1-20-88
Vol. 53 No. 12
Pages 1467-1600

federal register

Wednesday
January 20, 1988

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San Francisco, CA.
RESERVATIONS: Call the San Francisco Federal Information Center, 415–556–6600

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Wednesday, January 20, 1988

DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Part 405

[Amdt. No. 1; Doc. No. 5051S]

Apple Crop Insurance Regulations

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Interim rule with request for comment.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) amends the Apple Crop Insurance Regulations (7 CFR Part 405), by adding a new section, 7 CFR 405.9, Pilot Sunburn Option Amendment. The intended effect of this rule is to provide the regulations containing the provisions of crop insurance protection on apples against damage caused by excessive sun resulting in the apples grading less than U.S. Fancy. The authority for the promulgation of this rule is contained in the Federal Crop Insurance Act, as amended.

DATES: Effective January 20, 1988. Comments due March 21, 1988.

ADDRESSES: Written comments on this interim rule should be sent to Peter F. Cole, Office of the Manager, Federal Crop Insurance Corporation, Room 4090, South Building, U.S. Department of Agriculture, Washington, DC, 20250.

FOR FURTHER INFORMATION CONTACT: Peter F. Cole, Secretary, Federal Crop Insurance Corporation, U.S. Department of Agriculture, Washington, DC, 20250, telephone (202) 447–3325.

SUPPLEMENTARY INFORMATION: This action has been reviewed under USDA procedures established by Departmental Regulation 1512–1. This action does not constitute a review as to the need, currency, clarity, and effectiveness of these regulations under those procedures. The sunset review date established for these regulations is April 1, 1990.

Edward D. Hews, Acting Manager, FCIC, (1) has determined that this action is not a major rule as defined by Executive Order 12291 because it will not result in: (a) An annual effect on the economy of $100 million or more; (b) major increases in costs or prices for consumers, individual industries, federal, State, or local governments, or a geographical region; or (c) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets; and (2) certifies that this action will not increase the federal paperwork burden for individuals, small businesses, and other persons.

This action is exempt from the provisions of the Regulatory Flexibility Act; therefore, no Regulatory Flexibility Analysis was prepared.

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.450.

This program is not subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. See the Notice related to 7 CFR part 3015, Subpart V, published at 48 FR 29115, June 24, 1983.

This action is not expected to have any significant impact on the quality of the human environment, health, and safety. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

Insured apple producers have requested crop insurance coverage against losses brought about by apples being reduced in grade below U.S. Fancy due to sunburn. Some sunburn is suffered by an apple crop during any given year, but recently the protective cover of apple trees has been thinned or reduced by adverse weather conditions to the point where the apple crop is exposed to excessive sunshine resulting in an increase in sunburned apples which are reduced in grade below U.S. Fancy.

FCIC has determined that it is necessary to offer this form of protection to insureds who presently are insured under the basic Apple Crop Insurance Policy with the quality option as quickly as possible because of a relatively short time available for insureds to study the program and determine their crop insurance needs.

For this reason, good cause is shown for making this rule effective upon publication in the **Federal Register.**

FCIC is soliciting public comments, data, and opinions on this rule for 60 days after publication in the **Federal Register,** and will schedule a review of this rule as soon as possible after the 60-day period in order to publish any amendment made necessary by the comments received.

Written comment, data, and opinions on this rule should be sent to Peter F. Cole, Office of the Manager, Federal Crop Insurance Corporation, Room 4090, South Building, U.S. Department of Agriculture, Washington, DC 20250.

Written comments received pursuant to this proposed rule will be available for public inspection in the Office of the Manager, Federal Crop Insurance Corporation, Room 4090, South Building, U.S. Department of Agriculture, Washington, DC 20250, during regular business hours, Monday through Friday.

List of Subjects in 7 CFR Part 405

Crop insurance, Apples.

Interim Rule

Accordingly, pursuant to the authority contained in the Federal Crop Insurance Act, as amended (7 U.S.C. 1501 *et seq.*), the Federal Crop Insurance Corporation amends the Apple Crop Insurance Regulations (7 CFR Part 405), effective for the 1988 and succeeding crop years, as follows:

PART 405—[AMENDED]

1. The authority citiation for 7 CFR Part 405 continues to read as follows:

Authority: Secs. 506, 516, Pub.L. 75–430, 52 Stat. 73, 77, as amended (7 U.S.C. 1506, 1516).

2. 7 CFR Part 405 is amended to add a new section, Pilot Sunburn Option Amendment (7 CFR 405.9) to read as follows:

§ 405.9 Pilot Sunburn Option Amendment.

DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

Pilot Sunburn Option Amendment (Washington State)

Upon our approval, this amendment is applicable only for the 19____ crop year.

Insured's Name _____
Address _____
Contract Number _____
Crop Year _____
Identification Number _____
SSN _____
Tax _____

It is hereby agreed to amend the Federal Crop Insurance Apple Policy (basic policy) and the Fresh Fruit Option B in accordance with the following terms and conditions:

1. This option must be submitted to us on or before December 4, 1987. The sales closing date for the Apple Crop Insurance Policy and Fresh Fruit Option is extended through December 4, 1987, only if this option is purchased.

2. You must have a basic policy and Fresh Fruit Option B in force.

3. In addition to the causes of loss specified in paragraph 1a of the Apple Crop Insurance Policy, excess sun is an insurable cause of loss.

4. The Fresh Fruit Option B is, upon purchase of this option, amended to:

a. Change all references to "hail" to read "hail/excessive sun"; and

b. In paragraph 10(c) insert the following phrase after the words "russeting or color": "except that apples which grade less than U.S. Fancy due solely to sunburn (or hail and sunburn) will be adjusted according to paragraphs 10a(1) through 10a(4)."

5. The premium for this sunburn option will be ten (10) percent of the basic premium charged for Fresh fruit Option B.

6. All provisions of the basic policy and the Fresh Fruit Option not in conflict with this option are applicable.

7. a. Excessive sun is defined as the exposure of unharvested apples to direct or indirect sun sufficient to cause the apples to grade less than U.S. Fancy due to sunburn.

b. Sunburn is defined in accordance with applicable USDA Standards.

Insured's Signature Date

Corporation Representative's Signature and Code Number Date

Done in Washington, DC on January 12, 1988.

Edward D. Hews,

Acting Manager, Federal Crop Insurance Corporation.

[FR Doc. 88-1030 Filed 1-19-88; 8:45 am]

BILLING CODE 3410-08-M

SMALL BUSINESS ADMINISTRATION

13 CFR Part 108

[Rev. 4; Amdt. 16]

Loans to State and Local Development Companies; Correction

AGENCY: Small Business Administration.

ACTION: Interim final rule; correction.

SUMMARY: This document corrects an interim final rule on loans to state and local development companies which was published in the **Federal Register** on July 23, 1987 (52 FR 27672).

EFFECTIVE DATE: January 20, 1988.

FOR FURTHER INFORMATION CONTACT: LeAnn M. Oliver, Financial Analyst, Office of Economic Development, Small Business Administration, Room 720, 1441 L Street NW., Washington, DC 20416, (202) 653-6416.

SUPPLEMENTARY INFORMATION:

List of Subjects in 13 CFR Part 108

Loan programs—business, Reporting and recordkeeping requirements, Small business.

In order to correct FR Document 87-16575 appearing on page 27672 in the issue of July 23, 1987, the following changes are made to 13 CFR Part 108:

PART 108—[AMENDED]

1. The authority citation for Part 108 continues to read as follows:

Authority: Secs. 308(c), 501, 502, Pub. L. 85-699, 72 Stat. 689; Sec. 113, Pub. L. 96-302 (15 U.S.C. 631 note).

2. Section 108.503-10 is amended by revising the penultimate sentence to read as follows:

§ 108.503-10 [Amended]

* * * The interest on such injection shall not exceed a rate which is legal and reasonable.* * *

3. Section 108.505(f)(2)(iv) is revised to read as follows:

§ 108.505 [Amended]

* * * * *

(f) * * *

(2) * * *

(iv) Perform such other functions as SBA from time to time may prescribe.

Dated: January 6, 1988.

James Abdnor,

Administrator.

[FR Doc. 88-712 Filed 1-19-88; 8:45 am]

BILLING CODE 8025-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 87-CE-27-AD; Amdt. 39-5829]

Airworthiness Directives; SOCATA Models TB 20 and TB 21 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new Airworthiness Directive (AD), applicable to certain SOCATA Models TB 20 and TB 21 airplanes, which requires inspection of the main landing gear (MLG) hinge ball joints to detect looseness or interference of the MLG hinge strut with landing gear box stiffener, and subsequent modification of the main landing gear boxes to prevent the landing gear from binding and being unable to extend. This action is a result of FAA evaluation of the manufacturer's service information and an Airworthiness Directive issued by the responsible foreign certification airworthiness authority. The actions specified in this AD will preclude a gear up landing, and resulting damage to the airplane and hazard to the occupants.

DATE: *Effective date:* February 20, 1988. *Compliance:* Required as indicated in the body of this AD, unless already accomplished.

ADDRESSES: SOCATA TB Aircraft Service Bulletin No. 30, dated December 1986, applicable to this AD may be obtained from SOCATA Groupe Aerospatiale, B.P. 38, 65001 Tarbes, France; Telephone 62.51.73.00 or 62.93.99.45 (for recorder); or Mr. Bernard H. Veyssiere, Deputy Product Support Manager, U.S., Aerospatiale, 2701 Forum Drive, Grand Prairie, Texas 75053; Telephone (214) 641-3614. This information may be examined at the Rules Docket, FAA, Office of the Regional Counsel, Room 1558, 601 East 12th Street, Kansas City, Missouri 64106.

FOR FURTHER INFORMATION CONTACT: Mr. John P. Dow, Sr., Aerospace Engineer, ACE-109, Aircraft Certification Division, 601 East 12th Street, Kansas City, Missouri 64106; Telephone (816) 374-6932; or Mr. Roger Anderson, Aerospace Engineer, AEU-100, Aircraft Certification Office, Europe, Africa, and Middle East Office, c/o American Embassy, B-1000, Brussels, Belgium; Telephone 513.38.30.

SUPPLEMENTARY INFORMATION: A proposal to amend Part 39 of the Federal Aviation Regulations to include an AD requiring inspection of the main landing gear (MLG) hinge ball joints to detect looseness or interference of the MLG hinge strut with landing gear box stiffener on certain SOCATA Model TB 20 and TB 21 airplanes was published in the **Federal Register** on September 23, 1987 (52 FR 35727). The proposal resulted from an FAA evaluation of the manufacturer's service information and Airworthiness Directives issued by the responsible foreign certification airworthiness authority. SOCATA issued Service Bulletin (SB) No. 30, dated, December 1986 which requires inspection of the (MLG) hinge ball joint to detect looseness or interference of the

MLG hinge strut with landing box stiffener.

The Director General of Civil Aviation (DGCA), which has responsibility and authority to maintain the continuing airworthiness of these airplanes in France has classified this SB and the actions recommended therein by the manufacturer as mandatory to assure the continued airworthiness of the affected airplanes.

On airplanes operated under French registration, this action has the same effect as an AD on airplanes certified for operation in the United States. The FAA relies upon the certification of the DGAC combined with FAA review of pertinent documentation in finding compliance of the design of these airplanes with the applicable United States airworthiness requirements and the airworthiness and conformity of products of this design certificated for operation in the United States.

The FAA examined the available information related to the issuance of SOCATA SB No. 30, and the mandatory classification of this Service Bulletin by the DGAC, and concluded that the condition addressed by SB No. 30 was an unsafe condition that may exist on other airplanes of this type certificated for operation in the United States. Accordingly, the FAA proposed an amendment to Part 39 of the FAR to include an AD on this subject.

Interested persons have been afforded an opportunity to comment on the proposal. No comments or objections were received on the proposal or the FAA determination of related cost. Accordingly, the proposal is adopted without change, except for minor editorial corrections.

The FAA has determined that this regulation involves 120 airplanes at an approximate one-time cost of $80 for each airplane, or a total one-time fleet cost of $9,600. The cost of compliance with the proposed AD is so small that the expense of compliance will not be a significant financial impact on any small entities operating these airplanes.

Therefore, I certify that this action: (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) will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the final evaluation prepared for this action is contained in the regulatory docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **"ADDRESSES".**

List of Subjects in 14 CFR Part 39

Air transportation, Aviation safety, Aircraft, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends § 39.13 of Part 39 of the FAR as follows:

PART 39—[AMENDED]

1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C 106(g) (Revised, Pub. L. 97–449, January 12, 1983); and 14 CFR 11.89.

§ 39.13 [Amended]

2. By adding the following new AD.

SOCATA: Applies to Models TB 20 and TB 21 (Serial numbers 275 through 709) airplanes certificated in any category.

Compliance: Required as indicated after the effective date of this AD, unless already accomplished.

To detect interference between the moveable portions of the landing gear structure that may prevent extension of the landing gear, accomplish the following:

(a) Within the next 50 hours time-in-service (TIS) visually and tactilely (by touch) inspect the main landing gear hinge ball joints for play or interference marks between the articulated strut and the main landing gear box stiffeners as described in SOCATA TB Aircraft Service Bulletin (SB) No. 30, dated, December 1986.

(1) If detectable play is observed in the hinge ball joints or interference marks are found on the articulated strut or landing gear stiffener box, before further flight modify the airplane as prescribed in SOCATA TB Aircraft S/B No. 30, dated December 1986.

(2) If no looseness or interference is found, within 100 hours TIS after the effective date of this AD modify the airplane as prescribed in SOCATA TB Aircraft SB No. 30, dated December 1986.

(b) Airplanes may be flown in accordance with FAR 21. 197 to a location where this AD may be accomplished.

(c) An equivalent means of compliance with this AD may be used if approved by the Manager, Brussels Aircraft Certification Office, Europe, Africa, and Middle East Office, c/o American Embassy, B-1000, Brussels, Belgium; Telephone 513.38.30.

All persons affected by this directive may obtain copies of the document(s) referred to herein upon request to SOCATA Groupe AEROSPATIALE, B.P. 38, 65001 Tarbes, France; Telephone 62.51.73.00 or 62.93.99.45 (for recorder); or Mr. Bernard H. Veyssiere, Deputy Product Support Manager, U.S. Aerospatiale, 2701 Forum Drive, Grand Prairie, Texas 75053; Telephone (214) 641–3614; or may examine the document(s) referred to herein at FAA, Office of the Regional Counsel, Room 1558, 601 East 12th Street, Kansas City, Missouri 64106.

This amendment becomes effective on February 20, 1988.

Issued in Kansas City, Missouri, on January 6, 1988.

Paul K. Bohr,

Director, Central Region.

[FR Doc. 88–837 Filed 1–19–88; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 3, 375, 381 and 388

[Docket No. RM87–21–000; Order No. 488]

Revision of Freedom of Information Act Rules

Issued January 14, 1988.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Final rule.

SUMMARY: The Commission is amending its regulations relating to public information and to requests for information made pursuant to the Freedom of Information Act (5 U.S.C. 552 (1982)) *as amended by* Freedom of Information Reform Act of 1986, Pub. L. 99–570, sections 1801–1804, 100 Stat. 3207, 3207–48 (1986). This final rule consolidates regulations previously provided in § 3.8 and Part 388 of the Commission's regulations. The final rule also incorporates changes mandated by Congress in the Freedom of Information Reform Act of 1986.

EFFECTIVE DATE: February 19, 1988.

FOR FURTHER INFORMATION CONTACT: Julia Lake White, Office of the General Counsel, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, (202) 357–8530.

SUPPLEMENTARY INFORMATION:

Before Commissioners: Martha O. Hesse, Chairman; Anthony G. Sousa, Charles G. Stalon, Charles A. Trabandt and C. M. Naeve.

I. Introduction

The Federal Energy Regulatory Commission (Commission) is amending its regulations relating to public information and to requests for information made pursuant to the

Freedom of Information Act.[1] The final rule consolidates regulations previously provided in § 3.8 and Part 388 of the Commission's regulations. The final rule also incorporates changes mandated by Congress in the Freedom of Information Reform Act of 1986.

II. Background

A. Commission Regulations

The current regulations relating to public information are in one part of the Commission's regulations and the regulations relating to requests under the Freedom of Information Act (FOIA) are in another part of the Commission's regulations.[2] Section 3.8 in Part 3 of the Commission's regulations [3] provides procedures for obtaining (1) public information from the Commission's Public Reference Room; (2) stenographic records of Commission hearings; (3) the Commission's opinions, decisions, orders and rulemakings; (4) the Commission's list of formal documents; (5) the Commission's annual report to Congress; (6) the Commission's reports, decisions, maps, statistics and other information on the electric power and natural gas industries; (7) the Commission's news releases; and (8) informal advice from Commission staff. Section 3.8 also provides procedures for press, television, radio and photographic coverage of Commission proceedings; and provides the fees for FOIA requests.

Part 388 of the Commission's regulations [4] implements FOIA and Government in the Sunshine Act. Part 388 prescribes the rules governing (1) public notice of Commission proceedings; (2) public notice and publication of Commission decisions, rules, statements of policy, organization, and operations; (3) Commission public records available for inspection and copying; (4) an index of Commission actions available for inspection; (5) timetables and appeal procedures in the event public records are withheld; (6) procedures to be followed when Commission staff is served with a *subpoena duces tecum;* (7) procedures for requesting information from the Commission; and (8) procedures for requests for confidential treatment of documents submitted to the Commission.

B. Freedom of Information Reform Act of 1986 and OMB Guidelines

Congress recently enacted legislation to change the FOIA in the Freedom of Information Reform Act of 1986 (FOIA Reform Act).[5] Specifically, Congress broadened the enforcement exemption of FOIA to include not only investigation records, but also other records or information compiled for enforcement purposes.

The FOIA Reform Act also requires Federal agencies to promulgate regulations specifying a schedule of fees applicable to processing FOIA requests as well as regulations establishing procedures and guidelines for determining when these fees should be waived or reduced. The FOIA Reform Act also mandates that Federal agencies' fee schedules and fee reduction or waiver regulations must conform to guidelines established by the Director of the Office of Management and Budget (OMB). On March 27, 1987, OMB issued its uniform FOIA fee schedule and guidelines,[6] to apply to all agencies subject to the Freedom of Information Act.

C. Commission's Notice of Proposed Rulemaking

On June 23, 1987,[7] the Commission issued a notice of proposed rulemaking (NOPR), proposing to consolidate Commission regulations [8] on public information and requests for information made pursuant to FOIA into Part 388 of the Commission's regulations. The Commission proposed classifying Commission information into two categories—Commission records available in the Public Reference Room and Commission records not available through the Public Reference Room—and described procedures for obtaining each of these types of Commission records.[9] Additionally, the Commission's NOPR modified the procedures employees and former employees must follow upon receipt of a subpoena. The Commission's NOPR also proposed to modify the appeal procedures for FOIA requests. The Commission did not receive any comments on its proposed consolidation or its revised subpoena procedures. The Commission, therefore, adopts its NOPR as proposed.

Commenters raised several concerns regarding the Commission's proposed FOIA fees as well as the Commission's confidentiality procedures. The Commission received comments from the Society of Professional Journalists, the Reporters' Committee for Freedom of the Press, Texaco, Inc., ANR Pipeline Company and Colorado Interstate Gas Company and Natural Gas Pipeline Company of America. These comments are addressed below.

III. Discussion

A. FOIA Fees and Fee Waiver or Reduction

The majority of comments submitted in response to the Commission's NOPR focus on issues involving the FOIA fees and the Commission's confidentiality procedures. Commenters raised two issues on the proposed FOIA fees. First, the Society of Professional Journalists argues that the Commission's proposed regulations fail to meet OMB's requirements.

The Commission disagrees with the Society. In fact, in this final rule the Commission is adopting OMB's regulations verbatim. These regulations specify that advance payments may be charged and collected for FOIA requests if a FOIA fee is expected to exceed $250, or if a FOIA requester has previously failed to pay fees in a timely fashion. If the Commission determines that the estimated fee for a FOIA request is likely to exceed $250, the Commission will seek satisfactory assurances of payment if the FOIA requester has a record of prompt payment or, ask for an advance payment of the amount up to the estimated cost if the requester has no history of payment. The Commission will require full advance payment of the estimated amount for FOIA requesters who have failed to pay in a timely fashion in the past, or who are currently delinquent.

Second, both the Society of Professional Journalists and the Reporters' Committee for Freedom of the Press argue that the Commission's criteria for fee reduction or waiver for FOIA requests are too restrictive.

The Commission believes that its fee reduction or waiver guidelines comply with the fee waiver standards mandated by the FOIA Reform Act and promulgated in OMB's guidelines. The FOIA Reform Act's fee waiver standards establish two basic

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[1] 5 U.S.C. 552 (1982) *as amended by* Freedom of Information Reform Act of 1986, Pub. L. 99-570, sections 1801-1804, 100 Stat. 3207, 3207-48 (1986).

[2] *See* 18 CFR Parts 3 and 388 (1987).

[3] 18 CFR 3.8 (1987).

[4] 18 CFR Part 388 (1987).

[5] *See* note 1.

[6] The Freedom of Information Reform Act of 1986; Uniform Freedom of Information Act Fee Schedule and Guidelines, 52 FR 10012 (March 27, 1987).

[7] Revision of Freedom of Information Act Rules, 52 FR 24027 (June 26, 1987), IV FERC Stats & Regs. ¶ 32,448 (1987).

[8] *See* note 2.

[9] The Commission is deleting from § 388.106 of its existing regulations references to documents listed as available in the Public Reference Room, which in fact are not available from the Public Reference Room. However, the Commission notes that while these documents may not be available from the Public Reference Room, they may be obtained under the second category of Commission records.

requirements.[10] First, the Commission must determine if disclosure of the information is in the public interest because it is likely to contribute significantly to public understanding of the operation or activities of the government. Second, the Commission must determine whether the information disclosed is not primarily in the commercial interest of the requester. The FOIA Reform Act does not require the Commission to grant the requested fee waiver or reduction unless both of these requirements are met.

The Commission's new regulations list several factors it will use in determining the public interest and the commercial interest of the FOIA requester. The Commission will use these factors to determine if a request for fee reduction or waiver of a fee for an FOIA request meets the FOIA Reform Act's statutory requirements as promulgated in OMB's guidelines. The Commission will review requests for fee waiver or reductions for FOIA requests on a case-by-case basis and will give full and careful consideration to the merits of each request.

B. Commission's Confidentiality Procedures

Commenters express several concerns regarding the proposed confidentiality provisions. First, the Reporters' Committee for Freedom of the Press requests the Commission to clarify that the notification provisions that allow for consultation with submitter of confidential information when an FOIA request is made, will not interfere with the Commission's obligation to grant or deny an FOIA request for information within 10 days. FOIA regulations provide that Federal agencies must determine whether to comply with a FOIA request within 10 days (excluding Saturdays, Sundays and legal holidays) after receipt of the FOIA request.[11]

The Commission recognizes that it must act on FOIA requests within the 10 working day time limit prescribed in FOIA, which may be extended in unusual circumstances by an additional 10 working days.[12] However, the Commission also is required to implement the notification procedures in Executive Order 12600, which requires Federal agencies to establish predisclosure notification procedures for confidential commercial information.[13] The Commission intends to balance these two requirements in reviewing FOIA requests that involve confidential information.

Texaco recommends changes to the proposed procedures for notification as well as the time period for response under § 388.112(d). Under the proposed Commission regulations, when an FOIA requester seeks a document for which the submitter has claimed confidential commercial treatment, the Commission official who will decide whether to make the document public will notify the submitter. Texaco recommends that the Commission's notice be in writing and that it begin to calculate the time for a response by the submitter from the date of receipt of the written notice. Texaco also recommends that the person who submitted the confidential commercial information should have at least 10 working days to respond in writing. Finally, Texaco recommends that the time period for notice of denial of a claim of privilege in § 388.112(e) should be expanded from five days to no less than 10 working days.

The Commission is not adopting Texaco's recommendations with regard to the time period for notification. FOIA requires Commission action on an FOIA request for information within 10 days excepting Saturdays, Sundays, and legal public holidays after receipt of the FOIA request.[14] FOIA provides that this 10 day time period may be expanded for an additional 10 days under unusual circumstances.[15] Therefore, the Commission is limited by these requirements of the statute. In fact, Texaco's proposals would expand the Commission's FOIA procedures beyond this statutorily-mandated time-frame.

However, the Commission is adopting another Texaco recommendation, *i.e.*, that requests for confidential treatment of documents, contain the name, title, address, telephone number and telecopy information of person(s) to whom correspondence or communication in regard to a confidential request is to be addressed. The Commission believes this will facilitate the process of notification.

ANR Pipeline Company (ANR) and Colorado Interstate Gas Company (CIG) argue that the Commission's proposal does not adequately encompass the procedural protections of Executive Order 12600.[16] Specifically, ANR and CIG argue that the Executive Order requires an agency to provide a written statement explaining the reasons why it has declined confidential treatment. They request the Commission to amend its existing FOIA regulations to provide that when the Commission notifies the submitter of confidential information that the Commission intends to disclose the information to a FOIA requester, it will include a written explanation of its reasons for declining confidential treatment.

The Commission is adopting ANR's and CIG's suggestion. In fact, the Commission routinely explains decisions to deny a person's request for confidential treatment of documents before releasing the documents even though this practice has never been codified. Therefore, the Commission is amending its regulations to codify this procedure.

Additionally, in response to ANR and CIG, the Commission is clarifying that the "confidential commercial information" defined in Executive Order 12600 is included within the scope of § 388.107(d), "trade secrets and commercial or financial information obtained from a person and privileged or confidential" which is also Exemption 4 of the FOIA.[17]

Natural Gas Pipeline Company of America (Natural) and ANR and CIG argue that the Commission must establish separate procedures to protect the confidentiality of information produced by a company pursuant to the Commission's rules of discovery related to trial-type proceedings.[18] ANR and CIG request the Commission to amend or clarify § 388.107(d) to provide that any documents that have been sealed pursuant to a protective order issued under the discovery rules[19] should be entitled to a presumption that such documents constitute "privileged or confidential material" exempt from FOIA disclosure. Natural requests the Commission to clarify that documents obtained by Commission trial staff pursuant to discovery in trial-type proceedings are not agency records subject to FOIA. Alternatively, Natural requests the Commission to establish procedures to ensure confidentiality for such data, if the data become the subject of a FOIA request.

The Commission does not believe that it is necessary to create a presumption that material found to be protected from discovery is automatically protected from a FOIA request. Since the Commission's procedures for protecting confidential treatment of documents under FOIA in § 388.112 are adequate,

[10] *See* 5 U.S.C. 552(a)(4)(A) (iii) (1982).
[11] 5 U.S.C. 552(a)(6)(A) (1982).
[12] 5 U.S.C. 552(a)(6)(B) (1982).
[13] 52 FR 23781 (June 25, 1987).
[14] *See* note 15.
[15] *See* note 16.
[16] *See* note 7.
[17] 5 U.S.C. 552(b)(4) (1982).
[18] 18 CFR Part 385, Subpart D (1987).
[19] *See* 18 CFR 385.410(c)(3) (1987).

additional procedures are unnecessary. However, the Commission's FOIA decisionmaker will consider as a factor a decision by an administrative law judge or the Commission that data obtained during discovery should be protected in reaching a decision to grant or deny a FOIA request.

C. Miscellaneous

Commenters also raise two miscellaneous issues. The first issue relates to aggregating FOIA requests. OMB's regulations provide that there is no charge for the first 100 pages of a FOIA request for certain categories of requesters. However, in order to prevent requesters from submitting piecemeal requests that take advantage of this exclusion, OMB established a test to determine whether consecutive requests should be consolidated, treated as one large request, and assessed a fee. The Commission proposed to adopt these regulations. The Society of Professional Journalists argues that the Commission's regulations[20] fail to reflect a presumption against aggregating FOIA requests made more than 30 days apart for purposes of obtaining a lower fee.[21]

The Society misunderstands OMB's regulations. OMB's guidelines do not specify that a rigid 30-day limit must be adopted. OMB explained that a 30-day limit does not achieve the goal of allowing an agency to identify FOIA requesters who are attempting to circumvent the FOIA fee provisions. Instead, OMB indicated that it preferred a more flexible standard under which agencies could decide to aggregate requests made at intervals more than 30 days, if they had a solid basis for doing so. The Commission has adopted OMB's regulations. It will use OMB's guidelines to aggregate requests.

Second, both the Reporters' Committee for Freedom of the Press and the Society of Professional Journalists request the Commission to change its definition of "representative of the news media." Further, the Society of Professional Journalists requests the Commission to delete the definition for "freelance journalists." The definitions adopted by the Commission are OMB's definitions. The Commission declines to amend OMB's definitions.

Additionally, the Commission is increasing the fee for certification of Commission records used in Federal or State court proceedings from $2.00 to $5.00. The Commission receives very few certification requests, generally from companies subject to Commission jurisdiction.[22] Occasionally, these certification requests have required a great deal of Commission staff time to consolidate and certify the requested records. The Commission believes that because of the time and manpower involved, a $5.00 fee for certification is reasonable. The Commission is adopting this fee in lieu of a page count fee which the Commission believes would be counterproductive and an unnecessarily time-consuming burden. The Commission is also revising its regulations in § 388.109(a) to indicate that the fee for documents obtained from the Commission's Records Information Management System (RIMS) will be 15 cents per page. This is consistent with the 15 cent duplicating fee for FOIA requests.

IV. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA)[23] requires Federal agencies to consider whether a rule, if promulgated will have a "significant impact on a substantial number of small entities."[24] Since approximately 90% of the FOIA requests affected by these regulations will amount to less than $5, the amended regulations are unlikely to create significant impact on entities no matter how small. Moreover, FOIA requesters will still be able to inspect rather than purchase Commission records if they so choose. Since this final rule's changes are not substantive, or are made in response to a Congressional mandate in the Reform Act as promulgated by OMB guidelines, the Commission believes that any "significant economic impact" has already been determined during Congressional deliberations and again during OMB's notice and comment procedures pursuant to APA. Accordingly, the Commission certifies, pursuant to section 605(b) of the RFA, that this final rule will not have a significant economic impact on a substantial number of small entities.

V. Effective Date

This rule will be effective February 19, 1988.

List of Subjects

18 CFR Part 3

Freedom of information, Organization and function (Government agencies).

18 CFR Part 375

Authority delegations (Government agencies).

18 CFR Part 381

Natural gas, Reporting and recordkeeping requirements.

18 CFR Part 388

Freedom of information.

In consideration of the foregoing, the Commission amends Parts 3, 375, 381 and 388, Chapter I, Title 18, Code of Federal Regulations, as set forth below.

By the Commission.

Lois D. Cashell,

Acting Secretary.

PART 3—ORGANIZATION OPERATION; INFORMATION AND REQUESTS

1. The authority citation for Part 3 is revised to read as follows:

Authority: Department of Energy Organization Act, 42 U.S.C. 7101–7352 (1982); E.O. 12009, 3 CFR 1978 Comp., p. 142 (1978); Administrative Procedure Act, 5 U.S.C. 551–557 (1982); Natural Gas Act, 15 U.S.C. 717–717z (1982); Federal Power Act, 16 U.S.C. 791a–828c (1982); Natural Gas Policy Act, 15 U.S.C. 3301–3432 (1982); Public Utility Regulatory Policies Act, 16 U.S.C. 2601–2645 (1982); Interstate Commerce Act, 49 U.S.C. 1–27 (1976); Freedom of Information Act, 5 U.S.C. 552 (1982) as amended by Freedom of Information Reform Act of 1986.

§ 3.8 [Removed]

2. Part 3 is amended by removing § 3.8.

PART 375—THE COMMISSION

2. The authority citation for Part 375 is revised to read as follows:

Authority: Department of Energy Organization Act, 42 U.S.C. 7101–73521; E.O. 12009, 3 CFR 1978 Comp., p. 142; Administrative Procedure Act; 5 U.S.C. 553; Federal Power Act, 16 U.S.C. 791–828c, as amended; Natural Gas Act 15 U.S.C. 717–717w; Natural Gas Policy Act of 1978, 15 U.S.C. 3301, *et seq.*; Public Utility Regulatory Policies Act of 1978, 16 U.S.C. 2601 *et seq.*, as amended.

3. In § 375.313, paragraph (b) is revised to read as follows:

§ 375.313 Delegations to the Executive Director.

* * * * *

(b) Prescribe the updated fees for Part 381 of this chapter in accordance with § 388.109(b)(2) of this chapter.

* * * * *

PART 381—FEES

4. The authority citation for Part 381 is revised to read as follows:

Authority: Department of Energy Organization Act, 42 U.S.C. 7101–7352 (1982); E.O. 12009, 3 CFR 1978 Comp., p. 142;

[20] 8 CFR 388.109(b)(2)(vii) (1987).

[21] 52 FR at 19019.

[22] Commission records indicate these requests average 10 per month.

[23] 5 U.S.C. 601–612 (1982).

[24] Id., 605(b) (1982).

Independent Offices Appropriations Act, 31 U.S.C. 9701 (1982); Natural Gas Act 15 U.S.C. 717–717w (1982); Federal Power Act, 16 U.S.C. 791–828c (1982); Public Utility Regulatory Policies Act, 16 U.S.C 2601–2645 (1982); Interstate Commerce Act, 49 U.S.C. 1–27 (1976).

5. Section 381.301 is revised to read as follows:

Subpart C—Fees Applicable to General Activities

* * * * *

§ 381.301 Request for interpretation by the Office of Chief Accountant.

The fee established for a request for an interpretation by the Chief Accountant under Part 388 of the Commission's Rules of Practice and Procedure that requires a written response is $100.

The fee must be submitted in accordance with Subpart A of this part.

6. Part 388 is revised to read as follows:

PART 388—INFORMATION AND REQUESTS

Sec.

Authority: Freedom of Information Act, 5 U.S.C. 552 (1982) as amended by Freedom of Information Reform Act of 1986; Administrative Procedure Act, 5 U.S.C. 551–557 (1982).

§ 388.101 Scope.

This part prescribes the rules governing public notice of proceedings, publication of decisions, requests for informal advice from Commission staff, procedures for press, television, radio and photographic coverage, requests for Commission records, requests for confidential treatment of documents submitted to the Commission, procedures for responding to subpoenas seeking documents or testimony from Commission employees or former employees, fees for various requests for documents, and requests for reduction or waiver of these fees.

§ 388.102 Notice of proceedings.

(a) Public sessions of the Commission for taking evidence or hearing argument; public conferences and hearings before a presiding officer; and public conferences or hearings in substantive rulemaking proceedings, will not be held except upon notice.

(b) Notice of applications, complaints, and petitions, is governed by Rule 2009 (notice) in Part 385 of this chapter. Notice of applications for certificates of public convenience and necessity under section 7 of the Natural Gas Act is governed by § 157.9 of this chapter (notice of application). Notice of public sessions and proceedings and of meetings of the Commission is governed by Rule 2009 (notice) in Part 385 of this Chapter. Notice of hearings and of initiation or pendency of rulemaking proceedings is governed by Rule 1903 (notice in rulemaking proceedings) in Part 385 of this chapter. Notice of application under Part I of the Federal Power Act for preliminary permits and licenses is governed by §§ 4.31 and 4.81 of this chapter (acceptance or rejection and contents). Notice of proposed alterations or surrenders of license under section 6 of the Federal Power Act may be given by filing and publication in the **Federal Register** as stated in Rule 1903 (notice in rulemaking proceedings) in Part 385 of this chapter, and where deemed desirable by the Commission, by local newspaper advertisement. Notice of rates charged and changes therein is governed by the filing requirements of subchapters B and E of this chapter (regulations under the Federal Power Act and regulations under the Natural Gas Act). Other notice required by statute, rule, regulation, or order, or deemed desirable, may be given by filing and publication in the **Federal Register** as governed by Rule 1903 in Part 385 of this chapter (notice in rulemaking proceedings) or by service as governed by Rule 2010 (service) in Part 385 of this chapter.

§ 388.103 Notice and publication of decisions, rules, statements of policy, organization and operations.

Service of intermediate and final decisions upon parties to the proceedings is governed by Rule 2010 (service) in Part 385 of this chapter. Descriptions of the Commission's organization, its methods of operation, statements of policy and interpretations, procedural and substantive rules, and amendments thereto will be filed with and published in the **Federal Register.** Commission opinions together with accompanying orders, Commission orders, and intermediate decisions will be released to the press and made available to the public promptly. Copies of Commission opinions, orders in the nature of opinions, rulemakings and selected procedural orders, and intermediate decisions which have become final are published in the *Federal Energy Guidelines* and upon payment of applicable charges, may be obtained from: Commerce Clearing House, Inc. 4025 West Peterson Avenue, Chicago, Illinois 60646. Attention: Order Department.

§ 388.104 Informal advice from Commission staff.

