductory text of paragraph (a) as set forth below; and by adding a new paragraph (b). The revised introductory text of paragraph (a) and new paragraph (b) are set forth below:

**§ 171.2 Definitions.**

(a) *General.* Terms used in this subpart shall have the meanings set forth for such terms in the Act. In addition, the following definitions are applicable to all aspects of the certification of pesticide applicator program in this part:

* * * * *

(b) *Limited.* The following definitions apply only to dealers, dealerships and transactions in States or on Indian Reservations where EPA conducts a Federal Pesticide Applicator Certification Program.

(1) The term "restricted use pesticide retail dealer" means any person who makes available for use any restricted use pesticide, or who offers to make available for use any such pesticide.

(2) The term "make available for use" means to distribute, sell, ship, deliver for shipment, or receive and (having so received) deliver, to any person. However, the term excludes transactions solely between persons who are pesticide producers, registrants, wholesalers, or retail sellers, acting only in those capacities.

(3) The term "dealership" means any site owned or operated by a restricted use pesticide retail dealer where any restricted use pesticide is made available for use, or where the dealer offers to make available for use any such pesticide.

(4) The term "uncertified person" means any person who is not holding a currently valid certification document indicating that he is certified under section 4 of FIFRA in the category of the restricted use pesticide made available for use.

(5) The term "principal place of business" means the principal location, either residence or office, in the State in which an individual, partnership, or corporation applies pesticides.

2. In § 171.11 paragraph (c)(7)(i) is revised and paragraph (g) is added to read as follows:

**§ 171.11 Federal certification of pesticide applicators in States or on Indian Reservations where there is no approved State or Tribe certification plan in effect.**

* * * * *

(c) * * *

(7) *Recordkeeping requirements.* (i) Each self-employed certified commercial applicator, each firm employing a certified commercial applicator, and each person who contracts with a certified commercial applicator (or his or her employer) to have a restricted use pesticide applied on property owned or operated by another person shall keep and maintain at their principal place of business true and accurate records of the use of restricted use pesticides, providing the following information:

* * * * *

(g) *Pesticide dealer reporting and recordkeeping requirements, availability of records, and failure to comply—(1) Reporting requirements.* Each person who is a restricted use pesticide retail dealer in a State or on an Indian Reservation where the Administrator conducts the applicator certification and training program shall:

(i) Report to the Environmental Protection Agency (EPA) the business name by which the restricted use pesticide retail dealer operates, and the name and business address of each of his dealerships. For dealers or dealerships in Nebraska this initial report must be submitted to EPA, Region VII, 324 E. 11th Street, Kansas City, MO 64106. For dealers or dealerships in Colorado this initial report must be submitted to EPA, Region VIII, 1860 Lincoln Street, Denver, Colorado 80295. This report shall be submitted to the appropriate EPA regional office no later than 60 days after the date the person first becomes a restricted use pesticide retail dealer, or within 60 days after the publication of the effective date of this final rule, whichever date is later.

(ii) Submit revisions to the initial report to the appropriate EPA regional office listed above reflecting any name changes, additions or deletions of dealerships. Revisions shall be submitted to EPA within 10 days of the

occurrence of such change, addition or deletion.

(2) *Recordkeeping requirement.* Recordkeeping is required when making restricted use pesticides available to:

(i) *Certified applicators.* Each restricted use pesticide retail dealer shall maintain at each individual dealership records of each transaction where a restricted use pesticide is made available for use by that dealership to a certified applicator. Record of each such transaction shall be maintained for a period of 24 months after the date of the transaction, and shall include the following information:

(A) Name and address of the residence or principal place of business of each person to whom the pesticide was made available for use.

(B) The certification number on the document evidencing that person's certification, the State (or other governmental unit) that issued the doucment, the expiration date of the certification, and the categories in which the applicator is certified, if appropriate.

(C) The product name, EPA registration number, and the State special local need registration number, granted under section 24(c) of the FIFRA (if any) on the label of the pesticide.

(D) The quantity of the pesticide made available for use in the transaction.

(E) The date of the transaction.

(ii) *Uncertified persons.* No dealer or dealership may make a restricted use pesticide available to an uncertified person unless he can document that the restricted use pesticide will be used by a certified applicator, and he maintains the records required in this subsection. Each restricted use pesticide retail dealer shall maintain records at each individual dealership of each transaction where a restricted use pesticide was made available to an uncertified person for use by a certified applicator. Records of each such transaction shall be maintained for a period of 24 months after the date of the transaction, and shall include the following information:

(A) The name and address of the residence or principal place of business of the uncertified person to whom the restricted use pesticide is made available for use by a certified applicator.

(B) The name and address of the residence or principal place of business of the certified applicator who will use the restricted use pesticide.

(C) The certified applicator's certification number, the State (or other governmental unit) that issued his certification document, the expiration date of the certification, and the categories in which the applicator is certified, if appropriate.

(D) The product name, EPA registration number, and the State special local need registration number, granted under section 24(c) of the FIFRA (if any) on the label of the pesticide.

(E) The quantity of the pesticide made available for use in the transaction.

(F) The date of the transaction.

(G) At the time of each transaction, EPA recommends that the dealer obtain the information required in paragraph (g)(2)(ii) (A) through (C) of this section and assure himself that the restricted use pesticide is made available for use by a certified applicator by examining one of the following sets of documents:

*(1)* The original of the certified applicator's certification document, and a driver's license or other State, county, or Tribal identification document issued to the uncertified person to whom the restricted use pesticide is made available.

*(2)* A photocopy or facsimile of the certified applicator's certification document, together with a statement signed by the certified applicator authorizing the uncertified person to purchase the restricted use pesticide on his behalf, and a driver's license or other State, county, or Tribal identification document issued to the uncertified person to whom the restricted use pesticide is made available.

*(3)* A photocopy or facsimile of the certified applicator's certification document, together with a copy of a signed contract or agreement, between the uncertified person to whom the restricted use pesticide is being made available for use and the identified certified applicator, which provides for the use of the restricted use pesticide by the identified certified applicator, and a driver's license or other State, county, or Tribal identification document issued to the uncertified person to whom the restricted use pesticide is made available.

(3) *Availability of required records.* Each pesticide dealer shall, upon request of any officer or employee of EPA duly designated by the Administrator, furnish or permit such person at all reasonable times to have access to and copy all records required to be maintained under this section.

(4) *Failure to comply.* Any person who fails to comply with the provisions of this rule may be subject to civil or criminal sanctions, under section 14 of the Act, or 18 U.S.C. 1001. Violations include failure to submit or falsification of any report required under this paragraph, failure to maintain or falsification of records as required under this section, and making available for use any pesticide classified for restricted use to a person who is not a certified commercial applicator other than in accordance with these regulations and section 3(d) of the amended FIFRA or rules promulgated thereunder.

[FR Doc. 83-31836 Filed 11-28-83; 8:45 am]

BILLING CODE 6560-50-M

federal register

Tuesday
November 29, 1983

# Part VI

# Department of Energy

## Federal Energy Regulatory Commission

## Determinations by Jurisdictional Agencies Under the Natural Gas Policy Act of 1978

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Volume 1006]

### Determinations by Jurisdictional Agencies Under the Natural Gas Policy Act of 1978

Issued: November 22, 1983.

The following notices of determination were received from the indicated jurisdictional agencies by the Federal Energy Regulatory Commission pursuant to the Natural Gas Policy Act of 1978 and 18 CFR 274.104. Negative determinations are indicated by a "D" before the section code. Estimated annual production (PROD) is in million cubic feet (MMCF).

The applications for determination are available for inspection except to the extent such material is confidential under 18 CFR 275.206, at the Commission's Division of Public Information, Room 1000, 825 North Capitol St., Washington, D.C. Persons objecting to any of these determinations may, in accordance with 18 CFR 275.203 and 275.204, file a protest with the Commission within fifteen days after publication of notice in the **Federal Register.**

Source data from the Form 121 for this and all previous notices is available on magnetic tape from the National Technical Information Service (NTIS). For information, contact Stuart Weisman (NTIS) at (703) 487-4808, 5285 Port Royal Rd, Springfield, Va 22161.

Categories within each NGPA section are indicated by the following codes:

Section 102-1: New OCS lease
- 102-2: New well (2.5 Mile rule)
- 102-3: New well (1000 Ft rule)
- 102-4: New onshore reservoir
- 102-5: New reservoir on old OCS lease

Section 107-DP: 15,000 feet or deeper
- 107-GB: Geopressured brine
- 107-CS: Coal Seams
- 107-DV: Devonian Shale
- 107-PE: Production enhancement
- 107-TF: New tight formation
- 107-RT: Recompletion tight formation

Section 108: Stripper well
- 108-SA: Seasonally affected
- 108-ER: Enhanced recovery
- 108-PB: Pressure buildup

**Kenneth F. Plumb,**

*Secretary.*

NOTICE OF DETERMINATIONS — VOLUME 1006

ISSUED NOVEMBER 22, 1983

| JD NO | JA DKT | API NO | D | SEC(1) | SEC(2) | WELL NAME | FIELD NAME | PROD | PURCHASER |
|---|---|---|---|---|---|---|---|---|---|
| ********** | | | | | | | | | |
| WEST VIRGINIA DEPARTMENT OF MINES | | | | | | | | | |
| ********** | | | | | | | | | |
| -PEAKE OPERATING CO | | | | RECEIVED: | 10/27/83 | JA: WV | | | |
| 8403912 | | 4710900877 | | 107-DV | | BOND #1-A | (OCEANA DISTRICT) | 5.0 | |
| 8403904 | | 4708100574 | | 107-DV | | CRAB ORCHARD #1-AC | NONE (TRAP HILL DISTR | 5.0 | |
| 8403905 | | 4708100592 | | 107-DV | | CRAB ORCHARD #10-AC | (TRAP HILL DISTRICT) | 5.0 | |
| 8403906 | | 4708100596 | | 107-DV | | CRAB ORCHARD #9-AC | N A (TRAP HILL DISTRI | 5.0 | |
| 8403910 | | 4710900859 | | 107-DV | | EASTER #1-A | (OCEANA DISTRICT) | 5.0 | ROARING FORK GAS |
| 8403907 | | 4710900879 | | 107-DV | | GEORGIA PACIFIC #1-AGP | (OCEANA DISTRICT) | 5.0 | |
| 8403908 | | 4710900886 | | 107-DV | | GEORGIA PACIFIC #4-AGP | (OCEANA DISTRICT) | 5.0 | |
| 8403898 | | 4708100576 | | 107-DV | | JONES & GIBSON #2-AJ | (TRAP HILL DISTRICT) | 5.0 | |
| 8403899 | | 4708100577 | | 107-DV | | JONES & GIBSON #3-AJ | (TRAP HILL DISTRICT) | 5.0 | |
| 8403909 | | 4708100612 | | 107-DV | | LILLY #2-A | (BECKLEY 2 DISTRICT) | 5.0 | ROARING FORK GAS |
| 8403900 | | 4708100589 | | 107-DV | | NEW RIVER #10-AR | (TOWN DISTRICT) | 5.0 | |
| 8403901 | | 4708100590 | | 107-DV | | NEW RIVER #7-AR | (TOWN DISTRICT) | 5.0 | |
| 8403903 | | 4708100595 | | 107-DV | | NEW RIVER #8 - AR | (TOWN DISTRICT) | 5.0 | |
| 8403902 | | 4708100591 | | 107-DV | | NEW RIVER #9-AR | (TOWN DISTRICT) | 5.0 | |
| 8403911 | | 4701900466 | | 107-DV | | PRICE HEIRS #1-BR | (PLATEAU DISTRICT) | 5.0 | |
| 8403913 | | 4710900894 | | 107-DV | | RUNDLE #1-A | (OCEANA DISTRICT) | 5.0 | |
| -RARE EARTH ENERGY INC | | | | RECEIVED: | 10/27/83 | JA: WV | | | |
| 8403915 | | 4707301535 | | 103 | | WILES #1 | JEFFERSON DISTRICT | 0.0 | CONSOLIDATED GAS |
| 8403914 | | 4707301586 | | 103 | | WILES #2 | JEFFERSON DISTRICT | 0.0 | CONSOLIDATED GAS |
| ********** | | | | | | | | | |
| ** DEPARTMENT OF THE INTERIOR, MINERALS MANAGEMENT SERVICE, METAIRIE,LA | | | | | | | | | |
| ********** | | | | | | | | | |
| -ARCO OIL AND GAS COMPANY | | | | RECEIVED: | 10/27/83 | JA: LA 3 | | | |
| 8403793 | G3-3450 | 1770940354 | | 102-5 | | OCS G-0438 EUGENE ISL BLK 175 #F-1 | EUGENE ISLAND | 360.0 | MICHIGAN-WISCONSI |
| 8403834 | G3-3574 | 1781740188 | | 102-5 | | OCS G-2636 MISS CANYON BLK 92 #A-9 | MISSISSIPPI CANYON | 73.0 | TENNESSEE GAS TRA |
| 8403844 | G2-3241 | 1770040453 | | 102-5 | | OCS G-2832 W CAMERON BLK 205 #B-1MU | WEST CAMERON | 1800.0 | NORTHERN NATURAL |
| 8403813 | G2-3242 | 1770040453 | | 102-5 | | OCS G-2832 W CAMERON BLK 205 #B-1NL | WEST CAMERON | 1800.0 | NORTHERN NATURAL |
| 8403812 | G2-3238 | 1770040467 | | 102-5 | | OCS G-2832 W CAMERON BLK 205 #B-2MU | WEST CAMERON | 2000.0 | NORTHERN NATURAL |
| 8403804 | G2-3239 | 1770040467 | | 102-5 | | OCS G-2832 W CAMERON BLK 205 #B-2NL | WEST CAMERON | 2000.0 | NORTHERN NATURAL |
| 8403848 | G2-3247 | 1770040501 | | 102-5 | | OCS G-2832 W CAMERON BLK 205 #B-4MU | WEST CAMERON | 2100.0 | NORTHERN NATURAL |
| 8403801 | G2-3240 | 1770040501 | | 102-5 | | OCS G-2832 W CAMERON BLK 205 #B-4NL | WEST CAMERON | 2100.0 | NORTHERN NATURAL |
| 8403811 | G2-3243 | 1770040516 | | 102-5 | | OCS G-2832 W CAMERON BLK 205 #B-5MU | WEST CAMERON | 1900.0 | NORTHERN NATURAL |
| 8403796 | G2-3244 | 1770040516 | | 102-5 | | OCS G-2832 W CAMERON BLK 205 #B-5NL | WEST CAMERON | 1900.0 | NORTHERN NATURAL |
| 8403799 | G2-3245 | 1770040528 | | 102-5 | | OCS G-2832 W CAMERON BLK 205 #B-6MU | WEST CAMERON | 2000.0 | NORTHERN NATURAL |
| 8403800 | G2-3246 | 1770040528 | | 102-5 | | OCS G-2832 W CAMERON BLK 205 #B-6NL | WEST CAMERON | 2000.0 | NORTHERN NATURAL |
| 8403789 | G2-3191 | 1770140494 | | 102-5 | | OCS G-2834 W CAMERON BLK 238 #B2 | WEST CAMERON BLOCK | 1095.0 | NORTHERN NATURAL |
| 8403791 | G2-3192 | 1770140498 | | 102-5 | | OCS G-2834 W CAMERON BLK 238 #B3 | WEST CAMERON BLOCK | 2920.0 | NORTHERN NATURAL |
| 8403814 | G2-3193 | 1770140498 | | 102-5 | | OCS G-2834 W CAMERON BLK 238 #B3 | WEST CAMERON BLOCK | 2190.0 | NORTHERN NATURAL |
| 8403815 | G2-3194 | 1770140530 | | 102-5 | | OCS G-2834 W CAMERON BLK 238 #B4 | WEST CAMERON BLOCK | 4015.0 | NORTHERN NATURAL |
| 8403805 | G2-3284 | 1760817401 | | 102-5 | | OCS-G 2636 WELL #A-7 | MISSISSIPPI CANYON | 4930.0 | ARKANSAS LOUISIAN |
| -CONOCO INC | | | | RECEIVED: | 10/27/83 | JA: LA 3 | | | |
| 8403790 | G2-3360 | 1772440161 | | 102-5 | | MAIN PASS BLK 296 #C-1 | MAIN PASS | 50.0 | SOUTHERN NATURAL |
| 8403798 | G3-3464 | 1772440222 | | 102-5 | | MAIN PASS BLK 296 #C-11D | MAIN PASS | 50.0 | SOUTHERN NATURAL |
| 8403853 | G2-3341 | 1772440224 | | 102-5 | | MAIN PASS BLK 296 #C-13 | MAIN PASS | 50.0 | SOUTHERN NATURAL |
| 8403792 | G2-3342 | 1772440224 | | 102-5 | | MAIN PASS BLK 296 #C-13D | MAIN PASS | 50.0 | SOUTHERN NATURAL |