The Commission staff provides informal advice and assistance to the general public and to prospective applicants for licenses, certificates and other Commission authorizations. Opinions expressed by the staff do not represent the official views of the Commission, but are designed to aid the public and facilitate the accomplishment of the Commission's functions. Inquiries may be directed to the chief of the appropriate office or division. An inquiry directed to the Chief Accountant that requires a written response must be accompanied by the fee prescribed by § 381.301 of this chapter. An inquiry directed to the Office of the General Counsel for an interpretation of the Natural Gas Policy Act of 1978 must be accompanied by the fee prescribed in § 381.405 of this chapter.

§ 388.105 Procedures for press, television, radio, and photographic coverage.

(a) The Commission issues news releases on major applications, decisions, opinions, orders, rulemakings, new publications, major personnel changes, and other matters of general public interest. Releases are issued by and available to the media from the Office of External Affairs. Releases may be obtained by the public through the Public Reference Room.

(b) Press, television, radio and photographic coverage of Commission proceedings is permitted as follows:

(1) Press tables are located in each hearing room, and all sessions of hearings are open to the press, subject to standards of conduct applicable to all others present;

(2) Television, movie and still cameras, and recording equipment are

permitted in hearing rooms prior to the opening of a hearing or oral arguments, and during recesses, upon prior arrangement with the Commission or presiding administrative law judge. All equipment must be removed from the room before hearings or oral arguments begin or resume;

(3) Television, movie and still cameras, and recording equipment may not be used while hearings and oral arguments before administrative law judges are in progress;

(4) Television and press cameras and recording equipment may be used at Commission press conferences under prior arrangement with the Office of External Affairs, provided their use does not interfere with the orderly conduct of the press conference;

(5) Regulations pertaining to the use of television, movie and still cameras, and recording equipment in in connection with the Commission's open public meetings under the Government in the Sunshine Act are found in § 375.203 of this chapter.

§ 388.106 Requests for Commission records available in the Public Reference Room.

(a) A Public Reference Room is maintained at the Commission's headquarters and is open during regular business hours as provided in § 375.101(c) of this chapter. Documents may be obtained in person or in writing from the Public Reference Room by reasonably describing the records sought.

(b) The public records of the Commission that are available for inspection and copying upon request in the Public Reference Room include:

(1) Applications, declarations, complaints, petitions, and other papers seeking Commission action;

(2) Financial, statistical, and other reports to the Commission, power system statements of claimed cost of licensed projects, original cost and reclassification studies, proposed accounting entries, certificates of notification (under section 204(e) of the Federal Power Act), rates or rate schedules and related data and concurrences, and other filings and submittals to the Commission in compliance with the requirements of any statute, executive order, or Commission rule, regulation, order, license, or permit;

(3) Answers, replies, responses, objections, protests, motions, stipulations, exceptions, other pleadings, notices, certificates, proofs of service, transcripts of oral arguments, and briefs in any matter of proceeding;

(4) Exhibits, attachments and appendices to, amendments and corrections of, supplements to, or transmittals or withdrawals of any of the foregoing;

(5) All parts of the formal record in any matter or proceeding set for formal or statutory hearing, and any Commission correspondence related thereto;

(6) Presiding officer actions, correspondence, and memoranda to or from others, with the exception of internal communications within the Office of Administrative Law Judges;

(7) Commission orders, notices, findings, opinions, determinations, and other actions in a matter or proceeding;

(8) Commission correspondence relating to any furnishing of data or information, except to or by another branch, department, or agency of the Government;

(9) Commission correspondence with respect to the furnishing of data, information, comments, or recommendations to or by another branch, department, or agency of the Government where furnished to satisfy a specific requirement of a statute or where made public by that branch, department or agency;

(10) Staff reports on statements of claimed cost by licensees when such reports have been served on the licensee;

(11) Commission correspondence on interpretation of the Uniform System of Accounts and letters on such interpretation signed by the Chief Accountant and sent to persons outside the Commission;

(12) Commission correspondence on the interpretation or applicability of any statute, rule, regulation, order, license, or permit issued or administered by the Commision, and letters of opinion on that subject signed by the General Counsel and sent to persons outside the Commission;

(13) Copies of the filings, certifications, pleadings, records, briefs, orders, judgments, decrees, and mandates in court proceedings to which the Commission is a party and the correspondence with the courts or clerks of court;

(14) The Commission's Directives System;

(15) The Commission's opinions, decisions, orders and rulemakings;

(16) Reports, decisions, maps, and other information on electric power and natural gas industries;

(17) Subject index of major Commission actions;

(18) Annual report to Congress in which the Commission's operations during a past fiscal year are described; and

(19) Commission correspondence relating to the foregoing.

(c) For purposes of this section,

(1) "Commission correspondence" includes written communications and enclosures received from others outside the staff and intended for the Commission or sent to others outside the staff and signed by the Chairman, a Commissioner, the Secretary, the Executive Director, or other authorized official, except those which are personal.

(2) "Formal record" includes:

(i) Filings and submittals in a matter or proceeding,

(ii) Any notice or Commission order initiating the matter or proceeding, and

(iii) If a hearing is held, the designation of the presiding officer, transcript of hearing, exhibits received in evidence, exhibits offered but not received in evidence, offers of proof, motions, stipulations, subpoenas, proofs or service, references to the Commission, and determinations made by the Commission thereon, certifications to the Commission, and anything else upon which action of the presiding officer or the Commission may be based.

The "formal record" does not include proposed testimony or exhibits not offered or received in evidence.

(3) "Matter or proceeding" means the Commission's elucidation of the relevant facts and applicable law, consideration thereof, and action thereupon with respect to a particular subject within the Commission's jurisdiction, initiated by a filing or submittal or a Commission notice or order.

§ 388.107 Commission records exempt from public disclosure.

The following records are exempt from disclosure.

(a)(1) Records specifically authorized under criteria established by an Executive order to be kept secret in the interest of natural defense or foreign policy, and

(2) Those records are in fact properly classified pursuant to such Executive order;

(b) Records related solely to the internal personnel rules and practices of an agency;

(c) Records specifically exempted from disclosure by statute, provided that such statute:

(1) Requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or

(2) Establishes particular criteria for withholding or refers to particular types of matters to be withheld;

(d) Trade secrets and commercial or financial information obtained from a person and privileged or confidential;

(e) Interagency or intraagency memoranda or letters which would not be available by law to a party other than an agency in litigation with the agency;

(f) Personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

(g) Records or information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement records or information:

(1) Could reasonably be expected to interfere with enforcement proceedings,

(2) Would deprive a person of a right to a fair trial or an impartial adjudication,

(3) Could reasonably be expected to constitute an unwarranted invasion of personal privacy,

(4) Could reasonably be expected to disclose the identity of a confidential source, including a state, local, or foreign agency or authority or any private institution which furnished information on a confidential basis, and, in the case of a record or information compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, information furnished by a confidential source,

(5) Would disclose techniques and procedures for law enforcement investigations or prosecutions, or would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law, or

(6) Could reasonably be expected to endanger the life or physical safety of any individual;

(h) Geological and geophysical information and data, including maps, concerning wells.

§ 388.108 Requests for Commission records not available through the Public Reference Room (FOIA requests).

(a)(1) Except as provided in paragraph (a)(2), of this section, a person may request access to Commission records that are not available through the Public Reference Room by using the following procedures:

(i) The request must be in writing, addressed to the Director of Public Affairs, and clearly marked "Freedom of Information Act Request."

(ii) The request must include:

(A) A statement by the requester of a willingness to pay a reasonable fee or fees not to exceed a specific amount, or

(B) A request for waiver or reduction or fees.

(iii) The request must identify the category of the request, consistent with the definitions provided in § 388.109(b)(1).

(2) A request that fails to provide the identification required in paragraph (a)(1)(iii) of this section will not be processed until the Director of Public Affairs can ascertain the requester's category.

(3) A request for records received by the Commission not addressed and marked as indicated will be so addressed and marked by Commission personnel as soon as it is properly identified, and forwarded immediately to the Director of Public Affairs.

(4) Requests made pursuant to this section will be considered to be received upon actual receipt and, if necessary, categorization by the Director of Public Affairs.

(b)(1) Except as provided in paragraph (b)(2) of this section, within 10 working days after receipt of the request, the Director of Public Affairs will determine whether to comply with the request for agency records and will notify the person making the request of the determination and the reasons for a decision to deny the request, and of the right of the requester to appeal any adverse determination in writing to the General Counsel or General Counsel's designee.

(2) Pursuant to § 388.110, the time limit for an initial determination may be extended by up to 10 working days.

(c) The procedure for appeal of denial of a request for Commission records is set forth in § 388.110.

§ 388.109 Fees for record requests.

(a) *Fees for records available through the Public Reference Room.*—(1) *General rule.* The fee for finding and duplicating records available in the Commission's Public Reference Room will vary depending on the size and complexity of the request. A schedule of fees for such services is prescribed annually. A person can obtain a copy of the schedule of fees in person or by mail from the Public Reference Room. Copies of documents also may be made on self-service duplicating machines located in the Public Reference Room. In addition, copies of data extracted from the Commission's files through electronic media are available on a reimbursable basis, upon written request to the Public Reference Room.

(2) Stenographic reports of Commission hearings are made by a private contractor. Interested persons may obtain copies of public hearing transcripts from the contractor at prices set in the contract, or through the search and duplication service noted above. Copies of the contract are available for public inspection in the Public Reference Room.

(3) Copies of transcripts, electronic recordings, or minutes of Commission meetings closed to public observation containing material nonexempt pursuant to § 375.206(f) of this chapter are also available at the actual cost of duplication or transcription.

(4) The public may purchase hard copies of certain documents from the Commission's Records Information Management System (RIMS). The fee is 15 cents per page. There will be no charge for requests consisting of 10 or fewer pages.

(5) Except for requests for certification by Government agencies, certification of copies of official Commission records must be accompanied by a fee of $5.00 per document. Inquiries and orders may be made to the Public Reference Room in person or by mail.

(b) *Fees for records not available through the Public Reference Room (FOIA requests).* The cost of duplication of records not available in the Public Reference Room will depend on the number of documents requested, the time necessary to locate the documents requested, and the category of the persons requesting the records. The procedures for appeal of requests for fee waiver or reduction are set forth in § 388.110.

(1) *Definitions.* For the purpose of paragraph (b) of this section:

(i) "Commercial use" request means a request from or on behalf of one who seeks information for a use or purpose that furthers commercial, trade, or profit interests as these phrases are commonly known or have been interpreted by the courts in the context of the Freedom of Information Act;

(ii) "Educational institution" refers to a preschool, a public or private elementary or secondary school, an institution of graduate higher education, an institution of undergraduate higher education, an institution of professional education, and an institution of vocational education, which operates a program of scholarly research;

(iii) "Noncommercial scientific institution" refers to an institution that is not operated on a commercial basis and which is operated solely for the purpose of conducting scientific research the results of which are not intended to promote any particular product or industry;

(iv) "Representative of the news media" refers to any person actively gathering news for an entity that is organized and operated to publish or broadcast news to the public. The term "news" means information that is about current events or that would be of current interest to the public. Examples of news media entities include television or radio stations broadcasting to the public at large, and publishers of periodicals (but only in those instances when the periodicals can qualify as disseminations of "news") who make their products available for purchase or subscription by the general public. These examples are not intended to be all-inclusive. Moreover, as traditional methods of news delivery evolve (e.g., electronic dissemination of newspapers through telecommunications services), such alternative media may be included in this category. A "freelance" journalist may be regarded as working for a news organization if the journalist can demonstrate a solid basis for expecting publication through that organization, even though the journalist is not actually employed by the news organization. A publication contract would be the clearest proof, but the Commission may also look to the past publication record of a requester in making this determination.

(2) *Fees.* (i) If documents are requested for commercial use, the Commission will charge the employee's hourly pay rate plus 16 percent for benefits for document search time and for document review time, and 15 cents per page for duplication. Commercial use requests are not entitled to two hours of free seach time or 100 free pages of reproduction of documents.

(ii) If documents are not sought for commercial use and the request is made by an educational or noncommerical scientific institution, whose purpose is scholarly or scientific research, or a representative of the news media, the Commission will charge 15 cents per page for duplication. There is no charge for the first 100 pages.

(iii) For a request not described in paragraphs (b)(2) (i) or (ii) of this section the Commission will charge the employee's hourly pay rate plus 16 percent for benefits for document search time and document review time, and 15 cents per page for duplication. There is no charge for the first 100 pages of reproduction and the first two hours of search time will be furnished without charge.

(iv) If documents are mailed, requesters will be charged postage based on the current postage rate.

(v) The Commission, or its designee, may establish minimum fees below which no charges will be collected, if it determines that the costs of routine collection and processing of the fees are likely to equal or exceed the amount of the fees. If total fees assessed by Commission staff for a Freedom of Information Act request are less than the appropriate threshold, the Commission may not charge the requesters.

(vi) Payment of fees must be by check or money order made payable to the U.S. Treasury.

(vii) Requesters may not file multiple requests at the same time, each seeking portions of a document or documents, solely in order to avoid payment of fees. When the Commission reasonably believes that a requester, or a group of requesters acting in concert, is attempting to break a request down into a series of requests for the purpose of evading assessment of fees, the Commission may aggregate any such requests and charge the requester accordingly. The Commission will not aggregate multiple requests on unrelated subjects from a requester.

(3) *Fees for unsuccessful search.* The Commission may assess charges for time spent searching, even if it fails to locate the records, or if records located are determined to be exempt from disclosure. If the Commission estimates that search charges are likely to exceed $25, it will notify the requester of the estimated amount of search fees, unless the requester has indicated in advance willingness to pay fees as high as those anticipated. The requester can meet with Commission personnel with the object of reformulating the request to meet his or her needs at a lower cost.

(4) *Interest—notice and rate.* The Commission will assess interest charges on an unpaid bill starting on the 31st day following the day on which the billing was sent. Interest will be at the rate prescribed in 31 U.S.C. 3717 and will accrue from the date of the billing.

(5) *Advance payments.* The Commission will require a requester to make an advance payment, *i.e.*, payment before work is commenced or continued on a request, if:

(i) The Commission estimates or determines that allowable charges that a requester may be required to pay are likely to exceed $250. The Commission will notify the requester of the estimated cost and either require satisfactory assurance of full payment where the requester has a history of prompt payment of fees, or require advance payment of the charges if a requester has no history of payment; or

(ii) A requester has previously failed to pay a fee charged in a timely fashion, the Commission will require the requester to pay the full amount owed plus any applicable interest, and to make an advance payment of the full amount of the estimated fee before the Commission will begin the process a new request or a pending request from that requester.

(iii) When the Commission requires advance payment under this paragraph, the administrative time limits prescribed in this part will begin only after the Commission has received the fee payments described above.

(6) *Fee reduction or waiver.* (i) Any fee described in paragraph (b) of this section may be reduced or waived if the requester demonstrates that disclosure of the information sought is:

(A) In the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government, and

(B) Not primarily in the commercial interest of the requester.

(ii) The Commission will consider the following criteria to determine the public interest standard:

(A) Whether the subject of the requested records concerns the operations or activities of the government;

(B) Whether the disclosure is likely to contribute to an understanding of government operations or activities;

(C) Whether disclosure of the requested information will contribute to public understanding; and

(D) Whether the disclosure is likely to contribute significantly to public understanding of government operations or facilities.

(iii) The Commission will consider the following criteria to determine the commercial interest of the requester:

(A) Whether the requester has a commercial interest that would be furthered by the requested disclosure; and, if so

(B) Whether the magnitude of the identified commercial interest of the requester is sufficiently large, in comparison with the public interest in disclosure, that disclosure is primarily in the commercial interest of the requester.

(iv) This request for fee reduction or waiver must accompany the initial request for records and will be decided under the same procedures used for record requests.

(7) *Debt collection.* The Commission will use the authorities mandated in the Debt Collection Act of 1982, 31 U.S.C. 3711, 3716–3719 (1982), including disclosure to consumer reporting agencies and use of collection agencies, where appropriate, to encourage payment of outstanding unpaid FOIA invoices.

(8) *Annual adjustment of fees.*—(i) *Update and publication.* The Commission, by its designee, the Executive Director, will update the fees established in this section each fiscal year. The Executive Director will publish the fees in the **Federal Register.**

(ii) *Payment of updated fees.* The fee applicable to a particular Freedom of Information Act request will be the fee in effect on the date that the request is received.

§ 388.110 Procedure for appeal of denial of requests for Commission records not publicly available or not available through the Public Reference Room and denial of requests for fee waiver or reduction.

(a)(1) A person whose request for records or request for fee waiver or reduction is denied in whole or part may appeal that determination to the General Counsel or General Counsel's designee within 45 days of the determination. Appeals filed pursuant to this section must be in writing, addressed to the General Counsel of the Commission, and clearly marked "Freedom of Information Act Appeal." Such an appeal received by the Commission not addressed and marked as indicated in this paragraph will be so addressed and marked by Commission personnel as soon as it is properly identified and then will be forwarded to the General Counsel. Appeals taken pursuant to this paragraph will be considered to be received upon actual receipt by the General Counsel.

(2) The General Counsel or the General Counsel's designee will make a determination with respect to any appeal within 20 working days after the receipt of such appeal. If, on appeal, the denial of the request for records or fee reduction is in whole or in part upheld, the General Counsel or the General Counsel's designee will notify the person making such request of the provisions for judicial review of that determination.

(b) In unusual circumstances, the time limits prescribed for making the initial determination pursuant to § 388.108 and for deciding an appeal pursuant to this section may be extended by up to 10 working days, by the Secretary who will send written notice to the requester setting forth the reasons for such extension and the date on which a determination or appeal is expected to be dispatched. "Unusual circumstances" means:

(1) The need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the requests;

(2) The need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request; or

(3) The need for consultation, which will be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request or among two or more components of the agency having substantial subject-matter interest therein.

§ 388.111 Procedures in event of subpoena.

(a)(1) The procedures specified in this section will apply to all subpoenas directed to Commission employees that relate in any way to the employees' official duties. These procedures will also apply to subpoenas directed to former Commission employees if the subpoenas seek nonpublic materials or information acquired during Commission employment. The provisions of paragraph (c) of this section will also apply to subpoenas directed to the Commission.

(2) For purposes of this section,

(i) "Employees", except where otherwise specified, includes "special government employees" and other Commission employees; and

(ii) "Nonpublic" includes any material or information which is exempt from availability for public inspection and copying;

(iii) "Special government employees" includes consultants and other employees as defined by section 202 of Title 18 of the United States Code.

(iv) "Subpoena" means any compulsory process in a case or matter, including a case or matter to which the Commission is not a party;

(b) Any employee who is served with a subpoena must promptly advise the General Counsel of the Commission of the service of the subpoena, the nature of the documents or information sought, and all relevant facts and circumstances. Any former employee who is served with a subpoena that concerns nonpublic information shall promptly advise the General Counsel of the Commission of the service of the subpoena, the nature of the documents or information sought, and all relevant facts and circumstances.

(c) A party causing a subpoena to be issued to the Commission or any employee or former employee of the Commission must furnish a statement to the General Counsel of the Commission. This statement must set forth the party's interest in the case or matter, the relevance of the desired testimony or documents, and a discussion of whether the desired testimony or documents are reasonably available from other sources. If testimony is desired, the statement must also contain a general summary of the testimony and a discussion of whether Commission records could be produced and used in lieu of testimony. Any authorization for testimony will be limited to the scope of the demand as summarized in such statement.

(d) Commission records or information which are not part of the public record will be produced only upon authorization by the Commission.

(e) The Commission or its designee will consider and act upon subpoenas under this section with due regard for statutory restrictions, the Commission's Rules of Practice and Procedure, and the public interest, taking into account factors such as applicable privileges including the deliberative process privilege; the need to conserve the time of employees for conducting official business; the need to avoid spending the time and money of the United States for private purposes; the need to maintain impartiality between private litigants in cases where a substantial government interest is not involved; and the established legal standards for determining whether justification exists for the disclosure of confidential information and records.

(f) The Commission authorizes the General Counsel or the General Counsel's designee to make determinations under this section.

§ 388.112 Requests for privileged treatment of documents submitted to the Commission.

(a) *Scope.* Any person submitting a document to the Commission may request privileged treatment by claiming that some or all of the information contained in a particular document is exempt from the mandatory public disclosure requirements of the Freedom of Information Act, 5 U.S.C. 552, and should otherwise be withheld from public disclosure.

(b) *Procedures.* A person claiming that information is privileged under paragraph (a) of this section must file:

(1) A written statement requesting privileged treatment for some or all of the information in a document, and the justification for nondisclosure of the information;

(2) The original document, boldly indicating on the front page "Contains Privileged Information—Do Not Release" and identifying within the document the information for which the privileged treatment is sought;

(3) Fourteen copies of the document without the information for which

privileged treatment is sought, and with a statement indicating that information has been removed for privileged treatment;

(4) The name, title, address, telephone number, and telecopy information of the person or persons to be contacted regarding the request for privileged treatment of documents submitted to the Commission.

(c) *Effect of privilege claim.*—(1) *For documents filed with the Commission.* (i) The Secretary of the Commission will place documents for which privileged treatment is sought in accordance with paragraph (b)(2) of this section in a nonpublic file, while the request for confidential treatment is pending. By placing documents in a nonpublic file, the Commission is not making a determination on any claim for privilege. The Commission retains the right to make determinations with regard to any claim of privilege, and the discretion to release information as necessary to carry out its jurisdictional responsibilities.

(ii) The Secretary of the Commission will place the request for privileged treatment described in paragraph (b)(1) of this section and a copy of the original document described in paragraph (b)(3) of this section in a public file, while the request for privilege treatment is pending.

(2) *For documents submitted to Commission staff.* The notification procedures of paragraphs (d) (e) and (f) of this section will be followed by staff before making a document public.

(d) *Notification of request and opportunity to comment.* When a FOIA requester seeks a document for which privilege is claimed, the Commission official who will decide whether to make the document public will notify the person who submitted the document and give the person an opportunity (at least five days) in which to comment in writing on the request. A copy of this notice will be sent to the FOIA requester.

(e) *Notification before release.* Notice of a decision by the Director of the Division of Public Affairs, the Chairman of the Commission, the General Counsel or General Counsel's designee, a presiding officer in a proceeding under Part 385 of this chapter, or any other appropriate official to deny a claim of privilege, in whole or in part, will be given to any person claiming that information is privileged no less than five days before public disclosure. The notice will briefly explain why the person's objections to disclosure are not sustained by the Commission. A copy of this notice will be sent to the FOIA requester.

(f) *Notification of suit in Federal courts.* When a FOIA requester brings suit to compel disclosure of confidential commercial information, the Commission will notify the person who submitted documents containing confidential commercial information of the suit.

[FR Doc. 88-1029 Filed 1-19-88; 8:45 am]

BILLING CODE 6717-01-M

GENERAL SERVICES ADMINISTRATION

41 CFR Part 105-60

Freedom of Information; Uniform Fee Schedule and Administrative Guidelines

AGENCY: Office of Administration, GSA.

ACTION: Final rule.

SUMMARY: The General Services Administration (GSA) has revised its regulations to implement the provisions of the Freedom of Information Reform Act of 1986.

EFFECTIVE DATE: February 19, 1988.

FOR FURTHER INFORMATION CONTACT: Ms. Alexandra Mallus, GSA Freedom of Information Act (FOIA) Officer (202-535-7983).

SUPPLEMENTARY INFORMATION: On October 27, 1986, the President signed the Freedom of Information Reform Act of 1986 (Pub. L. 99-570). This legislation amended the FOIA to provide broader exemption protection for law enforcement information and modified the Act's fee and fee waiver provisions. On June 24, 1987, GSA published a proposed rule revising its FOIA regulations accordingly. The fee provisions conform to the uniform FOIA fee schedule and guidelines promulgated by OMB, 52 FR 10011-20 (March 27, 1987). Fee waiver criteria are derived from the policy guidance issued by the Department of Justice on April 2, 1987. Public comment was invited, with the comment period extending to July 24, 1987. A total of four comments were received concerning the proposed regulations. Three comments came from organizations or individuals representing the media, and one came from an organization that monitors FOIA matters. A discussion of the comments follows.

All of the commenters objected to certain definitions contained in § 105-60.305-1, especially the definitions for "representative of the news media", including "freelance journalist" and "news"; "commercial-use request", and "educational institution." These definitions were taken from the OMB fee guidelines which were made final only after a period of public comment during which concerns such as those raised by these commenters were considered. The statute specifically mandates that agencies follow OMB guidelines in promulgating their own regulations. GSA believes that these definitions properly implement the statutory terms of the amended Act.

All four commenters objected to the fee waiver standards and language under § 105-60.305-5. GSA's fee waiver regulations are derived from the policy guidance issued by the Department of Justice on April 2, 1987. Specific concerns raised are addressed by Justice in its notice of final rulemaking 52 FR 33230-31 (September 2, 1987). GSA has reviewed the Department of Justice's criteria independently and has determined that they are in compliance with the statute and its requirements. Therefore, GSA does not believe it is necessary to revise this section.

In connection with the above, GSA received a comment suggesting that agencies establish automatic fee waivers for certain categories of requesters—public interest organizations, scholars, and journalists. The agency declines to do this, as GSA feels that each case must be decided on its merits under the new law.

In addition, one commenter criticized GSA for suspending time limits until the fee waiver issue is resolved. GSA has modified § 105-60.305-5(b) so that it will begin processing a request if the requester guarantees payment pending the outcome of the fee waiver decision.

Several commenters objected to GSA requiring prepayment of fees of more than $250. The amendments to the Act allow agencies to charge and collect advance payments when "the agency has determined that the fee will exceed $250." Thus, the agency firmly believes that its regulations are fully within the scope of the law. Moreover, the requirement that fees of more than $250 be prepaid is intended to protect the Government from loss of revenue, as has occurred in the past. The agency has revised § 105-60.305-8, however, to offer the requester an opportunity to modify his or her request so as to lower the fee. Another commenter objected to charging twice for the same search if prepayment is not received within 30 days. GSA has deleted this provision. Another commenter questioned GSA's authority to modify or suspend FOIA time limits and recommended deleting the third sentence of this section. GSA's requirement is taken directly from

OMB's guidelines and has not been changed.

One commenter objected to GSA charging for review time where FOIA exemptions would preclude releasing the material and urged that the agency delete the last two sentences of § 105–60.305–7(c). The amendments to the Act allow agencies to charge for the time required to review a document to determine if exemptions apply and whether it is releasable. Furthermore, this language is identical to that in OMB's guidelines; therefore, GSA declines to make these changes.

One commenter objected to GSA's method of calculating the first two hours of free computer search time. GSA's regulations are consistent with OMB's guidelines on this matter.

With regard to § 105–60.305–12(e) on aggregating requests, one commenter suggested that GSA incorporate OMB's wording concerning the prohibition of aggregating requests on unrelated subjects. GSA has revised this section accordingly.

One commenter urged that a provision allowing the requester "to confer with agency personnel with the object of reformulating the request to meet his or her needs at a lower cost" be included under the section on charging for unsuccessful searches. GSA has already taken this into consideration under § 105–60.305–12(d) and § 105–60.305–8.

One commenter objected to the agency taking time extensions for the purposes of consulting with submitters of information. These extensions are consistent with court decisions and the intent of EO 12600, Predisclosure Notification Procedures for Confidential Commercial Information, of June 25, 1987. Hence, GSA does not feel that it is appropriate or proper to delete paragraph (4) from the list of circumstances under which a time extension may be granted (see § 105–60.404(a)).

It has always been GSA's policy to refer records which are the primary responsibility for another agency to that agency for releasability. One commenter objected to this procedure stating that records held from other agencies could probably be released. GSA believes that this is a false assumption and does not intend to change this procedure.

The regulations are revised to:

(a) Update organizational references and eliminate those sections which are the responsibility of the National Archives and Records Administration;

(b) Add various definitions which are to be applied when setting the fees for records requested under the FOIA;

(c) Establish four categories of requesters and specific levels of fees for each of these categories;

(d) Allow GSA to charge a commercial-use requester for the time spent in reviewing records to determine whether they are exempt from disclosure;

(e) Increase the fees for manual searches based on the class and average grade of the employee(s) performing the search;

(f) Provide that requesters subject to search fees, with the exception of commercial-use requesters, not be charged for the first 2 hours of search time;

(g) Raise the dollar amount for which there will be no charge from $5 to $10 and, with certain exceptions, the prepayment threshold from $10 to $250;

(h) Eliminate search fees for educational and noncommercial scientific institutions;

(i) Revise and clarify the general fee waiver standard;

(j) Add several administrative actions which GSA may take to improve the assessment and collection of fees; and

(k) Revise exemption 7 in accordance with the new statutory language concerning protection of law enforcement records and activities.

List of Subjects in 41 CFR Part 105–60

Freedom of information.

41 CFR Part 105–60 is revised to read as follows:

PART 105–60 PUBLIC AVAILABILITY OF AGENCY RECORDS AND INFORMATIONAL MATERIALS

Sec.

Authority: Sec. 205(c) of the Federal Property and Administrative Services Act of 1949, as amended, 63 Stat. 390, 40 U.S.C. 486(c); and 5 U.S.C. 552 (Pub. L. 90–23, as amended by Pub. L. 93–502 and Pub. L. 99–570).

§ 105–60.000 Scope of part.

This part sets forth policies and procedures concerning the availability to the public of records held by the General Services Administration (GSA) with respect to:

(a) Agency organization, functions, decisionmaking channels, and rules and regulations of general applicability,

(b) Agency final opinions and orders, including policy statements and staff manuals,

(c) Operational and other appropriate agency records, and

(d) Agency proceedings.

This part also covers exemptions from disclosure of these records; procedures for the public to inspect and obtain copies of GSA records; and the service of a subpoena or other legal demand with respect to records.

Subpart 105–60.1—General Provisions

§ 105–60.101 Purpose.

Part 105–60 implements the provisions of the Freedom of Information Act, 5 U.S.C. 552 ("FOIA") (Pub. L. 90–23, which codified Pub. L. 89–487 and amended section 3 of the Administrative Procedure Act, formerly 5 U.S.C. 1002

(1964 ed.); Pub. L. 93–502, popularly known as the Freedom of Information Act Amendments of 1974, as amended by Pub. L. 99–570, the Freedom of Information Reform Act of 1986. This part prescribes procedures by which the public may inspect and obtain copies of GSA records under the FOIA.

§ 105–60.102 Application.

This part applies to all records and informational materials generated, maintained, and controlled by GSA which come within the scope of 5 U.S.C. 552.

§ 105–60.103 Policy.

§ 105–60.103–1 Availability of records.

GSA records are available to the greatest extent possible in keeping with the spirit and intent of the FOIA. GSA will furnish them promptly to any member of the public upon request addressed to the office designated in § 105–60.402–1 at fees specified in § 105–60.305–10. The person making the request need not have a particular interest in the subject matter, nor must that person provide justification for the request. The requirement of the FOIA that records be available to the public refers only to records in being at the date of the request and imposes no obligation on GSA to compile a record including development of a new computer program to respond to a request.

§ 105–60.103–2 Applying exemptions.

GSA may deny a request for a GSA record if it falls within an exemption under the FOIA as outlined in Subpart 105–60.5. Except when a record is classified or when disclosure would violate any Federal statute, the authority to withhold a record from disclosure is permissive rather than mandatory. GSA will not withhold a record unless there is a compelling reason to do so. In the absence of a compelling reason, GSA will disclose a record although it otherwise is subject to exemption.

§ 105–60.104 Records of other agencies.

If GSA receives a request to make available current records that are the primary responsibility of another agency, GSA will refer the request to the agency concerned for appropriate action. GSA will inform the requester that GSA has forwarded the request to the responsible agency.

§ 105–60.105 Inconsistent directives of GSA superseded.

Any policies and procedures in any GSA directive that are inconsistent with the policies and procedures set forth in this part are superseded to the extent of that inconsistency.

Subpart 105–60.2—Publication of General Agency Information and Rules in the Federal Register.

§ 105–60.201 Published information and rules.

In accordance with 5 U.S.C. 552(a)(1), GSA publishes in the **Federal Register**, for the guidance of the public, the following general information concerning GSA:

(a) Description of the organization of the Central Office and regional offices and the established places at which, the employees from whom, and the methods whereby, the public may obtain information, make submittals or requests, or obtain decisions;

(b) Statements of the general course and method by which its functions are channeled and determined, including the nature and requirements of all formal and informal procedures available;

(c) Rules of procedure, descriptions of forms available or the places where forms may be obtained, and instructions on the scope and contents of all papers, reports, or examinations;

(d) Substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by GSA; and

(e) Each amendment, revision, or repeal of the materials described in § 105–60.201.

§ 105–60.202 Published materials available for sale to the public.

Substantive rules of general applicability adopted by GSA as authorized by law which this agency publishes in the **Federal Register** and which are available for sale to the public are: The General Services Administration Acquisition Regulation (48 CFR Ch. 5) and the Federal Acquisition Regulation (48 CFR Ch. 1); the Federal Property Management Regulations (41 CFR Ch. 101) and the Federal Information Resources Management Regulations (41 CFR Ch. 201). These regulations are available for sale by the Superintendent of Documents in

(a) Daily **Federal Register** form; and

(b) Code of Federal Regulations form, at prices established by the Government Printing Office.

Subpart 105–60.3—Availability of Opinions, Orders, Policies, Interpretations, Manuals, and Instructions

§ 105–60.301 General.

GSA makes available for public inspection and copying the materials described under 5 U.S.C. 552(a)(2), which are listed in § 105–60.302, and an Index of those materials as described in § 105–60.304, at convenient locations and times. Central Office materials are located in Washington, DC; some are also available at GSA regional offices. Each regional office has the materials for its region. All locations provide selected areas for the inspection and copying of documents. Reasonable copying services are furnished at the fees specified in § 105–60.305.

§ 105–60.302 Available materials.

GSA materials available under Subpart 105–60.3 are as follows:

(a) Final opinions, including concurring and dissenting opinions and orders, made in the adjudication of cases.

(b) Those statements of policy and interpretations which have been adopted by GSA and are not published in the **Federal Register.**

(c) Administrative staff manuals and instructions to staff affecting a member of the public unless these materials are promptly published and copies offered for sale.

§ 105–60.303 Rules for public inspection and copying.

(a) *Locations.* Selected areas containing the materials available for public inspection and copying, described in § 105–60.302, are located in the following places:

Central Office

(GSA Headquarters), Washington, DC. Telephone: 202–535–7788

General Services Administration, 18th and F Streets NW., Library (Room 1033), Washington, DC 20405

Region 1

Boston, Massachusetts (Comprising the States of Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont). Telephone: 617–565–8100

Business Service Center, General Services Administration (2SB–1), Thomas P. O'Neill, Jr., Federal Building, 10 Causeway Street, Boston, MA 02222

Region 2

New York, New York (Comprising the States of New Jersey, New York, the Commonwealth of Puerto Rico, and the Virgin Islands). Telephone 212–264–1234

Business Service Center, General Services Administration (2SB), 26 Federal Plaza, New York, NY 10278

Region 3

Philadelphia, Pennsylvania (Comprising the States of Delaware, Maryland, Pennsylvania, Virginia, and West Virginia). Telephone: 215–597–9613

Business Service Center, General Services Administration (3SB), Ninth and Market Streets, Room 5151, Philadelphia, PA 19107

Region 4

Atlanta, Georgia (Comprising the States of Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, and Tennessee). Telephone: 404–331–5103

Business Service Center, General Services Administration (4SB), Richard B. Russell Federal Building, U.S. Courthouse, 75 Spring Street, SW, Room 318, Atlanta, GA 30303

Region 5

Chicago, Illinois (Comprising the States of Illinois, Indiana, Michigan, Ohio, Minnesota, and Wisconsin). Telephone: 312–353–5383

Business Service Center, General Services Administration (5SB), 230 South Dearborn Street, Chicago, IL 60604

Region 6

Kansas City, Missouri (Comprising the States of Iowa, Kansas, Missouri, and Nebraska). Telephone: 816–926–7203

Business Service Center, General Services Administration (6SB), 1500 East Bannister Road, Kansas City, MO 64131

Region 7

Fort Worth, Texas (Comprising the States of Arkansas, Louisiana, New Mexico, Texas, and Oklahoma). Telephone: 817–334–3284

Business Service Center, General Services Administration (7SB), 819 Taylor Street, Room 11A05, Fort Worth, TX 76102

Region 8

Denver, Colorado (Comprising the States of Colorado, North Dakota, South Dakota, Montana, Utah, and Wyoming). Telephone: 303–236–7409

Business Service Center, General Services Administration (7SB–8), Building 41, Denver Federal Center, Room 145, Denver, CO 80225

Region 9

San Francisco, California (Comprising the States of Hawaii, California, Nevada, and Arizona). Telephone: 415–974–0523

Business Service Center, General Services Administration (9SB), 525 Market Street, San Francisco, CA 94105

Region 10

Seattle, Washington (Comprising the States of Alaska, Idaho, Oregon, and Washington). Telephone: 206–931–7956

Business Service Center, General Services Administration (9SB–10), GSA Center, 15th and C Streets, SW, Room 2413, Auburn, WA 98001

National Capital Region

Washington, DC (Comprising the District of Columbia and the metropolitan area). Telephone: 202–472–1804

Business Service Center, General Services Administration (WSB), Seventh and D Streets, SW, Room 1050, Washington, DC 20407

(b) *Time.* The reading rooms or selected areas will be open to the public during the business hours of the GSA office where they are located.