BILLING CODE 6717-01-M

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| JD NO | JA DKT | API NO | D | SEC(1) | SEC(2) | WELL NAME | FIELD NAME | PROD | PURCHASER |
|---|---|---|---|---|---|---|---|---|---|
| 8403854 | G2-3361 | 1772440212 | | 102-5 | | MAIN PASS BLK 296 #C-3 | MAIN PASS | 50.0 | SOUTHERN NATURAL |
| 8403851 | G2-3309 | 1772440217 | | 102-5 | | MAIN PASS BLK 296 #C-5 | MAIN PASS | 50.0 | SOUTHERN NATURAL |
| 8403841 | G2-3310 | 1772440217 | | 102-5 | | MAIN PASS BLK 296 #C-5D | MAIN PASS | 50.0 | SOUTHERN NATURAL |
| 8403824 | G3-3455 | 1772440215 | | 102-5 | | MAIN PASS BLK 296 #C-6 | MAIN PASS | 50.0 | SOUTHERN NATURAL |
| 8403821 | G3-3802 | 1772440248 | | 102-1 | | MAIN PASS BLK 303 #B-15 | MAIN PASS BLOCK | 5.0 | SOUTHERN NATURAL |
| 8403850 | G3-3791 | 1772440230 | | 102-1 | | MAIN PASS BLK 303 #B-5 | MAIN PASS BLOCK | 5.0 | SOUTHERN NATURAL |
| 8403830 | G3-3809 | 1772440234 | | 102-1 | | MAIN PASS BLK 303 #B-7 | MAIN PASS BLOCK | 5.0 | SOUTHERN NATURAL |
| 8403820 | G3-3792 | 1772440238 | | 102-1 | | MAIN PASS BLK 303 #B-9 | MAIN PASS BLOCK | 5.0 | SOUTHERN NATURAL |
| 8403808 | G3-3785 | 1772440233 | | 102-5 | | MAIN PASS BLK 304 #B-6 | MAIN PASS | 50.0 | SOUTHERN NATURAL |
| 8403822 | G3-3463 | 1772440222 | | 102-5 | | MAIN PASS BLOCK 296 #C-11 | MAIN PASS | 50.0 | SOUTHERN NATURAL |
| -EXXON CORPORATION | | | | RECEIVED: | 10/27/83 | JA: LA 3 | | | |
| 8403829 | G3-3632 | 1771040928 | | 102-5 | | OCS-G 2111 #C-1 | EUGENE ISLAND | 100.0 | COLUMBIA GAS TRAN |
| 8403817 | G3-3442 | 1771040999 | | 102-5 | | OCS-G 2111 #C-10 | EUGENE ISLAND | 100.0 | COLUMBIA GAS TRAN |
| 8403828 | G3-3643 | 1771040982 | | 102-5 | | OCS-G 2111 #C-13 | EUGENE ISLAND | 300.0 | COLUMBIA GAS TRAN |
| 8403819 | G3-3708 | 1771040961 | | 102-5 | | OCS-G 2111 #C-6 | EUGENE ISLAND | 100.0 | COLUMBIA GAS TRAN |
| 8403831 | G3-3585 | 1771040973 | | 102-5 | | OCS-G 2111 #C-7 | EUGENE ISLAND | 365.0 | COLUMBIA GAS TRAN |
| 8403838 | G3-3899 | 1770640529 | | 102-1 | | OCS-G 4261 #A-4 ST | VERMILION | 37.0 | TRANSCONTINENTAL |
| -GULF OIL CORPORATION | | | | RECEIVED: | 10/27/83 | JA: LA 3 | | | |
| 8403847 | G2-3369 | 1771540412 | | 102-5 | | OCS-G 1256 #C-1 | SOUTH TIMBALIER | 400.0 | TEXAS EASTERN TRA |
| -KERR-MCGEE CORPORATION | | | | RECEIVED: | 10/27/83 | JA: LA 3 | | | |
| 8403807 | G3-3758 | 1771240233 | | 102-5 | | OCS G 3168 #A-1 | SHIP SHOAL | 632.0 | TRANSCONTINENTAL |
| 8403832 | G3-3557 | 1771140668 | | 102-5 | | OCS G-1528 #B-9 | SHIP SHOAL | 48.0 | TRANSCONTINENTAL |
| 8403833 | G2-3378 | 1771240257 | | 102-5 | | OCS-G 3169 #A-3A (ST #1) | SHIP SHOAL | 0.0 | TRANSCONTINENTAL |
| 8403794 | G2-3358 | 1771240272 | | 102-5 | | OCS-G 3169 #A-5 | SHIP SHOAL | 292.0 | TRANSCONTINENTAL |
| -MESA PETROLEUM CO | | | | RECEIVED: | 10/27/83 | JA: LA 3 | | | |
| 8403818 | G3-3441 | 1771940112 | | 102-5 | | WEST DELTA BLK 61 #A-2A | WEST DELTA | 1800.0 | TENNESSEE GAS PIP |
| -NATOMAS OFFSHORE EXPLORATION INC | | | | RECEIVED: | 10/27/83 | JA: LA 3 | | | |
| 8403835 | G3-3906 | 1770040408 | | 102-1 | | WEST CAMERON BLK 281 A-6 | WEST CAMERON | 2920.0 | MID LOUISIANA GAS |
| -OCEAN PRODUCTION CO | | | | RECEIVED: | 10/27/83 | JA: LA 3 | | | |
| 8403849 | G3-3928 | 1775449700 | | 102-1 | | OCS-3592 #4A | SOUTH TIMBALIER 86 | 2349.0 | |
| -SONAT EXPLORATION CO | | | | RECEIVED: | 10/27/83 | JA: LA 3 | | | |
| 8403840 | G2-3330 | 1770340356 | | 102-5 | | EAST CAMERON 231 C-1 | EAST CAMERON | 114.0 | SEA ROBIN PIPELIN |
| 8403826 | G2-3329 | 1770340356 | | 102-1 | | EAST CAMERON 231 C-1D | EAST CAMERON | 161.0 | SEA ROBIN PIPELIN |
| 8403827 | G3-3855 | 1770340407 | | 102-1 | | EAST CAMERON 232 D-1 | EAST CAMERON | 0.0 | SOUTHERN NATURAL |
| -TENNECO OIL COMPANY | | | | RECEIVED: | 10/27/83 | JA: LA 3 | | | |
| 8403797 | G3-3689 | 1771140520 | | 102-1 | | SHIP SHOAL 181 #B-1 | SHIP SHOAL | 2080.0 | |
| 8403810 | G3-3691 | 1771140585 | | 102-1 | | SHIP SHOAL 181 #B-4 | SHIP SHOAL | 2418 0 | |
| 8403802 | G2-3038 | 1770540463 | | 102-5 | | VERMILION 250 #C-10 | VERMILION | 7300.0 | TENNESSEE GAS PIP |
| 8403803 | G2-3036 | 1770540381 | | 102-5 | | VERMILION 250 #C-6 | VERMILION | 7300.0 | TENNESSEE GAS PIP |
| 8403816 | G2-3124 | 1770540381 | | 102-5 | | VERMILION 250 #C-6 | VERMILION | 5475 0 | TENNESSEE GAS PIP |
| -TEXACO INC | | | | RECEIVED: | 10/27/83 | JA: LA 3 | | | |
| 8403845 | G2-3407 | 1770740377 | | 102-5 | | SOUTH MARSH ISLAND 236 #A-1 | SOUTH MARSH ISLAND | 139.0 | |
| 8403823 | G3-3454 | 1770740408 | | 102-5 | | SOUTH MARSH ISLAND 236 #A-3 | SOUTH MARSH ISLAND | 365.0 | |
| 8403856 | G3-3550 | 1770740409 | | 102-5 | | SOUTH MARSH ISLAND 236 #A-4 | SOUTH MARSH ISLAND | 548.0 | NATURAL GAS PIPEL |
| 8403825 | G3-3488 | 1770740407 | | 102-5 | | SOUTH MARSH ISLAND 236 #100 | SOUTH MARSH ISLAND | 0.0 | |
| -TRANSCO EXPLORATION COMPANY | | | | RECEIVED: | 10/27/83 | JA: LA 3 | | | |
| 8403846 | G3-3466 | 1770940387 | | 102-5 | | #1 | EUGENE ISLAND | 7300.0 | TRANSCONTINENTAL |
| -TENNECO OIL COMPANY | | | | RECEIVED: | 10/26/83 | JA: ND 3 | | | |
| 8403863 | ND 43-3 | 3300700861 | | 102-2 | | CHILDS USA 2-20 | ELKHORN RANCH | 87.6 | MONTANA DAKOTA UT |
| -ARCO OIL AND GAS COMPANY | | | | RECEIVED: | 10/27/83 | JA: TX 3 | | | |
| 8403806 | G2-3259 | 4270940470 | | 102-5 | | OCS G-2688 HIGH ISL BLK A-467 #A-3 | HIGH ISLAND BLOCK | 1825.0 | TRANSCO GAS SUPPL |
| 8403795 | G2-3258 | 4270940444 | | 102-5 | | OCS G-2688 HIGH ISL BLK A-467 #A-2A | HIGH ISLAND BLOCK | 1825.0 | TRANSCO GAS SUPPL |
| -CONOCO INC | | | | RECEIVED: | 10/27/83 | JA: TX 3 | | | |
| 8403842 | G2-3319 | 4271240015 | | 102-5 | | MUSTANG ISLAND A-85 A-1 | MUSTANG ISLAND | 5832.0 | TRANSCONTINENTAL |
| 8403809 | G2-3321 | 4271240048 | | 102-5 | | MUSTANG ISLAND A-85 A-10 | MUSTANG ISLAND | 2832.0 | TRANSCONTINENTAL |
| 8403843 | G2-3320 | 4271240018 | | 102-5 | | MUSTANG ISLAND A-85 A-2 | MUSTANG ISLAND | 2200.0 | TRANSCONTINENTAL |
| -ELF AQUITAINE INC | | | | RECEIVED: | 10/27/83 | JA: TX 3 | | | |
| 8403839 | G3-3910 | 4270340163 | | 102-1 | | OCS-G-4137 #A-4 | MATAGORDA | 0.0 | SOUTHERN NATURAL |
| -MESA PETROLEUM CO | | | | RECEIVED: | 10/27/83 | JA: TX 3 | | | |
| 8403837 | G3-3893 | 4270440055 | | 102-1 | | BRAZOS BLK A-7 #A-1 | BRAZOS BLOCK A-7 | 1095.0 | TRANSCONTINENTAL |
| 8403836 | G3-3894 | 4270440089 | | 102-1 | | BRAZOS BLK A-7 #A-3 | BRAZOS BLOCK A-7 #A-3 | 1095.0 | TRANSCONTINENTAL |
| -SUN EXPLORATION & PRODUCTION CO | | | | RECEIVED: | 10/27/83 | JA: TX 3 | | | |
| 8403855 | G2-3289 | 4270940424 | | 102-5 | | OCS-G-2702 #A-1 | HIGH ISLAND SOUTH A-5 | 0.0 | TRUNKLINE GAS CO |
| 8403852 | G2-3290 | 4270940610 | | 102-5 | | OCS-G-2702 #A-3 | HIGH ISLAND SOUTH A-5 | 71.0 | TRUNKLINE GAS CO |
| ********** | | | | | | | | | |
| ** DEPARTMENT OF THE INTERIOR, MINERALS MANAGEMENT SERVICE, CASPER,WY | | | | | | | | | |
| ********** | | | | | | | | | |
| -MIDLANDS GAS CORPORATION | | | | RECEIVED: | 10/26/83 | JA: MT 5 | | | |
| 8403893 | M 108-3 | 2507121856 | | 103 | | FEDERAL #1 1124 | SWANSON CREEK (BOWDOI | 61.0 | KN ENERGY INC |
| 8403897 | M 120-3 | 2507121623 | | 108 | | FEDERAL #1 2313 | BOWDOIN | 5.0 | KN ENERGY INC |
| 8403891 | M 106-3 | 2507121871 | | 102-2 | | FEDERAL #2 2441 | BOWDOIN | 55.0 | KN ENERGY INC |
| 8403892 | M 107-3 | 2507121872 | | 102-2 | | FEDERAL #2 3242 | WHITEWATER UNIT (BOWD | 67.0 | KN ENERGY INC |
| 8403857 | M 13-3 | 2507121222 | | 108 | | FEDERAL 1 0442 | BOWDOIN | 2.0 | KN ENERGY INC |
| 8403867 | M 63-3 | 2507121855 | | 103 | | FEDERAL 1 1224 | BOWDOIN (SWANSON CREE | 30.0 | KN ENERGY INC |
| 8403894 | M 114-3 | 2507121660 | | 108 | | FEDERAL 1 1324 | UNNAMED | 9.0 | KN ENERGY INC |
| 8403865 | M 61-3 | 2507121863 | | 102-2 | | FEDERAL 2 0141 | BOWDOIN | 35.0 | KN ENERGY INC |
| 8403859 | M-50 3 | 2507121859 | | 102-2 | | FEDERAL 2 2260 | BOWDOIN | 13.0 | KN ENERGY CORP |
| 8403866 | M 62-3 | 2507121865 | | 102-2 | | FEDERAL 2 2751 | BOWDOIN | 48.0 | KN ENERGY INC |
| -MONTANA-DAKOTA UTILITIES CO | | | | RECEIVED: | 10/26/83 | JA: MT 5 | | | |
| 8403890 | M 96-3 | 2507121830 | | 103 | | MDU 977 FEDERAL | BOWDOIN DOME | 2.0 | MONTANA-DAKOTA UT |
| -APACHE CORPORATION | | | | RECEIVED: | 10/26/83 | JA: ND 5 | | | |
| 8403869 | ND 71-3 | 3300700722 | | 102-2 | | FEDERAL #2-3 | BUCKHORN | 9 0 | KOCH HYDROCARBON |
| 8403870 | ND 72-3 | 3300700741 | | 102-2 | | FEDERAL #2-4 | BUCKHORN | 30.0 | KOCH HYDROCARBON |
| -DIAMOND SHAMROCK CORPORATION | | | | RECEIVED: | 10/26/83 | JA: ND 5 | | | |
| 8403868 | ND 68-3 | 3300700767 | | 102-2 | | CENEX FEDERAL #23-4 | ROOSEVELT | 0.0 | KOCH HYDROCARBON |
| 8403895 | ND 115-3 | 3300700543 | | 102-2 | | CENEX FEDERAL 34-4 | ROOSEVELT | 0.0 | KOCH HYDROCARBON |
| -FLORIDA GAS EXPLORATION COMPANY | | | | RECEIVED: | 10/26/83 | JA: ND 5 | | | |
| 8403858 | ND 32-3 | 3300700829 | | 102-2 | | FEDERAL 11-144-102 #1 | DEVILS PASS | 0.0 | KOCH HYDROCARBON |
| -GETTY OIL COMPANY | | | | RECEIVED: | 10/26/83 | JA: ND 5 | | | |
| 8403861 | ND 8-3 | 3305301440 | | 102-2 | | BOB CREEK #13-11 | LONE BUTTE | 7.0 | KOCH HYDROCARBON |
| -LADD PETROLEUM CORPORATION | | | | RECEIVED: | 10/26/83 | JA: ND 5 | | | |
| 8403872 | ND 74-3 | 3300700832 | | 102-2 | | FEDERAL #34-11 | ELK HORN RANCH | 21.6 | |
| -PATRICK PETROLEUM CORP (MI) | | | | RECEIVED: | 10/26/83 | JA: ND 5 | | | |
| 8403871 | ND 73-3 | 3300700702 | | 102-2 | | FEDERAL #3-28 | TREETOP | 25.0 | KOCH HYDROCARBON |
| -PETRO-LEWIS CORPORATION | | | | RECEIVED: | 10/26/83 | JA: ND 5 | | | |
| 8403875 | ND 80-3 | 3301100271 | | 108-SA | | FEDERAL 1-15 | LITTLE MISSOURI | 3.2 | MONTANA - DAKOTA |
| 8403876 | ND 81-3 | 3301100268 | | 108-SA | | FEDERAL 1-22 | LITTLE MISSOURI | 10.0 | MONTANA - DAKOTA |
| 8403877 | ND 82-3 | 3301100281 | | 108 | | FEDERAL 1-29 | LITTLE MISSOURI | 10.0 | MONTANA - DAKOTA |
| 8403874 | ND 79-3 | 3301100241 | | 108-SA | | FEDERAL 2-10 | LITTLE MISSOURI | 7.9 | MONTANA - DAKOTA |
| 8403879 | ND 84-3 | 3301100270 | | 108-SA | | FEDERAL 2-15 | LITTLE MISSOURI | 9.0 | MONTANA - DAKOTA |
| 8403880 | ND 85-3 | 3301100267 | | 108-SA | | FEDERAL 2-22 | | 7.9 | MONTANA - DAKOTA |
| 8403881 | ND 86-3 | 3301100239 | | 108-SA | | FEDERAL 2-23 | LITTLE MISSOURI | 4.6 | MONTANA - DAKOTA |
| 8403878 | ND 83-3 | 3301100249 | | 108-SA | | FEDERAL 2-4 | LITTLE MISSOURI | 17.0 | MONTANA - DAKOTA |
| 8403883 | ND 88-3 | 3301100240 | | 108-SA | | FEDERAL 3-10 | LITTLE MISSOURI | 6.8 | MONTANA - DAKOTA |

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| JD NO | JA DKT | API NO | D | SEC(1) | SEC(2) | WELL NAME | FIELD NAME | PROD | PURCHASER |
|---|---|---|---|---|---|---|---|---|---|
| 8403884 | ND 89-3 | 3301100269 | | 108-SA | | FEDERAL 3-15 | LITTLE MISSOURI | 11.7 | MONTANA - DAKOTA |
| 8403885 | ND 90-3 | 3301100265 | | 108-SA | | FEDERAL 3-23 | LITTLE MISSOURI | 6.6 | MONTANA-DAKOTA UT |
| 8403882 | ND 87-3 | 3301100290 | | 108-SA | | FEDERAL 3-3 | LITTLE MISSOURI | 2.8 | MONTANA - DAKOTA |
| 8403887 | ND 92-3 | 3301100081 | | 108 | | FEDERAL 4-15 | LITTLE MISSOURI | 7.9 | MONTANA-DAKOTA UT |
| 8403888 | ND 93-3 | 3301100282 | | 108 | | FEDERAL 4-29 | LITTLE MISSOURI | 7.5 | MONTANA-DAKOTA UT |
| 8403886 | ND 91-3 | 3301100296 | | 108-SA | | FEDERAL 4-8 | LITTLE MISSOURI | 9.0 | MONTANA-DAKOTA UT |
| -SHELL OIL CO | | | | RECEIVED: | 10/26/83 | JA: ND 5 | | | |
| 8403860 | ND 60-3 | 3302500232 | | 102-2 | | BURBANK BIA 23-8 | WILDCAT | 4.8 | |
| 8403862 | ND 16-3 | 3301100384 | | 103 | | USA 31X-3A-56 | CEDAR CREEK | 4.1 | MONTANA DAKOTA UT |
| 8403896 | ND 119-3 | 3305301391 | | 102-4 | | USA 33-23-154 | SQUAW GAP | 17.8 | MONTANA DAKOTA UT |
| 8403889 | ND 95-3 | 3300700669 | | 102-2 | | USA 34-10 | WHISKEY JOE | 40.2 | |
| -TEXACO INC | | | | RECEIVED: | 10/26/83 | JA: ND 5 | | | |
| 8403873 | ND 75-3 | 3305301496 | | 102-3 | | CHARLSON DEEP UNIT #2 | CHARLSON | 1226.0 | |
| 8403864 | ND 58-3 | 3305301166 | | 103 | | SILURIAN UNIT 14 WELL #1 | CHARLSON | 341.3 | MONTANA DAKOTA UT |

[FR Doc. 83-31892 Filed 11-28-83; 8:45 am]

BILLING CODE 6717-01-C

[Volume 1007]

## Determinations by Jurisdictional Agencies Under the Natural Gas Policy Act of 1978

Issued: November 22, 1983.

The following notices of determination were received from the indicated jurisdictional agencies by the Federal Energy Regulatory Commission pursuant to the Natural Gas Policy Act of 1978 and 18 CFR 274.104. Negative determinations are indicated by a "D" before the section code. Estimated annual production (PROD) is in million cubic feet (MMCF).

The applications for determination are available for inspection except to the extent such material is confidential under 18 CFR 275.206, at the Commission's Division of Public Information, Room 1000, 825 North Capitol St., Washington, D.C. Persons objecting to any of these determinations may, in accordance with 18 CFR 275.203 and 275.204, file a protest with the Commission within fifteen days after publication of notice in the **Federal Register**.

Source data from the Form 121 for this and all previous notices is available on magnetic tape from the National Technical Information Service (NTIS). For information, contact Stuart Weisman (NTIS) at (703) 487-4808, 5285 Port Royal Rd, Springfield, Va 22161.

Categories within each NGPA section are indicated by the following codes:

Section 102-1: New OCS lease
102-2: New well (2.5 Mile rule
102-3: New well (1000 Ft rule)
102-4: New onshore reservoir
102-5: New reservoir on old OCS lease

Section 107-DP: 15,000 feet or deeper
107-GB: Geopressured brine
107-CS: Coal Seams
107-DV: Devonian Shale
107-PE: Production enhancement
107-TF: New tight formation
107-RT: Recompletion tight formation

Section 108: Stripper well
108-SA: Seasonally affected
108-ER: Enhanced recovery
108-PB: Pressure buildup

**Kenneth F. Plumb,**
*Secretary.*

NOTICE OF DETERMINATIONS — VOLUME 1007

ISSUED NOVEMBER 22, 1983

| JD NO | JA DKT | API NO | D | SEC(1) | SEC(2) | WELL NAME | FIELD NAME | PROD | PURCHASER |
|---|---|---|---|---|---|---|---|---|---|
| ALASKA OIL & GAS CONSERVATION COMMISSION | | | | | | | | | |
| -ARCO OIL AND GAS COMPANY | | | | RECEIVED: | 10/31/83 | JA: AK | | | |
| 8404104 | | 5002920269 | | 103 | | PRUDHOE BAY UNIT #1-12 | PRUDHOE BAY | 450.0 | |
| FLORIDA DEPARTMENT OF NATURAL RESOURCES | | | | | | | | | |
| -EXXON CORPORATION | | | | RECEIVED: | 10/24/83 | JA: FL | | | |
| 8404092 | | 0911320208 | | 107-DP | | JESSE E MOORE #19-8 | JAY/LEC | 650.0 | FLORIDA GAS TRANS |
| KANSAS CORPORATION COMMISSION | | | | | | | | | |
| -LCG CO | | | | RECEIVED: | 10/31/83 | JA: KS | | | |
| 8404132 | K-82-1250 | 1509921784 | | 108 | | JOHN WALE #2 | SW 1/4 S12 T35 R20E | 18.3 | H C WACKERLE CO I |
| LOUISIANA OFFICE OF CONSERVATION | | | | | | | | | |
| -UNION TEXAS PETROLEUM | | | | RECEIVED: | 10/31/83 | JA: LA | | | |
| 8404095 | 83-1418 | 1706120283 | | 107-TF | | DOWLING 19#1 GRAY RA SUG | TERRYVILLE | 1460.0 | SUGAR BOWL GAS CO |
| 8404094 | 83-1419 | 1706120283 | | 103 | 107-TF | DOWLING 19#1-D UCV RA SUM | TERRYVILLE | 365.0 | SUGAR BOWL GAS CO |
| MONTANA BOARD OF OIL & GAS CONSERVATION | | | | | | | | | |
| -BEREN CORPORATION | | | | RECEIVED: | 10/31/83 | JA: MT | | | |
| 8404131 | 3-83-51 | 2508321441 | | 103 | | STATE HAY CREEK #1 | NORTHFORK | 16.0 | MGPC INC |
| -CELSIUS ENERGY CO | | | | RECEIVED: | 10/31/83 | JA: MT | | | |
| 8404122 | 3-83-50 | 2510122398 | | 103 | | BENJAMIN FEDERAL LAND BANK #1-22 | OLD SHELBY GAS FIELD/ | 60.0 | MICHAEL L LETSON |
| 8404126 | 3-83-49 | 2510121663 | | 108 | | STATE #1-23 | NORTH DUNKIRK | 18.0 | MICHAEL L LETSON |
| -DENMARK RESOURCES INC | | | | RECEIVED: | 10/31/83 | JA: MT | | | |
| 8404123 | 2-83-45 | 2502521155 | | 103 | | BN PICKARD BROS #1-35 | CEDAR CREEK | 10.0 | MONTANA DAKOTA UT |
| -J BURNS BROWN | | | | RECEIVED: | 10/31/83 | JA: MT | | | |
| 8404124 | 1-83-14 | 2504121956 | | 108 | | RANDALL 33-2 | WILDCAT | 9.0 | NORTHERN NATURAL |
| -MIDLANDS GAS CORPORATION | | | | RECEIVED: | 10/31/83 | JA: MT | | | |
| 8404121 | 4-83-61 | 2507121861 | | 103 | | BARNARD #2 1412 | BOWDOIN | 52.0 | KN ENERGY INC |
| -MONTANA-DAKOTA UTILITIES CO | | | | RECEIVED: | 10/31/83 | JA: MT | | | |
| 8404128 | 3-83-53 | 2502521163 | | 103 | | MDU 410 BN | CEDAR CREEK ANTICLINE | 10.0 | MONTANA-DAKOTA UT |
| 8404129 | 3-83-54 | 2502521164 | | 103 | | MDU 411 BN | CEDAR CREEK ANTICLINE | 12.0 | MONTANA-DAKOTA UT |
| 8404130 | 3-83-55 | 2502521192 | | 103 | | MDU 412 | CEDAR CREEK ANTICLINE | 12.0 | MONTANA-DAKOTA UT |
| 8404127 | 3-83-56 | 2502521191 | | 103 | | MDU 413 | CEDAR CREEK ANTICLINE | 12.0 | MONTANA-DAKOTA UT |
| 8404118 | 3-83-57 | 2502521190 | | 103 | | MDU 414 BN | CEDAR CREEK ANTICLINE | 12.0 | MONTANA-DAKOTA UT |
| 8404119 | 3-83-58 | 2502521189 | | 103 | | MDU 415 FEE | CEDAR CREEK ANTICLINE | 12.0 | MONTANA-DAKOTA UT |
| 8404117 | 3-83-59 | 2502521230 | | 103 | | MDU 416 FEE | CEDAR CREEK ANTICLINE | 12.0 | MONTANA-DAKOTA UT |
| 8404120 | 3-83-60 | 2502521231 | | 103 | | MDU 417 FEE | CEDAR CREEK ANTICLINE | 14.0 | MONTANA-DAKOTA UT |
| -SOUTHLAND ROYALTY CO | | | | RECEIVED: | 10/31/83 | JA: MT | | | |
| 8404125 | 3-83-48 | 2507121738 | | 108 | | STATE 1633 #2 | BOWDOIN | 4.7 | KN ENERGY INC |
| NEW YORK DEPARTMENT OF ENVIRONMENTAL CONSERVATION | | | | | | | | | |
| -AMERICAN PENN ENERGY INC | | | | RECEIVED: | 10/31/83 | JA: NY | | | |

BILLING CODE 6717-01-M

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| JD NO | JA DKT | API NO | D | SEC(1) | SEC(2) | WELL NAME | FIELD NAME | PROD | PURCHASEF |
|---|---|---|---|---|---|---|---|---|---|
| 8404138 | 5567 | 3102916680 | | 108 | | BLASZ-BOWMAN UNIT #1 (1455) | EVANS | 10.0 | NATIONAL FUEL GAS |
| 8404139 | 5571 | 3102915429 | | 108 | | CANNY UNIT #1 (#1443) | EVANS | 10.0 | NATIONAL FUEL GAS |
| 8404134 | 5570 | 3102915479 | | 108 | | CANNY UNIT #2 (#1444) | EVANS | 10.0 | NATIONAL FUEL GAS |
| 8404136 | 5569 | 3102916902 | | 108 | | RUSSO UNIT #1 (1522) | EVANS | 10.0 | NATIONAL FUEL GAS |
| 8404135 | 5568 | 3102916903 | | 108 | | RUSSO UNIT #2 (#1529) | EVANS | 10.0 | NATIONAL FUEL GAS |
| 8404137 | 5566 | 3102916681 | | 108 | | TWIN CREEK UNIT #1 (1521) | EVANS | 10.0 | NATIONAL FUEL GAS |
| -BAY ENERGY CO | | | | RECEIVED: | 10/27/83 | JA: NY | | | |
| 8404093 | 2029 | 3102915842 | | 103 | | WILK UNIT 80-E101 | ORCHARD PARK | 29.0 | NATIONAL FUEL GAS |
| -BOUNTY OIL & GAS INC | | | | RECEIVED: | 10/31/83 | JA: NY | | | |
| 8404133 | 4997 | 3101317933 | | 102-2 | 107-TF | CHRISTOPHERSON UNIT #1 | ELLICOTT | 0.0 | NATIONAL FUEL GAS |

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WEST VIRGINIA DEPARTMENT OF MINES