(c) *Copying.* GSA will furnish reasonable copying services at fees specified in § 105–60.305.

(d) *Reading room and selected area rules*—(1) *Age.* GSA will not give permission to inspect materials to a person under 16 years old unless accompanied by an adult who agrees to remain with the minor while the minor uses the materials.

(2) *Handling of materials.* The removal or mutilation of materials is forbidden by law and is punishable by fine or imprisonment or both. When requested by a reading room or selected area attendant, a person inspecting materials must present for examination any briefcase, handbag, notebook, package, envelope, book, or other article that could contain GSA informational materials.

(3) *Reproduction services.* The GSA Central Office Library or the Regional Business Service Centers will furnish "reasonable reproduction" services for available materials at the fees specified in § 105–60.305.

§ 105–60.304 Index.

GSA will maintain and make available for public inspection and copying current indexes arranged by subject matter providing identifying information for the public regarding any matter issued, adopted, or promulgated after July 4, 1967, and described in § 105–60.302.

§ 105–60.305 Fees.

§ 105–60.305–1 Definitions.

For the purpose of these regulations:

(a) A statute specifically providing for setting the level of fees for particular types of records (5 U.S.C. 552(a)(4)(A)(vi)) means any statute that specifically requires (as opposed to generally discussing) a Government agency to set the level of fees for particular types of records, in order to:

(1) Serve both the general public and private sector organizations by conveniently making available Government information;

(2) Ensure that groups and individuals pay the cost of publications and other services which are for their special use so that these costs are not borne by the general taxpaying public;

(3) Operate an information dissemination activity on a self-sustaining bases to the maximum extent possible; or

(4) Return revenue to the Treasury for defraying, wholly or in part, appropriated funds used to pay the cost of disseminating Government information.

(b) The term "direct costs" means those expenditures which GSA actually incurs in searching for and duplicating (and in the case of commercial requesters, reviewing) documents to respond to a FOIA request. Direct costs include, for example, the salary of the employee performing the work (the basic rate of pay for the employee plus 16 percent of that rate to cover benefits), and the cost of operating duplicating machinery. Not included in direct cost are overhead expenses such as costs of space, and heating or lighting the facility where the records are stored.

(c) The term "search" includes all time spent looking for material that is responsive to a request, including line-by-line identification of material within documents. Searches will be performed in the most efficient and least expensive manner so as to minimize costs for both the agency and the requester. Line-by-line searches will not be undertaken when it would be more efficient to duplicate the entire document. Such activity will be distinguished from "review" of material in determining whether the material is exempt from disclosure (see subparagraph e, below). Searches may be done manually or by computer using existing programming.

(d) The term "duplication" refers to the process of making a copy of a document in response to a FOIA request. Such copies can take the form of paper, microform, audiovisual materials, or machine-readable documentation. GSA will provide a copy of the material in a form that is usable by the requester unless it is administratively burdensome to do so.

(e) The term "review" refers to the process of examining documents located in response to request that is for commercial use (see paragraph (f) of this section) to determine if any portion of that document is permitted to be withheld and processing any documents for disclosure. See § 105–60.305–7.

(f) The term "commercial-use request" refers to a request from or on behalf of one who seeks information for a use or purpose that furthers the commercial, trade, or profit interests of the requester or person on whose behalf the request is made. In determining whether a

requester properly belongs in this category, GSA will look first at how the requester will use the documents.

(g) The term "educational institution" refers to a preschool, a public or private elementary or secondary school, an institution of graduate higher education, an institution of undergraduate higher education, an institution of professional education, and an institution of vocational education, which operates a program or programs of scholarly research.

(h) The term "noncommercial scientific institution" refers to an institution that is not operated on a "commercial" basis as that term is referenced in paragraph (f) of this section and which is operated solely for the purpose of conducting scientific research the results of which are not intended to promote any particular product or industry.

(i) The term "representative of the news media" refers to any person actively gathering news for an entity that is organized and operated to publish or broadcast news to the public. The term "news" means information that is about current events or that would be of current interest to the public. Examples of news media include television or radio stations broadcasting to the public at large, and publishers of periodicals (but only in those instances when they can qualify as disseminators of "news") who make their products available for purchase or subscription by the general public. In the case of "freelance" journalists, they may be regarded as working for a news organization if they can demonstrate a solid basis for expecting publication through that organization, even though not actually employed by it.

§ 105-60.305-2 Scope of section.

This section sets forth policies and procedures to be followed in the assessment and collection of fees from a requester for the search, review, and reproduction of GSA records.

§ 105-60.305-3 Record material available without charge.

GSA records available to the public are displayed in the business service center for that region. Certain material related to bids (excluding construction plans and specifications) and any material displayed are available without charge upon request.

§ 105-60.305-4 Copy of GSA records available at a fee.

GSA will make a record not subject to exemption available at a time and place mutually agreed upon by GSA and the requester. GSA will agree either to

(a) Show the originals to the requester,

(b) Make one copy available at a fee, or

(c) A combination of these alternatives.

In the case of voluminous materials, GSA will make copies as quickly as possible. GSA may make a reasonable number of additional copies for a fee when commercial reproduction services are not available to the requester.

§ 105-60.305-5 Waiver of fee.

(a) Any request for waiver or reduction of a fee should be included in the initial letter requesting access to GSA records under § 105-60.402-1. The waiver request should explain how disclosure of the information would contribute significantly to public understanding of the operations or activities of the Government and would not be primarily in the commercial interest of the requester. In responding to a request GSA will consider the following factors:

(1) Whether the subject of the requested records concerns "the operations or activities of the Government." The subject matter of the requested records must specifically concern identifiable operations or activities of the Federal Government—with a connection between them that is direct and clear, not remote or attenuated.

(2) Whether the disclosure is "likely to contribute" to an understanding of Government operations or activities. In this connection, GSA should consider whether the requested information is already in the public domain, either in a duplicative or a substantially identical form. If it is, then disclosure of the information would not be likely to contribute to an understanding of Government operations or activities, as nothing new would be added to the public record.

(3) Whether disclosure of the requested information will contribute to "public understanding." The focus here must be on the contribution to public understanding, rather than personal benefit to be derived by the requester. For purposes of this analysis, the identity and qualifications of the requester should be considered, to determine whether the requester is in a position to contribute to public understanding through the requested disclosure.

(4) Whether the requester has a commercial interest that would be furthered by the requested disclosure; and if so

(5) Whether the magnitude of the identified commercial interest of the requester is sufficiently large, in comparison with the public interest in disclosure, that disclosure is "primarily in the commercial interest of the requester."

(b) If the initial request provides insufficient information for the agency to evaluate the request, GSA may ask the requester to furnish additional information. GSA will not start processing a request until the fee waiver issue has been resolved, unless the requester has provided written assurance of payment in full if the fee waiver is denied by the agency.

§ 105-60.305-6 Searches.

(a) GSA may charge for the time spent in the following activities in determining "search time" subject to applicable fees as provided in § 105-60.305-10:

(1) Time spent in trying to locate GSA records which come within the scope of the request;

(2) Time spent in either transporting a necessary agency searcher to a place of record storage, or in transporting records to the locations of a necessary agency searcher; and

(3) Direct costs involving the use of computer time to locate and extract requested records.

(b) GSA will not charge for the time spent in monitoring a requester's inspection of disclosed agency records.

§ 105-60.305-7 Reviews.

(a) GSA may charge for the time spent in the following activities in determining "review time" subject to applicable fees as provided in § 105-60.305-10:

(1) Time spent in examining a requested record to determine whether the record is permitted to be withheld in whole or in part; and

(2) Time spent in deleting exempt matter being withheld from records otherwise made available.

(b) GSA will not charge for the time spent in resolving issues of law or policy regarding the application of exemptions.

(c) GSA may not charge for review at the administrative appeal level of an exemption already applied. However, records or portions of records withheld in full under an exemption which is subsequently determined not to apply may be reviewed again to determine the applicability of other exemptions not previously considered. The costs for such a subsequent review would be properly assessable.

(d) GSA will charge only commercial-use requesters for review time.

§ 105-60.305-8 Prepayment of fees over $250.

GSA will require prepayment of fees for search, review, and reproduction which are likely to exceed $250. When the anticipated total fee exceeds $250, the requester will receive notice to prepay and at the same time will be given an opportunity to modify his or her request to reduce the fee. GSA will also inform the requester that fees for search time will be charged even if the search proves unsuccessful. GSA will not start processing a request until payment is received.

§ 105-60.305-9 Form of payment.

Requesters should pay fees by check or money order made out to the General Services Administration and addressed to the official named by GSA in its correspondence.

§ 105-60.305-10 Fee schedule.

(a) When GSA is aware that documents responsive to a request are maintained for distribution by an agency operating a statutory fee based program, GSA will inform the requester of the procedures for obtaining records from those sources.

(b) In computing applicable fees, GSA will consider only the following costs in providing the requester records:

(1) *Review and search fees.*

Manual searches by clerical staff.	$9 per hour or fraction of an hour.
Manual searches and reviews by professional staff in cases in which clerical staff would be unable to locate the requested records.	$18 per hour or fraction of an hour.
Computer searches	Direct cost to GSA.
Transportation or special handling of records.	Direct cost to GSA.

(2) *Reproduction fees.*

Pages no larger than 8½ by 14 inches, when reproduced by routine electrostatic copying.	$0.10 per page.
Pages over 8½ by 14 inches.	Direct cost of reproduction to GSA.
Pages requiring reduction, enlargement, or other special services.	Direct cost of reproduction to GSA.
Reproduction by other than routine electrostatic copying.	Direct cost of reproduction to GSA.

(c) Any fees not provided for under paragraph (b) of this section, shall be calculated in accordance with § 105-60.305-1(b).

(d) Categories of requesters. There are four categories of requesters: Commercial-use; educational and noncommercial scientific institutions; news media; and all other. The fees listed above apply with the following exceptions:

(1) GSA will not charge the requester if the fee is $10 or less as the cost of collection would be greater than the fee.

(2) Educational and noncommercial scientific institutions and the news media will be charged for the cost of reproduction alone. These requesters are entitled to the first 100 pages (paper copies) of duplication at no cost. The following are examples of how these fees are calculated.

(i) A request that results in 150 pages of material. No fee would be assessed for duplication of 150 pages. The reason is that these requesters are entitled to the first 100 pages at no charge. The charge for the remaining 50 pages would be $5. This amount would not be billed under the preceding section.

(ii) A request that results in 250 pages of material. The requester in this case would be charged $15.

(3) Noncommercial requesters who are not included under (2), above, will be entitled to the first 100 pages (paper copies) of duplication at no cost and 2 hours of search without charge. The term "search time" in this context has as its basis, manual search. To apply this term to searches made by computer, GSA will determine the hourly cost of operating the central processing unit and the operator's hourly salary plus 16 percent. When the cost of search (including the operator time and the cost of operating the computer to process a request) equals the equivalent dollar amount of two hours of the salary of the person performing the search, i.e., the operator, GSA will begin assessing charges for computer search.

(4) GSA will charge commercial-use requesters fees which recover the full direct costs of searching for, reviewing for release, and duplicating the records sought. Commercial-use requesters are not entitled to 2 hours of free search time.

(e) Determining category of requester. GSA may ask the requester to provide additional information at any time to determine what fee category he or she falls under. This applies to all requesters.

§ 105-60.305-11 Fees for authenticated and attested copies.

The fees set forth in § 105-60.305-10 apply to requests for authenticated and attested copies of GSA records.

§ 105-60.305-12 Administrative actions to improve assessment and collection of fees.

(a) *Charging interest.* GSA may charge requesters who fail to pay fees interest on the amount billed starting on the 31st day following the day on which the billing was sent. Interest will be at the rate prescribed in 31 U.S.C. 3717.

(b) *Effect of the Debt Collection Act of 1982.* GSA will take any action authorized by the Debt Collection Act of 1982 (Pub. L. 97-365), including disclosure to consumer reporting agencies, use of collection agencies, and assessment of penalties and administrative costs, where appropriate, to encourage payment.

(c) *Charges for unsuccessful search.* The agency may assess charges for time spent searching for the records even if the agency fails to locate the records or if the records located are exempt from disclosure.

(d) *Notifying requester of charges over $25.* If charges are likely to exceed $25, GSA will notify the requester and obtain, in writing, assurance of the requester's willingness to pay the estimated fee. The requester shall also be offered an opportunity to modify his or her request to reduce the fee. GSA will not start processing the request until assurance of payment is received.

(e) *Aggregating requests.* When the agency reasonably believes that a requester, or group of requesters acting in concert, is attempting to break a request down into a series of requests related to the same subject for the purpose of evading the assessment of fees, GSA will combine any such requests and charge accordingly, including fees for previous requests where charges were not assessed. GSA will presume that multiple requests of this type made within a 30-day period are made to avoid fees.

(f) *Advance payments.* (1) See § 105-60.305-8 regarding prepayment of fees for FOIA requests.

(2) Where a requester has previously failed to pay a fee charged in a timely fashion (i.e., within 30 days of the date of the billing), GSA will require the requester to pay the full amount owed plus any applicable interest penalties and administrative costs as provided above, or demonstrate that he or she has, in fact, paid the fee, and to make an advance payment of the full amount of the estimated fee before the agency

begins to process a new request or a pending request from that requester.

(3) If GSA acts under paragraphs (f)(1) and (2) of this section, the administrative time limits in subsection (a)(6) of the FOIA (i.e., 10 working days from receipt of initial requests and 20 working days from receipt of appeals form initial denial plus permissible time extensions) will begin only after it has received the fee payments described above.

Subpart 105-60.4—Described Records

§ 105-60.401 General.

(a) Except for records made available in accordance with Subparts 105-60.2 and 105-60.3, GSA will make records available to a requester promptly when the request reasonably describes the records unless GSA invokes an exemption in accordance with Subpart 105-60.5. Although the burden of reasonable description of the records rests with the requester, GSA will assist in identification.

(b) Upon receipt of a request that does not reasonably describe the records requested, GSA may contact the requester to seek a more specific description. The 10-workday time limit set forth in § 105-60.402-2 will not start until the official identified in § 105-60.402-1 receives a request reasonably describing the records.

§ 105-60.402 Procedures for making records available.

This section sets forth initial procedures for making records available when they are requested.

§ 105-60.402-1 Submission of requests.

For records located in the GSA Central Office, the requester should submit a request in writing to the GSA FOIA Officer, General Services Administration (CAIR), Washington, DC 20405. For records located in the GSA regional offices, the requester should submit a request to the FOIA Officer for the relevant region, at the address listed in § 105-60.303(a), with the exception of Region 9. Requests for Region 9 should be sent to the following address: General Services Administration (9AA), 525 Market St., 28th Floor, San Francisco, CA 94105. Requests should include the words "Freedom of Information Act Request" prominently marked on both the face of the request letter and the envelope. The 10-workday time limit for agency decisions set forth in § 105-60.402-2 begins with receipt of a request in the office of the appropriate official identified in this section, unless the provisions under § 105-60.305-12(d) and (f) apply. Failure to include the words "Freedom of Information Act Request" or to sumbit a request to the official identified in this section will result in processing delays. A requester who has questions concerning an FOIA request may consult the GSA FOIA Officer, General Services Administration (CAIR), 18th and F Streets, NW., Washington, DC 20405, (202) 535-7983.

§ 105-60.402-2 Response to initial requests.

GSA will respond to an initial FOIA request within 10 workdays (that is, excluding Saturdays, Sundays, and legal public holidays) after receipt of a request by the office of the appropriate official specified in § 105-60.402-1. This letter should state the agency's decision with respect to disclosure or nondisclosure of the requested records. If the records to be disclosed are not provided with the initial letter, the records will be sent as soon as possible thereafter. In unusual circumstances, GSA will inform the requester of the agency's need to take an extension of time.

§ 105-60.403 Appeal within GSA.

(a) A requester who receives a denial of a request, in whole or in part, may appeal that decision within GSA. The requester must direct the appeal to the GSA FOIA Officer, General Services Administration (CAIR), Washington, DC 20405, regardless of whether the denial being appealed was made in the Central Office or in a regional office.

(b) The GSA FOIA Officer must receive an appeal no later than 30 calendar days after receipt by the requester of the initial denial of access.

(c) The requester must appeal in writing and include a brief statement of the reasons he or she thinks GSA should release the records and enclose copies of the initial request and denial. The appeal letter should include the words "Freedom of Information Act Appeal" on both the face of the appeal letter and on the envelope. Failure to follow these procedures will delay processing of the appeal. GSA has 20 workdays after receipt of an appeal to make a determination with respect to the appeal. The 20-workday time limit shall not begin until the GSA FOIA Officer receives the appeal.

(d) A requester who has received a denial of an appeal may seek judicial review of GSA's decision in the United States District Court in the district in which the requester resides or has a principal place of business, or where the records are situated, or in the United States District Court for the District of Columbia.

§ 105-60.404 Extension of time limits.

(a) In unusual circumstances, the GSA FOIA Officer or the regional FOIA Officer may extend the time limits prescribed in §§ 105-60.402 and 105-60.403. For purposes of this section, the term "unusual circumstances" means:

(1) The need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the request;

(2) The need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request;

(3) The need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request or among two or more components of the agency having substantial subject-matter interest therein; or

(4) The need to consult with the submitter of the requested information.

(b) If necessary, more than one extension of time may be taken. However, the total extension of time shall not exceed 10 workdays with respect to a particular request. The extension may be divided between the initial and appeal stages or within a single stage. GSA will provide a written notice to the requester of any extension of time limits.

Subpart 105-60.5—Exemptions

§ 105-60.501 Categories of records exempt from disclosure under the FOIA.

(a) 5 U.S.C. 552(b) provides that the requirements of the FOIA do not apply to matters that are:

(1) Specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy and that are, in fact, properly classified under the Executive order;

(2) Related solely to the internal personnel rules and practices of an agency;

(3) Specifically exempted from disclosure by statute, other than the Government in the Sunshine Act, provided that the statute (i) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue of (ii) establishes particular criteria for withholding or refers to particular types of matters to be withheld;

(4) Trade secrets and commercial or financial information obtained from a person that are privileged or confidential;

(5) Interagency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency;

(6) Personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy;

(7) Records or information compiled for law enforcement purposes, but only to the extent that the production of such law enforcement records or information:

(i) Could reasonably be expected to interfere with enforcement proceedings;

(ii) Would deprive a person of a right to a fair trial or an impartial adjudication;

(iii) Could reasonably be expected to constitute an unwarranted invasion of personal privacy;

(iv) Could reasonably be expected to disclose the identity of a confidential source, including a State, local, or foreign agency or authority or any private institution which furnished information on a confidential basis, and, in the case of a record or information compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, information furnished by a confidential source;

(v) Would disclose techniques and procedures for law enforcement investigations or prosecutions, or would disclose guidelines for law enforcement investigations or prosecutions if such disclosure could reasonably be expected to risk circumvention of the law; or

(vi) Could reasonably be expected to endanger the life or physical safety of any individual.

(8) Contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions; and

(9) Geological and geophysical information and data, including maps, concerning wells.

(b) GSA will provide any reasonably segregable portion of a record to a requester after deletion of the portions that are exempt under this section.

(c) GSA will invoke no exemption under this section to deny access to records that would be available pursuant to a request made under the Privacy Act of 1974 and implementing regulations, Part 105–64, or if disclosure would cause no demonstrable harm to any public or private interest.

(d) Whenever a request is made which involves access to records described in § 105–60.501(a)(7)(i) and

(1) The investigation or proceeding involves a possible violation of criminal law, and

(2) There is reason to believe that (i) the subject of the investigation or proceeding is not aware of its pendency, and (ii) disclosure of the existence of the records could reasonably be expected to interfere with enforcement proceedings, the agency may, during only such time as that circumstance continues, treat the records as not subject to the requirements of this section.

(e) Whenever informant records maintained by a criminal law enforcement agency under an informant's name or personal identifier are requested by a third party according to the informant's name or personal identifier, the agency may treat the records as not subject to the requirements of this section unless the informant's status as an informant has been officially confirmed.

(f) Whenever a request is made which involves access to records maintained by the Federal Bureau of Investigation pertaining to foreign intelligence or counterintelligence, or international terrorism, and the existence of the records is classified information as provided in paragraph (a)(1) of this section, the Bureau may, as long as the existence of the records remains classified information, treat the records as not subject to the requirements of this section.

Subpart 105–60.6—Subpoenas or Other Legal Demands for Records

§ 105–60.601 Service of subpoena or other legal demand.

(a) A subpoena duces tecum or other legal demand for the production of records held by GSA should be addressed to the General Counsel, General Services Administration (L), Washington, DC 20405, with respect to GSA Central office records; to the appropriate Regional Counsel, for records in GSA regional offices; or to the Administrator of General Services.

(b) The Administrator, the General Counsel, Deputy General Counsels, Associate General Counsels, the Chairman of the Board of Contract Appeals, Inspector General, and, with respect to records in a GSA regional office, the Regional Administrator and Regional Counsel are the only GSA employees authorized to accept service of a subpoena duces tecum or other legal demand on behalf of GSA.

Dated: December 21, 1987.

Paul Trause,

Acting Administrator of General Services.

[FR Doc. 88–601 Filed 1–19–88; 8:45 am]

BILLING CODE 6820–61–M

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 64

[Docket No. FEMA 6772]

List of Communities Eligible for the Sale of Flood Insurance

AGENCY: Federal Emergency Management Agency.

ACTION: Final rule.

SUMMARY: This rule lists communities participating in the National Flood Insurance Program (NFIP). These communities have applied to the program and have agreed to enact certain floodplain management measures. The communities' participation in the program authorizes the sale of flood insurance to owners of property located in the communities listed.

EFFECTIVE DATES: The dates listed in the third column of the table.

ADDRESS: Flood insurance policies for property located in the communities listed can be obtained from any licensed property insurance agent or broker serving the eligible community, or from the National Flood Insurance Program (NFIP) at: P.O. Box 457, Lanham, Maryland 20706, Phone: (800) 638–7418.

FOR FURTHER INFORMATION CONTACT:

Frank H. Thomas, Assistant Administrator, Office of Loss Reduction, Federal Insurance Administration, (202) 646–2717, Federal Center Plaza, 500 C Street, Southwest, Room 416, Washington, DC 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 floodplain management measures aimed at protecting lives and new construction from future flooding. Since the communities on the attached list have recently entered the NFIP, subsidized flood insurance is now available for property in the community.

In addition, the Director of the Federal Emergency Management Agency has identified the special flood hazard areas in some of these communities by publishing a Flood Hazard Boundary Map. The date of the flood map, if one has been published, is indicated in the fourth column of the table. In the communities listed where a flood map has been published, section 102 of the Flood Disaster Protection Act of 1973, as amended, requires the purchase of flood

insurance as a condition of Federal or federally related financial assistance for acquisition or construction of buildings in the special flood hazard area shown on the map.

The Director finds that the delayed effective dates would be contrary to the public interest. The Director also finds that notice and public procedure under 5 U.S.C. 553(b) are impracticable and unnecessary.

The Catalog of Domestic Assistance Number for this program is 83.100 "Flood Insurance."

Pursuant to the provisions of 5 U.S.C. 605(b), the Administrator, Federal Insurance Administration, 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. This rule provides routine legal notice stating the community's status in the NFIP and imposes no new requirements or regulations on participating communities.

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

PART 64—[AMENDED]

1. The authority citation for Part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 et seq., Reorganization Plan No. 3 of 1978, E.O. 12127.

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

In each entry, a complete chronology of effective dates appears for each listed community. The entry reads as follows:

§ 64.6 List of eligible communities.

State and location	Community No.	Effective dates of authorization/cancellation of sale of flood insurance in community	Current effective map date
Pennsylvania:			
Hegins, Township of, Schuylkill County.[1]	422008	July 15, 1975, Emerg.; Sept. 1, 1986, Reg.; Sept. 1, 1986, Susp.; Dec. 9, 1987, Rein.	Sept. 1, 1986.
Middlebury, Township of, Tioga County.[1]	421179	Aug 21, 1987, Emerg.; July 1, 1987, Reg.; July 1, 1987, Susp.; Dec. 9, 1987, Rein.	July 1, 1987.
Mt. Pleasant, Borough of, Westmoreland County.[1]	422181	July 7, 1975, Emerg.; Feb. 1, 1987, Reg.; Feb. 1, 1987, Susp.; Dec. 9, 1987, Rein.	Feb. 1, 1987.
Vermont:			
Dorset, Town of, Bennington County.[1]	500014	July 29, 1975, Emerg.; Sept. 24, 1976, Reg.; Aug. 1, 1986, Susp.; Dec. 10, 1987, Rein.	Aug. 1, 1986.
Woodford, Town of, Bennington County.[1]	500023	Nov. 13, 1975, Emerg.; Sept. 18, 1985, Reg.; June 3, 1986, Susp.; Dec. 10, 1987, Rein.	Sept. 18, 1986.
North Dakota: Stafford, Township of, Renville County.[1]	380306	Feb., 17, 1976, Emerg.; Mar. 1, 1987, Reg.; Dec. 2, 1987, Withdrawn.	Mar. 1,1987.
Michigan: Evart, Township of, Osceola County.[2]	[2] 260810	Dec. 10, 1987, Emerg	
Texas: Walnut Springs, City of, Bosque County	480713	Dec. 10, 1987, Emerg	Oct. 1,1976.
Tennessee: Hawkins County, Unincorporated Areas.	470085	Dec. 11, 1987, Emerg	Oct. 21,1977.
Nebraska: Dunning, Village of, Custer County.[1]	310007	Oct. 25, 1977, Emerg.; July 1, 1987, Reg.; July 1, 1987, Susp.; Dec. 2, 1987, Rein.	July. 1, 1987.
Oregon: Prescott, City of, Columbia County	410037	Dec. 17, 1987, Emerg.	Jan. 10,1975.
Texas: Hackberry, Town of, Denton County[2]	[2] 481607	Dec. 17, 1987, Emerg.	
North Carolina: Alamance, Village of, Alamance County.[3]	370457	Dec. 17, 1987, Emerg.; Dec. 17, 1987, Reg	
Louisiana: Winnfield, City of, Winn County	220247	Aug. 4, 1975, Emerg.; July 1, 1987, Reg.; July 1, 1987, Susp.; Aug. 25, 1987, Rein.	July 1, 1987.
Pennsylvania:			
Oakland, Township of, Venango County.[1]	422111	Feb 28, 1977, Emerg.; Feb. 1, 1987, Reg.; Feb. 1, 1987, Susp.; Dec. 21, 1987, Rein.	Feb. 1, 1987.
Perry, Township of, Lawrence County.[1]	421796	July 24, 1975, Emerg.; Nov. 1, 1986, Reg.; Dec. 18, 1986, Susp.; Dec. 21, 1987, Rein.	Nov. 1, 1986.
Iowa: Ellsworth, City of, Hamilton County.[1]	190136	Dec. 29, 1975, Emerg.; Aug. 1,1987, Reg.; Aug. 1, 1987, Susp.; Dec. 21, 1987, Rein.	Aug. 1,1987.
Louisiana: Killian, Village of, Livington Parish.[1]	220355	Oct. 26, 1977, Emerg.; Aug. 1, 1987, Reg.; Aug. 1, 1987, Susp.; Dec. 29, 1987, Rein.	Do.
Region I—Minimal Conversions			
Massachusetts: New Salem, Town of, Franklin County.	250123	Dec. 1, 1987, Suspension Withdrawn	Dec. 1, 1987.
Region II			
New York: Amsterdam, Town of, Montgomery County.	360441	.....do	Do.
Region III			
Pennsylvania: Roseto, Borough of, Northampton County.	422255	.....do	Do.
Region I—Regular Conversions			
Connecticut:			
Norfolk, Town of, Litchfield County	090181	Dec. 3, 1987, Suspension Withdrawn	Dec. 3, 1987.
Roxbury, Town of, Litchfield County	090051	.....do	Do.
Maine: Eastport, City of, Washington County	230137	.....do	Do.

State and location	Community No.	Effective dates of authorization/cancellation of sale of flood insurance in community	Current effective map date
Region III			
Pennsylvania:			
Lack, Township of, Juniata County	421742	.....do	Do.
West Perry, Township of, Snyder County	422042	.....do	Do.
Region IV			
Kentucky: Whitesburg, City of, Letcher County	210140	.....do	Do.
Region V			
Michigan: Sebewaing, Village of, Huron County	260572	.....do	Do.
Region VII			
Missouri: Chariton County, Unincorporated Areas.	290073	.....do	Do.
Region II—Regular Conversions			
New York:			
Varick, Town of, Seneca County	360758	December 17, 1987, Suspension Withdrawn	Dec. 17, 1987.
Youngstown, Village of, Niagara County	360515	.....do	Do.
Region IV—			
Alabama:			
Carbon Hill, City of, Walker County	010204	.....do	Do.
Childersburg, City of, Talladega County	010197	.....do	Do.
Demopolis, City of, Marengo County	010157	.....do	Do.
Jackson, City of, Clarke County	010040	.....do	Do.
Stevenson, City of, Jackson County	010113	.....do	Do.
Sylacauga, City of, Talladega County	010199	.....do	Do.
Vernon, City of, Lamar County	010139	.....do	Do.
Region V			
Michigan:			
Hamlin, Township of, Mason County	260134	.....do	Do.
Summit, Township of, Mason County	260307	.....do	Do.
Region VIII			
Montana: Lake County, Unincorporated Areas	300155	.....do	Do.

[1] Minimals.
[2] New.
[3] The Village of Alamance has adopted by reference Alamance County's Study and FIRM for floodplain management and insurance purposes. Alamanace County's FIRM Date is Dec. 1, 1981.
Code for reading fourth column: Emerg.—Emergency; Reg.—Regular; Susp.—Suspension; Rein.—Reinstatement.

Issued: January 14, 1988.

Harold T. Duryee,

Administrator, Federal Insurance Administration.

[FR Doc. 88-994 Filed 1-19-88; 8:45 am]

BILLING CODE 6718-03-M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 33

Refuge-Specific Fishing Regulations

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: The Fish and Wildlife Service (Service) is amending certain regulations in 50 CFR Part 33 that pertain to fishing on individual national wildlife refuges (NWR). Refuge fishing programs are reviewed annually to determine whether the regulations governing fishing on individual refuges should be modified. Changing environmental conditions, State and Federal regulations and other factors affecting fish populations and habitats may warrant such amendments. The modifications will ensure the continued compatibility of fishing with the purposes for which the individual refuges involved were established, and to the extent practical, make refuge fishing programs consistent with State regulations.

EFFECTIVE DATE: February 19, 1988.

FOR FURTHER INFORMATION CONTACT: David E. Heffernan, Division of Refuges, Fish and Wildlife Service, 18th and C Streets NW., Washington, DC 20240; Telephone 202-343-1014.

SUPPLEMENTARY INFORMATION: 50 CFR Part 33 contains the provisions that govern fishing on NWRs. Fishing is regulated on refuges to: (1) Ensure compatibility with refuge purposes, (2) properly manage the fishery resource and (3) protect other refuge values. On many refuges, the Service policy of adopting State fishing regulations is an adequate way of meeting these objectives. On other refuges it is necessary to supplement State regulations with refuge-specific fishing regulations which will ensure that the Service meets its management responsibilities, as outlined under the section entitled "Conformance with Statutory and Regulatory Authorities." Refuge-specific fishing regulations are issued only after the final publication of the opening of a wildlife refuge to fishing. These regulations may list the seasons, methods of taking fish, descriptions of open areas and other provisions. The Service previously issued refuge-specific fishing regulations in 50 CFR Part 33.

This final rule is amending and supplementing certain refuge-specific regulations in 50 CFR Part 33, §§ 33.5 through 33.55, which pertain to fishing on individual refuges in their respective alphabetically listed States.

The policy of the Department of the Interior (Department) is, whenever practicable, to afford the public an opportunity to participate in the rulemaking process. Accordingly, the October 5, 1987, proposed rule had a 30-day comment period. No public comments were received. Therefore, the proposed refuge-specific fishing regulations will be published, with minor technical corrections, as final in this rulemaking.

Conformance With Statutory and Regulatory Authorities

The National Wildlife Refuge System Administration Act (NWRSAA) of 1966, as amended (16 U.S.C. 668dd), and the Refuge Recreation Act of 1962 (16 U.S.C. 460k) govern the administration and the public use of NWRs. Specifically, section 4(d)(1)(A) of the Refuge System Administration Act authorizes the Secretary of the Interior (Secretary) under such regulations as he may prescribe, to permit the use of any area within the System for any purpose, including but not limited to hunting, fishing, public recreation and accommodations and access when he determines that such uses are compatible with the major purposes for which such areas were established.

The Refuge Recreation Act authorizes the Secretary to administer the refuge areas within the National Wildlife Refuge System for public recreation as an appropriate incidental or secondary use only to the extent that it is practicable and not inconsistent with the primary objectives for which the area was established. The Refuge Recreation Act also authorizes the Secretary to issue regulations to carry out the purposes of the Act.

Fishing plans are developed for each fishing program on a refuge prior to the opening of the refuge to fishing. In many cases, refuge-specific fishing regulations are included as a part of the fishing plans to ensure the compatibility of the fishing programs with the purposes for which the refuge was established. Compliance with the NWRSAA and Refuge Recreation Act is ensured when the fishing plans are developed and the determinations required by these Acts are made prior to the addition of the refuge to the list of areas open to fishing in 50 CFR. Continued compliance is ensured by annual review of fishing programs and regulations.

Economic Effect

Executive Order 12291 requires the preparation of regulatory impact analyses for major rules. A major rule is one likely to result in an annual effect on the economy of $100 million or more; a major increase in cost of prices for consumers, individual industries, government agencies or geographic regions; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises. The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) further requires the preparation of flexibility analyses for rules that will have a significant effect on a substantial number of small entities, which include small businesses, organizations or governmental jurisdictions.

These proposed amendments to the codified refuge-specific fishing regulations will make relatively minor adjustments to existing fishing programs. The regulations are not expected to have any gross economic effect and will not cause an increase in costs or prices for consumers, individual industries, Federal, State or local governments, agencies or geographic regions. The benefits accruing to the public are expected to exceed the costs of administering this rule. Accordingly, the Department has determined that this rule is not a "major rule" within the meaning of Executive Order 12291 and will not have a significant economic effect on a substantial number of small entities within the meaning of the Regulatory Flexibility Act.

Paperwork Reduction Act

The Service has received approval from the Office of Management and Budget (OMB) for the information collection requirements of these regulations pursuant to the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). These requirements are presently approved by OBM under #1018-0014 Economic and Public Use Permits. These regulations impose no new reporting or recordkeeping requirements that must be cleared by OMB.

Environmental Considerations

Compliance with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4332(2)(C)) and the Endangered Species Act of 1973 (16 U.S.C. 1531-1543) is ensured when fishing plans are developed and the determinations required by these Acts are made prior to the addition of refuges to the list of areas open to sport fishing in 50 CFR. Refuge-specific fishing regulations are subject to a categorical exclusion from the NEPA process if they do not significantly alter the existing use of a particular NWR. The changes proposed in this rulemaking will not significantly alter the existing uses of the refuges involved.

Information regarding the conditions that apply to individual refuge fishing programs, any restrictions related to public use on the refuge and a map of the refuge are available at refuge headquarters. This information can also be obtained from the Regional Offices of the Service at the addresses listed below.

Region 1—California, Hawaii, Idaho, Nevada, Oregon and Washington:
Assistant Regional Director—Refuges and Wildlife, U.S. Fish and Wildlife Service, Lloyd 500 Building, Suite 1692, 500 Multnomah Street, Portland, Oregon 97232; Telephone (503) 231-6214.

Region 2—Arizona, New Mexico, Oklahoma and Texas:
Assistant Regional Director—Refuges and Wildlife, U.S. Fish and Wildlife Service, Box 1306, Albuquerque, New Mexico 87103; Telephone (505) 766-2324.

Region 3—Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio and Wisconsin:
Assistant Regional Director—Refuges and Wildlife, U.S. Fish and Wildlife Service, Federal Building, Fort Snelling, Twin Cities, Minnesota 55111; Telephone (612) 725-3507.

Region 4—Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, Puerto Rico, Tennessee and the Virgin Islands:
Assistant Regional Director—Refuges and Wildlife, U.S. Fish and Wildlife Service, Richard B. Russell Federal Building, 75 Spring Street SW., Atlanta, Georgia 30303; Telephone (404) 221-3538.

Region 5—Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia and West Virginia:
Assistant Regional Director—Refuges and Wildlife, U.S. Fish and Wildlife Service, One Gateway Center, Suite 700, Newton Corner, Massachusetts 02158; Telephone (617) 965-9222.