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| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| -ALFRED E KNOBLER | | | | RECEIVED: | 10/28/83 | JA: WV | | | |
| 8404069 | | 4703903798 | | 107-DV | | CECIL K-56 | WASHINGTON DISTRICT | 91.2 | ROARING FORK GAS |
| 8404071 | | 4703903798 | | 103 | | CECIL K-56 | WASHINGTON DISTRICT | 91.2 | ROARING FORK GAS |
| 8404072 | | 4704302493 | | 103 | | KENAN W MCCALLISTER K-62-3 | DUVAL DISTRICT | 24.0 | ROARING FORK GAS |
| 8404073 | | 4704302560 | | 103 | | MCCALLISTER K-76 | DUVAL DISTRICT | 14.6 | ROARING FORK GAS |
| 8404081 | | 4703903515 | | 103 | | OLIVER DEXTER #1 K-57 | WASHINGTON DISTRICT | 14.6 | ROARING FORK GAS |
| 8404070 | | 4701100705 | | 103 | | R V LUCAS #2 K-70 | MCCOMAS DISTRICT | 40.0 | COLUMBIA GAS TRAN |
| -ASHLAND EXPLORATION INC | | | | RECEIVED: | 10/28/83 | JA: WV | | | |
| 8404033 | | 4708100545 | | 107-TF | | BEDFORD LAND CO #17 - 090191 | PAINT CREEK | 10.0 | COLUMBIA GAS TRAN |
| 8404035 | | 4701900459 | | 107-TF | | BEDFORD LAND CO #18 - 091801 | PAINT CREEK | 164.0 | COLUMBIA GAS TRAN |
| 8404034 | | 4701900446 | | 107-TF | | EASTERN GAS & FUEL #69 - 090361 | PAINT CREEK | 15.0 | COLUMBIA GAS TRAN |
| 8404032 | | 4701900504 | | 107-TF | | J F B PEYTON #6 - 095241 | PAINT CREEK | 10.0 | COLUMBIA GAS TRAN |
| -COLLINS-MCGREGOR OPERATING COMPANY | | | | RECEIVED: | 10/28/83 | JA: WV | | | |
| 8404082 | | 4708505652 | | 103 | | SIMMONS HEIRS #3 (B-2) | GRANT | 10.0 | CONSOLIDATED NATU |
| 8404083 | | 4708505652 | | 107-DV | | SIMMONS HEIRS #3 (B-2) | GRANT | 10.0 | CONSOLIDATED NATU |
| -KEY OIL INC | | | | RECEIVED: | 10/28/83 | JA: WV | | | |
| 8404042 | | 4708506158 | | 103 | | A M DOUGLAS #1 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404067 | | 4708506158 | | 107-DV | | A M DOUGLAS #1 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404019 | | 4708506211 | | 107-DV | | ADAMS #1 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404049 | | 4708506211 | | 103 | | ADAMS #1 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404023 | | 4708506236 | | 107-DV | | ADAMS #2 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404048 | | 4708506236 | | 103 | | ADAMS #2 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404022 | | 4708506235 | | 107-DV | | BURL LAYFIELD #1 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404057 | | 4708506235 | | 103 | | BURL LAYFIELD #1 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404056 | | 4708506187 | | 103 | | CHET WATERMAN #1 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404068 | | 4708506187 | | 107-DV | | CHET WATERMAN #1 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404018 | | 4708506189 | | 107-DV | | CLIFTON VALENTINE #1 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404050 | | 4708506189 | | 103 | | CLIFTON VALENTINE #1 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404054 | | 4708506290 | | 103 | | E D SALMONS #1 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404088 | | 4708506290 | | 107-DV | | E D SALMONS #1 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404017 | | 4708506214 | | 107-DV | | JAMES MCNAMEE #2 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404055 | | 4708506214 | | 103 | | JAMES MCNAMEE #2 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404030 | | 4708506215 | | 107-DV | | JAMES MCNAMEE #3 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404053 | | 4708506215 | | 103 | | JAMES MCNAMEE #3 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404031 | | 4708506216 | | 107-DV | | JAMES MCNAMEE #4 | GRANT | 0 0 | CONSOLIDATED GAS |
| 8404052 | | 4708506216 | | 103 | | JAMES MCNAMEE #4 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404027 | | 4708506217 | | 107-DV | | JAMES MCNAMEE #5 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404051 | | 4708506217 | | 103 | | JAMES MCNAMEE #5 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404046 | | 4708506283 | | 103 | | KELLAR HEIRS #2 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404025 | | 4708506284 | | 107-DV | | KELLAR HEIRS #3 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404047 | | 4708506284 | | 103 | | KELLAR HEIRS #3 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404020 | | 4708506283 | | 107-DV | | KELLER HEIRS #2 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404037 | | 4708506121 | | 103 | | LEONA SIX #1 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404063 | | 4708506121 | | 107-DV | | LEONA SIX #1 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404045 | | 4708506128 | | 103 | | LEONA SIX #2 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404064 | | 4708506128 | | 107-DV | | LEONA SIX #2 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404028 | | 4708506122 | | 107-DV | | LEONA SIX #3 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404039 | | 4708506122 | | 103 | | LEONA SIX #3 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404029 | | 4708506126 | | 107-DV | | MARIE ROLLINS #1 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404040 | | 4708506126 | | 103 | | MARIE ROLLINS #1 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404044 | | 4708506156 | | 103 | | MARIE ROLLINS #2 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404065 | | 4708506156 | | 107-DV | | MARIE ROLLINS #2 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404043 | | 4708506157 | | 103 | | MARIE ROLLINS #3 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404066 | | 4708506157 | | 107-DV | | MARIE ROLLINS #3 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404021 | | 4708506282 | | 107-DV | | P F KELLAR HEIRS #1 | GRANT | 0 0 | CONSOLIDATED GAS |
| 8404026 | | 4708506127 | | 107-DV | | R K SIX #3 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404041 | | 4708506127 | | 103 | | R K SIX #3 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404024 | | 4708506059 | | 107-DV | | RALPH K SIX #1 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404036 | | 4708506059 | | 103 | | RALPH K SIX #1 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404059 | | 4708506091 | | 103 | | RALPH K SIX #2 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404090 | | 4708506091 | | 107-DV | | RALPH K SIX #2 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404038 | | 4708506120 | | 103 | | WILDA MCWHORTER #1 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404091 | | 4708506120 | | 107-DV | | WILDA MCWHORTER #1 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404058 | | 4705806294 | | 103 | | WILSON #1 | GRANT | 0.0 | CONSOLIDATED GAS |
| 8404089 | | 4708506294 | | 107-DV | | WILSON #1 | GRANT | 0.0 | CONSOLIDATED GAS |
| -MARIETTA ROYALTY CO INC | | | | RECEIVED: | 10/28/83 | JA: WV | | | |
| 8404084 | | 4710701195 | | 103 | | F J PATTERSON #1 | GRANT | 6.0 | PENNZOIL CO |
| 8404085 | | 4710701195 | | 107-DV | | F J PATTERSON #1 | GRANT | 6.0 | PENNZOIL CO |
| -OHIO & WESTERN RESOURCES INC | | | | RECEIVED: | 10/28/83 | JA: WV | | | |
| 8404078 | | 4708505971 | | 103 | | FRANCIS #1 (5971) | GRANT | 20.0 | CONSOLIDATED GAS |
| 8404076 | | 4708505887 | | 103 | | FRANCIS #3 (5887) | GRANT | 14.0 | CONSOLIDATED GAS |
| 8404080 | | 4708505805 | | 103 | | HUFFMAN #1 (5805) | GRANT | 19.0 | CONSOLIDATED GAS |
| 8404075 | | 4708505817 | | 103 | | JACKSON/MADDEN #1 | GRANT | 20.0 | CONSOLIDATED GAS |
| 8404079 | | 4708505933 | | 103 | | MOSS #1 | GRANT | 15.0 | CONSOLIDATED GAS |
| 8404077 | | 4708505906 | | 103 | | NICHOLS #2 (5906) | GRANT | 17.0 | CONSOLIDATED GAS |
| 8404074 | | 4708505612 | | 103 | | TURNER #1 | GRANT | 18.0 | CONSOLIDATED GAS |
| -ROSS-WHARTON GAS CO | | | | RECEIVED: | 10/28/83 | JA: WV | | | |
| 8404061 | | 4704102981 | | 108 | | C W MAXWELL HEIRS #1 | JANE LEW | 20.0 | CONSOLIDATED GAS |
| 8404087 | | 4704102977 | | 103 | | J J MARKS #2 | JANE LEW | 0.0 | CONSOLIDATED GAS |
| 8404086 | | 4704102976 | | 108 | | J J MARKS WELL #3 | HACKERS CREEK DISTRIC | 25.0 | CONSOLIDATED GAS |
| 8404060 | | 4704102979 | | 108 | | SPIKER #2 | HACKERS CREEK | 35.0 | CONSOLIDATED GAS |
| 8404062 | | 4704103027 | | 108 | | SPIKER #3 | HACKERS CREEK | 25.0 | CONSOLIDATED GAS |

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** DEPARTMENT OF THE INTERIOR, MINERALS MANAGEMENT SERVICE, DENVER,CO

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|---|---|---|---|---|---|---|---|---|---|
| -COSEKA RESOURCES (USA) LIMITED | | | | RECEIVED: | 10/31/83 | JA: CO 1 | | | |
| 8404102 | CD 0178-83 | 0510308920 | | 102-2 | | FEDERAL #6-22-1N-103 | WILDCAT | 107.7 | NORTHWEST PIPELIN |
| 8404103 | CD 0179-83 | 0510309002 | | 102-2 | | FEDERAL #9-20-1N-103 | WILDCAT | 698.6 | NORTHWEST PIPELIN |
| -SOUTHLAND ROYALTY CO | | | | RECEIVED: | 10/31/83 | JA: CO 1 | | | |
| 8404099 | CD-0155-83 | 0506706374 | | 107-TF | | RED MESA #1 | IGNACIO BLANCO | 200.0 | NORTHWEST PIPELIN |
| 8404100 | CD 0156-83 | 0506706565 | | 107-TF | | RED MESA #3 | IGNACIO-BLANCO | 0.0 | NORTHWEST PIPELIN |

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| JD NO | JA DKT | API NO | D | SEC(1) | SEC(2) | WELL NAME | FIELD NAME | PROD | PURCHASER |
|---|---|---|---|---|---|---|---|---|---|
| 8404101 | CD 0157-83 | 0506706565 | | 107-TF | | RED MESA #3 | IGNACIO | 0.0 | NORTHWEST PIPELIN |
| ** DEPARTMENT OF THE INTERIOR, MINERALS MANAGEMENT SERVICE, LOS ANGELES,CA | | | | | | | | | |
| -UNION OIL COMPANY OF CALIF | | | | RECEIVED: | 10/31/83 | JA: CA 2 | | | |
| 8404096 | OCS-P 0216 | 0431120543 | | 102-5 | | SANTA CLARA UNIT WELL S-17 | CALIFORNIA OFFSHORE | 0.0 | PACIFIC LIGHTING |
| ** DEPARTMENT OF THE INTERIOR, MINERALS MANAGEMENT SERVICE, ALBUQUERQUE,NM | | | | | | | | | |
| -AMOCO PRODUCTION CO | | | | RECEIVED: | 10/27/83 | JA: NM 4 | | | |
| 8403957 | NM0793-83-PB | 3004520966 | | 108-PB | | A L ELLIOTT B #7 | BLANCO | 0.0 | EL PASO NATURAL G |
| 8403956 | NM0792-83-PB | 3004521014 | | 108-PB | | A L ELLIOTT C #3 | BLANCO | 0.0 | EL PASO NATURAL G |
| 8403954 | NM-0790-83PB | 3004509188 | | 108-PB | | E E ELLIOTT B #6 | BLANCO | 0.0 | EL PASO NATURAL G |
| 8403952 | NM-0787-83PB | 3004507137 | | 108-PB | | E E ELLIOTT C #2 | BLANCO | 0.0 | EL PASO NATURAL G |
| 8403955 | NM-791-83-PB | 3004507973 | | 108-PB | | EDERAL GAS COM 3 #1 | AZTEC | 0.0 | EL PASO NATURAL G |
| 8403950 | NM-0783-83PB | 3004520297 | | 108-PB | | ELLIOTT GAS COM "T" #1 | BLANCO | 0.0 | EL PASO NATURAL G |
| 8403962 | NM0784-83-PB | 3004506986 | | 108-PB | | FRED FEASEL A #1 | FULCHER KUTZ | 0.0 | SOUTHERN UNION GA |
| 8403961 | NM0786-83-PB | 3004506985 | | 108-PB | | FRED FEASEL C #1 | FULCHER KUTZ | 0.0 | SOUTHERN UNION GA |
| 8403947 | NM-0771-83PB | 3004507158 | | 108-PB | | GALLEGOS CANYON UNIT #175 | BASIN | 0.0 | EL PASO NATURAL G |
| 8403943 | NM-0780-83PB | 3004511622 | | 108-PB | | GALLEGOS CANYON UNIT #223 | BASIN | 0.0 | EL PASO NATURAL G |
| 8403958 | NM0797-83-PB | 3004511684 | | 108-PB | | GALLEGOS CANYON UNIT #226 | BASIN | 0.0 | EL PASO NATURAL G |
| 8403951 | NM-0785-83PB | 3004511687 | | 108-PB | | GALLEGOS CANYON UNIT #241 | BASIN | 0.0 | EL PASO NATURAL G |
| 8403946 | NM-0776-83PB | 3004511736 | | 108-PB | | GALLEGOS CANYON UNIT #242 | BASIN | 0.0 | EL PASO NATURAL G |
| 8403939 | NM-0767-83PB | 3004511739 | | 108-PB | | GALLEGOS CANYON UNIT #246 | BASIN | 0.0 | EL PASO NATURAL G |
| 8403938 | NM-0766-83PB | 3004511678 | | 108-PB | | GALLEGOS CANYON UNIT #247 | BASIN | 0.0 | EL PASO NATURAL G |
| 8403940 | NM-0768-83PB | 3004506981 | | 108-PB | | GALLEGOS CANYON UNIT #90 | BASIN | 0.0 | EL PASO NATURAL G |
| 8403941 | NM-0769-83PB | 3004506402 | | 108-PB | | H B MCGRADY A #2 | BASIN | 0.0 | EL PASO NATURAL G |
| 8403945 | NM-0778-83PB | 3003906153 | | 108-PB | | JICARILLA CONTRACT 146 #12 | OTERO | 0.0 | EL PASO NATURAL G |
| 8403960 | NM0799-83-PB | 3003906065 | | 108-PB | | JICARILLA CONTRACT 146 #16 | OTERO | 0.0 | EL PASO NATURAL G |
| 8403948 | NM-0770-83PB | 3003982337 | | 108-PB | | JICARILLA CONTRACT 148 #14 | OTERO | 0.0 | EL PASO NATURAL G |
| 8403942 | NM-0781-83PB | 3003905975 | | 108-PB | | JICARILLA CONTRACT 148 #16 | OTERO | 0.0 | EL PASO NATURAL G |
| 8403953 | NM-0789-83PB | 3003921999 | | 108-PB | | JICARILLA CONTRACT 148 #17 | OTERO | 0.0 | EL PASO NATURAL G |
| 8403959 | NM0798-83PB | 3004506631 | | 108-PB | | P O PIPKIN #2 | BASIN | 0.0 | EL PASO NATURAL G |
| 8403944 | NM-0779-83PB | 3004520715 | | 108-PB | | SHAW GAS COM B | BLANCO | 0.0 | EL PASO NATURAL G |
| 8403949 | NM-0782-83PB | 3004508409 | | 108-PB | | W D HEATH A #8 | BASIN | 0.0 | EL PASO NATURAL G |
| 8403937 | NM-0816-83PB | 3004520970 | | 108-PB | | WD HEATH B #5 | BLANCO | 0.0 | EL PASO NATURAL G |
| -CONSOLIDATED OIL & GAS INC | | | | RECEIVED: | 10/27/83 | JA: NM 4 | | | |
| 8403923 | NM-0818-83PB | 3004510936 | | 108-PB | | FREEMAN #1-11 | BASIN DAKOTA | 0.0 | EL PASO NATURAL G |
| 8403924 | NM-0817-83PB | 3004510866 | | 108-PB | | OWEN #1 | | 0.0 | EL PASO NATURAL G |
| -EL PASO EXPLORATION CO | | | | RECEIVED: | 10/27/83 | JA: NM 4 | | | |
| 8403920 | NM-0802-83PB | 3003922076 | | 108-PB | | JICARILLA 120 C#19 | SOUTH BLANCO | 0.0 | NORTHWEST PIPELIN |
| 8403919 | NM-0716-83PB | 3004506514 | | 108-PB | | SAN JUAN 27-8 A #2 | SOUTH BLANCO | 0.0 | NORTHWEST PIPELIN |
| -EL PASO NATURAL GAS COMPANY | | | | RECEIVED: | 10/27/83 | JA: NM 4 | | | |
| 8403968 | NM0729-83PB | 3004520760 | | 108-PB | | ATLANTIC A #11 | BLANCO PICTURED CLIFF | 0.0 | EL PASO NATURAL G |
| 8403997 | NM0732-83PB | 3004520589 | | 108-PB | | ATLANTIC B #10 | BLANCO PICTURED CLIFF | 0.0 | EL PASO NATURAL G |
| 8403975 | NM0764-83PB | 3004521171 | | 108-PB | | BARNES #12 | BLANCO PICTURED CLIFF | 0.0 | EL PASO NATURAL G |
| 8404001 | NM0741-83PB | 3004509866 | | 108-PB | | BRUINGTON #3 PC & MV | AZTEC PC & BLANCO MV | 0.0 | EL PASO NATURAL G |
| 8403976 | NM0795-83PB | 3003920790 | | 108-PB | | CANYON LARGO UNIT #228 | SOUTH BLANCO PICTURED | 0.0 | EL PASO NATURAL G |
| 8403987 | NM0806-83PB | 3003920888 | | 108-PB | | CANYON LARGO UNIT #279 | CANYON LARGO UNIT #27 | 0.0 | EL PASO NATURAL G |
| 8403993 | NM0701-83PB | 3003920793 | | 108-PB | | CANYON LARGO UNIT NP #238 | GONZALES MESAVERDE | 0.0 | EL PASO NATURAL G |
| 8404012 | NM836-83PB | 3004521114 | | 108-PB | | CASE #17 | BLANCO PC | 0.0 | EL PASO NATURAL G |
| 8403984 | NM0803-83PB | 3004507065 | | 108-PB | | DAUM #2 | AZTEC PICTURED CLIFFS | 0.0 | EL PASO NATURAL G |
| 8404005 | NM0745-83PB | 3004510273 | | 108-PB | | DAWSON #1 | BLANCO MESA VERDE | 0.0 | EL PASO NATURAL G |
| 8403994 | NM0726-83PB | 3004513037 | | 108-PB | | DAY B #7 | SOUTH BLANCO PC | 0.0 | EL PASO NATURAL G |
| 8403974 | NM0757-83PB | 3004511769 | | 108-PB | | FLORANCE #6 | BLANCO PICTURED CLIFF | 0.0 | EL PASO NATURAL G |
| 8403998 | NM0733-83PB | 3004520671 | | 108-PB | | GRAMBLING C #7 | BLANCO PICTURED CLIFF | 0.0 | EL PASO NATURAL G |
| 8403967 | NM0728-83-PB | 3004520669 | | 108-PB | | HEATON #25 | AZTEC PICTURED CLIFFS | 0.0 | EL PASO NATURAL G |
| 8404000 | NM0735-83PB | 3004505701 | | 108-PB | | HUERFANO UNIT #58 | BALLARD PICTURED CLIF | 0.0 | EL PASO NATURAL G |
| 8404015 | NM839-83PB | 3004505743 | | 108-PB | | HUERFANO UNIT NP #23 | HUERFANO PC | 0.0 | EL PASO NATURAL G |
| 8404003 | NM0743-83PB | 3004520308 | | 108-PB | | HUERFANO UNIT #181 | BASIN DAKOTA | 0.0 | EL PASO NATURAL G |
| 8404008 | NM0748-83PB | 3003921157 | | 108-PB | | JICARILLA C #11 | SOUTH BLANCO PC | 0.0 | EL PASO NATURAL G |
| 8404002 | NM0742-83PB | 3003921158 | | 108-PB | | JICARILLA C #13 | SOUTH BLANCO PICTURED | 0.0 | EL PASO NATURAL G |
| 8403979 | NM0738-83PB | 3003906448 | | 108-PB | | JICARILLA F #10 | SOUTH BLANCO | 0.0 | EL PASO NATURAL G |
| 8403995 | NM0727-83PB | 3003906359 | | 108-PB | | JICARILLA G #2 | SOUTH BLANCO PC | 0.0 | EL PASO NATURAL G |
| 8403977 | NM0736-83-PB | 3003906528 | | 108-PB | | JICARILLA J #16 | SOUTH BLANCO | 0.0 | EL PASO NATURAL G |
| 8403981 | NM0740-83-PB | 3003906368 | | 108-PB | | JICARILLA J #7 | SOUTH BLANCO | 0.0 | EL PASO NATURAL G |
| 8403985 | NM0804-83PB | 3003906430 | | 108-PB | | JICARILLA J 2 | SOUTH BLANCO PICTURED | 0.0 | EL PASO NATURAL G |
| 8403978 | NM0737-83PB | 3003900000 | | 108-PB | | JICARILLA 67 #1 | SOUTH BLANCO | 0.0 | EL PASO NATURAL G |
| 8403980 | NM0739-83-PB | 3004520793 | | 108-PB | | KELLY B #2 | BLANCO | 0.0 | EL PASO NATURAL G |
| 8404007 | NM0747-83PB | 3003906244 | | 108-PB | | KLEIN #7 CHAND PC | OTERO CHACHA & SOUTH | 0.0 | EL PASO NATURAL G |
| 8404016 | NM 0840-83PB | 3004520861 | | 108-PB | | LACKEY A#6 | AZTEC PC | 0.0 | EL PASO NATURAL G |
| 8403989 | NM0810-83PB | 3003905519 | | 108-PB | | LINDRITH UNIT #48 | SOUTH BLANCO PICTURED | 0.0 | EL PASO NATURAL G |
| 8404006 | NM0746-83PB | 3004509329 | | 108-PB | | LUDWICK #6 | AZTEC PICTURED CLIFFS | 0.0 | EL PASO NATURAL G |
| 8403970 | NM0833-83PB | 3004507056 | | 108-PB | | MICHENER A #1 | SOUTH BLANCO PC | 0.0 | EL PASO NATURAL G |
| 8403999 | NM0734-83PB | 3003906332 | | 108-PB | | QUANTIUS #3 | SOUTH BLANCO PC | 0.0 | EL PASO NATURAL G |
| 8403969 | NM0730-83PB | 3003960093 | | 108-PB | | RINCON UNIT #107 PC & MV | SOUTH BLANCO PC & BLA | 0.0 | EL PASO NATURAL G |
| 8403996 | NM0731-83PB | 3003906877 | | 108-PB | | RINCON UNIT #154 | SOUTH BLANCO PICTURED | 0.0 | EL PASO NATURAL G |
| 8404010 | NM0750-83PB | 3003906809 | | 108-PB | | RINCON UNIT #35 | SOUTH BLANCO PICTURED | 0.0 | EL PASO NATURAL G |
| 8404009 | NM0749-83PB | 3003906909 | | 108-PB | | RINCON UNIT #39 | SOUTH BLANCO PC | 0.0 | EL PASO NATURAL G |
| 8403982 | NM0800-83PB | 3003906782 | | 108-PB | | RINCON UNIT #42 | SOUTH BLANCO PICTURED | 0.0 | EL PASO NATURAL G |
| 8403991 | NM0811-83PB | 3003906820 | | 108-PB | | RINCON UNIT #76 | SOUTH BLANCO PICTURED | 0.0 | EL PASO NATURAL G |
| 8403983 | NM-0801-83PB | 3003906791 | | 108-PB | | RINCON UNIT #77 | SOUTH BLANCO PICTURED | 0.0 | EL PASO NATURAL G |
| 8403992 | NM832-83PB | 3003920961 | | 108-PB | | SAN JUAN UNIT #28-7 #201 | LARGO CHACRA | 0.0 | EL PASO NATURAL G |
| 8403988 | NM0807-83PB | 3003906786 | | 108-PB | | SAN JUAN 27-5 #35 | SOUTH BLANCO PICTURED | 0.0 | EL PASO NATURAL G |
| 8403972 | NM0753-83PB | 3003907049 | | 108-PB | | SAN JUAN 27-5 UNIT #47 | BLANCO PICTURED CLIFF | 0.0 | EL PASO NATURAL G |
| 8403973 | NM0754-83PB | 3004506443 | | 108-PB | | SAN JUAN 27-8 B #4 | BLANCO PICTURED CLIFF | 0.0 | EL PASO NATURAL G |
| 8403990 | NM0809-83PB | 3003920510 | | 108-PB | | SAN JUAN 28-4 UNIT #35 | BASIN DAKOTA | 0.0 | EL PASO NATURAL G |
| 8403971 | NM0752-83PB | 3003907073 | | 108-PB | | SAN JUAN 28-6 UNIT #82 | SOUTH BLANCO PICTURED | 0.0 | EL PASO NATURAL G |
| 8404014 | NM838-83-PB | 3003920406 | | 108-PB | | SAN JUAN 28-7 UNIT #160 | LARGO CHACRA | 0.0 | EL PASO NATURAL G |
| 8404011 | NM0751-83PB | 3003906898 | | 108-PB | | SAN JUAN 28-7 UNIT #17 | SOUTH BLANCO PICTURED | 0.0 | EL PASO NATURAL G |
| 8404004 | NM0744-83PB | 3004506766 | | 108-PB | | SCHWERDFEGER A #4 | SOUTH BLANCO PICTURED | 0.0 | EL PASO NATURAL G |
| 8403986 | NM0805-83PB | 3004509601 | | 108-PB | | STOREY B #5 | AZTEC PICTURED CLIFFS | 0.0 | EL PASO NATURAL G |
| 8404013 | NM0837-83PB | 3004505660 | | 108-PB | | WHAN JONES #1 | BALLARD PC | 0.0 | EL PASO NATURAL G |
| -GETTY OIL COMPANY | | | | RECEIVED: | 10/27/83 | JA: NM 4 | | | |
| 8403917 | NM-0828-83PB | 3004506772 | | 108-PB | | J A MARSHALL #1 | SOUTH BLANCO PC | 0.0 | EL PASO NATURAL G |
| -JACK A COLE | | | | RECEIVED: | 10/27/83 | JA: NM 4 | | | |
| 8403921 | NM-0830-83PB | 3004320227 | | 108-PB | | APACHE FLATS #10 | BALLARD PICTURED CLIF | 15.0 | EL PASO NATURAL G |
| 8403922 | NM 0831-83PB | 3003921908 | | 108-PB | | APACHE HILLS #4 | BALLARD PICTURED CLIF | 13.0 | EL PASO NATURAL G |
| -JEROME P MCHUGH | | | | RECEIVED: | 10/27/83 | JA: NM 4 | | | |
| 8403965 | NM0762-83-PB | 3003920266 | | 108-PB | | APACHE #5 | DAKOTA | 0.0 | NORTHWEST PIPELIN |
| 8403963 | NM0824-83PB | 3004512101 | | 108-PB | | HARDIE #4 | BASIN DAKOTA | 0.0 | EL PASO NATURAL G |
| 8403964 | NM0755-83-PB | 3004512101 | | 108-PB | | HARDIE #4 | BASIN DAKOTA | 0.0 | EL PASO NATURAL G |
| 8403966 | NM0763-83-PB | 3003920131 | | 108-PB | | JICARILLA #7 | DAKOTA | 0.0 | NORTHWEST PIPELIN |
| -KOCH INDUSTRIES INC | | | | RECEIVED: | 10/27/83 | JA: NM 4 | | | |

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| JD NO | JA DKT | API NO | D | SEC(1) | SEC(2) | WELL NAME | FIELD NAME | PROD | PURCHASER |
|---|---|---|---|---|---|---|---|---|---|
| 8403916 | NM-834-83-PB | 3004508504 | | 108-PB | | WRIGHT #2 | AZTEC PC | 0.0 | EL PASO NATURAL G |
| -MOBIL PRDG TEXAS & NEW MEXICO INC | | | | RECEIVED: | 10/27/83 | JA: NM 4 | | | |
| 8403933 | NM-0715-83PB | 3003900000 | | 108-PB | | JICARILLA OTERO FED #1 | BASIN DAKOTA | 0.0 | EL PASO NATURAL G |
| 8403932 | NM-0714-83PB | 3004509323 | | 108-PB | | STEPHENS UNIT #1 | BASIN DAKOTA | 0.0 | NORTHWEST PIPELIN |
| -NORTHERN NATURAL GAS PRODUCING CO | | | | RECEIVED: | 10/27/83 | JA: NM 4 | | | |
| 8403930 | NM-0713-83PB | 3004500000 | | 108-PB | | NYE FEDERAL #3 | BLANCO MESAVERDE | 0.0 | EL PASO NATURAL G |
| 8403931 | NM-0712-83PB | 3004500000 | | 108-PB | | NYE FEDERAL TRACT 1 #2 | BASIN DAKOTA | 0.0 | EL PASO NATURAL G |
| -NORTHWEST PIPELINE CORPORATION | | | | RECEIVED: | 10/27/83 | JA: NM 4 | | | |
| 8403925 | NM-0708-83PB | 3004521487 | | 108-PB | | HOLT #3 | BLANCO PC | 0.0 | NORTHWEST PIPELIN |
| 8403928 | NM-0704-83PB | 3003907907 | | 108-PB | | SAN JUAN 31-6 UNIT #14 | BLANCO MESAVERDE | 0.0 | EL PASO NATURAL G |
| 8403929 | NM-0823-83PB | 3003907907 | | 108-PB | | SAN JUAN 31-6 UNIT #14 | BLANCO MESAVERDE | 0.0 | EL PASO NATURAL G |
| 8403926 | NM-0706-83PB | 3004510675 | | 108-PB | | SAN JUAN 32-8 #23 | BLANCO MESAVERDE | 0.0 | EL PASO NATURAL G |
| 8403927 | NM-0705-83PB | 3004510700 | | 108-PB | | SAN JUAN 32-8 UNIT #16 | BLANCO MESAVERDE | 0.0 | EL PASO NATURAL G |
| -SOUTHERN UNION EXPLORATION COMPANY | | | | RECEIVED: | 10/27/83 | JA: NM 4 | | | |
| 8403936 | NM-0709-83PB | 3003920626 | | 108-PB | | JICARILLA D #12 | TAPACITO | 0.0 | GAS CO OF NEW MEX |
| 8403935 | NM-0710-83PB | 3003900000 | | 108-PB | | JICARILLA E #2 | TAPACITO | 0.0 | GAS CO OF NEW MEX |
| 8403934 | NM-0711-83PB | 3003900000 | | 108-PB | | JICARILLA E #3 | TAPACITO | 0.0 | GAS CO OF NEW MEX |
| -SOUTHLAND ROYALTY CO | | | | RECEIVED: | 10/27/83 | JA: NM 4 | | | |
| 8403918 | NM-835-83-PB | 3004508787 | | 108-PB | | HARE #1 | | 0.0 | EL PASO NATURAL G |
| ********** | | | | | | | | | |
| ** DEPARTMENT OF THE INTERIOR, MINERALS MANAGEMENT SERVICE, CASPER,WY | | | | | | | | | |
| ********** | | | | | | | | | |
| -MARATHON OIL COMPANY | | | | RECEIVED: | 10/27/83 | JA: UT 5 | | | |
| 8404097 | USL 004-83 | 4303730762 | | 102-2 | | TIN CUP MESA #3-26 | TIN CUP | 39.4 | |
| -BOYDSTON & FRANZEN WELL SERVICE | | | | RECEIVED: | 10/31/83 | JA: WY 5 | | | |
| 8404114 | W 133-3 | 4900320615 | | 103 | | WEGO 29-2 | FIVE MILE | 100.0 | MONTANA DAKOTA UT |
| -GETTY OIL COMPANY | | | | RECEIVED: | 10/31/83 | JA: WY 5 | | | |
| 8404111 | W 45-3 | 4900320638 | | 103 | | DOBIE CREEK #20-6 | DOBIE CREEK | 350.0 | MONTANA-DAKOTA UT |
| -GULF OIL CORPORATION | | | | RECEIVED: | 10/31/83 | JA: WY 5 | | | |
| 8404106 | W 716-2 | 4904320523 | | 103 | | SLICK FEDERAL 1-11-2B | SLICK CREEK | 9.0 | |
| -MARATHON OIL COMPANY | | | | RECEIVED: | 10/31/83 | JA: WY 5 | | | |
| 8404110 | W 31-3 | 4902921115 | | 103 | | ATHERLY "A" #8 (EMBAR FORMATION) | OREGON BASIN | 3.8 | COLORADO INTERSTA |
| 8404109 | W 765-2 | 4902921156 | | 103 | | FREEMAN #9 (EMBAR FORMATION) | OREGON BASIN | 22.4 | COLORADO INTERSTA |
| 8404108 | W 722-2 | 4902921096 | | 103 | | MORRIS #7 (EMBAR & TENSLEEP FORM | OREGON BASIN | 10.4 | COLORADO INTERSTA |
| 8404113 | W 125-3 | 4902921091 | | 103 | | MORRIS #8 (TENSLEEP FORMATION) | OREGON BASIN | 0.7 | COLORADO INTERSTA |
| 8404115 | W 144-3 | 4902921132 | | 103 | | OWENS 'A' #11 (EMBAR AND TENSLEEP | OREGON BASIN | 16.9 | COLORADO INTERSTA |
| 8404116 | W 335-A-3 | 4902921123 | | 103 | | SARAH #58 (EMBAR AND TENSLEEP FORM | OREGON BASIN | 13.7 | COLORADO INTERSTA |
| 8404105 | W 660-2 | 4902921120 | | 103 | | SONNERS A/C 2 #10 (EMBAR & TENSLEEP | OREGON BASIN | 6.2 | COLORADO INTERSTA |
| 8404107 | W 721-2 | 4902921122 | | 103 | | SONNERS A/C 2 #9 (EMBAR & TENSLEEP | OREGON BASIN | 9.1 | COLORADO INTERSTA |
| -MOUNTAIN FUEL SUPPLY COMPANY | | | | RECEIVED: | 10/31/83 | JA: WY 5 | | | |
| 8404098 | W 612-2 | 4904120174 | | 102-2 | | CLIFTON FEDERAL #28-1 | BRUFF | 835.0 | MOUNTAIN FUEL SUP |
| -PHILLIPS PETROLEUM COMPANY | | | | RECEIVED: | 10/31/83 | JA: WY 5 | | | |
| 8404112 | W 101-3 | 4902920402 | | 108 | | GOVT KOCH A #14-35 | BIG POLECAT | 19.5 | MONTANA-DAKOTA UT |

[FR Doc. 83-31893 Filed 11-28-83; 8:45 am]

BILLING CODE 6717-01-C

[Volume 1008]

## Determinations by Jurisdictional Agencies Under the Natural Gas Policy Act of 1978

Issued: November, 22, 1983.

The following notices of determination were received from the indicated jurisdictional agencies by the Federal Energy Regulatory Commission pursuant to the Natural Gas Policy Act of 1978 and 18 CFR 274.104. Negative determinations are indicated by a "D" before the section code. Estimated annual production (PROD) is in million cubic feet (MMCF).