Region 6—Colorado, Kansas, Montana, Nebraska, North Dakota, South Dakota, Utah and Wyoming:
Assistant Regional Director—Refuges and Wildlife, U.S. Fish and Wildlife Service, Box 25486, Denver Federal Center, Denver, Colorado 80225; Telephone (303) 236-7920.

Region 7—Alaska:
Assistant Regional Director—Refuges and Wildlife, U.S. Fish and Wildlife Service, 1011 E. Tudor Rd., Anchorage, Alaska 99503; Telephone (907) 786-3542.

David E. Heffernan, Division of

Refuges, Fish and Wildlife Service, Washington, DC, is primary author of this final rulemaking document.

List of Subjects in 50 CFR Part 33

Fishing, National Wildlife Refuge System, Wildlife refuges.

Accordingly, Part 33 of Chapter I of Title 50 of the Code of Federal Regulations is amended as set forth below:

PART 33—[AMENDED]

1. The authority citation for Part 33 continues to read as follows:

Authority: 5 U.S.C. 301; 16 U.S.C. 460k, 664, 668dd and 715i.

2. Section 33.5 is amended by revising (a)(1), (b) and (c)(2) as follows:

§ 33.5 Alabama.

(a) *Bon Secour National Wildlife Refuge.* * * *

(1) Fishing is permitted only from sunrise to sunset.

* * * * *

(b) *Choctaw National Wildlife Refuge.* Fishing is permitted on designated areas of the refuge subject to the following condition: Fishing is permitted only from sunrise to sunset.

(c) *Eufaula National Wildlife Refuge.* * * *

(2) Fishing, including bowfishing, is permitted from March 1 through October 31 only from sunrise to sunset on all refuge impoundments and waters other than the Walter F. George Reservoir.

* * * * *

3. Section 33.8 is amended by revising (a)(1), (b) introductory test and (d)(1); adding (d)(5) and (6) and revising (e)(1) as follows:

§ 33.8 Arkansas.

(a) *Big Lake National Wildlife Refuge.* * * *

(1) Fishing is permitted from March 1 through October 31 only from sunrise to sunset with the following exceptions: Bank fishing is permitted at any time in the area around Floodway Dam south of the Highway 18 bridge, and fishing only from sunrise to sunset from nonmotorized boats and boats with electric motors is permitted in the Sand Slough-Mud Slough Area from November 1 through the end of February.

* * * * *

(b) *Felsenthal National Wildlife Refuge.* Fishing, frogging and the taking of turtles and crawfish are permitted on designated areas of the refuge subject to the following conditions:

* * * * *

(d) *Wapanocca National Wildlife Refuge.* * * *

(1) Fishing is permitted from March 15 through September 30 only from sunrise to sunset.

* * * * *

(5) Big Creek and Ditch 8 are closed to fishing.

(6) Length limits for largemouth bass are required as posted.

(e) *White River National Wildlife Refuge.* * * *

(1) Fishing is permitted from March 1 through October 31 except as posted and as follows: Fishing is permitted year-round in LaGrue, Essex, Prairie, and Brooks Bayous, Big Island Chute, Moon Lake next to Highway 1, the portion of Indian Bay south of Highway 1, and those borrow ditches located adjacent to the west bank of that portion of the White River Levee north of the Arkansas Power and Light Company powerline right-of-way.

4. Section 33.13 is amended by revising (a)(1); redesignating (b) through (l) as (c) through (m); adding (b); revising newly redesignated (c)(1), (d), (f)(1), (g)(1), (h)(1) and (i)(1); adding (i) (6); revising newly redesignated (l) introductory text and (l)(1); adding (l)(3); revising newly redesignated (m)(1) and adding (m)(4) as follows:

§ 33.13 Florida.

(a) *Cedar Keys National Wildlife Refuge.* * * *

(1) Fishing is permitted only from sunrise to sunset.

* * * * *

(b) *Chassahowitzka National Wildlife Refuge.* Fishing is permitted on designated areas of the refuge subject to the following condition: Fishing is permitted year-round, except in a designated sanctuary that is closed to all public entry from October 15 to February 15.

(c) *Egmont Key National Wildlife Refuge.* * * *

(1) Fishing is permitted only from sunrise to sunset.

* * * * *

(d) *Hobe Sound National Wildlife Refuge.* Fishing is permitted on designated areas of the refuge subject to the following condition: Fishing is permitted year-round only from sunrise to sunset.

* * * * *

(f) *Lake Woodruff National Wildlife Refuge.* * * *

(1) Fishing is permitted only from sunrise to sunset.

* * * * *

(g) *Lower Suwannee National Wildlife Refuge.* * * *

(1) Bank fishing is permitted in interior refuge creeks, borrow pits and canals from March 15 to September 30 only from sunrise to sunset.

* * * * *

(h) *Loxahatchee National Wildlife Refuge.* * * *

(1) Fishing is permitted only from sunrise to sunset on all areas of the refuge except the management impoundments and those areas marked by signs as closed to public entry or fishing.

* * * * *

(i) *Merritt Island National Wildlife Refuge.* * * *

(1) Night fishing is permitted from a boat only. A permit is required.

* * * * *

(6) Air thrust boats are prohibited.

* * * * *

(l) *St. Marks National Wildlife Refuge.* Fishing and crabbing are permitted on designated areas of the refuge subject to the following conditions:

(1) Freshwater fishing and crabbing are permitted only from sunrise to sunset.

* * * * *

(3) Launching of commercial or sport net boats at the saltwater boat ramp on C.R.59 is prohibited.

(m) *St. Vincent National Wildlife Refuge.* * * *

(1) Fishing is permitted only from sunrise to sunset.

* * * * *

(4) Fishing seasons and largemouth bass length limits are posted.

5. Section 33.14 is amended by revising (a)(1), (d)(2), (f)(1), (h)(2) and (i)(3) as follows:

§ 33.14 Georgia.

(a) *Banks Lake National Wildlife Refuge.* * * *

(1) Fishing is permitted year-round only from sunrise to sunset.

* * * * *

(d) *Harris Neck National Wildlife Refuge.* * * *

(2) Bank fishing into estuarine waters is permitted only from sunrise to sunset.

* * * * *

(f) *Piedmont National Wildlife Refuge.* * * *

(1) Fishing is permitted from May 1 through September 30 only from sunrise to sunset.

* * * * *

(h) *Wassaw National Wildlife Refuge.* * * *

(2) Bank fishing into estuarine waters is permitted only from sunrise to sunset.

(i) *Wolf Island National Wildlife Refuge.* * * *

(3) Bank fishing into estuarine waters is permitted only from sunrise to sunset.

6. Section 33.19 is amended by revising (a)(7) and removing (a)(8) as follows:

§ 33.19 Iowa.

(a) *DeSoto National Wildlife Refuge.* * * *

(7) Minimum length and creel limits are required as posted.

* * * * *

7. Section 33.22 is amended by revising (b) (1) and (2), (d)(1), (e)(1), and (f)(7) as follows:

§ 33.22 Louisiana.

* * * * *

(b) *Catahoula National Wildlife Refuge.* * * *

(1) Fishing is permitted in Cowpen Bayou year-round only from sunrise to sunset.

(2) Fishing is permitted in the Duck Lake impoundment and discharge waters from March 1 through October 31 only from sunrise to sunset.

* * * * *

(d) *Delta National Wildlife Refuge.* * * *

(1) Fishing, shrimping and crabbing are permitted only from sunrise to sunset.

* * * * *

(e) *Lacassine National Wildlife Refuge.* * * *

(1) Fishing is permitted from March 1 through October 15 only from sunrise to sunset.

* * * * *

(f) *Sabine National Wildlife Refuge.* * * *

(7) Daily shrimp (heads on) take and/or possession limit is 5 gallons or 20 quarts per vehicle during the State inside water shrimp season; and 5 quarts take and/or possession limit per vehicle during the rest of the year.

* * * * *

8. Section 33.25 is amended by revising (a)(1) as follows:

§ 33.25 Massachusetts.

(a) *Great Meadows National Wildlife Refuge.* * * *

(1) Fishing is permitted along the main channel of the Sudbury River, Concord River and along designated banks of Heard Pond with the following exception: Fishing is not permitted within refuge impoundments.

* * * * *

9. Section 33.27 is amended by revising (a)(1) as follows:

§ 33.27 Minnesota.

(a) *Big Stone National Wildlife Refuge.* * * *

(1) Nonmotorized boats or boats with electric motors are permitted in the Minnesota River channel only.

* * * * *

10. Section 33.28 is amended by revising (b) as follows:

§ 33.28 Mississippi.

* * * * *

(b) *Noxubee National Wildlife Refuge.* Fishing is permitted on designated areas of the refuge subject to the following conditions:

(1) Fishing is permitted from March 1 through October 31, except for the Noxubee River and the borrow pits along Highway 25 which are open year-round.

(2) Fishing is permitted only from sunrise to sunset. Boats may not be left on the refuge overnight.

(3) Limb lines, snag lines and hand grappling are prohibited in the Bluff and Loakfoma Lakes. Only nongame fish may be taken with a bow.

(4) All trotline material must be cotton twine. One trotline per person, and no more than two per boat.

(5) The length limit for largemouth bass taken from Loakfoma and Ross Branch Lakes is less than 12 inches and more than 15 inches. Largemouth bass from 12 inches to 15 inches must be released unharmed.

(6) Boats are restricted to no-wake speeds on all refuge waters.

11. Section 33.37 is amended by redesignating (c) as (e) and (a) and (b) as (b) and (c); adding (a) and (d) and revising newly redesignated (b)(1), (c)(1) and (3) and (e)(2) as follows:

§ 33.37 North Carolina.

(a) *Alligator River National Wildlife Refuge.* Fishing and frogging are permitted on designated areas of the refuge subject to the following conditions:

(1) Fishing is permitted year-round only from sunrise to sunset.

(2) Only the use of pole and line, rod and reel or cast net is permitted.

(3) A permit is required for night fishing.

(4) Frogs may be taken by the use of frog gigs only. A permit is required.

(b) *MacKay Island National Wildlife Refuge.* * * *

(1) Fishing is permitted only from sunrise to sunset from March 15 through October 15 with the exception that bank fishing is permitted in Corey's Ditch and the canal adjacent to the Knotts Island Causeway year-round.

* * * * *

(c) *Mattamuskeet National Wildlife Refuge.* * * *

(1) Fishing and crabbing are permitted from March 1 through November 1 from one-half hour before sunrise to one-half hour after sunset or as posted.

* * * * *

(3) Herring (alewife) dipping is permitted from March 1 to May 15 only from sunrise to sunset or as posted.

* * * * *

(d) *Pea Island National Wildlife Refuge.* Fishing and crabbing are permitted on designated areas of the refuge subject to the following condition: Fishing and crabbing are prohibited in North Pond, South Pond and Newfield impoundments.

(e) *Pee Dee National Wildlife Refuge.* * * *

(2) Fishing is permitted only from sunrise to sunset.

* * * * *

12. Section 33.41 is amended by revising (g)(1) as follows:

§ 33.41 Oregon.

* * * * *

(g) *Umatilla National Wildlife Refuge.* * * *

(1) Fishing is permitted on refuge impoundments and ponds from February 1 through September 30. Other refuge waters (Columbia River and its backwaters) are open in accordance with State regulations.

* * * * *

13. Section 33.44 is amended by revising (a)(1) and (d)(1) as follows:

§ 33.44 South Carolina.

(a) *Cape Romain National Wildlife Refuge.* * * *

(1) Fishing is permitted from March 1 through September 30 only from sunrise to sunset.

* * * * *

(d) *Santee National Wildlife Refuge.* * * *

(1) Fishing is permitted on inland ponds only from sunrise to sunset or as posted.

* * * * *

14. Section 33.46 is amended by revising (a)(1), (b)(1), (c)(1) and (e)(2) and adding (a)(7) as follows:

§ 33.46 Tennessee.

(a) *Cross Creeks National Wildlife Refuge.* * * *

(1) Fishing is permitted in refuge pools and reservoirs from March 1 through October 31 only from sunrise to sunset.

* * * * *

(7) The length limit for largemouth bass taken from Elk and South Cross Creeks reservoirs is less than 12 inches

and more than 15 inches. Largemouth bass from 12 inches to 15 inches must be released unharmed.

(b) *Hatchie National Wildlife Refuge.* * * *

(1) Fishing is permitted only from sunrise to sunset.

* * * * *

(c) *Lake Isom National Wildlife Refuge.* * * *

(1) Fishing is permitted from March 15 through October 15 only from sunrise to sunset.

* * * * *

(e) *Reelfoot National Wildlife Refuge.* * * *

(2) Fishing is permitted only from sunrise to sunset.

* * * * *

15. Section 33.51 is amended by revising (a) (1) and (2) and adding (a) (3) and (4) as follows:

§ 33.51 Washington.

(a) *Columbia National Wildlife Refuge.* * * *

(1) Nonmotorized boats and boats with electric motors are permitted on Upper and Lower Hampton, Hutchinson, Royal and Shiner Lakes.

(2) Motorized and nonmotorized boats are permitted on all other refuge waters open to fishing except in Marsh Units I and II.

(3) Marsh Units I and II are restricted to shoreline fishing only.

(4) The taking of bullfrogs is prohibited.

* * * * *

16. Section 33.53 is amended by redesignating (c) as (d) and adding (c) as follows:

§ 33.53 Wisconsin.

* * * * *

(c) *Trempealeau National Wildlife Refuge.* Fishing is permitted on designated areas of the refuge subject to the following conditions:

(1) Only hand-powered craft and boats using electric trolling motors are permitted.

(2) Fishing from boats is not permitted from October 10 through November 30.

* * * * *

17. Section 33.55 is amended by revising (a) (1) and (2) as follows:

§ 33.55 Pacific Islands Territory.

(a) *Johnston Atoll National Wildlife Refuge.* * * *

(1) Lobsters of 3¼ inch carapace length or more may be taken from the lagoon area from September 1 through May 31, but not by spearing; no female lobsters bearing eggs may be taken at any time.

(2) The use of nets, except throw nets, is prohibited.

Date: December 11, 1987.

William P. Horn,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 88-1002 Filed 1-19-88; 8:45 am]

BILLING CODE 4310-55-M

Proposed Rules

Federal Register
Vol. 53, No. 12
Wednesday, January 20, 1988

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

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 9

[Notice No. 652]

Realignment of the Boundary Common to the Alexander Valley and Chalk Hill Viticultural Areas

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: ATF has received a petition for realignment of the boundary common to the Alexander Valley and Chalk Hill viticultural areas so that vineyards immediately within the north-central leg of the boundary of the Chalk Hill viticultural area would be relocated to the southeastern corner of the Alexander Valley viticultural area.

DATE: Written comments must be received by Febraury 19, 1988.

ADDRESS: Send written comments to Chief, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms, REF: Notice No. 652, P.O. Box 385, Washington, DC 20044–0385.

Copies of this proposal, the petition, the appropriate maps, and the written comments are available for public inspection during normal business hours at the ATF Reading Room, Ariel Rios Federal Building, Room 4412, 1200 Pennsylvania Avenue, NW., Washington, DC 20226.

FOR FURTHER INFORMATION CONTACT: Edward A. Reisman, Specialist, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms, Ariel Rios Federal Building, Room 6237, Washington, DC 20226, Telephone (202) 566–7626.

SUPPLEMENTARY INFORMATION:

Background

On August 23, 1978, ATF published Treasury Decision ATF–53 (43 FR 37672, 54624) revising regulations in Title 27, Code of Federal Regulations, Part 4. These regulations allow the establishment of definite American viticultural areas. The regulations also allow the name of an approved viticultural area to be used as an appellation of origin in the labeling and advertising of wine. On October 2, 1979, ATF published Treasury Decision ATF–60 (44 FR 56692) which added to Title 27 a new Part 9 providing for the listing of approved American viticultural areas.

Section 4.25a(e)(1) of Title 27, Code of Federal Regulations, Part 4, defines an American viticultural area as a delimited grape growing region distinguishable by geographical features. Section 4.25a(e)(2), outlines the procedure for proposing an American viticultural area. Any interested person may petition ATF to establish a grape-growing region as a viticultural area. The petition shall include—

(a) Evidence that the name of the proposed viticultural area is locally and/or nationally known as referring to the area specified in the petition;

(b) Historical or current evidence that the boundaries of the viticultural area are as specified in the petition;

(c) Evidence relating to the geographical features (climate, soil, elevation, physical features, etc.) which distinguish the viticultural features of the proposed area from surrounding areas;

(d) A description of the specific boundary of the proposed viticultural area, based on features which can be found on United States Geological Survey (U.S.G.S.) maps of the largest applicable scale; and,

(e) A copy (or copies) of the appropriate U.S.G.S. map(s) with the proposed boundary prominently marked.

Establishment of the Viticultural Areas

With the issuance of T.D. ATF–155 on October 21, 1983 and T.D. AFT–187 on October 24, 1984, ATF established, respectively, the Chalk Hill and the Alexander Valley viticultural areas in Sonoma County, California. On August 26, 1986, ATF issued T.D. ATF–233 which made several revisions to the boundary of the Alexander Valley viticultural area including the extension of the southern leg of the boundary to include the Digger Bend area east of Healdsburg.

Petition

By letter dated August 20, 1987, Ms. Willi Martin-Hilliard and Mr. Richard Godwin, owners and operators of separate vineyards sited on the south-facing slopes of Bell Mountain, filed a petition to extend the boundary of the Alexander Valley viticultural area approximately one mile south in order to include land on which is sited 76 acres of vineyards in the watershed of Martin Creek which flows into Barnes Creek to Brooks Creek and the Russian River.

The petition, researched and prepared by William K. Crowley, a professor of geography at Sonoma State University in Santa Rosa, California, documents the name recognition, history and physical features of this area and includes declarations of support from neighbors, grape growers and local winemakers.

The petition includes evidence that the land in the area enjoys name recognition and shares similar geological history, topographical features, soils, and climatic conditions as adjoining land within the boundary of the Alexander Valley viticultural area.

Name

The Alexander Valley viticultural area was established 30 days after the issuance of T.D. ATF–187 which was published in the **Federal Register** on October 24, 1984.

In early 1981, the Hilliards subdivided their property and sold the more northerly portion to Mr. Godwin. Also in 1981, the Hilliards planted 55 acres of wine grape vines on their portion of the subdivided property. In 1983, Mr. Godwin established a 21-acre vineyard on his property. The Hilliards and Mr. Godwin state that these vineyards are in closer proximity to vineyards planted in the Alexander Valley viticultural area than vineyards planted in either the Chalk Hill viticultural area or in the Russian River viticultural area. In fact, a part of Mr. Godwin's property, on which no grapes are presently planted, lies within the existing boundary of the Alexander Valley viticultural area.

The Hilliards have advised ATF that they were unaware until the Spring of 1986 that their vineyards had been excluded from the boundary established in November 1984 for the Alexander Valley viticultural area. Although the Hilliards planted their vineyards in 1981, they did not establish permanent

residence on their property until November 1983. Consequently, when ATF held a public hearing in Sonoma County in February 1983 to air the petition filed by the Alexander Valley Appellation Committee in 1981 and a second group's petition to include land north of Geyserville to the Mendocino County line, the Hilliards saw no need to give testimony at the hearing or to file a written comment.

The petition includes a declaration of support from Mr. Frederick P. Furth, the petitioner for the Chalk Hill viticultural area. Included in Mr. Furth's letter is the statement "I have no objection to this (petition) and frankly have always considered your vineyards were in the Alexander Valley Appellation originally."

The petition also includes letters of support from Messers. Hank Wetzel, Russell H. Green, Jr., and Robert A. Young, wine grape growers in the Aleander Valley viticultural area, and wine producer Michael G. Dacres Dixon, all of whom were members of the Appellation Committee which filed the June 18, 1981, petition to establish the Alexander Valley viticultural area. All have demonstrated great concern that the Alexander Valley viticultural area be carefully defined and all maintain that these properties should have been included in the originally petitioned area.

The declarations support the petitioners' statement that the vineyards planted in 1981 on the Hilliard property and in 1983 on the Godwin property "are most closely associated with the Alexander Valley, both by people living in the area and by their proximity to other Alexander Valley vineyards."

Climate

Thermograph readings for the petitioned area were taken in 1981 on the Hilliard property. These readings suggest that the vineyards lie on the boundary between Region I and Region II. The petition states that the reading of 2,475 heat summation units "is similar to locations in the southern end of Alexander Valley, though obviously cooler than the central and northern portions." The petition notes that "because the property is in the boundary area of regular summer fog intrusions, readings could vary considerably from one year to the next, with the best guess that the [1981] reading is a relatively cool year."

Soils

The petition states that the principal soils of the Martin Creek area, namely, Felta very gravelly loams, Spreckels loam, and Yolo silt loam, "represent soil series and associations common to the existing Alexander Valley (viticultural area)."

Topography

The southeastern leg of the boundary of the Alexander Valley viticultural area extends in an easterly direction from the summit of Chalk Hill to just south of the summit of Bell Mountain. The Martin Creek area lies on the south-facing slopes of Bell Mountain. The vineyards are planted on low hills ranging from 300 to 400 feet above sea level. Part of the petitioned area is within the Franz Creek drainage and part is within the Brooks Creek drainage. The points of confluence where the waters in these streams flow into the Russian River are within the boundary of the Alexander Valley viticultural area.

The terrain of the Chalk Hill viticultural area to the south and west of the petitioned area is higher in elevation and more rugged than that of the petitioned area.

Chalk Hill Viticultural Area

ATF's proposal to revise the boundary of the Alexander Valley viticultural area affects a portion of the boundary common to the Chalk Hill viticultural area.

The petitioners request that the common boundary between the two viticultural areas be realigned so as to extend the southern leg of the boundary for the Alexander Valley viticutural area and to curtail the north-central leg of the boundary for Chalk Hill viticultural area.

The statement from the petitioner for the Chalk Hill viticultural area, the letters of support from the original petitioners for the Alexander Valley appellation, and the physical proximity of the vineyards in the petitioned area to vineyards within the present boundary of the Alexander Valley viticultural area support the criteria for history and recognition of name. The limited climatic data suggests that the petitioned area lies in a transitional space between the inland "coastal warm" Alexander Valley viticultural area and the Chalk Hill viticultural area. The latter encompasses the higher elevation "coastal warm" areas near Mark West Springs as well as the "coastal cool" basin of the Russian River south of Fitch Mountain.

Proposed Realignment of Common Boundary

The description of the boundary of the established Alexander Valley viticultural, as found in 27 CFR 9.53, would be amended to include all of section 28 and portions of section 27, 29, 33 and 34 in Township 9 N., Range 8 W. The description of the boundary of the established Chalk Hill viticultural area, as found in 27 CFR 9.52, would be amended to exclude all of section 28 and portions of section 27, 29, 33 and 34 in Township 9 N., Range 8 W.

Public Participation

ATF requests comments from all interested parties. Comments received before the closing date will be carefully considered. Comments received after the closing date and too late for consideration will be treated as possible suggestions for future ATF action.

ATF will not recognize any comment as confidential. Comments may be disclosed to the public. Any material which a commenter considers to be confidential or inappropriate for disclosure to the public should not be included in the comment. The name of the person submitting a comment is not exempt from disclosure.

The Director reserves the right to determine, in light of all circumstances, whether a public hearing will be held.

Regulatory Flexibility Act

The provisions of the Regulatory Flexibility Act relating to an initial and final regulatory flexibility analysis (5 U.S.C. 603, 604) are not applicable to this proposal because the notice of proposed rulemaking, if promulgated as a final rule, will not have a significant economic impact on a substantial number of small entities. The proposal will not impose, or otherwise cause, a significant increase in reporting, recordkeeping, or other compliance burdens on a substantial number of small entities. The proposal is not expected to have significant secondary or incidental effects on a substantial number of small entities.

Accordingly, it is hereby certified under the provisions of section 3 of the Regulatory Flexibility Act (5 U.S.C. 605(b)) that this notice of proposed rulemaking, if promulgated as a final rule, will not have a significant economic impact on a substantial number of small entities.

Executive Order 12291

In compliance with Executive Order 12291, issued February 17, 1981, ATF has determined that this proposed regulation is not a "major rule" since it will not result in:

(a) An annual effect on the economy of $100 million or more;

(b) A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or,

(c) Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1980, Pub. L. 96-511, 44 U.S.C. Chapter 35, and its implementing regulations, 5 CFR Part 1320, do not apply to this notice because no requirement to collect information is proposed.

Drafting Information

The author of this document is Michael J. Breen, Coordinator, Wine and Beer Branch, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects in 27 CFR Part 9

Administrative practice and procedure, Consumer protection, Viticultural areas, Wine.

Authority and Issuance

Title 27, Code of Federal Regulations, Part 9, American Viticultural Areas, is amended as follows:

PART 9—[AMENDED]

Paragraph 1. The authority citation for 27 CFR Part 9 continues to read as follows:

Authority: 27 U.S.C. 205.

Par. 2. ATF is amending § 9.53 if Subpart C of Title 27, Code of Federal Regulations, Part 9, by removing existing paragraphs (c)(27) and (c)(28), redesignating paragraphs (c)(29) through (c)(40) as paragraphs (c)(35) through (c)(46), and adding new paragraphs (c)(27) through (c)(34) to read as follows:

§ 9.53 Alexander Valley.

* * * * *

(c) *Boundary.* * * *

(27) Then south from said peak, in a straight line, approximately 0.2 mile to the point where Chalk Hill Road crosses Brooks Creek (on the Healdsburg Quadrangle map);

(28) Then southeasterly, approximately 1.3 miles, along the roadbed of Chalk Hill Road to the point near the confluence of Brooks Creek and Barnes Creek where Chalk Hill Road intersects an unnamed unimproved road (known locally as Spurgeon Road) that parallels Barnes Creek in section 32, T. 9 N., R. 8 W.;

(29) Then easterly, approximately 0.45 mile, along said road (known locally as Spurgeon Road) to the point where the road is intersected by an unnamed unimproved road (known locally as the access to the Shurtleff Ranch) in section 33, T. 9 N., R. 8 W.;

(30) Then continuing along the unnamed unimproved road (known locally as the access to the Shurtleff Ranch), approximately 1.33 miles, in a generally easterly direction, to the eastern terminus of said road at a small dwelling along the north fork of Barnes Creek in section 34, T. 9 N., R. 8 W. on the Mark West Springs, California, Quadrangle map;

(31) Then easterly along the north fork of Barnes Creek, approximately 0.5 mile, to the point in the northeast corner of section 34, T. 9 N., R. 8 W. where the north fork of Barnes Creek intersects the east line of section 34, T. 9 N., R. 8 W.;

(32) Then north, approximately 0.65 mile, along the east lines of sections 34 and 27, T. 9 N., R. 8 W., to the point at which an unnamed unimproved road which parallels the south bank of Martin Creek intersects the eastern border of section 27, T. 9 N., R. 8 W.

(33) Then in a generally northwesterly direction, approximately 1.07 miles, along said road to the point at which the road is crossed by the west line of section 27, T. 9 N., R. 8 W.;

(34) Then north, approximately 0.08 mile, along the west line of section 27, T. 9 N., R. 8 W., to the southeast corner of section 21, T. 9 N., R. 8 W.;

* * * * *

Par. 3. ATF is amending § 9.52 of Subpart C of Title 27, Code of Federal Regulations, Part 9, by removing existing paragraphs (c)(13) and (c)(14), redesignating paragraphs (c)(15) through (c)(24) as paragraphs (c)(21) through (c)(30), and adding new paragraphs (c)(13) through (c)(20) to read as follows:

§ 9.52 Chalk Hill.

* * * * *

(c) *Boundary.* * * *

(13) Then southerly, approximately 0.08 mile, along the west line of section 27, T. 9 N., R. 8 W., to the point at which an unnamed unimproved road which parallels the south bank of Martin Creek intersects the west line of section 27, T. 9 N., R. 8 W.;

(14) Then southeasterly, approximately 1.07 miles, along said road to the point at which the road is crossed by the east line of section 27, T. 9 N., R. 8 W.;

(15) Then southerly, approximately 0.65 mile, along the east lines of sections 27 and 34, T. 9 N., R. 8 W., to the point in the northeast corner of section 34, T. 9 N., R. 8 W. where the north fork of Barnes Creek intersects such line in section 34, T. 9 N., R. 8 W.;

(16) Then continuing along the north fork of Barnes Creek, approximately 0.5 mile, in a generally westerly direction to a small dwelling at the eastern terminus of an unnamed unimproved road (known locally as the access to the Shurtleff Ranch) in section 34, T. 9 N., R. 8 W.;

(17) Then continuing in a generally westerly direction, approximately 1.4 miles, along the unnamed unimproved road (known locally as the access to the Shurtleff Ranch) to its intersection with an unnamed unimproved road (known locally as Spurgeon Road) in section 33, T. 9 N., R. 8 W. on the Healdsburg, California, Quadrangle Map;

(18) Then westerly, approximately 0.45 mile, along the unnamed unimproved road (known locally as Spurgeon Road) to the point where the road intersects Chalk Hill Road in section 32, T. 9 N., R. 8 W.;

(19) Then in a generally northwesterly direction, approximately 1.3 miles, along Chalk Hill Road to the point where Chalk Hill Road crosses Brooks Creek in section 29, T. 9 N., R. 8 W.;

(20) Then north in a straight line, approximately 0.2 mile, to the top of a peak identified as Chalk Hill;

* * * * *

Approved: January 11, 1988.

Stephen E. Higgins,

Director.

[FR Doc. 88-991 Filed 1-19-88; 8:45 am]

BILLING CODE 4810-31-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 156 and 170

[OPP-300164A; FRL-33174]

Worker Protection Standards for Agricultural Pesticides; Notification to the Secretary of Agriculture

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; Related notice.

SUMMARY: Notice is given that the Administrator of EPA has forwarded to the Secretary of the U.S. Department of Agriculture a proposed regulation on worker protection standards for agricultural pesticides (40 CFR Parts 156 and 170). This action is required by section 25(a)(2)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

FOR FURTHER INFORMATION CONTACT: Dr. Patricia Breslin, Director, Pesticide Farm Safety Staff, Office of Pesticide Programs, Environmental Protection Agency, Rm. 1009, CM No. 2, 1921

Jefferson Davis Highway, Arlington, VA 22202, (703)–557–7666.

SUPPLEMENTARY INFORMATION: Section 25(a)(2)(A) of FIFRA provides that the Administrator of EPA shall provide the Secretary of Agriculture with a copy of any proposed regulation at least 60 days prior to signing it for publication in the **Federal Register.** If the Secretary comments in writing regarding the proposed regulation within 30 days after receiving it, the Administrator shall issue for publication in the **Federal Register,** with the proposed regulation, the comments of the Secretary, if requested by the Secretary, and the response of the Administrator concerning the Secretary's comments. If the Secretary does not comment in writing within 30 days after receiving the proposed regulation, the Administrator may sign the regulation for publication in the **Federal Register** any time after the 30-day period.

As required by FIFRA section 25(a)(3), a copy of this proposed regulation has been forwarded to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.

(Sec. 25, Pub. L. 92–516, 86 Stat. 973 as amended (7 U.S.C. 136 et seq.)

Dated: December 30, 1987.

Douglas D. Campt,

Director, Office of Pesticide Programs.

[FR Doc. 88–878 Filed 1–19–88; 8:45 am]

BILLING CODE 6560–50–M

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40 CFR Part 180

[PP 9E2249/P433; FRL–3216–8]

Pesticide Tolerances for Pentachloronitrobenzene

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes that tolerances be established for the combined residues of the fungicide pentachloronitrobenzene and its metabolites in or on the raw agricultural commodities collards, kale, and mustard greens. The proposed regulation to establish a maximum permissible level for residues of the fungicide in or on the commodity was requested in a petition submitted by the Interregional Research Project No. 4 (IR–4).

DATE: Comments, identified by the document control number [PP 9E2249/P433], must be received on or before February 19, 1988.

ADDRESS: By mail, submit written comments to: Information Services Section, Program Management and Support Division (TS–757C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. In person, bring comments to: Rm. 236, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 236 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Donald R. Stubbs, Emergency Response and Minor Use Section (TS–767C), Registration Division, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460.

Office location and telephone number: Rm. 716H, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703)–557–1806.

SUPPLEMENTARY INFORMATION: The Interregional Research Project No. 4 (IR–4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903, has submitted pesticide petition 9E2249 to EPA on behalf of Dr. Robert H. Kupelian, National Director, IR–4 Project and the Agricultural Experiment Station of Georgia.

This petition requested that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act, propose the establishment of tolerances for the combined residues of the fungicide pentachloronitrobenzene (PCNB) and its metabolites pentacholoraniline (PCA) and methylpentachlorophenyl sulfide (MPCPS) in or on the raw agricultural commodities collards, kale, and mustard greens at 0.1 part per million (ppm). The petition was later amended to propose residues of the fungicide at 0.2 ppm. The petitioner proposed that this use of PCNB and its metabolites on collards, kale, and mustard greens be limited to Georgia based on the geographical representation of the residue data submitted. Additional residue data will be required to expand the area of usage. Persons seeking geographically broader registration should contact the Agency's Registration Division at the address provided above.

The data submitted in the petition and other relevant material have been evaluated. The pesticide is considered useful for the purpose for which the tolerances are sought. The toxicological data considered in support of the proposed tolerances include:

1. A 2-year dog feeding study (1.4 percent HCB) with a no-observed-effect level (NOEL) of 30 ppm (0.75 milligram (mg)/kilogram (kg)/day) and a lowest-observed-effect level (LOEL) of 180 ppm with liver weight increases, increased liver-to-body weight ratios, elevated serum alkaline phosphatase levels and microscopically observed cholestatic hepatosis with secondary nephrosis.

2. A three-generation rat reproduction study with a reproductive NOEL >500 ppm (25 mg/kg/day, highest level tested).

3. A 3-month mouse feeding study with NOELs of 1,250 ppm (187.5 mg/kg/day) for males and 2,500 ppm (375 mg/kg/day) for females and with LELs of 2,500 for males and 5,000 ppm (750 mg/kg/day) for females (increase liver weight and liver-to-body weight ratio, no liver histopathology).

4. A 2-year mouse oncogenicity study with a NOEL >5,000 ppm with no observed oncogenicity potential under conditions of the study at all levels tested (0, 2,500 and 5,000 ppm).

5. Mutagenicity tests include: An Ames assay for reverse or forward mutations, differential toxicity and DNA repair, a point mutation assay in mouse lymphoma cells, a mitotic recombination assay in yeast, a recessive lethal assay in fruit flies, an unscheduled DNA synthesis (UDS) assay in human fibroblast cells, a mouse dominant lethal assay, and a sister chromatid exchange assay in Chinese hamster ovary (CHO) cells, with no mutagenic potential observed. However, one of two assays with *E. coli* was positive, and a chromosomal aberration assay in CHO cells suggested that the fungicide has genotoxic activity.

Data gaps include chronic toxicity/carcinogenicity study in rats and teratology studies in two species.

The provisional acceptable daily intake (PADI), based on the dog feeding study with a NOEL of 30 ppm (0.75 mg/kg/day) and using a 300-fold safety factor, is calculated to be 0.0025 mg/kg/day. The maximum permitted intake (MPI) for a 60-kg human is calculated to be 0.15 mg/day. The theoretical maximum residue contribution (TMRC) from existing tolerances (permanent and

interim) for a 1.5-kg daily diet is calculated to be 0.000415 mg/kg/day; the current action will increase the TMRC by 0.0000085 mg/kg/day (2.0 percent). Published tolerances utilize 16.6 percent of the PADI; the current action will utilize an additional 0.34 percent.

A permanent tolerance has previously been established for residues of PCNB at 0.1 ppm in or on cottonseed and interim tolerances have been established for residues of PCNB in or on peanuts at 1.0 ppm and in or on bananas, beans, broccoli, Brussels sprouts, cabbage, cauliflower, garlic, peppers, potatoes and tomatoes at 0.1 ppm.

A comprehensive review of the data available was conducted in connection with a Special Review of pentachloronitrobenzene (PCNB) initiated on October 20, 1977 (42 FR 56072). The Special Review was based on a presumption that PCNB was potentially carcinogenic. On April 28, 1982, a Notice of Determination concluding the Special Review of PCNB was issued (47 FR 18177). The Agency stated that the evidence did not positively establish a correlation between exposure to PCNB itself and carcinogenicity. The Notice concluded that an impurity, hexachlorobenzene (HCB), was likely to be responsible for any potential carcinogenic effect of commercial PCNB, and the Agency stated that reducing the level of the impurity would reduce the potential risks posed by PCNB. Registrants of PCNB have agreed as a condition of continued registration to reduce the level of HCB to 0.1 percent or less by April of 1988.