The applications for determination are available for inspection except to the extent such material is confidential under 18 CFR 275.206, at the Commission's Division of Public Information, Room 1000, 825 North Capitol St., Washington, D.C. Persons objecting to any of these determinations may, in accordance with 18 CFR 275.203 and 275.204, file a protest with the Commission within fifteen days after publication of notice in the **Federal Register.**

Source data from the Form 121 for this and all previous notices is available on magnetic tape from the National Technical Information Service (NTIS). For information, contact Stuart Weisman (NTIS) at (703) 487-4808, 5285 Port Royal Rd, Springfield, Va. 22161.

Categories within each NGPA section are indicated by the following codes:

Section 102-1: New OCS lease
- 102-2: New well (2.5 Mile rule)
- 103-2: New well (1000 Ft rule)
- 104-2: New onshore reservoir
- 105-2: New reservoir on old OCS lease

Section 107-DP: 15,000 feet or deeper
- 107-GB: Geopressured brine
- 107-CS: Coal Seams
- 107-DV: Devonian Shale
- 107-PE: Production enhancement
- 107-TF: New tight formation
- 107-RT: Recompletion tight formation

Section 108: Stripper well
- 108-SA: Seasonally affected
- 108-ER: Enhanced recovery
- 108-PB: Pressure buildup

**Kenneth F. Plumb,**
*Secretary.*

NOTICE OF DETERMINATIONS — VOLUME 1008

ISSUED NOVEMBER 22, 1983

KENTUCKY DEPARTMENT OF MINES & MINERALS

-COLUMBIA GAS TRANSMISSION CORP — RECEIVED: 10/31/83 — JA: KY

| JD NO | JA DKT | API NO | D | SEC(1) | SEC(2) | WELL NAME | FIELD NAME | PROD | PURCHASER |
|---|---|---|---|---|---|---|---|---|---|
| 8404246 | 505329 | 1611900000 | | 108 | | A C CROFT 805068 | KENTUCKY AREA B | 6.0 | COLUMBIA GAS TRAN |
| 8404218 | 505301 | 1619500000 | | 108 | | A J AKERS ETAL 805151 | KENTUCKY AREA C | 7.0 | COLUMBIA GAS TRAN |
| 8404370 | 505453 | 1619500000 | | 108 | | AMANDA CHARLES #2 806225 | KENTUCKY AREA C | 2.0 | COLUMBIA GAS TRAN |
| 8404369 | 505452 | 1619500000 | | 108 | | AMANDA CHARLES 805125 | KENTUCKY AREA C | 8.0 | COLUMBIA GAS TRAN |
| 8404313 | 505396 | 1607100000 | | 108 | | ANGIE HUNT 804736 | KENTUCKY AREA B | 5.0 | COLUMBIA GAS TRAN |
| 8404150 | 505233 | 1619500000 | | 108 | | ANNA B PHILLIPS #2 805376 | KENTUCKY AREA C | 2.0 | COLUMBIA GAS TRAN |
| 8404149 | 505232 | 1619500000 | | 108 | | ANNA B PHILLIPS #3 805377 | KENTUCKY AREA C | 12.0 | COLUMBIA GAS TRAN |
| 8404151 | 505234 | 1619500000 | | 108 | | ANNA B PHILLIPS 805367 | KENTUCKY AREA C | 3.0 | COLUMBIA GAS TRAN |
| 8404331 | 505414 | 1607100000 | | 108 | | ANNA MAY ETAL 804086 | KY AREA B | 8.0 | COLUMBIA GAS TRAN |
| 8404309 | 505392 | 1619500000 | | 108 | | ANNIE E YOUNG #2 805853 | KENTUCKY AREA C | 8.0 | COLUMBIA GAS TRAN |
| 8404268 | 505351 | 1619500000 | | 108 | | ANNIE E YOUNG #2 806525 | KENTUCKY AREA C | 5.0 | COLUMBIA GAS TRAN |
| 8404269 | 505352 | 1619500000 | | 108 | | ANNIE E YOUNG #3 806748 | KENTUCKY AREA C | 5.0 | COLUMBIA GAS TRAN |
| 8404206 | 505289 | 1607100000 | | 108 | | B ELKHORN COAL CO 803819 | KENTUCKY AREA B | 8.0 | COLUMBIA GAS TRAN |
| 8404205 | 505288 | 1607100000 | | 108 | | B ELKHORN COAL CO 803838 | KENTUCKY AREA B | 9.0 | COLUMBIA GAS TRAN |
| 8404204 | 505287 | 1607100000 | | 108 | | B ELKHORN COAL CO 803841 | KENTUCKY AREA B | 3.0 | COLUMBIA GAS TRAN |
| 8404203 | 505286 | 1607100000 | | 108 | | B ELKHORN COAL CO 803842 | KENTUCKY AREA B | 9.0 | COLUMBIA GAS TRAN |
| 8404319 | 505402 | 1619500000 | | 108 | | B F WILLIAMSON ETAL 809394 | KENTUCKY AREA C | 7.0 | COLUMBIA GAS TRAN |
| 8404228 | 505311 | 1607100000 | | 108 | | B J MULLENS 803912 | KENTUCKY AREA B | 3.0 | COLUMBIA GAS TRAN |
| 8404237 | 505320 | 1615900000 | | 108 | | B P & FRANK ROSS 802577 | KENTUCKY AREA C | 5.0 | COLUMBIA GAS TRAN |
| 8404261 | 505344 | 1607100000 | | 108 | | BELLE PORTER 805244 | KENTUCKY AREA B | 10.0 | COLUMBIA GAS TRAN |
| 8404275 | 505358 | 1611900000 | | 108 | | BENTON STAMPER 805862 | KENTUCKY AREA B | 11.0 | COLUMBIA GAS TRAN |
| 8404264 | 505347 | 1611900000 | | 108 | | BETTIE BANKS 806577 | KENTUCKY AREA B | 3.0 | COLUMBIA GAS TRAN |
| 8404387 | 505470 | 1615900000 | | 108 | | BIRCH MARCUM ETAL 804554 | KY AREA C | 2.0 | COLUMBIA GAS TRAN |
| 8404198 | 505281 | 1619500000 | | 108 | | BLANCHE TAYLOR ETAL 805331 | KENTUCKY AREA C | 14.0 | COLUMBIA GAS TRAN |
| 8404341 | 505424 | 1607100000 | | 108 | | BURLEY HALL ETAL 804344 | KY AREA B | 6.0 | COLUMBIA GAS TRAN |
| 8404316 | 505399 | 1619500000 | | 108 | | BYRON COLEMAN #3 806747 | KENTUCKY AREA C | 15.0 | COLUMBIA GAS TRAN |
| 8404318 | 505401 | 1619500000 | | 108 | | BYRON COLEMAN 804996 | KENTUCKY AREA C | 11.0 | COLUMBIA GAS TRAN |
| 8404317 | 505400 | 1619500000 | | 108 | | BYRON COLEMAN 805053 | KENTUCKY AREA C | 36.0 | COLUMBIA GAS TRAN |
| 8404225 | 505308 | 1607100000 | | 108 | | C S ALLEN 803915 | KENTUCKY AREA B | 9.0 | COLUMBIA GAS TRAN |
| 8404272 | 505355 | 1611900000 | | 108 | | COLLINS HARVEY LAND CO 804511 | KENTUCKY AREA B | 10.0 | COLUMBIA GAS TRAN |
| 8404310 | 505393 | 1615900000 | | 108 | | CONG CHR BLDG SOC 805040 | KENTUCKY AREA C | 17.0 | COLUMBIA GAS TRAN |
| 8404177 | 505260 | 1615900000 | | 108 | | CONG CHURCH BUILDING SOC 805570 | KENTUCKY AREA C | 14.0 | COLUMBIA GAS TRAN |
| 8404374 | 505457 | 1615900000 | | 108 | | CONGREGATION CHR 805192 | KY AREA C | 2.0 | COLUMBIA GAS TRAN |
| 8404375 | 505458 | 1615900000 | | 108 | | CONGREGATION CHR 805356 | KY AREA C | 0.2 | COLUMBIA GAS TRAN |
| 8404260 | 505343 | 1619500000 | | 108 | | DAVID COX #2 806228 | KENTUCKY AREA C | 7.0 | COLUMBIA GAS TRAN |
| 8404311 | 505394 | 1619500000 | | 108 | | DAVID COX 805038 | KENTUCKY AREA C | 5.0 | COLUMBIA GAS TRAN |
| 8404303 | 505386 | 1619500000 | | 108 | | DELMAN LAYNE #2 805749 | KENTUCKY AREA C | 3.0 | COLUMBIA GAS TRAN |
| 8404184 | 505267 | 1611900000 | | 108 | | DOCK MADDIN 804734 | KENTUCKY AREA B | 6.0 | COLUMBIA GAS TRAN |
| 8404243 | 505326 | 1619500000 | | 108 | | E C THOMPSON 808252 | KENTUCKY AREA C | 4.0 | COLUMBIA GAS TRAN |
| 8404238 | 505321 | 1607100000 | | 108 | | E L DINGESS 801952 | KENTUCKY AREA B | 3.0 | COLUMBIA GAS TRAN |
| 8404332 | 505415 | 1619500000 | | 108 | | E M HATFIELD 804203 | KY AREA C | 15.0 | COLUMBIA GAS TRAN |
| 8404233 | 505316 | 1607100000 | | 108 | | E MOORE 803861 | KENTUCKY AREA B | 10.0 | COLUMBIA GAS TRAN |
| 8404323 | 505406 | 1607100000 | | 108 | | ELIE SALISBURY 804006 | KY AREA B | 6.0 | COLUMBIA GAS TRAN |
| 8404141 | 505224 | 1607100000 | | 108 | | ELKHORN COAL CORP 63 805295 | KENTUCKY AREA B | 20.0 | COLUMBIA GAS TRAN |
| 8404142 | 505225 | 1607100000 | | 108 | | ELKHORN COAL CORP 64 805296 | KENTUCKY AREA B | 17.0 | COLUMBIA GAS TRAN |