PCNB has since been classified into Group D (inadequate evidence for classification), and the Agency has classified HCB as a Group B2 (probable human carcinogen) based on the increased incidence of liver tumors observed in rats, mice, and hamsters. A $Q1^*$ of 1.7 (mg/kg/day)–1 was calculated for HCB on the basis of liver tumors in rats. Although PCNB has been classified into Group D with respect to its carcinogenic potential, a mouse study conducted with relatively pure PCNB (containing 0.07 percent HCB) was negative for carcinogenicity, and other results in mice indicate that HCB may have a role in the previously suggested carcinogenic potential of PCNB.

The Agency has evaluated the oncogenic risk from dietary exposure resulting from existing uses of PCNB based on the maximum expected HCB residue level and percent of crops treated. Total dietary exposure multiplied by the oncogenic potency for HCB results in an upper bound for increased oncogenic risk of 3.5×10^{-6} for PCNB contaminated with 0.5 percent HCB. At 0.1 percent HCB contamination, exposure would be reduced five-fold, and the risk would be 7×10^{-7}. The oncogenic risk from dietary exposure resulting from PCNB (contaminated with 0.5 percent HCB) use on collards, kale, and mustard greens would amount to 7.2×10^{-8}, and from PCNB (contaminated with 0.1 percent HCB) the risk would be 1.4×10^{-8}.

The nature of the residues is adequately understood, and an adequate analytical method, gas-liquid chromatography, is available for enforcement purposes. An analytical enforcement method is currently available in the Pesticide Analytical Manual (PAM), Vol. I. There are currently no actions pending against the continued registration of this chemical.

Based on the above information considered by the Agency and the fact that collards, kale, and mustard greens are not considered as animal feed commodities, the tolerances established by amending 40 CFR 180.291 would protect the public health. Therefore, it is proposed that the tolerances be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this document in the **Federal Register** that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the Federal Food, Drug, and Cosmetic Act.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [PP 9E2249/P433]. All written comments filed in response to this petition will be available in the Information Services Section, at the address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96–354, 94 Stat. 1164, 5 U.S.C. 601–612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Recording and recordkeeping requirements.

Dated: December 30, 1987.

Edwin F. Tinsworth,

Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR Part 180 be amended as follows:

PART 180—[AMENDED]

1. The authority citation for Part 180 continues to read as follows:

Authority: 21 U.S.C. 346a.

2. Section 180.291 is amended by designating the existing text as paragraph (a) and adding new paragraph (b), to read as follows:

§ 180.291 Pentachloronitrobenzene; tolerances for residues.

(a) * * *

(b) Tolerances with regional registration (refer to § 180.1(n)) are established for the combined residues of the fungicides pentachloronitrobenzene (PCNB) and its metabolites pentachloroaniline (PCA) and methylpentachlorophenyl sulfide (MPCPS) in or on the following raw agricultural commodities:

Commodities	Parts per million
Collards	0.2
Kale	0.2
Mustard greens	0.2

[FR Doc. 88–763 Filed 1–19–88; 8:45 am]

BILLING CODE 6560–50–M

ACTION

45 CFR Part 1215

Freedom of Information Act Regulation

AGENCY: ACTION.

ACTION: Proposed rule.

SUMMARY: Notice is hereby given that the Director of ACTION proposes to revise Chapter 45, Code of Federal Regulations, Part 1215, ACTION's Freedom of Information Act (FOIA) regulation, in order to update the existing regulation which was published in 1975. Specifically, the proposed

revision: (1) Reflects changes in the Agency's FOIA procedures necessitated by internal reorganizations and by the 1982 separation of Peace Corps from ACTION; (2) codifies the centralized coordination of responses to FOIA requests which has for some time been the *de facto* practice of the Agency; and (3) implements certain provisions of the Freedom of Information Reform Act of 1986, Pub. L 99–570, in accordance with the Office of Management and Budget's (OMB's) Uniform Freedom of Information Act Fee Schedule and Guidelines, 52 FR 10012 (March 27, 1987).

DATE: Comments on the proposed rule must be received on or before February 19, 1988.

ADDRESS: Comments should be sent to: Assistant Director, Office of Administration, ACTION, Room M–306, 806 Connecticut Avenue NW., Washington, DC 20525.

FOR FURTHER INFORMATION CONTACT: Gregory C. La Rosa, Assistant General Counsel, (202) 634–9333.

SUPPLEMENTARY INFORMATION: The Freedom of Information Act, 5 U.S.C. 552, as amended, requires each agency of the Federal Government to promulgate regulations informing the public of procedures for requesting information under the Act, specifying the schedule of fees applicable to the processing of such requests, and establishing procedures and guidelines for determining when such fees should be waived or reduced. ACTION's current FOIA regulation was promulgated in 1975 (40 FR 18558, Apr. 29, 1975).

Further, under the provisions of the Freedom of Information Reform Act of 1986, Pub. L. 99–570, §§ 1801–1804, 100 Stat. 3207, 3207–48 (1986), all Federal agencies subject to the FOIA are required to promulgate new fee and fee waiver regulations. Such regulations must inform the public of criteria (based on the identity of the requester) for assessing FOIA request processing fees; and of the factors to be considered in determining whether requests for fee waivers or reductions will be granted by the agency. Under the new legislation, such fee waivers or reductions may be granted only where disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the Government, *and* it is established that disclosure of the information is not primarily in the commercial interest of the requester. OMB published guidance for all Federal agencies in drafting such fee regulations in the **Federal Register** on March 27, 1987; additional guidance was provided to the agencies by the Department of Justice in a Memorandum dated April 2, 1987. Section 1215.7 of this proposed regulation, ACTION's schedule of fees, is consistent with the guidance of OMB and the Department of Justice.

The proposed revision is intended both (1) to provide to the public detailed information regarding ACTION's adminstrative procedures for FOLA requests, responses, appeals, and fee assessments, and (2) to set forth for FOIA requesters the criteria the Agency will apply in accepting FOIA requests, in responding to FOIA requests for business information, and in ruling on requests for fee waivers or reductions. The factors to be considered by the Agency in making determinations regarding fee waivers and reductions conform to criteria established in guidence provided to Executive agencies by OMB and the Department of Justice.

Additionally, the proposed regulation no longer gives examples of the types of records which may be withheld from disclosure under the FOIA exemptions (set forth at § 1215.5 of the current regulation), because it is felt that such examples are gratuitous to the extent they simply repeat the language of the Act, and may be misleading and/or become easily outdated to the extent they suggest that denial of access may be based on generalizations rather than on case-by-case review.

ACTION has determined that this proposed regulation is not a major rule as defined by Executive Order 12291. The regulation will not result in:

1. A major effect on the economy;

2. A major increase in costs or prices for consumers, individual industries, Federal, state, or local government agencies, or geographic regional; or

3. Any adverse effects on competition, employment, investment, productively, innovation or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

This proposed regulation will not have a significant impact on a substantial number of small entities as defined by section 605(b) of the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601, *et seq.*), as the rule codifies changes in the Agency's internal practice and procedure only.

The proposed regulation does not constitute a major Federal action significantly affecting the quality of the human environment, as defined by the National Environmental Policy Act (Pub. L. 91–190, 42 U.S.C. 4321, *et seq.*).

List of Subjects in 45 CFR Part 1215

Freedom of Information Act, Administrative practice and procedure.

For the reasons set out in the Preamble, the Director of ACTION proposes to revise 45 CFR Part 1215 to read as follows:

PART 1215—PROCEDURES FOR DISCLOSURE OF RECORDS UNDER THE FREEDOM OF INFORMATION ACT

Sec.

Authority: Pub. L. 93–113, 87 Stat. 411 (42 U.S.C. 4951, *et seq.*); and 5 U.S.C. 552.

§ 1215.1 Purpose.

The purpose of this part is to prescribe rules for the inspection and copying of opinions, policy statements, manuals, instructions, and other records of ACTION pursuant to the Freedom of Information Act (5 U.S.C 552). Information customarily furnished to the public in the regular course of ACTION's official business may continue to be furnished to the public without complying with this part, provided that the furnishing of such information would not violate the Privacy Act of 1974 (5 U.S.C. 552a). Rules for the disclosure by ACTION of records protected by the Privacy Act are set forth at 45 CFR Part 1224.

§ 1215.2 Definitions.

As used in this part, the following definitions shall apply:

(a) "The Act" means the Freedom of Information Act (5 U.S.C. 552).

(b) "The Agency" means ACTION.

(c) "Records" include all books, papers, maps, photographs or other documentary material, or copies thereof, regardless of physical form or characteristics, made or received by ACTION and preserved as evidence of its organization, functions, policies, decisions, procedures, operations or other activities; but do not include books, magazines, or other materials not produced by ACTION and acquired solely for reference purposes.

(d) "Search" means time spent locating records responsive to a request, including page-by-page or line-by-line identification of responsive material within a record.

(e) "Review" means the process of examining records located in response to a request to determine whether any record or portion of a record is permitted to be withheld. It also includes processing records for disclosure (*i.e.*, excising portions not subject to disclosure under the Act and otherwise preparing them for release). Review does not include time spent resolving legal or policy issues regarding the application of exemptions under the Act.

(f) "Commercial use request" means a request from, or on behalf of, a person who seeks information for a use or purpose that furthers the commercial, trade, or profit interests of the requester or the person on whose behalf the request is made. The use to which a requester will put the records sought will be considered in determining whether the request is a commercial use request.

(g) "Educational institution" means a preschool, a public or private elementary or secondary school, an institution of undergraduate or graduate higher education, an institution of professional education, or an institution of vocational education, which operates a program or programs of scholarly research.

(h) "Non-commercial scientific institution" means an institution that is not operated on a for-profit basis and which is operated solely for the purpose of conducting scientific research the results of which are not intended to promote any particular product or industry.

(i) "Representative of the news media" means any person actively gathering news for an entity that is organized and operated to disseminate news to the public. The term "news" means information that is about current events or that would otherwise be of current interest to the public. Examples of news media entities include, but are not limited to, television and radio stations broadcasting to the public at large, and publishers of periodicals (but only those publishers who qualify as disseminators of "news") who make their products available for purchase or subscription by the general public. Moreover, as new methods of news disseminatioin evolve (*e.g.*, electronic dissemination of newspapers through telecommunications services), such alternative media would be included in this category. "Freelance" journalists may be regarded as working for a news organization if they can demonstrate a solid basis for expecting publication through that organization, even though not actually employed by it. A publication contract would be the clearest proof, but the Agency may also look to the past publication record of a requester in making this determination.

(j) "Business information" means trade secrets or other commercial or financial information.

(k) "Business submitter" means any commercial entity which provides business information to ACTION and which has a proprietary interest in such information.

(l) "Appeal" means the appeal by a requester of an adverse Agency determination on his request, or on his application for a waiver of fees, as described in 5 U.S.C. 552(a)(6)(A)(ii).

§ 1215.3 Availability of records.

(a) All publications and other documents heretofore provided by ACTION to the public in the normal course of Agency business will continue to be made available upon request to the Agency.

(b) The Agency will promptly make available to any member of the public who requests them, the following Agency records:

(1) Final opinions and orders made in the adjudication of cases;

(2) Statements of policy and interpretation adopted by an office which have not been published in the **Federal Register**; and

(3) Administrative staff manuals and instructions to the staff which affect the public.

(c) A current index, which shall be updated at least quarterly, of the foregoing materials, is maintained by the Agency, and copies of some or any portion thereof will be furnished upon request. The Agency deems further publication of such index in the **Federal Register** unnecessary and impractical.

(d) To the extent necessary to prevent a clearly unwarranted invasion of personal privacy, the Agency may delete identifying details from materials furnished under this section.

(e) Brochures, leaflets, and other similar published materials shall be furnished to the public on request to the extent they are available. Copies of any such materials which are out of print shall be furnished at the cost of duplication, provided, however, that, in the event no copy exists, the Agency shall not be responsible for reprinting the document.

(f) All records of ACTION which are requested by a member of the public in accordance with the procedures established in this part shall be timely made available for inspection or copying, at the Agency's option, except to the extent that the Agency determines such records are exempt from disclosure under the Act.

(g) The Agency will not be required to create new records, compile lists of selected items from its files, or provide a requester with statistical or other data (unless such data have been compiled previously and are available in the form of a record, in which event such data shall be made available as provided in this part).

§ 1215.4 Location of records.

(a) The Agency maintains a central records room at its headquarters, located at 806 Connecticut Avenue NW., Washington, DC 20525. The specific location of the central records room may change from time to time, but may be ascertained by inquiry to the receptionist in the Office of the Director, ACTION.

(b) The Agency maintains regional offices in the following locations:

Region I—Boston, Massachusetts (Connecticut, Maine, Massachusetts, New Hampshire, Vermont and Rhode Island)

Region II—New York, New York (New Jersey, New York, Puerto Rico and Virgin Islands)

Region III—Philadelphia, Pennsylvania (Delaware, District of Columbia, Kentucky, Maryland, Ohio, Pennsylvania, Virginia and West Virginia)

Region IV—Atlanta, Georgia (Alabama, Florida, Georgia, Mississippi, North Carolina, South Carolina and Tennessee)

Region V—Chicago, Illinois (Illinois, Indiana, Iowa, Michigan, Minnesota and Wisconsin)

Region VI—Dallas, Texas (Arkansas, Kansas, Louisiana, Missouri, New Mexico, Oklahoma and Texas)

Region VIII—Denver, Colorado (Colorado, Montana, Nebraska, North Dakota, South Dakota, Utah and Wyoming)

Region IX—San Francisco, California (American Samoa, Arizona, California, Guam, Hawaii and Nevada)

Region X—Seattle, Washington, (Alaska, Idaho, Oregon and Washington)

ACTION also maintains offices in most states, usually in the state capital. These field offices are not responsible for maintaining indexes, reading rooms, or records or documents other than those created and maintained in the normal course of the official business of such offices.

§ 1215.5 Record request and response procedures.

(a) *How made and addressed.* Requests under the Act for access to

ACTION records must be in writing, and may be mailed or hand-delivered to the Director, Administrative Services Division, 806 Connecticut Avenue NW., Washington, DC 20525. All such requests, and the evelopes in which they are sent, must be plainly marked "FOIA Request". Hand-delivered requests will be received between 10 a.m. and 4 p.m., Monday through Friday, except on official holidays.

(b) *Agreement to pay fees.* The filing of a request under this subpart shall be deemed to constitute an agreement by the requester to pay all applicable fees under § 1215.7 of this part, up to $25, unless a waiver of fees is sought in the request letter. When filing a request, a requester may agree to pay a greater amount, if costs are expected to exceed $25.00.

(c) *Request must adequately describe the record sought.* A request must describe the records sought in sufficient detail to enable Agency personnel to locate the records with reasonable effort. A request shall be regarded as fulfilling this requirement if it enables the Agency to identify responsive documents without unreasonable burden to or disruption of Agency operations. Persons wishing to inspect or secure copies of records should describe and identify such records as fully and as accurately as possible. Among the kinds of identifying information which a requester may provide are the following:

(1) The unit or program of the Agency which may have produced or may otherwise have custody of the record (*e.g.*, VISTA, RSVP, FGP);

(2) The specific event or action, if any, to which the record pertains;

(3) The date of the record, or the time period to which it refers or relates;

(4) The type of record (*e.g.*, application, contract, grant or report);

(5) The name(s) of Agency personnel who may have prepared or been referenced in the record; and

(6) Citation to newspapers or other publications which refer to the record;

(7) The distribution made of the record.

(d) *Initial processing.* Upon receipt of a request for Agency records, the Director, Administrative Services Division, will make an initial determination as to whether the request describes requested records with sufficient specificity to determine the office of the Agency having custody of any responsive records. If so, upon making such initial determination, he shall refer such request to the head of the custodial office. The office head shall promptly ascertain whether the description of records(s) requested is sufficient to permit a determination as to existence, identification, and location.

(e) *Insufficiently identified records.* On making a determination that the description contained in the request does not sufficiently describe a requested record, the Director, Administrative Services Division, shall promptly so advise the requester in writing; the requester may submit an amended request providing necessary additional identifying information. Such a request shall be deemed to have been received by the Agency on the date it receives the amended request.

(f) *Release of records; denial and right to appeal.* Upon receipt of a request specifically identifying existing Agency records, the Agency shall, within ten working days, either grant or deny the request in whole or in part, as provided in this subpart. Any notice of denial in whole or in part shall also inform the requester of this right to appeal the denial, in accordance with the procedures set forth at § 1215.9 below. If the Assistant Director, Administrative Services Division, determines that a request describes a requested record sufficiently to permit its identification, he/she shall review the requested records with the custodial office and the General Counsel, and shall make it available as provided herein, unless he/she decides to withhold the records as exempt from mandatory disclosure under the Act.

(g) *Form and content of notice granting a request.* The Agency shall provide written notice of a determination to grant a request. Such notice shall describe the manner in which the record will be disclosed, whether by providing a copy of the record to the requester or by making the record available to the requester for inspection at a reasonable time and place. The procedure for inspection shall not unreasonably disrupt the operations of the Agency. The Agency shall inform the requester in the notice of any fees charged in accordance with the provisions of § 1215.7 of this part.

(h) *Form and content of notice denying a request.* The Agency shall notify a requester in writing of the denial of a request in whole or in part. Such notice shall include:

(1) The name and title or position of the person responsible for the denial;

(2) A brief statement of the reason or reasons for the denial, including the exemption or exemptions under the Act on which the Agency has relied in denying the request, and a specific explanation of the manner in which the exemption or exemptions apply to each record withheld; and

(3) A statement that the denial may be appealed under § 1215.9 of this part, and a copy of that section.

§ 1215.6 Time limits and extensions.

(a) The time limits specified for the Agency's initial response in § 1215.5, and for its determination on an appeal in § 1215.9, are mandatory, and a person requesting records shall be deemed to have exhausted his administrative remedies with respect to such request in the event the Agency fails to comply with the applicable time limits in accordance with this section.

(b) The time limits specified for the Agency's initial response in § 1215.5, and for its determination on an appeal in § 1215.9, may be extended by the Agency upon written notice to the requester which sets forth the reasons for such extension and the date upon which the Agency will respond to the request. Such extension may be applied at either the initial response stage or the appeal stage, or both, provided the aggregate of such extensions shall not exceed ten working days. Circumstances justifying an extension under this subpart may include the following:

(1) Time necessary to search for and collect requested records from field offices of the Agency;

(2) Time necessary to locate, collect and review voluminous records responsive to a single request; or

(3) Time necessary for consultation with another agency having an interest in the request; or among two or more offices of ACTION which have an interest in the request; or with a submitter of business information having an interest in the request.

§ 1215.7 Schedule of fees.

(a) It is the policy of ACTION to encourage the widest possible dissemination of information concerning the programs under its jurisdiction. To the extent practicable, this policy will be applied under this part so as to permit requests for inspection of copies of records to be met without substantial cost to requesters.

(b) Request processing charges will be determined by category of request, as follows:

(1) *Commercial use requests.* When a request for records is made for commercial use, charges will be assessed to cover the costs of searching for, reviewing for release, and reproducing the records sought.

(2) *Requests from educational and non-commercial scientific institutions.* When a request for records is made by an educational or a non-commercial scientific institution in furtherance of scholarly or scientific research, respectively, charges will be assessed to cover the cost of reproduction alone,

excluding charges for reproduction of the first 100 pages.

(3) *Requests from representatives of the news media.* When a request for records is made by a representative of the news media for the purpose of news dissemination, charges will be assessed to cover the cost of reproduction alone, excluding charges for reproduction of the first 100 pages.

(4) *All other requests.* When a request for records is made by a requester who does not fit into any of the preceding categories, charges will be assessed to cover the costs of searching for and reproducing the records sought, excluding charges for the first two hours of search time and for reproduction of the first 100 pages. (However, requests from record subjects for records about themselves contained in the Agency's systems of records will be treated under the fee provisions of the Privacy Act of 1974 which permit the assessment of fees for reproduction costs only, regardless of the requester's characterization of the request).

(c) Fees assessed shall provide only for recovery of the Agency's direct costs of search, review, and reproduction. Review costs shall include only the direct costs incurred during the initial examination of a record for the purposes of determining whether a record must be disclosed under this part and whether any portion of a record is exempt from disclosure under this part. Review costs shall not include any costs incurred in resolving legal or policy issues raised in the course of processing a request or an appeal under this part.

(d) When the Agency believes that a requester or group of requesters has divided one request into a series of requests for the purpose of evading the assessment of fees, the Agency may treat such requests as a single request.

(e) The following charges may be assessed for copies of records provided to a requester:

(1) Copies made by photostat shall be charged at the rate of $0.10 per page.

(2) Searches for requested records performed by clerical/administrative personnel shall be charged at the rate of $3.00 per quarter hour.

(3) Where a search for requested records cannot be performed by clerical/administrative personnel (for example, where the tasks of identifying and compiling records responsive to a request must be performed by a skilled technician or professional), such search shall be charged at the rate of $5.50 per quarter hour.

(4) Computer searches for requested records shall be charged at a rate commensurate with the combined cost of computer operation and operator's salary attributable to the search.

(f) In the event a request for records does not state that the requester will pay all reasonable costs, or costs up to a specified dollar amount, and the Director, Administrative Services Division, determines that the anticipated assessable costs for search, review and reproduction of requested records will exceed $25.00, or will exceed the limit specified in the request, the requester shall be promptly notified in writing. Such notification shall state the anticipated assessable costs of search, review and reproduction of records requested. The requester shall be afforded an opportunity to amend the request to narrow the scope of the request, or, alternatively, may agree to be responsible to pay the anticipated costs. Such a request shall be deemed to have been received by the Agency upon the date of receipt of the amended request.

(g) Advance payment of assessable fees may be required from a requester when:

(1) The Agency estimates or determines that assessable charges are likely to exceed $250.00, and the requester has no history of payment of FOIA fees. (Where the requester has a history of prompt payment of fees, the Agency may require satisfactory assurance of full payment.)

(2) A requester has previously failed to pay a FOIA fee charged in a timely fashion (*i.e.*, within 30 days of the date of the billing).

When the Agency acts under paragraph (g) (1) or (2) of this section, the administrative time limits prescribed in subsection (a)(6) of the Act will begin to run only after the Agency has received fee payments or assurances.

(h) Interest charges on an unpaid bill may be assessed starting on the 31st day following the day on which the billing was sent. Interest will be assessed at the rate prescribed in section 3717 of Title 31 U.S.C., and will accrue from the date of billing.

(i) Payment of fees shall be made to the Director, Administrative Services Division, by check or money order payable to "ACTION." A receipt for any fees paid will be provided upon written request.

(j) Charges may be assessed for search and review time, even if the Agency fails to locate records responsive to a request or if records located are determined to be exempt from disclosure.

(k) No fee shall be charged if the costs of routine collection and processing of the fee will equal or exceed the amount of the fee.

(l)(1) a requester may, in the original request, or subsequently, apply for a waiver or reduction of document search, review and reproduction fees. Such application shall be in writing, and shall set forth in detail the reason(s) a fee waiver or reduction should be granted. The amount of any reduction requested shall be specified in the request. Upon receipt of such a request, the Director of Administrative Services shall refer the request to the Deputy Director or to such official as the Deputy Director may designate, who shall promptly determine whether such fee waiver or reduction shall be granted.

(2) A waiver or reduction of fees shall be granted only if release of the requested information to the requester is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the Agency, and is not primarily in the commercial interest of the requester. The Agency shall consider the following factors in determining whether an application for a fee waiver or reduction will be granted:

(i) Does the requested information concern the operations or activities of the Agency?

(ii) If so, will disclosure of the information be likely to contribute to public understanding of the Agency's operations and activities?

(iii) If so, would such a contribution be significant?

(iv) Does the requester have a commercial interest that would be furthered by disclosure of the information?

(v) If so, is the magnitude of the identified commercial interest of the requester sufficiently large, in comparison with the public interest in disclosure, that disclosure is primarily in the commercial interest of the requester? In applying this criterion, the Agency will weigh the requester's commercial interest against any public interest in disclosure. Where there is a public interest in disclosure, and that public interest can fairly be regarded as being of greater magnitude than the requester's commercial interest, a fee waiver or reduction will be granted.

(3) When a fee waiver application has been included in a request for records, or has been made subsequent thereto, the request shall not be deemed to have been received until an Agency determination is made regarding the fee waiver application, provided, however, that such determination shall be made within five working days from the date any such request is received by the Agency.

(m) The Agency may use the authorities of the Debt Collection Act of 1982 (Pub. L. 97–365), including disclosure to consumer reporting agencies and the use of collection agencies, to encourage payment of delinquent fees.

§ 1215.8 Business information.

(a) Business information provided to ACTION by a business submitter shall be disclosed pursuant to a request under the Act in accordance with this section.

(b) The Agency shall promptly notify a business submitter is writing of any request for Agency records containing business information. Such written notice shall either specifically describe the nature of the business information requested or provide copies of the records, or portions thereof containing the business information.

(c) Through the notice required in paragraph (b) of this section, the Agency shall afford a business submitter a reasonable opportunity to object to disclosure of the information in question, and to provide the Agency with a written statement of grounds for such objection. Such statement shall specify all grounds for withholding any information under any exemption of the Act and, in cases where it argues information should be withheld under exemption (b)(4) of the Act, a business submitter shall state specifically why the information is a trade secret or is otherwise protected as proprietary commercial or financial information. Information provided by a business submitter pursuant to this paragraph may itself be subject to disclosure under the Act.

(d) The Agency shall consider carefully a business submitter's objections and specific grounds for nondisclosure prior to determining whether to release requested business information. Whenever the Agency decides to disclose business information over the objection of a business submitter, the Agency shall forward to the business submitter a written notice of such decision, which shall include:

(1) The name, and title or position, of the person responsible for denying the submitter's objection;

(2) A statement of the reasons for which the business submitter's objection was not sustained;

(3) A description of the business information to be disclosed; and

(4) A specific disclosure date.

Such notice of intent to disclose business information shall be mailed by the Agency not less than six working days prior to the date upon which disclosure will occur, with a copy of such notice to the requester.

(e) Whenever a requester brings suit to compel disclosure of business information, the Agency shall promptly notify the business submitter.

(f) The notice to submitter requirements of this section shall not apply if:

(1) The Agency determines that the information shall not be disclosed;

(2) The information has previously been published or otherwise lawfully made available to the public; or

(3) Disclosure of the information is required by law (other than 5 U.S.C. 552).

§ 1215.9 Appeal procedures.

Upon receipt of a notice of denial, a requester may, within 15 calendar days from the date of receipt of such notice, appeal such adverse determination to the Deputy Director. Such appeal shall be in writing and shall specify the date upon which the notice of denial was received by the person making such appeal. The Deputy Director shall make a determination with respect to any appeal within 20 working days after receipt of such appeal, and shall give written notice of such determination to the person making the appeal. To the extent the Deputy Director's determination on appeal upholds the original denial, the notice of such determination shall inform the person making the appeal of his right to seek judicial review of the Agency's denial and ruling on appeal as provided in 5 U.S.C. 552(a)(4).

(42 U.S.C. 5042(13); 5 U.S.C. 552)

Issued at Washington, DC, on October 21, 1987.

Donna M. Alvarado,

Director.

[FR Doc. 88–1038 Filed 1–19–88; 8:45 am]

BILLING CODE 6050–28–M

Notices

Federal Register
Vol. 53, No. 12
Wednesday, January 20, 1988

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.

ACTION

Foster Grandparent and Senior Companion Programs; Income Eligibility Levels

AGENCY: Action.

ACTION: Notice of revision of income eligibility levels for foster grandparents and senior companion programs.

SUMMARY: This notice revises the schedules of income eligibility levels for participation in the Foster Grandparent and Senior Companion Programs published in the **Federal Register**, October 2, 1986 (51 FR 35258). The revised schedule is based on revised Poverty Income Guidelines from the Department of Health and Human Services (DHHS), effective February 20, 1987 (52 FR 5341) and Supplemental Security Income (SSI) guidelines published by the Social Security Administration, January 1987. This revision adopts as the income eligibility level for each State the higher amount of either: (a) 125% of the DHHS Poverty Income Guideline, or (b) 100% of the DHHS Poverty Income Guideline plus the amount each state supplements Federal SSI, rounded to the next highest multiple of $5.00.

Any person whose income is not more than 100 percentum of the DHHS poverty income guideline for her/his specific household unit status shall be given special consideration for participation in the Foster Grandparent and Senior Companion Programs.

EFFECTIVE DATE: January 20, 1988.

FOR FURTHER INFORMATION CONTACT: C. Wade Freeman, Assistant Director, Older American Volunteer Programs, ACTION, 806 Connecticut Avenue NW., M–1006, Washington, DC 20525 or telephone (202) 634–9355.

SUPPLEMENTARY INFORMATION: Thses ACTION programs are authorized pursuant to sections 211 and 213 of the Domestic Volunteer Service Act of 1973, as amended, Pub. L. 93–113, 97 Stat. 394. The income eligibility levels are determined by the currently applicable guideline published by DHHS pursuant to sections 652 and 673(2) of the Omnibus Budget Reconciliation Act of 1981 which requires poverty income guidelines to be adjusted for Consumer Price Index changes.

The income eligibility levels will be reviewed at least once a year, and similar schedules will be prepared to reflect any changes required as a result of that review.

Schedule of Income Eligibility Levels: Foster Grandparent and Senior Companion Programs

For all States, (except Alaska, Hawaii, California, Connecticut, Massachusetts, Missouri, New Jersey and Wisconsin) the District of Columbia, Puerto Rico and the Virgin Islands

For household units of—							
One	Two	Three	Four	Five	Six	Seven	Eight
$6,875	9,250	11,625	14,000	16,375	18,750	21,125	23,500

For the following States:

State	For household units of—							
	One	Two	Three	Four	Five	Six	Seven	Eight
AK	10,530	14,175	16,475	18,745	21,075	23,375	25,675	27,975
CA	9,005	16,450	18,350	20,250	22,150	24,050	25,950	27,850
CT	7,255	8,470	10,370	12,270	14,170	16,070	17,970	19,870
HI	10,365	14,365	16,665	18,965	21,265	23,565	25,865	28,165
MA	6,875	9,825	11,725	13,625	15,525	17,425	19,325	21,225
MO	7,160	10,715	12,615	14,515	16,415	18,315	20,215	22,115
NJ	7,300	12,825	22,125	24,025	25,925	27,825	29,725	31,625
WI	6,875	9,380	11,625	14,000	16,375	18,750	21,125	23,500

For household units with more than eight members add the appropriate supplement for each additional member (over eight) as follows:

Alaska, $2,300
Hawaii, 2,190
All Others, 1,900

All of the above levels are calculated from the base DHHS Poverty Income Guidelines now in effect.

Those guidelines are:

Size of family unit	For all states (except Alaska and Hawaii) and the District of Columbia	For Alaska	For Hawaii
1	$5,500	$6,860	$6,310
2	7,400	9,240	8,500
3	9,300	11,620	10,690
4	11,200	14,000	12,880
5	13,100	16,380	15,070
6	15,000	18,760	17,250
7	16,900	21,140	19,450
8	18,800	23,520	21,640

Signed in Washington, DC, on January 13, 1988.

Donna M. Alvarado,

Director of ACTION.

[FR Doc. 88–1009 Filed 1–19–88; 8:45 am]

BILLING CODE 6050–28–M

DEPARTMENT OF AGRICULTURE

[Docket No. 87-012N-1]

National Advisory Committee on Microbiological Criteria for Foods; Change in Name

This notice announces a change in the name of the National Advisory Committee on Microbiological Quality Standards for Foods. On November 10, 1987, the Department published a notice announcing its intention to establish the National Advisory Committee on Microbiological Quality Standards for Foods (52 FR 43216). Interested persons were invited to submit written comments concerning this notice. As a result, four comments were received by the Department, all of which supported establishment of the Committee. However, the commenters believed that the name of the Committee should be changed to the National Advisory Committee on Microbiological Criteria for Foods to better reflect the intent of the National Academy of Sciences Committee on Food Protection, Subcommittee on Microbiological Criteria with initially recommended that this Advisory Committee be formed.

The Department concurs with this recommendation and has changed the name of the Committee to the National Advisory Committee on Microbiological Criteria for Foods.

John J. Franke, Jr.,

Assistant Secretary for Administration.

January 13, 1988.

[FR Doc. 88-1041 Filed 1-19-88; 8:45 am]

BILLING CODE 3410-DM-M

Soil Conservation Service

Tesnatee Creek Watershed, GA; Environmental Impact Statement

AGENCY: Soil Conservation Service, USDA.

ACTION: Notice of a finding of no significant impact.

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969; the Council on Environmental Quality Guidelines (40 CFR Part 1500); and the Soil Conservation Service Guidelines (7 CFR Part 650); the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the Tesnate Creek Watershed, Lumpkin and White Counties, Georgia.

FOR FURTHER INFORMATION CONTACT: B. C. Graham, State Conservationist, Soil Conservation Service, Federal Building, Box 13, 335 East Hancock Avenue, Athens, Georgia 30601; telephone: 404-546-2273.

SUPPLEMENTARY INFORMATION: The environmental assessment of this federally assisted action, prepared by the Corps of Engineers in the 404 Permit process and supplemented by data developed by the Soil Conservation Service, indicates that the project will not cause significant local, regional, or national impacts on the environment. As as result of these findings, B.C. Graham, State Conservationist, has determined that the preparation and review of an environmental impact statement are not needed for this project.

The project concerns a plan for flood control and municipal water storage. The planned works of improvement include the construction of a dam approximately 700 feet long, 60 feet high, and 250 feet wide on Turner Creek, 2 miles west of Cleveland, White County, Georgia. The purpose of the project is flood control and water supply for the City of Cleveland. Approximately 550 feet of the channel below the outlet will be realigned. Above the dam, a reservoir aproximately 40 acres in surface area will be created at normal pool elevation.

The Finding of No Significant Impact (FONSI) has been forwarded to the Environmental Protection Agency and to various Federal, State, and local agencies and interested parties. A limited number of copies of the FONSI are available to fill single copy requests at the above address. Basic data developed during the environmental assessment are on file and may be reviewed by contacting Mr. B.C. Graham.

No administrative action on implementation of the proposal will be taken until 30 days after the date of this publication in the **Federal Register.**

(This activity is listed in the Catalog of Federal Domestic Assistance under No. 10.904—Watershed Protection and Flood Prevention—and is subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials.)

Dated: December 7, 1987.

B.C. Graham,

State Conservationist.

[FR Doc. 88-963 Filed 1-19-88; 8:45 am]

BILLING CODE 3410-16-M

Waterfall-Gilford Creek Watershed, OK; Environmental Impact Statement

AGENCY: Soil Conservation Service, USDA.

ACTION: Notice of availability of a record of decision.

SUMMARY: Budd Fountain, responsible Federal official for projects administered under the provisions of Pub. L. 83-566, 16 U.S.C. 1001-1008, in the State of Oklahoma, is hereby providing notification that a record of decision to proceed with installation of the Waterfall-Gilford Creek watershed project is available. Single copies of this record of decision may be obtained from C. Budd Fountain at the address shown below.

FOR FURTHER INFORMATION CONTACT: C. Budd Fountain, State Conservationist, Soil Conservation Service, USDA Agricultural Center Building, Stillwater, Oklahoma 74074, telephone (405) 624-4360.

(Catalog of Federal Domestic Assistance Program No. 10.904, Watershed Protection and Flood Prevention. State and local review procedures for Federal and federally assisted programs projects are applicable.)

Donald R. Vandersypen,

Assistant State Conservationist (WR).

Date: December 9, 1987.

[FR Doc. 88-964 Filed 1-19-88; 8:45 am]

BILLING CODE 3410-16-M

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 370]

Resolution and Order Approving the Application of the Caddo-Bossier Parishes Port Commission for a Foreign-Trade Zone in Shreveport, LA

Proceedings of the Foreign-Trade Zones Board, Washington, DC.

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 Caddo-Bossier Parishes Port Commission, a Louisiana public corporation, filed with the Foreign-Trade Zones Board (the Board) on February 20, 1987, requesting a grant of authority for establishing, operating, and maintaining a general-purpose foreign-trade zone in Shreveport, Louisiana, within the Shreveport-Bossier City 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 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 of Authority To Establish, Operate, and Maintain a Foreign-Trade Zone in Shreveport, Louisiana

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 Caddo-Bossier Parishes Port Commission (the Grantee), a Louisiana public corporation, has made application (filed February 20, 1987, Docket 1–87, 52 FR 7633) in due and proper form to the Board, requesting the establishment, operation, and maintenance of a foreign-trade zone in Shreveport, Louisiana, within the Shreveport-Bossier City 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. 145, 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 the following express conditions and limitations:

Operation 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 site in the performance of their official duties.

The grant does not include authority for manufacturing operations, and the Grantee shall notify 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, DC, this 7th day of January, 1988, pursuant to Order of the Board.

Foreign-Trade Zones Board.

C. William Verity,

Chairman and Executive Officer.

Attest:

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 88–1036 Filed 1–19–88; 8:45 am]

BILLING CODE 3510-DS-M

International Trade Administration

[C-565-001]

Canned Tuna From the Philippines; Intention To Review and Preliminary Results of Changed Circumstances Administrative Review and Tentative Determination To Revoke Countervailing Duty Order

AGENCY: International Trade Administration, Import Administration, Commerce.

ACTION: Notice of intention to review and preliminary results of changed circumstances administrative review and tentative determination to revoke countervailing duty order.

SUMMARY: The Department of Commerce has received information which shows changed circumstances sufficient to warrant an administrative review of the countervailing duty order on canned tuna from the Philippines. Because the petitioner has notified the Department that it is no longer interested in maintaining the countervailing duty order, we tentatively determine to revoke the order. We invite interested parties to comment on these preliminary results and tentative determination to revoke.

EFFECTIVE DATE: January 1, 1986.

FOR FURTHER INFORMATION CONTACT: Christopher Beach or Bernard Carreau, Office of Compliance, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230; telephone: (202) 377–2786.

SUPPLEMENTARY INFORMATION:

Background

On October 30, 1987, the petitioner, the Tuna Research Foundation, informed the Department of Commerce ("the Department") that it was no longer interested in maintaining the countervailing duty order on canned tuna from the Philippines (48 FR 50133 October 31, 1983).

Scope of Review

The United States has developed a system of tariff classification based on the international harmonized system of Customs nomenclature. Congress is considering legislation to convert the United States to this Harmonized System ("HS"). In view of this, we will be providing both the appropriate *Tariff Schedule of the United States Annotated* ("TSUSA") item numbers and the appropriate HS item numbers with our product descriptions on a test basis, pending Congressional approval. As with the TSUSA, the HS item numbers are provided for convenience and Customs purposes. The written description remains dispositive.

We are requesting petitioners to include the appropriate HS item number(s) as well as the TSUSA item number(s) in all new petitions filed with the Department. A reference copy of the proposed Harmonized System schedule is available for consultation at the Central Records Unit, Room B–099, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230. Additionally, all Customs offices have reference copies, and petitioners may contact the Import

Specialist at their local Customs office to consult the schedule.

Imports covered by the review are shipments of Philippine tuna packed and preserved in any manner, not in oil, in airtight containers. Such merchandise is currently classifiable under TSUSA item numbers 112.3020, 112.3040, and 112.3400. These products are currently classifiable under HS item numbers 1604.14.20–0 and 1604.14.30–0. We invite comments from all interested parties on these HS numbers. The review covers the period from January 1, 1986.

Preliminary Results of Review and Tentative Determination

As a result of our review, we preliminarily determine that the statement by the petitioner, the Tuna Research Foundation, that it is no longer interested in maintaining the countervailing duty order on canned tuna from the Philippines provides a reasonable basis for revocation of the order. Therefore, we tentatively determine to revoke the order on canned tuna from the Philippines effective January 1, 1986.

We intend to instruct the Customs Service to liquidate, without regard to countervailing duties, all unliquidated entries of this merchandise entered, or withdrawn from warehouse, for consumption on or after January 1, 1986, and to refund any estimated countervailing duties collected with respect to those entries. The current waiver of cash deposits of estimated countervailing duties will continue until publication of the final results of this review.

Interested parties may submit written comments on these preliminary results and tentative determination to revoke within 30 days of the date of publication of this notice and may request disclosure and/or a hearing within five days of the date of publication. Any hearing, if requested, will be held 30 days after the date of publication, or the first workday following. The Department will publish the final results of the review and its decision on revocation, including its analysis of issues raised in any such written comments or at a hearing.

This intention to review, administrative review, tentative determination to revoke, and notice are in accordance with sections 751 (b) and (c) of the Tariff Act of 1930 (19 U.S.C. 1675 (b) and (c)) and §§ 355.41 and 355.42 of the Commerce Regulations (19 CFR 355.41, 355.42).

Gilbert B. Kaplan,

Acting Assistant Secretary for Import Administration.

Date: January 13, 1988.

[FR Doc. 88–1035 Filed 1–19–88; 8:45 am]

BILLING CODE 3510-DS-M

Subcommittee on Export Administration of the President's Export Council; Closed Meeting

A closed meeting of the President's Export Council Subcommittee on Export Administration will be held February 10, 1988, 9 a.m. to 3 p.m., U.S. Department of Commerce, Herbert Hoover Building, Room 4830, 14th and Constitution Avenue, NW., Washington, DC.

The Subcommittee provides advice on matters pertinent to those portions of the Export Administration Act, as amended, that deal with United States policies of encouraging trade with all countries with which the United States has diplomatic or trading relations, and of controlling trade for national security and foreign policy reasons.

Executive Session

9:00 a.m.–3:00 p.m. Discussion of matters properly classified under Executive Order 12610 pertaining to the control of exports for national security, foreign policy or short supply reasons under the Export Administration Act of 1979, as amended. A Notice of Determination to close meetings, or portions of meetings, of the subcommittee to the public on the basis of 5 U.S.C. 522(c)(1) was approved October 27, 1987, in accordance with the Federal Advisory Committee Act. A copy of the Notice of Determination is available for public inspection and copying in the Central Reference and Records Inspection Facility, Room 6628, U.S. Department of Commerce, (202) 377–4217.

For further information contact Sharon A. Gongwer, (202) 377–4275.

Vincent F. DeCain,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 88–1034 Filed 1–19–88; 8:45 am]

BILLING CODE 3510-DT-M

National Oceanic and Atmospheric Administration

National Marine Fisheries Service, Marine Fisheries Advisory Committee; Meeting

AGENCY: National Marine Fisheries Service (NMFS), NOAA.

Time and Date: The meeting will convene at 8:15 a.m., February 3, 1988, and adjourn at approximately 3:00 p.m., Febraury 4, 1988.

Place: La Jolla Village Inn, 3299 Holiday Court, La Jolla, California.

Status: As required by section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1982), notice is hereby given of a meeting of the Marine Fisheries Advisory Committee (MAFAC). Parts of this meeting will be open to the public. The remainder of the meeting will be closed to the public. MAFAC was established by the Secretary of Commerce on Febraury 17, 1971, to advise the Secretary on all living marine resource matters which are the responsibility of the Department of Commerce. This Committee ensures that the living marine resource policies and programs of this Nation are adequate to meet the needs of commercial and recreational fishermen, environmental, state, consumer, academic, and other national interests.

Matters to Be Considered

Portions Open to the Public

February 3, 1988, 8:30 a.m.–12:00 noon, marine mammal protection act reauthorization, marine debris, proposed regulations/guidelines on Council/NMFS operations.

February 4, 1988, 8:00 a.m.–300 p.m., budget and program planning, marine fishing license proposals, MAFAC subcommittee reports, federal fisheries responsibilities, and fishery highlights.

Portion Closed to The Public

February 3, 1988, 1:30–3:30 p.m. (Executive Session), budget and program priorities.

SUPPLEMENTARY INFORMATION: The Assistant Secretary for Administration of the Department of Commerce, with concurrence of the General Counsel, formally determined on January 13, 1988, pursuant to section 10(d) of the Federal Advisory Committee Act, that the agenda item to be covered during the Executive Session may be exempt from the provisions of the Act relating to open meetings and public participation therein, because the item will be concerned with matters that are within the purview of 5 U.S.C. 552b(c)(9)(B) as information the premature disclosure of which will be likely to significantly frustrate the implementation of proposed agency action. (A copy of the determination is available for public inspection and duplication in the Central Reference and Records Inspection Facility, Room 6628, Department of Commerce.) All other

portions of the meeting will be open to the public.

FOR FURTHER INFORMATION CONTACT: Ann Smith, Executive Secretary, Marine Fisheries Advisory Committee, Constituent Affairs Staff—Fisheries, Office of Legislative Affairs, NOAA, Washington, DC 20235. Telephone: (202) 673–5429.

Date: January 13, 1988.

Bill Powell,

Executive Director.

[FR Doc. 88–980 Filed 1–19–88; 8:45 am]

BILLING CODE 3510–08–M

Regional Fishery Management Councils; Public Meeting

AGENCY: National Marine Fisheries Service, NOAA, Commerce.

Representatives of the Scientific and Statistical Committees of the Western Pacific, North Pacific and Pacific Fishery Management Councils will convene a joint public meeting, February 4, 1988, at 1:30 p.m., at the Seattle Airport Hilton, 17620 Pacific Highway South, Seattle, WA, to review the proposed revisions to the Code of Federal Regulations, Guidelines for Fishery Management Plans. The public meeting will adjourn February 5, 1988.

FOR FURTHER INFORMATION CONTACT: Lawrence D. Six, Executive Director, Pacific Fishery Management Council, Metro Center, Suite 420, 2000 SW. First Avenue, Portland, OR 97201; telephone: (503) 221–6352.

Date: January 13, 1988.

Ann D. Terbush,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 88–1048 Filed 1–19–88; 8:45 am]

BILLING CODE 3510–22–M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Solicitation of Public Comment on Bilateral Negotiations During 1988

January 14, 1988.

The U.S. Government anticipates holding negotiations during 1988 concerning expiring bilateral agreements covering certain cotton, wool and man-made fiber textiles and apparel from Brazil (March 31, 1988), Costa Rica (December 31, 1988), Dominican Republic (May 31, 1988), Guatemala (December 31, 1988), Maldives (September 28, 1988), Sri Lanka (May 31, 1988), Thailand (December 31, 1988), Turkey (June 30, 1988) and the Union of the Socialist Soviet Republics (December 31, 1988). (The dates noted in parenthesis are the expiration dates of the agreements.)

The purpose of this notice is to invite any party wishing to comment or provide data or information regarding these agreements, or to comment on domestic production or availability of textiles and apparel affected by these agreements, submit such comments or information in ten copies to Mr. James H. Babb, Chairman, Committee for the Implementation of Textile Agreements, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230. Because the exact timing of the consultations is not yet certain, comments should be submitted promptly. Comments or information submitted in response to this notice will be available for public inspection in the Office of Textiles and Apparel, Room 3100, U.S. Department of Commerce, 14th and Constitution Avenue NW., Washington, DC. Further comment may be invited regarding particular comments or information received from the public which the Committee for the Implementation of Textile Agreements considers appropriate for further consideration.

The solicitation of comments regarding any aspect of the agreement or the implementation thereof is not a waiver in any respect of the exemption contained in 5 U.S.C. 553(a)(1) relating to matters which constitute "a foreign affairs function of the United States."

Donald R. Foote,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 88–1033 Filed 1–19–88; 8:45 am]

BILLING CODE 3510–DR–M

Adjustment of Import Limits for Certain Cotton, Wool, Man-Made Fiber, Silk Blend and Other Vegetable Fiber Textiles and Textile Products From Malaysia; Correction

In the **Federal Register** notice (52 FR 45371) and the corresponding letter to the Commissioner of November 20, 1987, which announced adjusted import limits for certain cotton, wool, man-made fiber, silk blend and other vegetable fiber textiles and textile products, produced or manufactured in Malaysia, Category 438pt. should be changed to Category 438–W.

Footnote 3 should be changed to read: In Category 438–W, only TSUSA numbers 384.1307, 384.1309, 384.2711, 384.5434, 384.5910, 384.6310, 384.7724 and 384.9640.

Donald R. Foote,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 88–1032 Filed 1–19–88; 8:45 am]

BILLING CODE 3510–DR–M

COMMODITY FUTURES TRADING COMMISSION

Public Information Collection Requirement Submitted to Office of Management and Budget for Review

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of information collection.

SUMMARY: The Commodity Futures Trading Commission has submitted information collection 3038–0017, Market Surveys, to OMB for review and clearance under the Paperwork Reduction Act of 1980, Pub. L. 96–511. The information collected pursuant to this rule provides a basis for periodic Commission publications and is used by Commission economists and universities for research projects.

ADDRESS: Persons wishing to comment on this information collection should contact Robert Neal, Office of Management and Budget, Room 3228, NEOB, Washington, DC 20502, (202) 395–7340. Copies of the submission are available from Joseph G. Salazar, Agency Clearance Officer, (202) 254–9735.

Title: Market Surveys.

Control Number: 3038–0017.

Action: Extension.

Respondents: Businesses (excluding small businesses).

Estimated Annual Burden: 700.

Estimated Number of Respondents: 400.

Issued in Washington, DC on January 14, 1988.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 88–1031 Filed 1–19–88; 8:45 am]

BILLING CODE 6351–01–M

DEPARTMENT OF EDUCATION

[CFDA No. 84.083]

Applications for New Awards Under the Women's Educational Equity Act Program for Fiscal Year 1988

AGENCY: Department of Education.

ACTION: Correction notice.

SUMMARY: This notice corrects an error made in the application notice published on November 5, 1987, in the **Federal Register** on page 42472. Under the heading "Priorities", the citation for model projects to eliminate persistent barriers to educational equity for women in 34 CFR is corrected to read § 745.27.

FOR APPLICATIONS OR FURTHER INFORMATION CONTACT: Ms. Alice T. Ford, Women's Educational Equity Act Program, U.S. Department of Education, 400 Maryland Avenue SW., Room 2053, FOB–6, Washington, DC 20202. Telephone (202) 732–4351.

Program Authority: 20 U.S.C. 3341–3348.

Dated: January 13, 1988.

Beryl Dorsett,

Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 88–1015 Filed 1–19–88; 8:45 am]

BILLING CODE 4000–01–M

DEPARTMENT OF ENERGY

Economic Regulatory Administration

[ERA Docket No. 87–69–NG]

Development Associates, Inc.; Application To Import Natural Gas From Canada

AGENCY: Economic Regulatory Administration, DOE.

ACTION: Notice of application to extend blanket authorization to import natural gas from Canada.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) gives notice of receipt on December 4, 1987, of an application filed by Development Associates, Inc. (DA), a wholly owned subsidiary of the Washington Water Power Company (Washington Water Power), to extend for two years its existing blanket authorization to import Canadian natural gas granted by the ERA in DOE/ERA Opinion and Order No. 102 (Order No. 102) issued January 14, 1986 (1 ERA 70,620). DA further requests that during this extended period it be authorized to import a maximum of 30 Bcf of natural gas, an increase from the 20 Bcf allowed under its present authorization for the period ending March 29, 1988. The applicant maintains that the increase in volume is necessary to supply the needs of end-use customers and local distribution companies who are increasingly availing themselves of opportunities to purchase natural gas in the spot market on competitive terms.

The application is filed with the ERA pursuant to section 3 of the Natural Gas Act and DOE Delegation Order No. 0204–111. Protests, motions to intervene, notices of intervention and written comments are invited.

DATE: Protests, motions to intervene, or notices of intervention as applicable, and written comments are to be filed no later than February 19, 1988.

FOR FURTHER INFORMATION CONTACT:

John Boyd, Natural Gas Division, Economic Regulatory Administration, Forrestal Building, Room GA–076, 1000 Independence Avenue SW., Washington, D.C. 20585, (202) 586–4523

Diane Stubbs, Natural Gas and Mineral Leasing, Office of General Counsel, U.S. Department of Energy, Forrestal Building, Room 6E–042, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–6667.

SUPPLEMENTARY INFORMATION: The gas will be supplied by individual producers, producer groups, associations, and pipeline companies on a short-term basis. DA would import such gas either on behalf of, or for resale to, Washington Water Power, other natural gas distributors and a variety of industrial and institutional end-users. The terms and conditions of each supply contract will be determined as a result of negotiations between DA and the Canadian supplier and would be responsive to competitive market prices in the U.S. domestic gas market.

DA proposes to file quarterly reports with the ERA within 30 days after the end of each calender quarter giving the details of the individual transactions. DA's prior quarterly reports filed with the ERA indicate that approximately 9.8 Bcf of natural gas was imported under Order No. 102 through September 30, 1987.

The decision on this application will be made consistent with the DOE's gas import policy guidelines, under which the competitiveness of an import arrangement in the markets served is the primary consideration in determining whether it is in the public interest (49 FR 6684, February 22, 1984). Parties that may oppose this application should comment in their responses on the issue of competitiveness as set forth in the policy guidelines. The applicant asserts that this import arrangement is competitive. Parties opposing the arrangement bear the burden of overcoming this assertion.

Public Comment Procedures

In response to this notice, any person may file a protest, motion to intervene or notice of intervention, as applicable, and written comments. Any person wishing to become a party to the proceeding and to have the written comments considered as the basis for any decision on the application must, however, file a motion to intervene or notice of intervention, as applicable. The filing of a protest with respect to this application will not serve to make the protestant a party to the proceeding, although protests and comments received from persons who are parties will be considered in determining the appropriate action to be taken on the application. All protests, motions to intervene, notices of intervention, and written comments must meet the requirements that are specified by the regulations in 10 CFR Part 590. They should be filed with the Natural Gas Division, Office of Fuels Programs, Economic Regulatory Adminstration, Room GA–076, RG–23, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–9478. They must be filed no later than 4:30 p.m., e.s.t., February 19, 1988.

The Administrator intends to develop a decisional record on the application through responses to this notice by parties, including the parties' written comments and replies thereto. Additional procedures will be used as necessary to acheive a complete understanding of the facts and issues. A party seeking intervention may request that additional procedures be provided, such as additional written comments, an oral presentation, a conference, or trial-type hearing. Any request to file additional written comments should explain why they are necessary. Any request for an oral persentation should identify the substantial question of fact, law, or policy at issue, show that it is material and relevant to a decision in the proceeding, and demonstrate why an oral presentation is needed. Any request for a conference should demonstrate why the conference would materially advance the proceeding. Any request for a trial-type hearing must show that there are factual issues genuinely in dispute that are relevant and material to a decision and that a trial-type hearing is necessary for a full and true disclosure of the facts.

If an additional procedure is scheduled, the ERA will provide notice to all parties. If no party requests additional procedures, as final opinion and order may be issued based on the official record, including the application and responses filed by parties pursuant to this notice, in accordance with 10 CFR 590.316.

A copy of DA's application is available for inspection and copying in the National Gas Division Docket Room,

GA–076–A at the above address. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC., January 7, 1988.

Constance L. Buckley,

Director, Natural Gas Division, Office of Fuels Programs, Economic Regulatory Administration.

[FR Doc. 88–987 Filed 1–19–88; 8:45 am]

BILLING CODE 6450–01–M

[ERA Docket No. 87–70–NG]

Dynasty Gas Marketing, Inc.; Application To Import Natural Gas From Canada

AGENCY: Economic Regulatory Administration, DOE.

ACTION: Notice of application for blanket authorization to import natural gas.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) gives notice of receipt on December 10, 1987, of an application filed by Dynasty Gas Marketing, Inc. (DGM), for blanket authorization to import up to 100 Mcf per day or up to 36.5 Bcf per year of Canadian natural gas over a two-year period, begining on the date of the first delivery, for short-term and spot market sales to customers in the United States. DGM, a marketer of natural gas, is a Texas corporation with its principal place of business in Stafford, Texas. DGM proposes to import the gas from suppliers in the Canadian province of Saskatchewan through existing facilities located on the international border at Monchy, Saskatchewan, Canada. DGM intends to use available capacity on existing pipelines and distribution systems. The specific terms of each import and sale would be negotiated on an individual basis, including the price and volumes, based on competition in the market. DMG states that it will submit quarterly reports giving details of individual transactions.

The application is filed with the ERA pursuant to section 3 of the Natural Gas Act and DOE Delegation Order No. 0204–111. Protests, motions to intervene, notices of intervention and written comments are invited.

DATE: Protests, motions to intervene, or notices of intervention, as applicable, and written comments are to be filed no later than February 19, 1988.

FOR FURTHER INFORMATION CONTACT:

Larine A. Moore, Natural Gas Division, Economic Regulatory Administration, Forrestal Building, Room GA–076, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–9478

Diane Stubbs, Natural Gas and Mineral Leasing, Office of General Counsel, U.S. Department of Energy, Forrestal Building, Room 6E–042, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–6667.

SUPPLEMENTARY INFORMATION: The decision on this application will be made consistent with the DOE's gas import policy guidelines, under which the competitiveness of an import arrangement in the markets served is the primary consideration in determining whether it is in the public interest (49 FR 6684, February 22, 1984). Parties that may oppose this application should comment in their responses on the issue of competitiveness as set forth in the policy guidelines. The applicant asserts that this import arrangement is competitive. Parties opposing the arrangement bear the burden of overcoming this assertion.

In the event ERA approves this request, it may designate only a total volume of natural gas to be imported during the authorized term rather than daily or annual limits in order to provide the importer with maximum operating flexibility.

Public Comment Procedures

In response to this notice, any person may file a protest, motion to intervene or notice of intervention, as applicable, and written comments. Any person wishing to become a party to the proceeding and to have the written comments considered as the basis for any decision on the application must, however, file a motion to intervene or notice of intervention, as applicable. The filing of a protest with respect to this application will not serve to make the protestant a party to the proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate action to be taken on the application. All protests, motions to intervene, notices of intervention, and written comments must meet the requirements that are specified by the regulations in 10 CFR Part 590. They should be filed with the Natural Gas Division, Office of Fuels Programs, Economic Regulatory Administration, Room GA–076, RG–23, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–9478. They must be filed no later than 4:30 p.m. e.s.t., February 19, 1988.

The Administrator intends to develop a decisional record on the application through responses to this notice by parties, including the parties' written comments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. A party seeking intervention may request that additional procedures be provided, such as additional written comments, an oral presentation, a conference, or trial-type hearing. Any request to file additional written comments should explain why they are necessary. Any request for an oral presentation should identify the substantial question of fact, law, or policy at issue, show that it is material and relevant to a decision in the proceeding, and demonstrate why an oral presentation is needed. any request for a conference should demonstrate why the conference would materially advance the proceeding. Any request for a trial-type hearing must show that there are factual issues genuinely in dispute that are relevant and material to a decision and that a trial-type hearing is necessary for a full and true disclosure of the facts.

If an additional procedure is scheduled, the ERA will provide notice to all parties. If no party requests additional procedures, a final opinion and order may be issued based on the official record, including the application and responses filed by parties pursuant to this notice, in accordance with 10 CFR 590.316.

A copy of Dynasty's application is available for inspection and copying in the Natural Gas Division Docket Room, GA–076 at the above address. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, January 7, 1988.

Constance L. Buckley,

Director, Natural Gas Division, Office of Fuels Programs, Economic Regulatory Administration.

[FR Doc. 88–988 Filed 1–19–88; 8:45 am]

BILLING CODE 6450–01–M

[ERA Docket No. 87–54–NG]

St. Lawrence Gas Co., Inc.; Order Granting an Extension of Terms of an Existing Import Authorization

AGENCY: Economic Regulatory Administration, DOE.

ACTION: Notice of order granting an extension of terms of an existing import authorization.

SUMMARY: The Economic Regulatory Administation (ERA) of the Department of Energy (DOE) gives notice that it has issued an order extending St. Lawrence

Gas Company, Inc. (St. Lawrence), authorization to import up to 50,000 Mcf per day through October 31, 1989. The order issued in ERA Docket No. 87–54–NG does not otherwise change the terms of St. Lawrence's existing authorization.

A copy of this order is available for inspection and copying in the Natural Gas Division Docket Room, GA–076, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC, 20585, (202) 586–9478. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, January 13, 1988.

Constance L. Buckley,

Director, Natural Gas Division, Office of Fuels Programs, Economic Regulatory Administration.

[FR Doc. 88–989 Filed 1–19–88; 8:45 am]

BILLING CODE 6450–01–M

[ERA Docket No. 87–67–NG]

Shell Gas Trading Co.; Application To Export Natural Gas to Canada

AGENCY: Economic Regulatory Administration, DOE.

ACTION: Notice of application for blanket authorization to export natural gas.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) gives notice of receipt of December 2, 1987, of an application filed by Shell Gas Trading Company (Shell Gas) for blanket authorization to enter into short and intermediate term natural gas export arrangements with various Canadian purchasers. Authorization is requested to export up to 60 Bcf of natural gas over a two-year period beginning on the date of first delivery. Shell Gas, a wholly-owned subsidiary of Shell Energy Resources Inc., a Delaware corporation, purchases its gas from its affiliated companies, Shell Offshore Inc. and Shell Western E&P, as well as from non-affiliated domestic producers and sellers.

Shell Gas proposes to negotiate its gas export arrangements primarily with domestic open-access interstate pipelines for transportation to the international border. Shell Gas intends to us existing facilities at the border and within the United States for the transportation of the proposed exports. Each export sale would be negotiated individually, including its price and volume. Shell Gas will advise the ERA of the date of first delivery of the export and submit quarterly reports giving details of individual transactions.

The application is filed with the ERA pursuant to section 3 of the Natural Gas Act and DOE Delegation Order No. 0204–111. Protests, motions to intervene, notices of intervention and written comments are invited.

DATE: Protests, motions to intervene, or notices of intervention, as applicable, and written comments are to be filed no later than February 19, 1988.

FOR FURTHER INFORMATION CONTACT:

Tom Dukes, Natural Gas Division, Economic Regulatory Administration, Forrestal Building, Room GA–076, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–9590

Diane J. Stubbs, Natural Gas and Mineral Leasing, Office of General Counsel, U.S. Department of Energy, Forrestal Building, Room 6E–042, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–6667

SUPPLEMENTARY INFORMATION: This export application will be reviewed pursuant to section 3 of the Natural Gas Act and the authority contained in DOE Delegation Order No. 02024–111. The decision on whether the export of natural gas is in the public interest will be based upon the domestic need for the gas and on whether the arrangement is consistent with the DOE policy of promoting competition in the natural gas marketplace by allowing parties to freely negotiate their own trade arrangements. The applicant asserts that the requested authorization would reduce the U.S. trade deficit, promote competition, and, in light of the continuing "gas bubble," would benefit the public interest. Parties, especially those that may oppose this application, should comment in their response on these matters.

Public Comment Procedures

In response to this notice, any person may file a protest, motion to intervene or notice of intervention, as applicable, and written comments. Any person wishing to become a party to the proceeding and to have the written comments considered as the basis for any decision on the application must, however, file a motion to intervene or notice of intervention, as applicable. The filing of a protest with respect to this application will not serve to make the protestant a party to the proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate action to be taken on the application. All protests, motions to intervene, notices of intervention, and written comments must meet the requirements that are specified by the regulations in 10 CFR Part 590. They should be filed with the Natural Gas Division, Office of Fuels Programs, Economic Regulatory Administration, Room GA–076, RG–23, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–9478. They must be filed no later than 4:30 p.m. e.s.t., February 19, 1988.

The Administrator intends to develop a decisional record on the application through responses to this notice by parties, including the parties' written coments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. A party seeking intervention may request that additional procedures be provided, such as additional written comments, an oral presentation, a conference, or trial-type hearing. Any request to file additional written comments should explain why they are necessary. Any request for an oral presentation should identify the substantial question of fact, law, or policy at issue, show that it is material and relevant to a decision in the proceeding, and demonstrate why an oral presentation is needed. Any request for a conference should demonstrate why the conference would materially advance the proceeding. Any request for a trial-type hearing must show that there are factual issues genuinely in dispute that are relevant and material to a decision and that a trial-type hearing is necessary for a full and true disclosure of the facts.

If an additional procedure is scheduled, the ERA will provide notice to all parties. If no party requests additional procedures, a final opinion and order may be issued based on the official record, including the application and responses filed by parties pursuant to this notice, in accordance with 10 CFR 590.316.

A copy of Shell Gas' application is available for inspection and copying in the Natural Gas Division Docket Room, GA–076–A at the above address. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, December 30, 1987.

Constance L. Buckley,

Director, Natural Gas Division, Office of Fuels Programs, Economic Regulatory Administration.

[FR Doc. 88–990 Filed 1–19–88; 8:45 am]

BILLING CODE 6450–01–M

ENVIRONMENTAL PROTECTION AGENCY

[FRL-3317-6]

Agency Information Collection Activities Under OMB Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 3507(a)(2)(B) of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*) requires the Agency to publish in the **Federal Register** a notice of proposed information collection requests (ICRs) that have been forwarded to the Office of Management and Budget (OMB) for review. The ICR describes the nature of the solicitation and the expected impact, and where appropriate includes the actual data collection instrument. The following ICR is available for review and comment.

FOR FURTHER INFORMATION CONTACT: Carla Levesque at EPA, (202) 382-2740 (FTS 382-2740).

SUPPLEMENTARY INFORMATION:

Office of Air and Radiation

Title: New Source Review and Prevention of Significant Deterioration Permitting Programs. (EPA ICR #1230).

Abstract: All new major sources of air pollution emitting SO_2 and/or particulate matter must submit estimates of emissions, proposed control technology, and air quality impact before commencing construction so the appropriate reviewing authority can ensure that the construction will comply with Part C, Part D, and section 110 of the Clean Air Act. Existing facilities undergoing modification are also subject to these requirements.

Respondents: Major sources emitting SO_2 and particulate matter.

Estimated Burden: 675,000 hours.

Frequency of Collection: On occasion.

Comments on the abstracts on this notice may be sent to:

Carla Levesque, U.S. Environmental Protection Agency, Office of Standard and Regulations (PM-223), Information and Regulatory Systems Division, 401 M St., SW., Washington, DC 20460

and

Nicolas Garcia, Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building (Room 3019), 726 Jackson Place, NW., Washington, DC 20503.

Date: January 7, 1988.

Daniel Fiorino,

Director, Information Regulatory Systems Division.

[FR Doc. 88-1028 Filed 1-19-88; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL ELECTION COMMISSION

[Notice 1988-2]

Filing Dates for Louisiana Special Elections

AGENCY: Federal Election Commission.

ACTION: Notice of filing dates for Louisiana Special Elections.

SUMMARY: Committees required to file reports in connection with the Special Primary Election to be held on March 8, 1988, must file a 12-day Pre-Election Report by February 25, 1988, and if there is a majority winner, a 30-day Post-Election Report by April 7, 1988. In the event no candidate receives a majority vote in the Special Primary Election, the 30-day Post-Election Report would not be required. Rather a Special General Election would be held on April 16, 1988, and the committees required to file reports in connection with the Special General Election would be required to file a 12-day Pre-Election Report due on April 4, 1988, and a 30-day Post-Election Report due on May 16, 1988.

For further information contact: Ms. Bobby Werfel, Public Information Office, 999 E Street NW., Washington, DC 20463. Telephone: (202) 376-3120, Toll-free: (800) 424-9530.

Notice of Filing Dates for Special Elections, 4th Congressional District, Louisiana

All principal campaign committees of candidates in the special election and all other political committees not filing monthly, which support candidates in the Special Primary Election shall file a 12-day Pre-Election Report due on February 25, 1988, with coverage dates from the last report filed through February 17, 1988. Political committees that have not previously filed a financial report should report all financial activity through February 17, 1988. If one candidate receives a majority of votes cast, a 30-day Post-Election Report is due on April 7, 1988, with coverage dates from Februrary 18, 1988, through March 28, 1988. Committees that file this report in a timely manner will be granted a waiver of the April Quarterly reporting requirement.

In the event that no candidate achieves a majority vote in the Special Primary Election, the 30-day Post-Election Report would not be required. Rather a Special General Election would be held on April 16, 1988. Committees involved in this Special General Election would be required to file a 12-day Pre-Election Report due on April 4, 1988, with coverage dates from February 18, 1988, through March 27, 1988, and a 30-day Post-Election Report due on May 16, 1988, with coverage dates from April 1, 1988, through May 6, 1988. These committees also file an April Quarterly Report covers activity through March 31, 1988, and is due April 15, 1988.

Committees involved in just the first of the two Special Elections would be required to file the report due February 25 on an April Quarterly Report due April 15, 1988, with coverage dates from February 18, 1988, through March 31, 1988.

Thomas J. Josefiak,

Chairman, Federal Election Commission.

Dated: January 14, 1988.

[FR Doc. 88-1023 Filed 1-19-88; 8:45 am]

BILLING CODE 6715-01-M

FEDERAL EMERGENCY MANAGEMENT AGENCY

Agency Information Collection Submitted to the Office of Management and Budget for Clearance

The Federal Emergency Management Agency (FEMA) has submitted to the Office of Management and Budget the following information collection package for clearance in accordance with the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Type: Extension of 3067-0049.

Title: Request for Advance or Reimbursement.

Abstract: This form is a modified Standard Form 270 which is used by applicants to request a final payment.

Type of Respondents: State or local governments Non-profit institutions.

Number of Respondents: 2,500.

Burden Hours: 1,250.

Frequency of Recordkeeping or Reporting: On occasion.

Copies of the above information collection request and supporting documentation can be obtained by calling or writing the FEMA Clearance Officer, Linda Shiley, (202) 646-2624, 500 C. Street, SW., Washington, DC 20472.

Comments should be directed to Francine Picoult, (202) 395-7231, Office of Management and Budget, 3235 NEOB, Washington, DC 20503 within two weeks of this notice.

Date: January 14, 1988.

Wesley C. Moore,

Director, Office of Administrative Support.

[FR Doc. 88-993 Filed 1-19-88; 8:45 am]

BILLING CODE 6718-21-M

FEDERAL MARITIME COMMISSION

[Docket No. 88-2]

Delhi Petroleum PTY. Limited v. U.S. Atlantic & Gulf/Australia-New Zealand Conference and Columbus Line, Inc.; Filing of Complaint and Assignment

Notice is given that a complaint filed by Delhi Petroleum Pty. Limited ("Complainant") against U.S. Atlantic & Gulf-Australia-New Zealand Conference and Columbus Line, Inc. ("Respondents") was served January 14, 1988.

Complainant alleges that Respondents have violated sections 10(b)(1), 10(b)(6)(A), 10(b)(6)(E) and 10(b)(12), Shipping Act of 1984, 46 U.S.C. app. 1709(b)(1), (b)(6)(A), (b)(6)(E) and (b)(12), and sections 14 and 15, Shipping Act, 1916, 46 U.S.C. app. 812 and 814 through the assessment of freight charges in excess of those lawfully applicable on a shipment of oilwell equipment and supplies moving from the Port of Houston, Texas U.S.A. to the Port of Brisbane, Australia.

This proceeding has been assigned to Administrative Law Judge Norman D. Kline ("Presiding Officer"). Hearing in this matter, if any is held, shall commence within the time limitations prescribed in 46 CFR 502.61. The hearing shall include oral testimony and cross-examination in the discretion of the Presiding Officer only upon proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record. Pursuant to the further terms of 46 CFR 502.61, the initial decision of the Presiding Officer in this proceeding shall be issued by January 16, 1989, and the final decision of the Commission shall be issued by May 16, 1989.

Joseph C. Polking,

Secretary.

[FR Doc. 88-1046 Filed 1-19-88; 8:45 am]

BILLING CODE 6730-01-M

[Docket No. 88-3]

North Carolina State Ports Authority v. The 8900 Lines et al.; Filing of Complaint and Assignment

Notice is given that a complaint filed by the North Carolina State Ports Authority ("NCSPA") against a conference of water carriers operating under FMC Agreement No. 8900 (hereinafter "The 8900 Lines") was served January 14, 1988.

NCSPA alleges that The 8900 Lines and its member carriers have violated various sections of the Shipping Act of 1984 and section 205 of the Merchant Marine Act, 1936 through the imposition of an arbitrary sucharge in the amount of $275.00 per container at the Port of Wilmington against export cargo destined for the Middle East. Specific violations of the Shipping Act of 1984 alleged include sections 10(b)(6)—unfair and unjustly discriminatory practices in the matter of rates; 10(b)(10)—assessment of a rate or charge that is unjustly discriminatory between shippers or ports; 10(b)(11)—making or giving any undue or unreasonable preference or advantage to ports and shippers that compete with NCSPA; 10(b)(12)—subjecting NCSPA and those using its facilities to an unreasonable refusal to deal and an undue or unreasonable prejudice or disadvantage; 10(c)(1)—imposition of a boycott upon NCSPA; 10(c)(2) engaging in conduct that unreasonably restricts the use of intermodal services, and 10(d)(1)—imposition of an unjust and unreasonable regulation or practice; 46 U.S.C. app. 1709 10(b)(6), 10(b)(10), 10(b)(11), 10(b)(12), 10(c)(1), 10(c)(2), and 10(d)(1).

This proceeding has been assigned to Administrative Law Judge Norman D. Kline ("Presiding Officer"). Hearing in this matter, if any is held, shall commence within the time limitations prescribed in 46 CFR 502.61. The hearing shall include oral testimony and cross-examination in the discretion of the Presiding Officer only upon proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record. Pursuant to the further terms of 46 CFR 502.61, the initial decision of the Presiding Officer in this proceeding shall be issued by January 16, 1989, and the final decision of the Commission shall be issued by May 16, 1989.

Joseph C. Polking,

Secretary.

[FR Doc. 88-1045 Filed 1-19-88; 8:45 am]

BILLING CODE 6730-01-M

Ocean Freight Forwarder License Applicants; Interport Co. Inc. et al.

Notice is given that the following applicants have filed with the Federal Maritime Commission applications for licenses as ocean freight forwarders pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718 and 46 CFR Part 510).

Persons knowing of any reason why any of the following applicants should not receive a license are requested to contact the Office of Freight Forwarder and Passenger Vessel Operations, Federal Maritime Commission, Washington, DC 20573.