BILLING CODE 6717-01-M

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| JD NO | JA DK | API NO | D | SEC(1) | SEC(2) | WELL NAME | FIELD NAME | PROD | PURCHASER |
|---|---|---|---|---|---|---|---|---|---|
| 8404168 | 505251 | 1607100000 | | 108 | | ELKHORN COAL CORP 65 805299 | KENTUCKY AREA B | 5.0 | COLUMBIA GAS TRAN |
| 8404209 | 505292 | 1607100000 | | 108 | | ELKHORN COAL CORP 66 805334 | KENTUCKY AREA B | 10.0 | COLUMBIA GAS TRAN |
| 8404208 | 505291 | 1607100000 | | 108 | | ELKHORN COAL CORP 67 805335 | KENTUCKY AREA B | 11.0 | COLUMBIA GAS TRAN |
| 8404169 | 505252 | 1607100000 | | 108 | | ELKHORN COAL CORP 68 805336 | KENTUCKY AREA B | 12.0 | COLUMBIA GAS TRAN |
| 8404170 | 505253 | 1607100000 | | 108 | | ELKHORN COAL CORP 69 805337 | KENTUCKY AREA B | 12.0 | COLUMBIA GAS TRAN |
| 8404171 | 505254 | 1607100000 | | 108 | | ELKHORN COAL CORP 70 805392 | KENTUCKY AREA B | 11.0 | COLUMBIA GAS TRAN |
| 8404180 | 505263 | 1607100000 | | 108 | | ELKHORN COAL CORP 71 805393 | KENTUCKY AREA B | 5.0 | COLUMBIA GAS TRAN |
| 8404172 | 505255 | 1607100000 | | 108 | | ELKHORN COAL CORP 73 805454 | KENTUCKY AREA B | 10.0 | COLUMBIA GAS TRAN |
| 8404175 | 505258 | 1607100000 | | 108 | | ELKHORN COAL CORP 75 805470 | KENTUCKY AREA B | 3.0 | COLUMBIA GAS TRAN |
| 8404176 | 505259 | 1607100000 | | 108 | | ELKHORN COAL CORP 77 805472 | KENTUCKY AREA B | 3.0 | COLUMBIA GAS TRAN |
| 8404207 | 505290 | 1607100000 | | 108 | | ELKHORN COAL CORP 78 805568 | KENTUCKY AREA B | 5.0 | COLUMBIA GAS TRAN |
| 8404173 | 505256 | 1607100000 | | 108 | | ELKHORN COAL CORP 79 805610 | KENTUCKY AREA B | 13.0 | COLUMBIA GAS TRAN |
| 8404236 | 505319 | 1607100000 | | 108 | | ELKHORN COAL CORP 803748 | KENTUCKY AREA B | 6.0 | COLUMBIA GAS TRAN |
| 8404367 | 505450 | 1607100000 | | 108 | | ELKHORN COAL CORP 803764 | KY AREA B | 7.0 | COLUMBIA GAS TRAN |
| 8404355 | 505438 | 1607100000 | | 108 | | ELKHORN COAL CORP 803766 | KY AREA B | 3.0 | COLUMBIA GAS TRAN |
| 8404357 | 505440 | 1607100000 | | 108 | | ELKHORN COAL CORP 803824 | KENTUCKY AREA B | 6.0 | COLUMBIA GAS TRAN |
| 8404363 | 505446 | 1607100000 | | 108 | | ELKHORN COAL CORP 803828 | KENTUCKY AREA B | 8.0 | COLUMBIA GAS TRAN |
| 8404358 | 505441 | 1607100000 | | 108 | | ELKHORN COAL CORP 803831 | KENTUCKY AREA B | 21.0 | COLUMBIA GAS TRAN |
| 8404356 | 505439 | 1607100000 | | 108 | | ELKHORN COAL CORP 803836 | KY AREA B | 4.0 | COLUMBIA GAS TRAN |
| 8404235 | 505318 | 1607100000 | | 108 | | ELKHORN COAL CORP 803844 | KENTUCKY AREA B | 11.0 | COLUMBIA GAS TRAN |
| 8404353 | 505436 | 1607100000 | | 108 | | ELKHORN COAL CORP 803933 | KY AREA B | 0.7 | COLUMBIA GAS TRAN |
| 8404354 | 505437 | 1607100000 | | 108 | | ELKHORN COAL CORP 803934 | KY AREA B | 3.0 | COLUMBIA GAS TRAN |
| 8404359 | 505442 | 1607100000 | | 108 | | ELKHORN COAL CORP 804088 | KENTUCKY AREA B | 4.0 | COLUMBIA GAS TRAN |
| 8404368 | 505451 | 1607100000 | | 108 | | ELKHORN COAL CORP 804282 | KENTUCKY AREA B | 2.0 | COLUMBIA GAS TRAN |
| 8404364 | 505447 | 1607100000 | | 108 | | ELKHORN COAL CORP 804283 | KENTUCKY AREA B | 4.0 | COLUMBIA GAS TRAN |
| 8404336 | 505419 | 1607100000 | | 108 | | ELKHORN COAL CORP 804303 | KY AREA B | 1.0 | COLUMBIA GAS TRAN |
| 8404384 | 505467 | 1607100000 | | 108 | | ELKHORN COAL CORP 804304 | KY AREA B | 1.0 | COLUMBIA GAS TRAN |
| 8404385 | 505468 | 1607100000 | | 108 | | ELKHORN COAL CORP 804368 | KY AREA B | 6.0 | COLUMBIA GAS TRAN |
| 8404245 | 505328 | 1607100000 | | 108 | | ELKHORN COAL CORP 805071 | KENTUCKY AREA B | 3.0 | COLUMBIA GAS TRAN |
| 8404244 | 505327 | 1607100000 | | 108 | | ELKHORN COAL CORP 805072 | KENTUCKY AREA B | 19.0 | COLUMBIA GAS TRAN |
| 8404210 | 505293 | 1607100000 | | 108 | | ELKHORN COAL CORP 805106 | KENTUCKY AREA B | 8.0 | COLUMBIA GAS TRAN |
| 8404212 | 505295 | 1607100000 | | 108 | | ELKHORN COAL CORP 805126 | KENTUCKY AREA B | 2.0 | COLUMBIA GAS TRAN |
| 8404211 | 505294 | 1611900000 | | 108 | | ELKHORN COAL CORP 805127 | KENTUCKY AREA B | 15.0 | COLUMBIA GAS TRAN |
| 8404217 | 505300 | 1607100000 | | 108 | | ELKHORN COAL CORP 805196 | KENTUCKY AREA B | 4.0 | COLUMBIA GAS TRAN |
| 8404201 | 505284 | 1607100000 | | 108 | | ELKHORN COAL CORP 805197 | KENTUCKY AREA B | 19.0 | COLUMBIA GAS TRAN |
| 8404200 | 505283 | 1607100000 | | 108 | | ELKHORN COAL CORP 805250 | KENTUCKY AREA B | 19.0 | COLUMBIA GAS TRAN |
| 8404360 | 505443 | 1607100000 | | 108 | | ELKHORN COAL CORP 805469 | KENTUCKY AREA B | 19.0 | COLUMBIA GAS TRAN |
| 8404182 | 505265 | 1607100000 | | 108 | | ELKHORN COAL CORP 805679 | KENTUCKY AREA B | 18.0 | COLUMBIA GAS TRAN |
| 8404174 | 505257 | 1607100000 | | 108 | | ELKHORN COAL CORP 86 805689 | KENTUCKY AREA B | 10.0 | COLUMBIA GAS TRAN |
| 8404299 | 505382 | 1607100000 | | 108 | | ELKHORN COAL CORP 88 805691 | KENTUCKY AREA B | 1.0 | COLUMBIA GAS TRAN |
| 8404242 | 505325 | 1607100000 | | 108 | | ELSIE CRIDER 805091 | KENTUCKY AREA B | 3.0 | COLUMBIA GAS TRAN |
| 8404195 | 505278 | 1615900000 | | 108 | | ESSIE DEMPSEY ETAL 805446 | KENTUCKY AREA C | 8.0 | COLUMBIA GAS TRAN |
| 8404320 | 505403 | 1619500000 | | 108 | | ESTER LOWE ETAL 808778 | KENTUCKY AREA C | 9.0 | COLUMBIA GAS TRAN |
| 8404361 | 505444 | 1607100000 | | 108 | | EZRA MAYO ETAL 803988 | KY AREA B | 3.0 | COLUMBIA GAS TRAN |
| 8404362 | 505445 | 1607100000 | | 108 | | EZRA MAYO 804306 | KY AREA B | 10.0 | COLUMBIA GAS TRAN |
| 8404229 | 505312 | 1607100000 | | 108 | | F B MAY 803893 | KENTUCKY AREA B | 1.0 | COLUMBIA GAS TRAN |
| 8404371 | 505454 | 1607100000 | | 108 | | FANNIE FLANNERY 804059 | KY AREA B | 6.0 | COLUMBIA GAS TRAN |
| 8404372 | 505455 | 1607100000 | | 108 | | FANNIE FLANNERY 804205 | KY AREA B | 12.0 | COLUMBIA GAS TRAN |
| 8404373 | 505456 | 1607100000 | | 108 | | FANNIE FLANNERY 804302 | KY AREA B | 8.0 | COLUMBIA GAS TRAN |
| 8404215 | 505298 | 1615900000 | | 108 | | FED GAS OIL & COAL CO 805253 | KENTUCKY AREA C | 8.0 | COLUMBIA GAS TRAN |
| 8404252 | 505335 | 1615900000 | | 108 | | FED GAS OIL & COAL 805045 | KENTUCKY AREA C | 19.0 | COLUMBIA GAS TRAN |
| 8404216 | 505299 | 1615900000 | | 108 | | FED GAS OIL & COAL 805249 | KENTUCKY AREA C | 14.0 | COLUMBIA GAS TRAN |
| 8404190 | 505273 | 1615900000 | | 108 | | FEDERAL COAL & COKE CO 29 805447 | KENTUCKY AREA C | 10.0 | COLUMBIA GAS TRAN |
| 8404287 | 505370 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL #55 805707 | KENTUCKY AREA C | 8.0 | COLUMBIA GAS TRAN |
| 8404192 | 505275 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL CO 43 805601 | KENTUCKY AREA C | 4.0 | COLUMBIA GAS TRAN |
| 8404162 | 505245 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL CO 805342 | KENTUCKY AREA C | 0.2 | COLUMBIA GAS TRAN |
| 8404146 | 505229 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL CO 805343 | KENTUCKY AREA C | 17.0 | COLUMBIA GAS TRAN |
| 8404293 | 505376 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL CO 808484 | KENTUCKY AREA C | 4.0 | COLUMBIA GAS TRAN |
| 8404296 | 16159 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL CO 809560 | KENTUCKY AREA C | 6.0 | COLUMBIA GAS TRAN |
| 8404297 | 505380 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL CO 809561 | KENTUCKY AREA C | 9.0 | COLUMBIA GAS TRAN |
| 8404199 | 505282 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL 15 805310 | KENTUCKY AREA C | 3.0 | COLUMBIA GAS TRAN |
| 8404197 | 505280 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL 22 805413 | KENTUCKY AREA C | 2.0 | COLUMBIA GAS TRAN |
| 8404140 | 505223 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL 23 805414 | KENTUCKY AREA C | 4.0 | COLUMBIA GAS TRAN |
| 8404147 | 505230 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL 24 805415 | KENTUCKY AREA C | 5.0 | COLUMBIA GAS TRAN |
| 8404143 | 505226 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL 25 805440 | KENTUCKY AREA C | 2.0 | COLUMBIA GAS TRAN |
| 8404144 | 505227 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL 26 805441 | KENTUCKY AREA C | 2.0 | COLUMBIA GAS TRAN |
| 8404166 | 505249 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL 27 805442 | KENTUCKY AREA C | 9.0 | COLUMBIA GAS TRAN |
| 8404194 | 505277 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL 28 805443 | KENTUCKY AREA C | 3.0 | COLUMBIA GAS TRAN |
| 8404148 | 505231 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL 30 805448 | KENTUCKY AREA C | 8.0 | COLUMBIA GAS TRAN |
| 8404189 | 505272 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL 31 805449 | KENTUCKY AREA C | 3.0 | COLUMBIA GAS TRAN |
| 8404145 | 505228 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL 32 805450 | KENTUCKY AREA C | 14.0 | COLUMBIA GAS TRAN |
| 8404153 | 505236 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL 33 805519 | KENTUCKY AREA C | 3.0 | COLUMBIA GAS TRAN |
| 8404152 | 505235 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL 34 805520 | KENTUCKY AREA C | 3.0 | COLUMBIA GAS TRAN |
| 8404286 | 505369 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL 35 805531 | KENTUCKY AREA C | 28.0 | COLUMBIA GAS TRAN |
| 8404163 | 505246 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL 36 805538 | KENTUCKY AREA C | 5.0 | COLUMBIA GAS TRAN |
| 8404179 | 505262 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL 38 805540 | KENTUCKY AREA C | 1.0 | COLUMBIA GAS TRAN |
| 8404185 | 505268 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL 42 805600 | KENTUCKY AREA C | 3.0 | COLUMBIA GAS TRAN |
| 8404157 | 505240 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL 46 805614 | KENTUCKY AREA C | 6.0 | COLUMBIA GAS TRAN |
| 8404158 | 505241 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL 47 805615 | KENTUCKY AREA C | 6.0 | COLUMBIA GAS TRAN |
| 8404178 | 505261 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL 48 805616 | KENTUCKY AREA C | 6.0 | COLUMBIA GAS TRAN |
| 8404187 | 505270 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL 49 805673 | KENTUCKY AREA C | 4.0 | COLUMBIA GAS TRAN |
| 8404270 | 505353 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL 54 806163 | KENTUCKY AREA C | 1.0 | COLUMBIA GAS TRAN |
| 8404290 | 505373 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL 62 806509 | KENTUCKY AREA C | 2.0 | COLUMBIA GAS TRAN |
| 8404291 | 505374 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL 65 806794 | KENTUCKY AREA C | 22.0 | COLUMBIA GAS TRAN |
| 8404292 | 505375 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL 66 806795 | KENTUCKY AREA C | 6.0 | COLUMBIA GAS TRAN |
| 8404255 | 505338 | 1619500000 | | 108 | | FEDERAL GAS OIL & COAL 69 806824 | KENTUCKY AREA C | 1.0 | COLUMBIA GAS TRAN |
| 8404295 | 505378 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL 809384 | KENTUCKY AREA C | 8.0 | COLUMBIA GAS TRAN |
| 8404294 | 505377 | 1615900000 | | 108 | | FEDERAL GAS OIL & COAL 89 808509 | KENTUCKY AREA C | 9.0 | COLUMBIA GAS TRAN |
| 8404288 | 505371 | 1615900000 | | 108 | | FEDERAL GAS OIL #59 806361 | KENTUCKY AREA C | 23.0 | COLUMBIA GAS TRAN |
| 8404254 | 505337 | 1619500000 | | 108 | | FEDERAL GAS OIL #60 806362 | KENTUCKY AREA C | 1.0 | COLUMBIA GAS TRAN |
| 8404289 | 505372 | 1615900000 | | 108 | | FEDERAL GAS OIL #61 806504 | KENTUCKY AREA C | 6.0 | COLUMBIA GAS TRAN |
| 8404285 | 505368 | 1615900000 | | 108 | | FEDERAL OIL & GAS CO 801903 | KENTUCKY AREA C | 1.0 | COLUMBIA GAS TRAN |
| 8404251 | 505334 | 1615900000 | | 108 | | FEO GAS OIL & COAL 805046 | KENTUCKY AREA C | 3.0 | COLUMBIA GAS TRAN |
| 8404301 | 505384 | 1607100000 | | 108 | | FLOYD LOWE 804508 | KENTUCKY AREA C | 1.0 | COLUMBIA GAS TRAN |
| 8404274 | 505357 | 1619500000 | | 108 | | FRANK DOTSON ETAL 806147 | KENTUCKY AREA C | 12.0 | COLUMBIA GAS TRAN |
| 8404219 | 505302 | 1619500000 | | 108 | | FRED MOORE ETAL 805115 | KENTUCKY AREA C | 19.0 | COLUMBIA GAS TRAN |
| 8404276 | 505359 | 1619500000 | | 108 | | G C ROWE #3 806226 | KENTUCKY AREA C | 7.0 | COLUMBIA GAS TRAN |
| 8404304 | 505387 | 1619500000 | | 108 | | G C ROWE ETAL 805787 | KENTUCKY AREA C | 3.0 | COLUMBIA GAS TRAN |
| 8404300 | 505383 | 1619500000 | | 108 | | G C ROWE 805780 | KENTUCKY AREA C | 2.0 | COLUMBIA GAS TRAN |
| 8404305 | 505388 | 1619500000 | | 108 | | G G ROWE #2 805868 | KENTUCKY AREA C | 6.0 | COLUMBIA GAS TRAN |
| 8404386 | 505469 | 1615900000 | | 108 | | GABRIEL ENDICOTT 804235 | KENTUCKY AREA C | 3.0 | COLUMBIA GAS TRAN |
| 8404188 | 505271 | 1619500000 | | 108 | | GEMIMA MCCOY ETAL 805495 | KENTUCKY AREA C | 16.0 | COLUMBIA GAS TRAN |
| 8404239 | 505322 | 1607100000 | | 108 | | GEORGE HALE 801897 | KENTUCKY AREA B | 18.0 | COLUMBIA GAS TRAN |
| 8404248 | 505331 | 1607100000 | | 108 | | GROVER C KEATHLEY 805066 | KENTUCKY AREA B | 3.0 | COLUMBIA GAS TRAN |