The Interport Co., Inc., 2300 East Higgins Road, Elk Grove Village, IL 60007

Sankyu U.S.A., Incorporated, 235 Montgomery Street, Suite 467, San Francisco, CA 94104; Officer: Tsutomu Nakamura, President

Marina Air-Ocean International, 139 Mitchell Ave., So. San Francisco, CA 94080

Stephen A. Mace, Concourse A. Municipal Airport, Birmingham, AL 35212

Future Freight Systems, Inc., 60 Jacobus Avenue, South Kearny, NJ 07032; Officer: Joseph Sade, President/Director

Alltransport Incorporated, 17 Battery Place North, New York, NY 10004; Officers: Joachim Schoenfeld, President; Kurt Konodi-Floch, Exec. Vice President; Walter Gartner, Secretary/Treasurer

Braunkohle Transport U.S.A., Inc., 306 Axminister Drive, St. Louis, MO 63026, Officer: Dennis Denham, President

Maurice Pincoffs Co., 2040 North Loop West, Houston, Texas 77018; Officers: John Griffith, President; J.T. Symonds, Vice President; Daniel Breem, Director

World Trade Transport of Virginia, 22 Export Drive, Sterling, VA 22170; Officers: Henry R. Youngblood, President; Jack P. Moore, Vice President; Michael C. Moore, Vice President

By the Federal Maritime Commission.

Dated: January 14, 1988.

Joseph C. Polking,

Secretary.

[FR Doc. 88-1047 Filed 1-19-88; 8:45 am]

BILLING CODE 6730-01-M

Federal Mediation and Conciliation Service

Labor-Management Cooperation Program; Application Solicitation

AGENCY: Federal Mediation and Conciliation Service.

ACTION: Final FY 1988 Program Guidelines/Application Solicitation.

SUMMARY: The Federal Mediation and Conciliation Service (FMCS) is publishing the final Fiscal Year 1988 Program Guidelines/Application Solicitation for the Labor-Management Cooperation Program. The program is supported by Federal funds authorized by the Labor Management Cooperation Act of 1978, subject to annual appropriations. No comments were received during the period set aside for public comments.

ADDRESS: Send applications to: Peter L. Regner, Director, Staff Operations and Programs, FMCS, 2100 K Street NW., Washington, DC 20427.

FOR FURTHER INFORMATION CONTACT: Peter L. Regner, 202/653-5320.

Labor-Management Cooperation Program, Application Solicitation—FY 1988

A. Introduction

The following is the final solicitation for the Fiscal Year 1988 cycle of the Labor-Management Cooperation Program. These guidelines represent the continuing efforts of the Federal Mediation and Conciliation Service to implement the provisions of the Labor-Management Cooperation Act of 1978 which was initially implemented in Fiscal Year 1981. The Act generally authorizes FMCS to provide assistance in the establishment and operation of plan, area, public sector, and industry-wide labor and management committees which:

(A) Have been organized jointly by employeres and labor organizations representing employees in that plant, area, government agency, or industry; and

(B) Are established for the purpose of improving labor management relationships, job security, organizational effectiveness, enhancing economic development or involving workers in decisions affecting their jobs including improving communication with respect to subjects of mutual interest and concern.

The Program Description and other sections that follow as well as a separately published FMCS Financial and Administrative Grants Manual make up the basic guidelines, criteria, and program elements a potential applicant for assistance under this program must know in order to develop an application for funding consideration for either a plant, area-wide, industry, or public sector labor-management committee. Directions for obtaining an application kit may be found in section H. A copy of the Labor-Management Cooperation Act of 1978 follows this solicitation and should be reviewed in conjunction with this solicitation.

B. Program Description

Objectives

The Labor Management Cooperation Act of 1978 identifies the following seven general areas for which financial assistance would be appropriate:

(1) To improve communications between representatives of labor and management;

(2) To provide workers and employers with opportunities to study and explore new and innovative joint approaches to achieving organizational effectiveness;

(3) To assist workers and employers in solving problems of mutual concern not susceptible to resolution within the collective bargaining process;

(4) To study and explore ways of eliminating potential problems which reduce the competitiveness and inhibit the economic development of the plant, area, or industry;

(5) To enhance the involvement of workers in making decisions that affect their working lives;

(6) To expand and improve working relationships between workers and managers; and

(7) To encourage free collective bargaining by establishing continuing mechanisms for communication between employers and their employees through Federal assistance to the formation and operation of labor-management committees.

The primary objective of this program is to encourage and support the establishment and operation of joint labor-management committees to carry out specific objectives that meet the aforementioned general criteria. The term "labor" refers to employees represented by a labor organization and covered by a formal collective bargaining agreement. These committees may be found at either the plant (worksite), area, industry, or public sector levels. A plant or worksite committee is generally characterized as restricted to one or more organizational or productive units operated by a single employer. An area committee is generally composed of multiple employers of diverse industries as well as multiple labor unions operating within and focusing upon city, county, contiguous multicounty, or statewide jurisdictions. An industry committee generally consists of a collection of agencies or enterprises and related labor unions producing a common product or service in the private sector on a local, state, regional, or nationwide level. A public sector committee consists of government employees and managers in one or more units of a local or state government. Those employees must be covered by a formal collective bargaining agreement. Employees covered by so-called "meet and confer" agreements are not eligible under this program. In deciding whether an application is for an area or industry committee, consideration should be given to the above definitions as well as to the focus of the committee.

In FY 88, competition will be open to plant, area, private industry, and public sector committees. In-plant committee applications should offer an innovative or unique effort. All application budget requests should focus directly on supporting the committee. Applicants should avoid seeking funds for activities that are clearly available under other Federal programs (e.g., job training, mediation of contract disputes, etc.).

Required Program Elements

1. *Problem Statement*—The application, which should have numbered pages, must discuss in detail what specific problem(s) face the plant, area, government, or industry and its workforce that will be addressed by the committee. Applicants must document the problems using as much relevant data as possible and discuss the full range of impacts these problems could have or are having on the plant, government, area, or industry. An industrial or economic profile of the area and workforce might prove useful in explaining the problems. This section basically discusses *WHY* the effort is needed.

2. *Results or Benefits Expected*—By using specific goals and objectives, the application must discuss in detail *WHAT* the labor-management committee as a demonstration effort will accomplish during the life of the grant. While a goal of "improving communication between employers and employees" may suffice as one over-all goal of a project, the objectives must, whenever possible, be expressed in measurable terms. Applicants should focus on the impacts or changes that the committee's efforts will have. Existing committees should focus on *expansion* efforts/results expected from FMCS funding. The goals, objectives, and

projected impacts will become the foundation for future monitoring and evaluation efforts.

3. *Approach*—This section of the application specifies *HOW* the goals and objectives will be accomplished. At a minimum, the following elements must be included in all grant applications:

(a) A discussion of the strategy the committee will employ to accomplish its goals and objectives;

(b) A listing, by name and title, of all existing or proposed members of the labor-management committee. The application should also offer a rationale for the selection of the committee members (e.g., members represent 70% of the area or plant workforce).

(c) A discussion of the number, type, and role of all committee staff persons. Include proposed position descriptions for all staff that will have to be hired as well as resumes for staff already on board;

(d) In addressing the proposed approach, applicants must also present their justification as to why Federal funds are needed to implement the proposed approach;

(e) A statement of how often the committee will meet as well as any plans to form subordinate committees for particular purposes; and

(f) For applications from existing committees (i.e., in existence at least 12 months prior to the submission deadline), a discussion of the past efforts and accomplishments and how they would integrate with the proposed future expanded effort.

4. *Major Milestones*—This section must include an implementation plan that indicates what major steps, operating activities, and objectives will be accomplished as well as a timetable for *WHEN* they will be finished. A milestone chart must be included that indicates what specific accomplishments (process and impact) will be completed by month over the life of the grant. The chart should identify months as "month 1, 2," etc., rather than by name of month as the grant start date will not be determined until all applications are reviewed. The accomplishment of these tasks and objectives, as well as problems and delays therein, will serve as the basis for quarterly progress reports to FMCS.

5. *Evaluation*—Applicants must provide for an external evaluation or internal assessment of the project's success in meeting its goals and objectives.

An evaulation plan must be developed which will briefly discuss what basic questions or issues the assessment would examine and what baseline data the committee staff would already have/ or will grant for the assessment. This section should be written with the application's own goals and objectives clearly in mind and the impacts or changes that the effort is expected to cause.

6. *Letters of Commitment*—Applications must include current letters of commitment from *all* proposed or existing committee participants and chairpersons. These letters should indicate that the participants support the application and will attend scheduled committee meetings. A blanket letter signed by a committee chairperson on behalf of all members is not acceptable.

7. *Other Requirements*—Applicants are also responsible for the following:

(a) The submission of data indicating approximately how many employees will be covered or represented through the labor-management committee;

(b) From existing committees, a copy of the existing staffing levels, a copy of the by-laws, a breakout of annual operating costs and identification of all sources and levels of current financial support;

(c) A detailed budget narrative based on policies and procedures contained in the FMCS Financial and Administrative Grant Manual;

(d) An assurance that the labor-management committee will not interfere with any collective bargaining agreements; and

(e) An assurance that committee meetings will be held at least every other month and that written minutes of all committee meetings will be prepared and made available to FMCS.

Selection Criteria

The following criteria will be used in the scoring and selection of applications for award:

(1) The extent to which the application has clearly identified the problems and justified the needs that the proposed project will address.

(2) The degree to which appropriate and measurable goals and objectives have been developed to address the problems/needs of the area. For existing committees, the extent to which the committee will focus on expanded efforts.

(3) The feasibility of the approach proposed to attain the goals and objectives of the project and the perceived likelihood of accomplishing the intended project results. For in-plant applications, the section will address the degree of innovativeness or uniqueness of the proposed effort.

(4) The appropriateness of committee membership and the degree of commitment of these individuals to the goals of the application.

(5) The feasibility and thoroughness of the implementation plan in specifying major milestones and target dates.

(6) The cost effectiveness and fiscal soundness of the application's budget request, as well as the application's fiscal feasibility vs. its goals and approach.

(7) The overall feasibility of the proposed project in light of all of the information presented for consideration and quality of the application; and,

(8) The cost value to the government of the application in light of the overall objectives of the Labor-Management Cooperation Act of 1978. This includes such factors as innovativeness, site locations, and other qualities that impact upon an applicant's value in encouraging the labor-management committee concept.

C. Eligibility

Eligible grantees include State and local units of government, private non-profit labor-management committees (or a labor or management entity on behalf of a committee that will be created through the grant), and certain third party private non-profit entities on behalf of one or more committees to be created through the grant. Federal government agencies are not eligible.

Third party private non-profit entities which can document that a major purpose or function of their organization has been the improvement of labor relations are eligible to apply. However, all funding must be directed to the functioning of the labor-management committee, and all requirements under Part B must be followed. Applications from third-party entities must document particularly strong support and participation from all labor and management parties with whom the applicant will be working. Applicants from third-parties which do not directly support the operation of a new or expanded committee will not be deemed eligible.

Applicants who received funding under this program in the past for committee operations are generally not eligible to apply. The only exception applies to third-party grantees who seek funds on behalf of an entirely different committee.

D. Allocations

The FMCS FY88 allocation for this program in $817,000. Specific funding levels will not be established for each type of committee. Instead, the review process will be conducted in such a manner that at least two awards will be made in each category (in-plant, industry, public sector, and area),

providing the FMCS determines that at least two outstanding applications exist in each category. After these applications are selected for award, the remaining applications will be awarded according to merit without regard to category.

FMCS reserves the right to retain up to 5 percent of the FY88 appropriation to contract for program support purposes (other than administrative).

E. Dollar Range and Length of Grants and Continuation Policy

Awards to continue and expand existing labor-management committee (i.e., in existance at least 12 months prior to the submission deadline) will be for a period of 12 months. If successful progress is made during this initial budget period and if sufficient appropriations for expansion and continuation projects are available, these grants may be continued up to an additional 12 months at double the initial cash match ratio.

The total project period will thus normally be no more than 24 months.

Initial awards to establish new labor-management committees (i.e., not yet established or in existence less than 12 months prior to the submission deadline), will be for a period of 18 months. If successful progress is made during this initial budget period and if sufficient appropriations for expansion and continuation projects are available, these grants may be continued up to an additional 18 months at double the initial cash match ratio. The total project period will thus normally be no more than 36 months.

The dollar range of awards is as follows:

—Up to $35,000 in FMCS funds per annum for existing inplant applicants; up to $50,000 over 18 months for new in-plant committee applicants;
—Up to $75,000 in FMCS funds per annum for existing are, industry and public sector committees applicants;
—Up to $100,000 per 18-month period for new area, industry, and public sector committee applicants.

Applicants are reminded that these figures represent maximum Federal funds only. If total costs to accomplish the objectives of the application exceed the maximum allowable Federal funding level and grantee match, applicants may supplement these funds through voluntary contributions from other sources.

F. Match Requirements and Cost Allowability

Applicants for new labor-management committees must provide at least 10 percent of the total allowable project costs. Applicants of existing committees must provide at least 25 percent of the total allowable project costs. All matching funds must be in cash rather than in-kind goods or services. Matching funds may come from state or local government sources or private sector contributions, but may generally not include other Federal funds. Funds generated by grant-supported efforts are considered "project income," and may not be used for matching purposes.

It will be the policy of this program to reject all requests for indirect or overhead costs. In addition, grant funds must not be used to supplant private or local/state government funds currently employed for these purposes. Funding requests from existing committees should focus entirely on the costs associated with the expansion efforts only. Also, under no circumstances will business or labor officials participating on a labor-management committee be compensated out of grant funds for *time* spent at committee meetings or *time* spent in training sessions. Applicants generally will not be allowed to claim all or a portion of *existing* staff time as an expense or match contribution.

For a more complete discussion of cost allowability, applicants are encouraged to consult the FY88 FMCS Financial and Administrative Grants Manual which will be included in the application kit.

G. Application Submission and Review Process

Applications should be signed by *both* a labor and management representative and be postmarked no later than April 16, 1988. No applications or supplementary materials can be accepted after the deadline. It is the responsibility of the applicant to ensure that the application is correctly postmarked by the U.S. Postal Service or other carrier. An original application, containing numbered pages, *plus three copies* should be addressed to the Federal Mediation and Conciliation Service, Labor-Management Grant Programs, 2100 K Street, NW, Washington, DC 20427. Applications submitted without sufficient copies may be returned.

After the deadline has passed, all eligible applications will be reviewed and scored initially by one or more FMCS Grant Review Board(s). The Board(s) will decide which applications will be recommended for funding consideration. The Director, Labor-Management Grant Programs, will finalize the scoring and selection process of those applications recommended by the Board(s).

All FY88 grant applicants will be notified of results, and all grant awards will be made, prior to September 30, 1988. Applications submitted after the deadline dates or that fail to adhere to eligibility or other major requirements will be administratively rejected by the Director, Labor-Management Grant Programs.

H. Contact

Individuals wishing to apply for funding under this program should contact the Federal Mediation and Conciliation Service as soon as possible to obtain an application kit. These kits, as well as additional information or clarification, can be obtained free of charge by contacting Lee A. Buddendeck, Federal Mediation and Conciliation Service, Labor-Management Grant Programs, 2100 K Street, NW., Washington, DC 20427, or by calling 202/653–5320.

Kay McMurray,

Director, Federal Mediation and Conciliation Service.

[FR Doc. 88–965 Filed 1–19–88; 8:45 am]

BILLING CODE 6732–01–M

FEDERAL RESERVE SYSTEM

Community National Bancorp, Inc., et al.; Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications

must be received not later than February 10, 1988.

A. **Federal Reserve Bank of New York** (William L. Rutledge, Vice President) 33 Liberty Street, New York, New York 10045:

1. *Community National Bancorp, Inc.*, Staten Island, New York; to become a bank holding company by acquiring 100 percent of the voting shares of Community National Bank and Trust Company of New York, Staten Island, New York.

B. **Federal Reserve Bank of Cleveland** (John J. Wixted, Jr., Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101:

1. **Fifth Third Bancorp**, Cincinnati, Ohio; to merge with C & H Bancorp, Piqua, Ohio, and thereby indirectly acquire Citizens Heritage Bank, N.A., Piqua, Ohio.

C. **Federal Reserve Bank of Richmond** (Lloyd W. Bostian, Jr., Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. *Dominion Bankshares Corporation*, Roanoke, Virginia; to merge with Citizens Union Corporation, Rogersville, Tennessee, and thereby indirectly acquire Citizens Union Bank, Rogersville, Tennessee.

2. **Dominion Bankshares Corporation**, Roanoke, Virginia; to merge with Greene County Bancshares, Inc., Greeneville, Tennessee, and thereby indirectly acquire Greene County Bank, Greeneville, Tennessee.

3. **Dominion Bankshares Corporation**, Roanoke, Virginia; to merge with Merchants & Planters Corporation, Newport, Tennessee, and thereby indirectly acquired Merchants & Planters Bank, Newport, Tennessee.

D. **Federal Reserve Bank of Atlanta** (Robert E. Heck, Vice President) 104 Marietta Street, NW., Atlanta, Georgia 30303:

1. **Putnam-Greene Financial Corporation**, Eatonton, Georgia; to acquire 100 percent of the voting shares of The Pembroke State Bank, Pembroke, Georgia.

E. **Federal Reserve Bank of Kansas City** (Thomas M. Hoenig, Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. **CNB Financial Corporation**, Kansas City, Kansas; to acquire 100 percent of the voting shares of First National Bank of Overland Park, Overland Park, Kansas.

Board of Governors of the Federal Reserve System, January 13, 1988.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 88-973 Filed 1-19-88; 8:45 am]

BILLING CODE 6210-01-M

Leslie Formell and Malcolm Deisenroth, Jr., Change in Bank Control; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than February 4, 1988.

A. **Federal Reserve Bank of Minneapolis** (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. *Leslie Formell*, New Brighton, Minnesota; to acquire 100 percent of the voting shares of Graceville Bancorporation Inc., Graceville, Minnesota, and thereby indirectly acquire First State Bank of Graceville, Graceville, Minnesota.

B. **Federal Reserve Bank of Kansas City** (Thomas M. Hoenig, Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *Malcolm Deisenroth, Jr.*, Tulsa, Oklahoma; to acquire an additional 14.60 percent of the voting shares of Tulbancorp, Inc., Tulsa, Oklahoma, and thereby indirectly acquire Bank of Tulsa, Tulsa, Oklahoma.

Board of Governors of the Federal Reserve System, January 13, 1988.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 88-974 Filed 1-19-88; 8:45 am]

BILLING CODE 6210-01-M

Montana Bancsystem, Inc.; Application To Engage de Novo in Permissible Nonbanking Activities

The company listed in this notice has filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 10, 1988.

A. **Federal Reserve Bank of Minneapolis** (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480:

1. *Montana Bancsystem, Inc.*, Billings, Montana; to engage *de novo* in making and servicing loans on a limited basis pursuant to § 225.25(b)(1) of the Board's Regulation Y. This activity will be conducted in the States of Montana, Colorado and Texas.

Board of Governors of the Federal Reserve System, January 13, 1988.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 88-975 Filed 1-19-88; 8:45 am]

BILLING CODE 6210-01-M

Progressive Bank, Inc.; Acquisition of Company Engaged in Permissible Nonbanking Activities

The organization listed in this notice has applied under § 225.23 (a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23 (a)(2) or (f)) for the Board's approval

under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 10, 1988.

A. **Federal Reserve Bank of New York** (William L. Rutledge, Vice President) 33 Liberty Street, New York, New York 10045:

1. *Progressive Bank, Inc.*, Pawling, New York; to acquire the Stockbridge Group, Ltd., Hopewell Junction, New York, and thereby engage in making and servicing mortgage loans pursuant to § 225.25(b)(1) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, January 13, 1988.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 88-976 Filed 1-19-88; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Alcohol, Drug Abuse, and Mental Health Administration; Meetings

AGENCY: Alcohol, Drug Abuse, and Mental Health Administration, HHS.

ACTION: Notice of meetings.

SUMMARY: This notice sets forth the schedule and proposed agenda of the forthcoming meetings of the agency's initial review committees and national advisory councils in the month of February 1988. These committees will be performing initial review of applications for Federal assistance. Therefore, portions of the meetings will be closed to the public as determined by the Administrator, ADAMHA, in accordance with 5 U.S.C. 552(b)(6) and 5 U.S.C. app. 2 10(d). Notice of these meetings is required under the Federal Advisory Committee Act, Pub. L. 92-463.

Committee Name: National Advisory Council on Drug Abuse, NIDA.

Date and Time: February 2-3: 9:00 a.m.

Place: National Institutes of Health, Building #31C, Conference Room #9, 9000 Rockville Pike, Bethesda, Maryland 20892

Status of Meeting:

Open—February 2: 9:00 a.m.-12 noon; February 3: 9:00 a.m.-5:00 p.m.

Closed—Otherwise.

Contact: Ms. Shelia H. Gardner, Parklawn Building, Room 8A-54, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443-0441

Purpose: The Council advises and makes recommendations to the Secretary, Department of Health and Human Services, the Administrator, Alcohol, Drug Abuse, and Mental Health Administration, and the Director, National Institute on Drug Abuse, on the development of new initiatives and priorities and the efficient administration of drug abuse research, including prevention and treatment research, and research training.

Committee Name: National Advisory Council on Alcohol Abuse and Alcoholism, NIAAA.

Date and Time: February 4-5: 10:30 a.m.

Place: National Institutes of Health, Building #1, Wilson Hall, 9000 Rockville Pike, Bethesda, MD 20892.

Status of Meeting:

Open—February 4: 10:30 a.m.-5:00 p.m.

Closed—Otherwise.

Contact: James Vaughan, Parklawn Building, Room 16C-20, 5600 Fishers Lane, Rockville, MD 20857, (301) 443-4375.

Purpose: The Council advises the Secretary, Department of Health and Human Services, regarding policy direction and program issues of national significance in the area of alcohol abuse and alcoholism. Reviews all grant applications submitted, evaluates these applications in terms of scientific merit and adherence to Department policies, and makes recommendations to the Secretary with respect to approval and amount of award.

Committee Name: National Advisory Mental Health Council, MIMH

Date and Time: February 8-10: 9:00 a.m.

Place: February 8: National Institutes of Health, Building #31, Conference Room 6, 9000 Rockville Pike, Bethesda, MD 20892 February 9-10: Parklawn Building, Conference Rooms G & H, 5600 Fishers Lane, Rockville, MD 20857.

Status of Meeting:

Open—February 8: 9:00 a.m.-5:00 p.m.

Closed—Otherwise.

Contact: Rachel Townson, Parklawn Building, Room 9-105, 5600 Fishers Lane, Rockville, MD 20857, (301) 443-3367

Purpose: The Council advises the Secretary, Department of Health and Human Services, the Administrator, Alcohol, Drug Abuse, and Mental Health Administration, and the Director, National Institute of Mental Health regarding policies and programs of the Department in the field of mental health. The Council reviews applications for grants-in-aid relating to research and training in the field of mental health and makes recommendations to the Secretary with respect to approval of applications for, and amount of, these grants.

Committee Name: Psychopharmacological, Biological, and Physical Treatments Subcommittee of the Treatment Development and Assessment Research Review Committee, NIMH.

Date and Time: February 11-12: 9:00 a.m.

Place: J.W. Marriott, 1331 Pennsylvania Avenue, NW., Washington, DC 20004

Status of Meeting:

Open—February 11: 9:00-10:00 a.m.

Closed—Otherwise.

Contact: Pamela J. Mitchell, Parklawn Building, Room 9C-14, 5600 Fishers Lane, Rockville, MD 20857, (301) 443-1367.

Purpose: The Committee is charged with the initial review of applications for assistance from the National

Institute of Mental Health for support of research and research training activities in the fields of treatment development and assessment, with recommendations to the National Advisory Mental Health Council for final review.

Committee Name: Child and Family and Prevention Subcommittee of the Life Course and Prevention Research Review Committee, NIMH.

Date and Time: February 11–13: 9:00 a.m.

Place: The Ramada Inn, 8400 Wisconsin Avenue, Bethesda, MD 20814.

Status of Meeting:

Open—February 11: 9:00–10:00 a.m.
Closed—Otherwise.

Contact: Dorothy Tengood, Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–3857.

Purpose: The Committee is charged with the initial review of applications for assistance from the National Institute of Mental Health for support of research and research training activities relating to basic psychopharmacology and neuropsychology, with recommendations to the National Advisory Mental Health Council for final review.

Committee Name: Cognition, Emotion, and Personality Research Review Committee, NIMH.

Date and Time: February 11–13: 9:00 a.m.

Place: The Dupont Plaza Hotel, 1500 New Hampshire Avenue NW., Washington, DC 20036.

Status of Meeting:

Open—February 11: 9:00–10:00 a.m.
Closed—Otherwise.

Contact: Shirley Maltz, Parklawn Building, Room 9C–26, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–3944.

Purpose: The Committee is charged with the initial review of applications for assistance from the National Institute of Mental Health for support of research and research training activities relating to the fields of personality, cognition, emotion, and higher mental processes, with recommendations to the National Advisory Mental Health Council for final review.

Committee Name: Neurosciences Reserach Review Committee, NIMH.

Date and Time: February 11–13: 8:30 a.m.

Place: The Bethesda Ramada Inn, 8400 Wisconsin Avenue, Bethesda, MD 20814.

Status of Meeting:

Open—February 11: 8:30–9:30 a.m.
Closed—Otherwise.

Contact: Gerry, Parklawn Building, Room 9C–14, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–3936.

Purpose: The Committee is charged with the initial review of applications for assistance from the National Institute of Mental Health for support of research and research training activities relating to basic psychopharmacology and neuropsychology with recommendations to the National Advisory Mental Health Council for final review.

Committee Name: Biochemistry, Physiology, and Medicine Subcommittee of the Alcohol Biomedical Research Review Committee, NIAAA.

Date and Time: February 16–17: 9:00 a.m.

Place: Holiday Inn Crown Plaza, Rockville Room, 1750 Rockville Pike, Rockville, MD 20852.

Status of Meeting:

Open—February 16: 9:00–9:30 a.m.
Closed—Otherwise.

Contact: Ronald F. Suddendorf, Parklawn Building, Room 16C–26, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–6106.

Purpose: The Committee is charged with the initial review of applications for assistance from the National Institute on Alcohol Abuse and Alcoholism for support of research and training activities and makes recommendations to the National Advisory Council on Alcohol Abuse and Alcoholism for final review.

Committee Name: Biochemistry Research Subcommittee of the Drug Abuse Biomedical Research Review Committee, NIDA.

Date and Time: February 16–19: 8:30 a.m.

Place: Ambassador II Room, Bethesda Ramada Inn, 8400 Wisconsin Avenue, Bethesda, MD 20816.

Status of Meeting:

Open—February 16: 8:30–8:45 a.m.
Closed—Otherwise.

Contact: Elmore S. King, Parklawn Building, Room 10–42, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–2755.

Purpose: The Committee is charged with the initial review of applications for assistance from the National Institute on Alcohol Abuse for support of research and research training activities and make recommendations to the National Advisory Council on Drug Abuse for final review.

Committee Name: Drug Abuse Clinical and Behavioral Research Review Committee, NIDA.

Date and Time: February 16–19: 9:00 a.m.

Place: Embassy II, The Bethesda Ramada Inn, 8400 Wisconsin Avenue, Bethesda, MD 20814.

Status of Meeting:

Open—February 16: 9:00–9:30 a.m.
Closed—Otherwise.

Contact: Daniel Mintz, Parklawn Building, Room 10–42, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–2620.

Purpose: The Committee is charged with the initial review of applications for assistance from the National Institute on Alcohol Abuse for support of research and research training activities and makes recommendations to the National Advisory Mental Health Council for final review.

Committee Name: Drug Abuse Epidemiology and Prevention Research Review Committee, NIDA.

Date and Time: February 16–19: 8:30 a.m.

Place: Embassy I, The Bethesda Ramada Inn, 8400 Wisconsin Avenue, Rockville, MD 20814.

Status of Meeting:

Open—February 16: 8:30–9:30 a.m.
Closed—Otherwise.

Contact: Ron Gold, Parklawn Building, Room 10–42, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–2620.

Purpose: The Committee is charged with the initial review of applications for assistance from the National Institute on Drug Abuse for support of research and research training activities and makes recommendations to the National Advisory Council on Drug Abuse for final review.

Committee Name: Pharmacology Research Subcommittee of the Drug Abuse Biomedical Research Review Committee, NIDA.

Date and Time: February 16–19: 8:30 a.m.

Place: Ambassador I Room, Bethesda Ramada Inn, 8400 Wisconsin Avenue, Bethesda, MD 20816.

Status of Meeting:

Open—February 16: 8:30–8:45 a.m.
Closed—Otherwise.

Contact: Heinz Sorer, Parklawn Building, Room 10–42, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–2620.

Purpose: The Committee is charged with the initial review of applications for assistance from the National Institute on Drug Abuse for support of research and research training activities and makes recommendations to the National Advisory Council on Drug Abuse for final review.

Committee Name: Criminal and Violent Behavior Research Review Committee, NIJMH.

Date and Time: February 17–19: 9:15 a.m.

Place: Sheraton Washington Hotel, 2660 Woodley Road NW., Washington, DC 20008.

Status of Meeting:

Open—February 17: 9:15–10:00 a.m.
Closed—Otherwise.

Purpose: The Committee is charged with the initial review of applications for assistance from the National Institute of Mental Health for support of research grants, individual postdoctoral research fellowships and institutional research training grants, cooperative agreements, and research and development contracts, as they relate to the mental health aspects of criminal, delinquent, and antisocial behavior; individual violent behavior; sexual assault; and law-mental health interactions related to these areas, with recommendations to the National Advisory Mental Health Council for final review.

Committee Name: Aging Subcommittee of the Life Course and Prevention Research Review Committee, NIMH.

Date and Time: February 18–19: 9:00 a.m.

Place: Shoreham Hotel, 2500 Calvert Street NW., Washington, DC 20008.

Status of Meeting:

Open—February 18: 9:00–9:30.9:30 a.m.
Closed—Otherwise.

Contact: Naomi Lichtenberg, Parklawn Building, Room 9C–18, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–3857.

Purpose: The Committee is charged with the initial review of applications for assistance from the National Institute of Mental Health for support of research grants, individual postdoctoral research fellowships and institutional research training grants, cooperative agreements, and research and development contracts, as they relate to mental health in the fields of child, family and aging, with recommendations to the National Advisory Mental Health Council for final review.

Committee Name: Clinical Program Projects and Clinical Research Centers Subcommittee of the Treatment Development and Assessment Research Review Committee, NIMH.

Date and Time: February 18–19: 9:00 a.m.

Place: J.W. Marriott, 1331 Pennsylvania Avenue, NW., Washington, DC 20004.

Status of Meeting:

Open—February 18: 9:00–10:00 a.m.
Closed—Otherwise.

Contact: Pamela J. Mitchell, Parklawn Building, Room 9C–14, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–1367.

Purpose: The Committee is charged with the initial review of applications for assistance from the National Institute of Mental Health for support of Mental Health Clinical Research Centers, clinical program projects, and other large-scale multi-disciplinary research projects and makes recommendations to the National Advisory Mental Health Council for final review.

Committee Name: Mental Health Behavioral Sciences Research Review Committee, NIMH.

Date and Time: February 18–20: 9:00 a.m.

Place: Guest Quarters Hotel, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Status of Meeting:

Open–February 18: 9:00–10:00 a.m.
Closed–Otherwise.

Contact: Cathy Oliver, Parklawn Building, Room 9C–26, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–3936.

Purpose: The Committee is charged with the initial review of applications for assistance from the National Institute of Mental Health for support of research and research training activities relating to behavioral science areas relevant to mental health and makes recommendations to the National Advisory Mental Health Council for final review.

Committee Name: Clinical and Treatment Subcommittee of the Alcohol Psychosocial Research Review Committee, NIAAA.

Date and Time: February 22–23: 9:00 a.m.

Place: Crown Plaza Hotel, 1750 Rockville Pike, Rockville, MD 20852.

Status of Meeting:

Open—February 22: 9:00 a.m.—9:30 a.m.
Closed—Otherwise.

Contact: Thomas D. Sevy, Parklawn Building, Room 16C–26, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–6106.

Purpose: The Committee is charged with the initial review of applications for assistance from the National Institute on Alcohol Abuse and Alcoholism for support of research and training activities and makes recommendations to the National Advisory Council on Alcohol Abuse and Alcoholism for final review.

Committee Name: Psychopathology and Clinical Biology Research Review Committee, NIMH.

Date and Time: February 22–24: 9:00 a.m.

Place: The Canterbury Hotel, 1733 "N" Street NW., Washington, DC 20036.

Status of Meeting:

Open—February 22: 9:00–10:00 a.m.
Closed—Otherwise.

Contact: Emilie A. Embrey, Parklawn Building, Room 9C–08, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–1340.

Purpose: The Committee is charged with the initial review of applications for assistance from the National Institute of Mental Health for support of activities in the fields of research and research training activities in the areas of clinical psychopathology and clinical biology as they relate to mental health, with recommendations to the National Advisory Mental Health Council for final review.

Committee Name: Alcohol, Drug Abuse, and Mental Health Advisory Board, ADAMHA.

Date and Time: February 23–24: 9:00 a.m.

Place: National Institutes of Health, Building #31, Conference Room 10, 9000 Rockville Pike, Bethesda, MD 20892.

Status of Meeting: Open.

Contact: Barbara Wagner, Parklawn Building, Room 12C–05, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–1910.

Purpose: The Board assesses the national needs for alcoholism, alcohol abuse, drug abuse, and mental health treatment and prevention services and the extent to which those needs are being met by State, local, and private programs, and programs receiving funds under Title V and Parts B & C of Title XIX of the public Health Service Act. The Board provides advice and recommendations to the Secretary and to the Administrator, Alcohol, Drug Abuse, and Mental Health Administration respecting these activities to assist in guiding national strategies aimed at the amelioration of alcohol, drug abuse, and mental health problems.

Committee Name: Basic Behavioral Processes Research Review Committee, NIMH.

Date and Time: February 24–25: 9:00 a.m.

Place: The Holiday Inn Hotel, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Status of Meeting:

Open—February 24: 9:00–10:00 a.m.
Closed—Otherwise.

Contact: Doris East, Parklawn Building, Room 9C–26, 5600 Fishers

Lane, Rockville, MD 20857, (301) 443–3936.

Purpose: The Committee is charged with the initial review of applications for assistance from the National Institute of Mental Health for support of research and research training activities relating to experimental and physiological psychology and comparative behavior, with recommendations to the National Advisory Mental Health Council for final review.

Committee Name: Neuroscience and Behavior Subcommittee of the Alcohol Biomedical Research Review Committee, NIAAA.

Date and Time: February 24–26: 9:00 a.m.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

Status of Meeting:
Open—February 24: 9:00–11:00 a.m.
Closed—Otherwise.

Contract: Samir Zakhari, Parklawn Building, Room 16C26, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–6106.

Purpose: The Committee is charged with the initial review of applications for assistance from the National Institute on Alcohol Abuse and Alcoholism for support of research and training activities and makes recommendations to the National Advisory Council on Alcohol Abuse and Alcoholism for final review.

Committee Name: Services Subcommittee of the Epidemiologic and Services Research Review Committee, NIMH.

Date and Time: February 24–26: 9:00 a.m.

Place: Guest Quarters Hotel, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Status of Meeting:
Open—February 24: 9:00–10:00 a.m.
Closed—Otherwise.

Contact: Gloria Yockelson, Parklawn Building, Room 9C–14, 5600 Fishers Lane, Rockville, MD 20857, (301) 445–1367.

Purpose: The Committee is charged with the initial review of applications for assistance from the National Institute of Mental Health for support of research and research training activities as they relate to mental health epidemiology, mental health service systems research, and evaluation of clinical mental health services, with recommendations to the National Advisory Mental Health Council for final review.

Committee Name: Prevention and Epidemiology Subcommittee of the Alcohol Psychosocial Research Review Committee, NIAAA.

Date and Time: February 25–26: 9:00 a.m.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814.

Status of Meeting:
Open—February 25: 9:00–9:30 a.m.
Closed—Otherwise.

Contact: Thomas D. Sevy, Parklawn Building, Room 16C–26, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–6106.

Purpose: The Committee is charged with the initial review of applications for assistance from the National Institute on Alcohol Abuse and Alcoholism for support of research and training activities and makes recommendations to the National Advisory Council on Alcohol Abuse and Alcoholism for final review.

Committee Name: Psychosocial and Biobehavioral Treatments Subcommittee of the Treatment Development and Assessment Research Review Committee, NIMH

Date and Time: February 25–26: 9:00 a.m.

Place: The Governor's House, Rhode Island Avenue at 17th Street NW., Washington, DC 20036.

Status of Meeting:
Open—February 25: 9:00–10:00 a.m.
Closed—Otherwise.

Contact: Frances Smith, Parklawn Building, Room 9C–02, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–4868.