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| JD NO | JA DKT | API NO | D | SEC(1) | SEC(2) | WELL NAME | FIELD NAME | PROD | PURCHASER |
|---|---|---|---|---|---|---|---|---|---|
| 8404220 | 505303 | 1611900000 | | 108 | | H B JONES ETAL 805111 | KENTUCKY AREA B | 5.0 | COLUMBIA GAS TRAN |
| 8404380 | 505463 | 1607100000 | | 108 | | H C STEPHENS JR 804099 | KY AREA B | 12.0 | COLUMBIA GAS TRAN |
| 8404381 | 505464 | 1607100000 | | 108 | | H C STEPHENS JR 804561 | KENTUCKY AREA B | 10.0 | COLUMBIA GAS TRAN |
| 8404259 | 505342 | 1619500000 | | 108 | | H G WILLIAMSON 806545 | KENTUCKY AREA C | 2.0 | COLUMBIA GAS TRAN |
| 8404214 | 505297 | 1607100000 | | 108 | | H I HARRIS 801935 | KENTUCKY AREA B | 12.0 | COLUMBIA GAS TRAN |
| 8404265 | 505348 | 1611900000 | | 108 | | HARDIN CAUDILL 806589 | KENTUCKY AREA B | 6.0 | COLUMBIA GAS TRAN |
| 8404213 | 505296 | 1607100000 | | 108 | | HIRAM HARRIS 802547 | KENTUCKY AREA B | 5.0 | COLUMBIA GAS TRAN |
| 8404342 | 505425 | 1607100000 | | 108 | | I M HALL 804347 | KENTUCKY AREA B | 4.0 | COLUMBIA GAS TRAN |
| 8404335 | 505418 | 1607100000 | | 108 | | ISSAC STRATEN 804301 | KY AREA B | 0.9 | COLUMBIA GAS TRAN |
| 8404267 | 505350 | 1619500000 | | 108 | | J C STRATTON #2 806586 | KENTUCKY AREA C | 9.0 | COLUMBIA GAS TRAN |
| 8404365 | 505448 | 1607100000 | | 108 | | J D TURNER 803721 | KENTUCKY AREA B | 2.0 | COLUMBIA GAS TRAN |
| 8404366 | 505449 | 1607100000 | | 108 | | J D TURNER 803762 | KY AREA B | 5.0 | COLUMBIA GAS TRAN |
| 8404281 | 505364 | 1615900000 | | 108 | | J G MOORE 806510 | KENTUCKY AREA C | 9.0 | COLUMBIA GAS TRAN |
| 8404231 | 505314 | 1607100000 | | 108 | | J H ALLEN 803876 | KENTUCKY AREA B | 11.0 | COLUMBIA GAS TRAN |
| 8404230 | 505313 | 1607100000 | | 108 | | J H ALLEN 803877 | KENTUCKY AREA B | 14.0 | COLUMBIA GAS TRAN |
| 8404377 | 505460 | 1619500000 | | 108 | | J M MOORE #2 805282 | KENTUCKY AREA C | 9.0 | COLUMBIA GAS TRAN |
| 8404376 | 505459 | 1619500000 | | 108 | | J M MOORE ETAL 805152 | KY AREA C | 6.0 | COLUMBIA GAS TRAN |
| 8404202 | 505285 | 1619500000 | | 108 | | J M TAYLOR ETAL 805283 | KENTUCKY AREA C | 6.0 | COLUMBIA GAS TRAN |
| 8404196 | 505279 | 1615900000 | | 108 | | J R FAIRCHILD 805365 | KENTUCKY AREA C | 6.0 | COLUMBIA GAS TRAN |
| 8404167 | 505250 | 1619500000 | | 108 | | J S CLINE JR ETAL 805523 | KENTUCKY AREA C | 12.0 | COLUMBIA GAS TRAN |
| 8404250 | 505333 | 1619500000 | | 108 | | J T PARSONS ETAL 805054 | KENTUCKY AREA C | 4.0 | COLUMBIA GAS TRAN |
| 8404324 | 505407 | 1607100000 | | 108 | | J W FLANNERY 804015 | KY AREA B | 13.0 | COLUMBIA GAS TRAN |
| 8404306 | 505389 | 1619500000 | | 108 | | JACK KEENE 806144 | KENTUCKY AREA C | 15.0 | COLUMBIA GAS TRAN |
| 8404325 | 505408 | 1607100000 | | 108 | | JAMES MARTIN 804031 | KY AREA B | 12.0 | COLUMBIA GAS TRAN |
| 8404279 | 505362 | 1611900000 | | 108 | | JASPER PRATT 805764 | KENTUCKY AREA B | 8.0 | COLUMBIA GAS TRAN |
| 8404350 | 505433 | 1611900000 | | 108 | | JOE HALL 801905 | KY AREA B | 1.0 | COLUMBIA GAS TRAN |
| 8404222 | 505305 | 1607100000 | | 108 | | JOHN B BUSH ETAL 805065 | KENTUCKY AREA B | 5.0 | COLUMBIA GAS TRAN |
| 8404321 | 505404 | 1607100000 | | 108 | | JOHN COX 801836 | KY AREA B | 8.0 | COLUMBIA GAS TRAN |
| 8404302 | 505385 | 1619500000 | | 108 | | JOHN DAVIS ETAL #3 806714 | KENTUCKY AREA C | 11.0 | COLUMBIA GAS TRAN |
| 8404256 | 505339 | 1619500000 | | 108 | | JOHN F PHILLIPS #2 805379 | KENTUCKY AREA C | 3.0 | COLUMBIA GAS TRAN |
| 8404344 | 505427 | 1607100000 | | 108 | | JOHN N HAMILTON 804380 | KY AREA B | 1.0 | COLUMBIA GAS TRAN |
| 8404298 | 505381 | 1619500000 | | 108 | | JOHN W JUSTICE 804897 | KENTUCKY AREA C | 4.0 | COLUMBIA GAS TRAN |
| 8404351 | 505434 | 1611900000 | | 108 | | JOSEPH & LENA HALL 804341 | KENTUCKY AREA B | 8.0 | COLUMBIA GAS TRAN |
| 8404257 | 505340 | 1615900000 | | 108 | | JUDGE HARDIN 806558 | KENTUCKY AREA C | 2.0 | COLUMBIA GAS TRAN |
| 8404340 | 505423 | 1607100000 | | 108 | | K F HALL 804343 | KENTUCKY AREA B | 7.0 | COLUMBIA GAS TRAN |
| 8404165 | 505248 | 1619500000 | | 108 | | KELSIE CHILDERS #2 805358 | KENTUCKY AREA C | 4.0 | COLUMBIA GAS TRAN |
| 8404164 | 505247 | 1619500000 | | 108 | | KELSIE CHILDERS ETAL 805291 | KENTUCKY AREA C | 18.0 | COLUMBIA GAS TRAN |
| 8404392 | 505475 | 1619500000 | | 108 | | KENTLAND C & C #13 805645 | KENTUCKY AREA C | 15.0 | COLUMBIA GAS TRAN |
| 8404393 | 505476 | 1619500000 | | 108 | | KENTLAND C & C #14 805646 | KENTUCKY AREA C | 6.0 | COLUMBIA GAS TRAN |
| 8404394 | 505477 | 1619500000 | | 108 | | KENTLAND C & C #16 805648 | KENTUCKY AREA C | 8.0 | COLUMBIA GAS TRAN |
| 8404395 | 505478 | 1619500000 | | 108 | | KENTLAND C & C #17 805649 | KENTUCKY AREA C | 12.0 | COLUMBIA GAS TRAN |
| 8404396 | 505479 | 1619500000 | | 108 | | KENTLAND C & C #18 805750 | KENTUCKY AREA C | 6.0 | COLUMBIA GAS TRAN |
| 8404397 | 505480 | 1619500000 | | 108 | | KENTLAND C & C #19 805751 | KENTUCKY AREA C | 4.0 | COLUMBIA GAS TRAN |
| 8404398 | 505481 | 1619500000 | | 108 | | KENTLAND C & C #21 806145 | KENTUCKY AREA C | 10.0 | COLUMBIA GAS TRAN |
| 8404399 | 505482 | 1619500000 | | 108 | | KENTLAND C & C #22 806146 | KENTUCKY AREA C | 3.0 | COLUMBIA GAS TRAN |
| 8404390 | 505473 | 1619500000 | | 108 | | KENTLAND C & C 804382 | KENTUCKY AREA C | 1.0 | COLUMBIA GAS TRAN |
| 8404391 | 505474 | 1619500000 | | 108 | | KENTLAND C & C 804518 | KENTUCKY AREA C | 11.0 | COLUMBIA GAS TRAN |
| 8404400 | 505483 | 1619500000 | | 108 | | KENTLAND C&C #23 806164 | KENTUCKY AREA C | 3.0 | COLUMBIA GAS TRAN |
| 8404402 | 505485 | 1619500000 | | 108 | | KENTLAND C&C #26 806293 | KENTUCKY AREA C | 4.0 | COLUMBIA GAS TRAN |
| 8404401 | 505484 | 1619500000 | | 108 | | KENTLAND C&C NO 25 806292 | KENTUCKY AREA C | 11.0 | COLUMBIA GAS TRAN |
| 8404273 | 505356 | 1611900000 | | 108 | | L DAY ETAL #2 805602 | KENTUCKY AREA B | 3.0 | COLUMBIA GAS TRAN |
| 8404186 | 505269 | 1619500000 | | 108 | | L SMITH ETAL 805612 | KENTUCKY AREA C | 6.0 | COLUMBIA GAS TRAN |
| 8404330 | 505415 | 1607100000 | | 108 | | LACKEY SALISBURY 804084 | KY AREA B | 5.0 | COLUMBIA GAS TRAN |
| 8404247 | 505330 | 1611900000 | | 108 | | LAURANIA DAY ETAL 805067 | KENTUCKY AREA B | 18.0 | COLUMBIA GAS TRAN |
| 8404352 | 505435 | 1611900000 | | 108 | | LENA HALL ETAL 804636 | KENTUCKY AREA B | 4.0 | COLUMBIA GAS TRAN |
| 8404262 | 505345 | 1611900000 | | 108 | | LINDSEY AMBURGEY ETAL 806527 | KENTUCKY AREA B | 14.0 | COLUMBIA GAS TRAN |
| 8404315 | 505398 | 1607100000 | | 108 | | LINEY BOYD SR 804547 | KENTUCKY AREA B | 8.0 | COLUMBIA GAS TRAN |
| 8404240 | 505323 | 1615900000 | | 108 | | M C COLLINSWORTH ETAL 801863 | KENTUCKY AREA C | 10.0 | COLUMBIA GAS TRAN |
| 8404338 | 505421 | 1607100000 | | 108 | | M M COLLINS 804308 | KENTUCKY AREA B | 8.0 | COLUMBIA GAS TRAN |
| 8404277 | 505360 | 1611900000 | | 108 | | M PIGMAN ETAL #1 806300 | KENTUCKY AREA B | 8.0 | COLUMBIA GAS TRAN |
| 8404312 | 505395 | 1611900000 | | 108 | | M S CRAIN 804881 | KENTUCKY AREA B | 13.0 | COLUMBIA GAS TRAN |
| 8404249 | 505332 | 1607100000 | | 108 | | M T BUSH 805059 | KENTUCKY AREA B | 15.0 | COLUMBIA GAS TRAN |
| 8404224 | 505307 | 1607100000 | | 108 | | M U ALLEN 803916 | KENTUCKY AREA B | 7.0 | COLUMBIA GAS TRAN |
| 8404232 | 505315 | 1607100000 | | 108 | | MARTHA COLLINS 803862 | KENTUCKY AREA B | 15.0 | COLUMBIA GAS TRAN |
| 8404343 | 505426 | 1607100000 | | 108 | | MARTHA E HALL 804349 | KY AREA B | 3.0 | COLUMBIA GAS TRAN |
| 8404346 | 505429 | 1611900000 | | 108 | | MARTHA VANCE ETAL 805833 | KY AREA B | 9.0 | COLUMBIA GAS TRAN |
| 8404389 | 505472 | 1607100000 | | 108 | | MARY A ALLEN ETAL 804339 | KY AREA B | 8.0 | COLUMBIA GAS TRAN |
| 8404388 | 505471 | 1607100000 | | 108 | | MARY A ALLEN 804330 | KY AREA B | 5.0 | COLUMBIA GAS TRAN |
| 8404327 | 505410 | 1607100000 | | 108 | | MARY SALISBURY 804044 | KY AREA B | 4.0 | COLUMBIA GAS TRAN |
| 8404314 | 505397 | 1607100000 | | 108 | | MELVIN EDINCOTT 804743 | KENTUCKY AREA B | 5.0 | COLUMBIA GAS TRAN |
| 8404326 | 505409 | 1607100000 | | 108 | | MINERVA MAYO 804041 | KY AREA B | 4.0 | COLUMBIA GAS TRAN |
| 8404382 | 505465 | 1607100000 | | 108 | | MINERVA MAYO 804042 | KY AREA B | 6.0 | COLUMBIA GAS TRAN |
| 8404383 | 505466 | 1607100000 | | 108 | | MINERVA MAYO 804043 | KY AREA B | 23.0 | COLUMBIA GAS TRAN |
| 8404227 | 505310 | 1607100000 | | 108 | | N O ALLEN 803913 | KENTUCKY AREA B | 18.0 | COLUMBIA GAS TRAN |
| 8404234 | 505317 | 1607100000 | | 108 | | NANCY MARTIN 803850 | KENTUCKY AREA B | 2.0 | COLUMBIA GAS TRAN |
| 8404183 | 505266 | 1615900000 | | 108 | | NANNIE WARD ETAL 805576 | KENTUCKY AREA C | 4.0 | COLUMBIA GAS TRAN |
| 8404334 | 505417 | 1619500000 | | 108 | | PIKE FLOYD COAL CO 804299 | KY AREA C | 7.0 | COLUMBIA GAS TRAN |
| 8404347 | 505430 | 1607100000 | | 108 | | PIKE FLOYD COAL CO 804322 | KY AREA B | 13.0 | COLUMBIA GAS TRAN |
| 8404348 | 505431 | 1607100000 | | 108 | | PIKE FLOYD COAL CO 804589 | KY AREA B | 12.0 | COLUMBIA GAS TRAN |
| 8404349 | 505432 | 1607100000 | | 108 | | PIKE FLOYD COAL CO 804653 | KY AREA B | 14.0 | COLUMBIA GAS TRAN |
| 8404221 | 505304 | 1619500000 | | 108 | | PIKE FLOYD COAL CO 805104 | KENTUCKY AREA C | 6.0 | COLUMBIA GAS TRAN |
| 8404191 | 505274 | 1615900000 | | 108 | | PILGRIM COAL CO 800995 | KENTUCKY AREA C | 9.0 | COLUMBIA GAS TRAN |
| 8404280 | 505363 | 1615900000 | | 108 | | PP MCCOY ETAL 806311 | KENTUCKY AREA C | 5.0 | COLUMBIA GAS TRAN |
| 8404223 | 505306 | 1607100000 | | 108 | | R C ELLIOTT 804206 | KENTUCKY AREA B | 7.0 | COLUMBIA GAS TRAN |
| 8404339 | 505422 | 1607100000 | | 108 | | R C ELLIOTT 804316 | KY AREA B | 10.0 | COLUMBIA GAS TRAN |
| 8404181 | 505264 | 1619500000 | | 108 | | R H RATLIFF HEIRS 2 805465 | KENTUCKY AREA C | 10.0 | COLUMBIA GAS TRAN |
| 8404160 | 505243 | 1619500000 | | 108 | | R H RATLIFF HEIRS 3 805524 | KENTUCKY AREA C | 3.0 | COLUMBIA GAS TRAN |
| 8404159 | 505242 | 1619500000 | | 108 | | R H RATLIFF HEIRS 4 805525 | KENTUCKY AREA C | 9.0 | COLUMBIA GAS TRAN |
| 8404161 | 505244 | 1619500000 | | 108 | | R H RATLIFF HEIRS 6 805564 | KENTUCKY AREA C | 6.0 | COLUMBIA GAS TRAN |
| 8404156 | 505239 | 1619500000 | | 108 | | R H RATLIFF HEIRS 7 805565 | KENTUCKY AREA C | 1.0 | COLUMBIA GAS TRAN |
| 8404155 | 505238 | 1619500000 | | 108 | | R H RATLIFF HEIRS 8 805566 | KENTUCKY AREA C | 2.0 | COLUMBIA GAS TRAN |
| 8404154 | 505237 | 1619500000 | | 108 | | R H RATLIFF HEIRS 9 805567 | KENTUCKY AREA C | 2.0 | COLUMBIA GAS TRAN |
| 8404322 | 505405 | 1607100000 | | 108 | | ROYAL ELKHORN CORP 803765 | KY AREA B | 18.0 | COLUMBIA GAS TRAN |
| 8404278 | 505361 | 1619500000 | | 108 | | S M CAMPBELL NO 1 806217 | KENTUCKY AREA C | 10.0 | COLUMBIA GAS TRAN |
| 8404333 | 505416 | 1607100000 | | 108 | | S NUNNERY 804234 | KY AREA B | 1.0 | COLUMBIA GAS TRAN |
| 8404378 | 505461 | 1607100000 | | 108 | | S P OSBORN 804100 | KENTUCKY AREA B | 15.0 | COLUMBIA GAS TRAN |
| 8404379 | 505462 | 1607100000 | | 108 | | S P OSBORN 804224 | KY AREA B | 3.0 | COLUMBIA GAS TRAN |
| 8404329 | 505412 | 1607100000 | | 108 | | SUSIE HAGANS 804058 | KY AREA B | 9.0 | COLUMBIA GAS TRAN |
| 8404282 | 505365 | 1619500000 | | 108 | | T H BLACKBURN 806489 | KENTUCKY AREA C | 4.0 | COLUMBIA GAS TRAN |
| 8404253 | 505336 | 1619500000 | | 108 | | T H JUSTICE 806498 | KENTUCKY AREA C | 7.0 | COLUMBIA GAS TRAN |
| 8404241 | 505324 | 1607100000 | | 108 | | TAULBEE MAYNARD 805092 | KENTUCKY AREA B | 7.0 | COLUMBIA GAS TRAN |
| 8404337 | 505420 | 1607100000 | | 108 | | TOWNSEL COMBS 804305 | KY AREA B | 5.0 | COLUMBIA GAS TRAN |
| 8404226 | 505309 | 1607100000 | | 108 | | TROY ALLEN 803914 | KENTUCKY AREA B | 8.0 | COLUMBIA GAS TRAN |
| 8404283 | 505366 | 1611900000 | | 108 | | V PIGMAN & W HANKS 806524 | KENTUCKY AREA B | 12.0 | COLUMBIA GAS TRAN |

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| JD NO | JA DKT | API NO | D | SEC(1) | SEC(2) | WELL NAME | FIELD NAME | PROD | PURCHASER |
|---|---|---|---|---|---|---|---|---|---|
| 8404307 | 505390 | 1619500000 | | 108 | | VIRGIE BLACKBURN #2 806301 | KENTUCKY AREA C | 11.0 | COLUMBIA GAS TRAN |
| 8404308 | 505391 | 1619500000 | | 108 | | VIRGIE BLACKBURN 806150 | KENTUCKY AREA C | 6.0 | COLUMBIA GAS TRAN |
| 8404345 | 505428 | 1615900000 | | 108 | | VIRGIE ROBINSON 804391 | KY AREA C | 3.0 | COLUMBIA GAS TRAN |
| 8404263 | 505346 | 1619500000 | | 108 | | W C YORK ETAL 806491 | KENTUCKY AREA C | 11.0 | COLUMBIA GAS TRAN |
| 8404271 | 505354 | 1611900000 | | 108 | | W J AMBURGEY 804634 | KENTUCKY AREA B | 10.0 | COLUMBIA GAS TRAN |
| 8404266 | 505349 | 1619500000 | | 108 | | W M MILLARD 806629 | KENTUCKY AREA C | 6.0 | COLUMBIA GAS TRAN |
| 8404328 | 505411 | 1607100000 | | 108 | | W M STUMBO 804057 | KENTUCKY AREA B | 14.0 | COLUMBIA GAS TRAN |
| 8404284 | 505367 | 1619500000 | | 108 | | W R BELCHER 806289 | KENTUCKY AREA C | 6.0 | COLUMBIA GAS TRAN |
| 8404258 | 505341 | 1619500000 | | 108 | | WILDA YOUNG #1 806490 | KENTUCKY AREA C | 11.0 | COLUMBIA GAS TRAN |
| 8404193 | 505276 | 1619500000 | | 108 | | ZETTA MORRISON ETAL 805238 | KENTUCKY AREA C | 2.0 | COLUMBIA GAS TRAN |

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WEST VIRGINIA DEPARTMENT OF MINES

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|---|---|---|---|---|---|---|---|---|---|
| -ALLEGHENY & WESTERN ENERGY CORP | | | RECEIVED: | 10/31/83 | JA: WV | | | | |
| 8404474 | | 4703903806 | | 103 | | L M MCCOWN #2 | UNION DISTRICT | 36.0 | ROARING FORK GAS |
| -ALLEGHENY LAND & MINERAL COMPANY | | | RECEIVED: | 10/31/83 | JA: WV | | | | |
| 8404418 | | 4709702218 | | 108 | | A-1003 | WASHINGTON DISTRICT | 0.0 | COLUMBIA GAS TRAN |
| 8404427 | | 4708300438 | | 108 | | A-1012 | MIDDLE FORK DISTRICT | 0.0 | COLUMBIA GAS TRAN |
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