Purpose: The Committee is charged with the initial review of applications for assistance from the National Institute of Mental Health for support of research and research training activities in the fields of treatment development and assessment and makes recommendations to the National Advisory Mental Health Council for final review.

Committee Name: Epidemiology Subcommittee of the Epidemiologic and Services Research Review Committee, NIMH.

Date and Time: February 29–March 1: 9:00 a.m.

Place: Guest Quarters Hotel, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Status of Meeting:
Open—February 29: 9:00–10:00 a.m.
Closed—Otherwise.

Contact: Gloria Yockelson, Parklawn Building, Room 9C–14, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–1367.

Purpose: The Committee is charged with the initial review of applications for assistance from the National Institute of Mental Health for support of research and research training activities as they relate to mental health epidemiology, mental health service systems research, and evaluation of clinical mental health services, with recommendations to the National Advisory Metal Health Council for final review.

Substantive information, summaries of the meetings, and rosters of committee members may be obtained as follows: Ms. Diana Widner, NIAAA Committee Management Officer, Room 16C–20, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443–4375; Ms. Camilla Holland, NIDA Committee Management Officer, Room 10–42, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857, (301) 443–2620; Ms. Joanna Kieffer, NIMH Committee Management Officer, Room 9–94, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443–4333.

Date: January 13, 1988.

Peggy W. Cockrill,

Committee Management Officer, Alcohol, Drug Abuse, and Mental Health Administration.

[FR Doc. 88–1010 Filed 1–19–88; 8:45 am]

BILLING CODE 4160–20–M

Centers for Disease Control

National Institute for Occupational Safety and Health, Mine Health Research Advisory Committee; Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control (CDC) announces the following National Institute for Occupational Safety and Health (NIOSH) committee meeting:

Name: Mine Health Research Advisory Committee (MHRAC).

Date: February 4–5, 1988.

Place: Kentucky Room, Hyatt Regency Knoxville, 500 Hill Avenue, SE, Knoxville, Tennessee 37901.

Time and Type of Meeting: Open 8:30 a.m. to 5 p.m.—February 4; Open 8 a.m. to 1 p.m.—February 5.

Contact Person: Robert E. Glenn, Executive Secretary, MHRAC, NIOSH, CDC, 944 Chestnut Ridge Road, Morgantown, West Virginia 26505. Telephone: Commercial: (304) 291–4474, FTS: 923–4474.

Purpose: The Committee is charged with advising the Secretary of Health and Human Services on matters involving or relating to mine health

research, including grants and contracts for such research.

Agenda: Agenda items for the meeting will include announcements; consideration of minutes of previous meeting and future meeting dates; and discussions of musculoskeletal injuries, silicosis among miners, and coal workers pneumoconiosis.

Agenda items are subject to change as priorities dictate.

The meeting is open to the public for observation and participation. Anyone wishing to make an oral presentation should notify the contact person listed above as soon as possible before the meeting. The request should state the amount of time desired, the capacity in which the person will appear, and a brief outline of the presentation. Oral presentations will be scheduled at the discretion of the Chairperson and as time permits. Anyone wishing to have a question answered by a scheduled speaker during the meeting should submit the question in writing, along with his or her name and affiliation, through the Executive Secretary to the Chairperson. At the discretion of the Chairperson and as time permits, appropriate questions will be asked of the speakers.

A roster of members and other relevant information regarding the meeting may be obtained from the contact person listed above.

The requirement for a 15-day advance publication notice of this meeting was not met due to inclement weather and the closing of the CDC facility.

Dated: January 13, 1988.

Elvin Hilyer,

Associate Director for Policy Coordination, Centers for Disease Control.

[FR Doc. 88-1000 Filed 1-19-88; 8:45 am]

BILLING CODE 4160-19-M

Food and Drug Administration

[Docket Nos. 80D-0097 and 82D-0049]

Defect Action Levels for the Adulteration of Wheat Flour and Macaroni Products by Insects

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its final decision on the revised defect action levels for insect fragments in wheat flour other than durum wheat flour and in macaroni and noodle products. Based on the review of the comments, FDA is issuing the revised Compliance Policy Guide 7104.06, "Wheat Flour—Adulterated with Insect Fragments and Rodent Hairs," and is withdrawing the tentative revisions to Compliance Policy Guide 7102.06, "Macaroni and Noodle Products—Adulteration Involving Insect Fragments and Rodent Hairs." The comments and the agency's analysis of the comments are on file in the Dockets Management Branch under the appropriate docket number.

DATE: The revised defect action level will be effective January 20, 1988.

ADDRESS: Written requests for single copies of Compliance Policy Guide 7104.06 should be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857. (Send two self-addressed adhesive labels to assist the branch in processing your request.)

FOR FURTHER INFORMATION CONTACT: Terry C. Troxell, Center for Food Safety and Applied Nutrition (HFF-312), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0229.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 25, 1986 (51 FR 34142), FDA announced the availability of two revised Compliance Policy Guides, in draft form: Compliance Policy Guide 7104.06, "Wheat Flour Adulterated With Insect Fragments and Rodent Hairs," and Compliance Policy Guide 7102.06, "Macaroni and Noodle Products—Adulteration Involving Insect Fragments and Rodent Hairs." The draft Compliance Policy Guides set forth revised defect action levels for insect fragments in wheat flour and in macaroni and noodle products. This action was initiated by a petition filed by the Millers' National Federation. Interested persons were given until November 24, 1986, to comment.

Ten letters, each containing one or more comments, were received from industry, industry associations, the U.S. Department of Agriculture, Kansas State University, and a consumer.

Based on the agency's review of the comments concerning the tentative revision of the defect action level for insect fragments in wheat flour other than durum flour, the agency has determined that the revised defect action level of wheat flour is more reflective of the capabilities of the flour milling industry, and therefore the revised defect action level should become effective.

FDA based its tentative revision of the defect action level for insect fragments in macaroni and noodle products on the tentative revised defect action level for insect fragments in wheat flour other than durum flour. However, the review of the comment in regard to the revision of the defect action level for insect fragments in macaroni and noodle products revealed a need to reevaluate the extent of the use of wheat flour other than durum flour in macaroni and noodle products. Therefore, until new data can be gathered concerning the extent of the use of wheat flour other than durum flour in macaroni and noodle products, the agency has determined that the defect action level for macaroni and noodle products should not be revised and the current defect action level should be retained.

The comments and the agency's analysis of the comments are on file in the Dockets Management Branch (address above) under the appropriate docket number: Docket Number 80D-0097 for wheat flour and Docket Number 82D-0049 for macaroni and noodle products. These documents are available in that office for public examination between 9 a.m. and 4 p.m., Monday through Friday.

Having reviewed and considered all the comments, the agency is announcing that: (1) The defect action level for insect fragments in wheat flour, other than durum flour in Compliance Policy Guide 7104.06, is established as 75 fragments per 50 grams of flour, (2) the tentative revision of the defect action level for insect fragments in Compliance Policy Guide 7102.06 for macaroni and noodle products is withdrawn, and (3) the current defect action level of 225 insect fragments per 225 grams for macaroni and noodle products is retained.

Effective dates for defect action levels are normally 60 days after publication of the notice of availability in the **Federal Register** in order to provide manufacturers with time to make any adjustments necessary to achieve compliance. However, such a delay is not needed for the revision of the defect action level for insect fragments in wheat flour because the revised defect action level is less restrictive than the previous one. Accordingly, the revised defect action level for wheat flour other than durum flour will become effective January 20, 1986.

Requests for single copies of Compliance Policy Guide 7104.06 are to be identified with Docket Number 80D-0097 and submitted in writing to the Dockets Management Branch (address above).

Dated: January 4, 1988.

Ronald A. Chesemore,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 88-1011 Filed 1-19-88; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing—Federal Housing Commissioner

[Docket No. N-88-1776; FR-2441]

Mortgage and Loan Insurance Programs Under the National Housing Act; Debenture Interest Rates

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice of change in debenture interest rates.

SUMMARY: This notice announces changes in the interest rates to be paid on debentures issued with respect to a loan or mortgage insured by the Federal Housing Commissioner under the provisions of the National Housing Act (the "Act"). The interest rate for debentures issued under section 221(g)(4) of the Act during the six-month period beginning January 1, 1988, is 8⅜ percent. The interest rate for debentures issued under any other provision of the Act is the rate in effect on the date that the commitment to insure the loan or mortgage was issued, or the date that the loan or mortgage was endorsed (or initially endorsed if there are two or more endorsements) for instance, whichever rate it higher. The interest rate for debentures issued under these other provisions with respect to a loan or mortgage committed or endorsed during the six-month period beginning January 1, 1988, is 9⅛ percent.

FOR FURTHER INFORMATION CONTACT: James B. Mitchell, Financial Policy Division, Room 9132, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410. Telephone (202) 426-4325 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: Section 224 of the National Housing Act (24 U.S.C. 1715o) provides that debentures issued under the Act with respect to an insured loan or mortgage (except for debentures issued pursuant to section 221(g)(4) of the Act) will bear interest at the rate in effect on the date the commitment to insure the loan or mortgage was issued, or the date the loan or mortgage was endorsed (or initially endorsed if there are two or more endorsements) for insurance, whichever rate is higher. This provision is implemented in HUD's regulations at 24 CFR 203.405, 203.479, 207.259(e)(6) and 220.830. Each of these regulatory provisions states that the applicable rates of interest will be published twice each year as a notice in the **Federal Register.**

Section 224 further provides that the interest rate on these debentures will be set from time to time by the Secretary of HUD, with the approval of the Secretary of the Treasury, in an amount not in excess of the interest rate determined by the Secretary of the Treasury pursuant to a formula set out in the statute.

The Secretary of the Treasury (1) has determined, in accordance with the provisions of section 224, that the statutory maximum interest rate for the period beginning January 1, 1988, is 9⅛ percent and (2) has approved the establishment of the debenture interest rate by the Secretary of HUD at 9⅛ percent for the six-month period beginning January 1, 1988. This interest rate will be the rate borne by debentures issued with respect to any insured loan or mortgage (except for debentures issued pursuant to section 221(g)(4)) with an insurance commitment or endorsement date (as applicable) within the first six months of 1988.

For convenience of reference, HUD is publishing the following chart of debenture interest rates applicable to mortgages committed or endorsed since January 1, 1979:

Effective rate (percent)	On or after	Prior to
8	Jan. 1, 1979	July 1, 1979.
8¼	July 1, 1979	Jan. 1, 1980.
9⅛	Jan. 1, 1980	July 1, 1980.
9⅜	July 1, 1980	Jan. 1, 1981.
11¾	Jan. 1, 1981	Jan. 1, 1981.
12⅛	July 1, 1981	Jan. 1, 1982.
12¾	Jan. 1, 1982	July 1, 1983.
10¼	Jan. 1, 1983	July 1, 1983.
10⅜	July 1, 1983	Jan. 1, 1984.
11⅛	Jan. 1, 1984	July 1, 1984.
13⅜	July 1, 1984	Jan. 1, 1985.
11⅝	Jan. 1, 1985	July 1, 1985.
11⅛	July 1, 1985	Jan. 1, 1986.
10¼	Jan. 1, 1986	July 1, 1986.
8¼	July 1, 1986	Jan. 1, 1987.
8	Jan. 1, 1987	July 1, 1987.
8	July 1, 1987	Jan 1, 1988.
9⅛	Jan. 1, 1988	

Section 221(g)(4) of the Act provides that debentures issued pursuant to that paragraph (with respect to the assignment of an insured mortgage to the Secretary) will bear interest at the "going Federal rate" in effect at the time the debentures are issued. The term "going Federal rate", as used in that paragraph, is defined to mean the interest rate that the Secretary of the Treasury determines, pursuant to a formula set out in the statute, for the six-month periods of January through June and January through December of each year. Section 221(g)(4) is implemented in the HUD regulations at 24 CFR 221.790.

The Secretary of the Treasury has determined that the interest rate to be borne by debentures issued pursuant to section 221(g)(4) during the six-month period beginning January 1, 1988, is 8⅜ percent.

HUD expects to publish its next notice of change in debenture interest rates in July 1988.

The subject matter of this notice falls within the categorical exclusion from HUD's environmental clearance procedures set forth in 24 CFR 50.20(1). For that reason, no environmental finding has been prepared for this notice.

Sections 211, 221, 224, National Housing Act, 12 U.S.C. 1715b, 17151, 1715o; sec. 7(d), Department of HUD Act, 42 U.S.C. 3535(d)).

Dated: January 6, 1988.

James E. Schoenberger,

General Deputy Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 88-1022 Filed 1-19-88; 8:45 am]

BILLING CODE 4210-27-M

DEPARTMENT OF THE INTERIOR

National Strategic Materials and Minerals Program Advisory Committee Meeting

Notice is hereby given, in accordance with the Federal Advisory Committee Act, that the National Strategic Materials and Minerals Program Advisory Committee (NSMMPAC) will meet on Thursday, February 4, 1988, from 9:30 a.m. until 12:30 p.m. or until business is concluded. The meeting will convene in Rooms 7000 A&B at the Department of the Interior, 18th and C Streets, NW., Washington, DC. It will be open to the public, subject to the availability of space.

The agenda will include: Introduction of new members, reports of task force activities, and any recommendations for possible action by the Committee. The final report of the Advanced Materials Task Force will be considered at this meeting. There will be a presentation on new technologies using pig iron and anthracite coal in the production of ferroalloys given by Thomas A. Schott, Chairman of Schott Incorporated. A second presentation will be made by Thomas F. Bates of GeoVision, Incorporated, on the production of a documentary on the every day use of minerals in society.

Statements are invited from groups and members of the general public who have an interest in mining, minerals or materials issues. The Committee is particularly interested in hearing any comments or suggestions regarding advanced materials and technology issues which fall within the purview of the Committee. To ensure that time will be available to hear such statements, prospective witnesses are requested to notify the Executive Director (see below) of their intention to appear.

FOR FURTHER INFORMATION CONTACT: Gully Walter, Department of the Interior, Washington, DC., Room 6650, (202) 343–2136.

Dated: January 14, 1988.

Gully Walter,

Executive Director.

[FR Doc. 88–978 Filed 1–19–88; 8:45 am]

BILLING CODE 4316–10–M

Bureau of Indian Affairs

Buy Indian Act Eligibility for Contracts

January 12, 1988.

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice, change in policy.

SUMMARY: It is the Bureau's policy that all purchases or contracts be made or entered into with qualified Indian contractors to the maximum extent practicable and to contact non-Indian contractors only after it has been determined that there are no qualified Indian contractors within the normal competitive area that can fill and are interested in filling the procurement requirement.

For the purposes of the Buy Indian Act (25 U.S.C. 47, June 25, 1910), the term "Indian" means a person who is a member of an Indian tribe or otherwise considered to be an Indian by the tribe with which affiliation is claimed. Since 1971, the policy of the Bureau of Indian Affairs has been that an Indian contractor had to be 100% Indian owned and controlled in order to compete for contracts under the Buy Indian Act. The Bureau of Indian Affairs, however, has changed its policy with regard to the definition of Indian contractor to be "a legal entity that is 51% Indian owned." The reason for this change in policy is to encourage the development of Indian economic enterprises. The policy change became effective on January 12, 1988, however, the Bureau believes it is in the best interest of the public to have an opportunity to comment on and codify this policy in the Code of Federal Regulations. Accordingly, the public will have an opportunity to comment on proposed regulations for the Buy Indian Act program which are being prepared for publication. The contracts for this program will, in all other respects, adhere to the requirements of the Federal Acquisition Regulations (48 CFR Parts 1 and 14).

This notice is published in exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 209 DM 8.

EFFECTIVE DATE: January 12, 1988.

FOR FURTHER INFORMATION CONTACT: Nancy C. Garrett, Director, Office of Administration, Bureau of Indian Affairs, 18th and C Streets, NW., Washington, DC 20240; telephone (202) 343–4174.

Ross O. Swimmer,

Assistant Secretary — Indian Affairs.

[FR Doc. 88–962 Filed 1–19–88; 8:45 am]

BILLING CODE 4310–02–M

Bureau of Land Management

[CA–940–08–4212–13; CA 20256]

California; Realty Action; Exchange of Public and Private Lands in Riverside County and Order Providing for Opening of Public Land

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of issuance of land exchange conveyance document and opening order.

ADDRESS: Inquiries concerning the land should be addressed to: Chief, Branch of Adjudication and Records, Bureau of Land Management, California State Office, 2800 Cottage Way (Room E–2841), Sacramento, California 95825.

SUMMARY: The purpose of this exchange was to acquire a portion of the non-Federal land within the proposed 13,030-acre preserve for the Coachella Valley fringe-toed lizard. The lizard is Federally listed as threatened and State listed as endangered. The Bureau of Land Management's goal is to acquire approximately 6,700 acres within the preserve. The land acquired does not constitute habitat for the lizard, but provides a sand source required for the continuing production of active sand dune areas that are critical habitat for the lizard. Other State and Federal agencies will acquire the remaining portion for the preserve. The public interest was well served through completion of this exchange. The land acquired in this exchange will be opened to operation of the public land laws and to the full operation of the United States mining and mineral leasing laws.

FOR FURTHER INFORMATION CONTACT: Dianna Storey, California State Office, (916) 978–4815.

1. The United States issued a land exchange conveyance document to The Nature Conservancy on December 15, 1987, pursuant to the authority of section 206 of the Act of October 21, 1976 (43 U.S.C. 1716) for the following described public land:

San Bernardino Meridian, California

T. 6 S., R. 2 W.,
Sec. 14, Lots 1 to 16, inclusive;
Sec. 24, NW¼ NW¼;

The area described contains 685.36 acres in Riverside County.

2. In exchange for the land described in paragraph 1, on December 15, 1987, the United States accepted title to the following described private land from The Nature Conservancy:

San Bernardino Meridian, California

T. 4 S., R. 7 E.,
Sec. 7, E½ NE¼, SW¼ NE¼, and N½ SE¼.

EXCEPT 50% of all mineral, gas, oil, and geothermal rights and substances under the real estate described in the deed, without rights of surface entry, as reserved in the deed recorded April 27, 1971, as Instrument No. 43314 of Official Records of Riverside County, California.

The area described contains 200 acres in Riverside County.

3. The values of the Federal public land and the non-Federal private land were equalized by the procedures set forth in the Memorandum of Agreement dated December 10, 1987.

4. At 10 a.m. on February 22, 1988, the land described above in paragraph 2 shall be open to operation of the public land laws generally, subject to valid existing rights and the requirements of applicable law. All valid applications received at or prior to 10 a.m. on February 22, 1988, shall be considered as simultaneously filed at that time. Those received thereafter shall be considered in the order of filing.

5. At 10 a.m. on February 22, 1988, the land described in paragraph 2 above shall be open to location under the United States mining laws. Appropriation of any of the land described in this order under the general mining laws prior to the date and time of opening is unauthorized. Any such attempted appropriation, including attempted adverse possession under 30 U.S.C. 38, shall vest no rights against the United States. Acts required to establish a location and to initiate a right of possession are governed by State law where not in conflict with Federal law.

The Bureau of Land Management will not intervene in disputes between rival locators over possessory rights since Congress has provided for such determinations in local courts.

6. At 10 a.m. on February 22, 1988, the land described in paragraph 2 above shall be open to applications and offers under the mineral leasing laws.

Date: January 11, 1988.

Robert C. Nauert,

Chief, Branch of Adjudication and Records.

[FR Doc. 88-966 Filed 1-19-88; 8:45 am]

BILLING CODE 4310-40-M

[CA-940-08-4212-13; CA 18782]

California; Realty Action; Exchange of Public and Private Lands in Riverside County and Order Providing for Opening of Public Land

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of issuance of land exchange conveyance document and opening order.

ADDRESS: Inquiries concerning the land should be addressed to: Chief, Branch of Adjudication and Records, Bureau of Land Management, California State Office, 2800 Cottage Way (Room E-2841), Sacramento, California 95825.

SUMMARY: The purpose of this exchange was to acquire a portion of the non-Federal land within the proposed 13,030-acre preserve for the Coachella Valley fringe-toed lizard. The lizard is Federally listed as threatened and State listed as endangered. The Bureau of Land Management's goal is to acquire approximately 6,700 acres within the preserve. The land acquired does not constitute habitat for the lizard, but provides a sand source required for the continuing production of active sand dune areas that are critical habitat for the lizard. Other State and Federal agencies will acquire the remaining portion for the preserve.

The public interest was well served through completion of this exchange. The land acquired in this exchange will be opened to operation of the public land laws and to the full operation of the United States mining and mineral leasing laws.

FOR FURTHER INFORMATION CONTACT: Dianna Storey, California State Office, (916) 978-4815.

1. The United States issued a land exchange conveyance document to The Nature Conservancy on December 14, 1987, pursuant to the authority of sec. 206 of the Act of October 21, 1976 (43 U.S.C. 1716) for the following described public land:

San Bernardino Meridian, California

T. 8 S., R. 8 E.,
Sec. 16, lots 1 to 7, inclusive, S½NE¼, SE¼ NW¼, E½SW¼, and SE¼;

The area described contains 647.83 acres in Riverside County.

2. In exchange for the land described in paragraph 1, on December 11, 1987, the United States accepted title to the following described private land from The Nature Conservancy:

San Bernardino Meridian, California

T. 4 S., R. 6 E.,
Sec. 1, SE¼SE¼;
T. 4 S., R. 7 E.,
Sec. 7, lots 1 and 2 of the SW¼, E½NW¼ NE¼, and W½SW¼SE¼.

EXCEPT 50% of all mineral, gas, oil, and geothermal rights and substances under the real estate described in the deed, without rights of surface entry, as reserved in the deed recorded April 27, 1971, as Instrument No. 43314 of Official Records of Riverside County, California.

The areas described contain 246.53 acres in Riverside County.

3. The values of the Federal public land and the non-Federal (private) land were equalized by the procedures set forth in the Memorandum of Agreement dated December 10, 1987.

4. At 10 a.m. on February 22, 1988, the land described above in paragraph 2 shall be open to operation of the public land laws generally, subject to valid existing rights and the requirements of applicable law. All valid applications received at or prior to 10 a.m. on February 22, 1988, shall be considered as simultaneously filed at that time. Those received thereafter shall be considered in the order of filing.

5. At 10 a.m. on February 22, 1988, the land described in paragraph 2 above shall be open to location under the United States mining laws. Appropriation of any of the land described in this order under the general mining laws prior to the date and time of opening is unauthorized. Any such attempted appropriation, including attempted adverse possession under 30 U.S.C. 38, shall vest no rights against the United States. Acts required to establish a location and to initiate a right of possession are governed by State law where not in conflict with Federal law. The Bureau of Land Management will not intervene in disputes between rival locators over possessory rights since Congress has provided for such determinations in local courts.

6. At 10 a.m. on February 22, 1988, the land described in paragraph 2 above shall be open to applications and offers under the mineral leasing laws.

Robert C. Nauert,

Chief, Branch of Adjudication and Records.

Date: January 11, 1988.

[FR Doc. 88-967 Filed 1-19-88; 8:45 am]

BILLING CODE 4310-40-M

Bureau of Reclamation Central Valley Project, California; Realty Action; Competitive Sale of Public Land

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of realty action.

SUMMARY: The following described land has been identified for disposal under the Act of February 2, 1911 (36 Stat. 895, 43 U.S.C 374), at no less than the appraised fair market value. The Bureau of Reclamation will accept bids on the land described below and will reject any bids for less than $22,400.00, the appraised value.

DATE: April 7, 1988.

FOR FURTHER INFORMATION CONTACT: Merle Hopper, Civil Engineering Technician, Willows Office (CVP), P.O. Box 988, 1140 West Wood Street, Willows, California 95988-0988, telephone (916) 934-7066.

SUPPLEMENTARY INFORMATION: A tract of land in the west one-half of Section Twenty-three (23), Township Seventeen (17) North, Range Four (4) West, Mount Diablo Meridian, County of Colusa, State of California, containing an area of 112 acres, more or less.

Said above tract shall be subject to easements or rights-of-way existing or of record in favor of the public or to third parties.

The land will be offered for sale through the competitive bidding process. A sealed bid sale will be held at 1140 West Wood Street, Willows, California on April 7, 1988 at 10:00 a.m., at which time the sealed bids will be opened. Sealed bids will be accepted at the Bureau of Reclamation, Willows Office (CVP), at the above address until close of business on April 6, 1988. Reclamation may accept or reject any and all offers, or withdraw any land or interest in land for sale, if, in the opinion of the Regional Director, consummation of the sale would not be fully consistent with the Act of February 2, 1911 (36 Stat. 895, 43 U.S.C. 374), or other applicable laws. In order to promote full and free competition, a certificate of independent price determination must accompany each sealed bid which is included in the bid package. This can be obtained from the Willows Office.

The land is within the County of Colusa, State of California. The sale is consistent with the Bureau of Reclamation land use planning and it was determined that the public interest would best be served by offering this land for sale. Interested parties are advised that no public access exists and no access will be provided by the United States.

Resource clearances consistent with the National Environmental Policy Act requirements have been completed and approved. A Categorical Exclusion Checklist is available for public review at the Bureau of Reclamation, Willows Office (CVP), 1140 West Wood Street, Willows, California.

The quitclaim deed issued for the land sold will be subject to easements or rights-of-way existing or of record in favor of the public or third parties. The quitclaim deed shall also make the land subject to conditions and covenants pursuant to Executive Orders 11988 and 11990.

For a period of 60 days from the date of this notice, interested parties may submit comments to the Regional Director, Mid-Pacific Region, Bureau of Reclamation, 2800 Cottage Way, Sacramento, CA 95825. Any adverse comments will be evaluated by the Regional Director who may vacate or modify this Realty Action and issue a final determination. In the absence of any action by the Regional Director, this Realty Action will become the final determinaiton of the Department of the Interior.

Neil M. Schild,

Acting Regional Director, Mid-Pacific Region, Bureau of Reclamation.

Date: January 7, 1988.

[FR Doc. 88-977 Filed 1-19-88; 8:45 am]

BILLING CODE 4310-09-M

Fish and Wildlife Service

Receipt of Applications for Permits

The following applicants have applied for permits to conduct certain activities with endangered species. This notice is provided pursuant to section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531, *et seq.*):

Applicant: Willis D. Hamilton, Orange, CA—PRT-723971

The applicant requests a permit to import a sport-hunted trophy of a bontebok (Damaliscus dorcas dorcas) culled from the captive herd maintained by Mr. Phil van der Merwe, Cape Province, South Africa, for the purpose of enhancement of survival of the species.

Applicant: Bob Clark, Oklahoma City, OK—PRT-723928

The applicant requests a permit to import four captive born radiated tortoises (Geochelone radiata) from Mr. Olaf Pronk, The Netherlands, for the purpose of captive breeding.

Applicant: Steven A. Bilbro, Monroe, WA—PRT-724251

The applicant requests a permit to import one pair of captive-bred peregrine falcons (Falco peregrinus anatum) from Mr. John Lejeune, British Columbia, Canada, for captive breeding purposes.

Documents and other information submitted with these applications are available to the public during normal business hours (7:45 am to 4:15 pm) Room 403, 1375 K Street NW., Washington, DC 20005, or by writing to the Director, U.S. Office of Management Authority, P.O. Box 27329, Central Station, Washington, DC 20038-7329.

Interested persons may comment on any of these applications within 30 days of the date of this publication by submitting written views, arguments, or data to the Director of the above address. Please refer to the appropriate PRT number when submitting comments.

Date: January 14, 1988.

R.K. Robinson,

Chief, Branch of Permits, U.S. Office of Management Authority.

[FR Doc. 88-1025 Filed 1-19-88; 8:45 am]

BILLING CODE 4310-55-M

Minerals Management Service

Development Operations Coordination Document; ARCO Oil and Gas Co.

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of the receipt of a proposed Development Operations Coordination Document (DOCD).

SUMMARY: Notice is hereby given that ARCO Oil and Gas Company has submitted a DOCD describing the activities it proposes to conduct on Lease OCS-G 3980, Block 104, portion, Vermilion Area, offshore Louisiana. Proposed plans for the above area provide for the development and production of hydrocarbons with support activities to be conducted from an existing onshore base located at Sabine Pass, Texas.

DATE: The subject DOCD was deemed submitted on January 8, 1988.

ADDRESS: A copy of the subject DOCD is available for public review at the Public Information Office, Gulf of Mexico OCS Region, Minerals Management Service, 1201 Elmwood Park Boulevard, Room 114, New Orleans, Louisiana (Office Hours: 8 a.m. to 4:30 p.m., Monday through Friday).

FOR FURTHER INFORMATION CONTACT: Michael J. Tolbert; Minerals Management Service, Gulf of Mexico OCS Region, Field Operations, Plans, Platform and Pipeline Section, Exploration/Development Plans Unit; Telephone (504) 736-2867.

SUPPLEMENTARY INFORMATION: The purpose of this Notice is to inform the public, pursuant to sec. 25 of the OCS Lands Act Amendments of 1978, that the Minerals Management Service is considering approval of the DOCD and that it is available for public review..

Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in DOCDs available to affected States, executives of affected local governments, and other interested parties became effective December 13, 1979 (44 FR 53685). Those practices and procedures are set out in revised § 250.34 of Title 30 of the CFR.

Date: January 11, 1988.

J. Rogers Pearcy,

Regional Director, Gulf of Mexico OCS Region.

[FR Doc. 88-968 Filed 1-19-88; 8:45 am]

BILLING CODE 4310-MR-M

Development Operations Coordination Document; Hall-Houston Oil Co.

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of the receipt of a proposed Development Operations Coordination Document (DOCD).

SUMMARY: Notice is hereby given that Hall-Houston Oil Company has submitted a DOCD describing the activities it proposes to conduct on Lease OCS-G 5016, Block 379, West Cameron Area, offshore Louisiana. Proposed plans for the above area provide for the development and production of hydrocarbons with support activities to be conducted from an existing onshore base located at Cameron, Louisiana.

DATE: The subject DOCD was deemed submitted on January 8, 1988. Comments must be received within 15 days of the date of this Notice or 15 days after the Coastal Management Section receives a copy of the plan from the Minerals Management Service.

ADDRESSES: A copy of the subject DOCD is available for public review at

the Public Information Office, Gulf of Mexico OCS Region, Minerals Management Service, 1201 Elmwood Park Boulevard, Room 114, New Orleans, Louisiana (Office Hours: 8 a.m. to 4:30 p.m., Monday through Friday). A copy of the DOCD and the accompanying Consistency Certification are also available for public review at the Coastal Management Section Office located on the 10th Floor of the State Lands and Natural Resources Building, 625 North 4th Street, Baton Rouge, Louisiana (Office Hours: 8 a.m. to 4:30 p.m., Monday through Friday). The public may submit comments to the Coastal Management Section, Attention OCS Plans, Post Office Box 44487, Baton Rouge, Louisiana 70805.

FOR FURTHER INFORMATION CONTACT: Mr. Michael D. Joseph; Minerals Management Service, Gulf of Mexico OCS Region, Field Operations, Plans, Platform and Pipeline Section, Exploration/Development Plans Unit; Telephone (504) 736–2875.

SUPPLEMENTARY INFORMATION: The purpose of this Notice is to inform the public, pursuant to sec. 25 of the OCS Lands Act Amendments of 1978, that the Minerals Management Service is considering approval of the DOCD and that it is available for public review. Additionally, this Notice is to inform the public, pursuant to § 930.61 of Title 15 of the CFR, that the Coastal Management Section/Louisiana Department of Natural Resources is reviewing the DOCD for consistency with the Louisiana Coastal Resources Program.

Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in DOCDs available to affected States, executives of affected local governments, and other interested parties became effective December 13, 1979 (44 FR 53685).

Those practices and procedures are set out in revised § 250.34 of Title 30 of the CFR.

Date: January 11, 1988.

J. Rogers Pearcy,

Regional Director, Gulf of Mexico OCS Region.

[FR Doc. 88–969 Filed 1–19–88; 8:45 am]

BILLING CODE 4310–MR–M

Development Operations Coordination Document; Phillips Petroleum Co.

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of the receipt of a proposed Development Operations Coordination Document (DOCD).

SUMMARY: Notice is hereby given that Phillips Petroleum Company has submitted a DOCD describing the activities it proposes to conduct on Lease OCS–G 4534, Block 791, Mustang Island Area, offshore Texas. Proposed plans for the above area provide for the development and production of hydrocarbons with support activities to be conducted from an existing onshore base located at Corpus Christi, Texas.

DATE: The subject DOCD was deemed submitted on January 8, 1988.

ADDRESS: A copy of the subject DOCD is available for public review at the Public Information Office, Gulf of Mexico OCS Region, Minerals Management Service, 1201 Elmwood Park Boulevard, Room 114, New Orleans, Louisiana (Office Hours: 8 a.m. to 4:30 p.m., Monday through Friday).

FOR FURTHER INFORMATION CONTACT: Ms. Angie D. Gobert; Minerals Management Service, Gulf of Mexico OCS Region, Field Operations, Plans, Platform and Pipeline Section, Exploration/Development Plans Unit; Telephone (504) 736–2876.

SUPPLEMENTARY INFORMATION: The purpose of this Notice is to inform the public, pursuant to sec. 25 of the OCS Lands Act Amendments of 1978, that the Minerals Management Service is considering approval of the DOCD and that it is available for public review.

Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in DOCDs available to affected States, executives of affected local governments, and other interested parties became effective December 13, 1979 (44 FR 53685). Those practices and procedures are set out in revised § 250.34 of Title 30 of the CFR.

Date: January 11, 1988

J. Rogers Pearcy,

Regional Director, Gulf of Mexico OCS Region.

[FR Doc. 88–870 Filed 1–19–88; 8:45 am]

BILLING CODE 4310–MR–M

National Park Service

Proposed Middle Fork of the Vermilion National Scenic River, IL; Receipt of Application and 45-day Public Review Period

SUMMARY: On August 20, 1987, the Governor of the State of Illinois submitted an application to the Secretary of the Interior requesting that a 17.1-mile segment of the Middle Fork of the Vermilion River in east central Illinois be designated a State-administered component of the National Wild and Scenic Rivers System, in accordance with provisions of the Wild and Scenic Rivers Act (16 U.S.C. 1271 *et seq.*). The segment involved extends from approximately river mile 46.9 downstream to river mile 29.8. The proposal is currently undergoing review by affected Federal Agencies as required by section 4(c) of the Act.

The general public and non-Federal Agencies are also invited to review and comment on the State's application and proposed national designation of the Middle Fork of the Vermilion River. Copies of the State application have been placed at the following locations for public inspection and review. The number in parenthesis behind the locations indicates the number of copies available for review.

Danville Public Library (5), Reference Desk, 307 North Vermilion Street, Danville, Illinois 61832
Urbana Free Library (2), Reference Desk, 201 South Race Street, Urbana, Illinois 61801
Kickapoo State Park Headquarters (1), Located at the east entrance of the park off Henning Road west of Danville, Illinois
Illinois Department of Conservation (2), Division of Planning, Room 300, 524 South Second Street, Springfield, Illinois 62706
State of Illinois Center (3), Department of Conservation, Suite 4–300, 100 West Randolph, Chicago, Illinois 60601
Illinois Department of Conservation (1), Region II Office, 110 James Road, Spring Grove, Illinois 60081
Illinois Department of Conservation (1), Region III Office, 8 Henson Place, Champaign, Illinois 61820
Illinois Department of Conservation (1), Region IV Office, 34 West Broadway, Alton, Illinois 62002
Illinois Department of Conservation (1), Region V Office, Located on State Route 37 a few miles north of Benton, Illinois.
National Park Service (2), Midwest Regional Office, 1709 Jackson Street, Omaha, Nebraska 68102

DATE: Written comments will be accepted until March 7, 1988.

ADDRESSES: Written comments should be sent to: Regional Director, National Park Service, Midwest Region, 1709 Jackson Street, Omaha, Nebraska 68102.

FOR FURTHER INFORMATION CONTACT: Tom Gilbert, Regional Coordinator, National Wild and Scenic Rivers System, (402) 221–3481.

SUPPLEMENTARY INFORMATION: The Middle Fork of the Vermilion River was designated a State Protected River by Public Act 84–1257, enacted by the State

legislature and approved by the Governor of Illinois, on August 8, 1986. Section 2(a)(ii) of the Wild and Scenic Rivers Act provides that a river protected by or pursuant to an act of the State legislature may be designated as a component of the national system by the Secretary of the Interior upon application from the Governor of the State and findings that the river qualifies for inclusion.

Date: January 6, 1988.

Denis P. Galvin,

Acting Director, National Park Service.

[FR Doc. 88-997 Filed 1-19-88; 8:45 am]

BILLING CODE 4310-70-M

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 January 9, 1988. 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 February 4, 1988.

Carol D. Shull,

Chief of Registration, National Register.

ARIZONA

Yavapai County

Prescott, *Santa Fe, Prescott and Phoenix Railroad Depot,* Cortez St.

CALIFORNIA

San Francisco County

San Francisco, *US Mint,* 155 Herman St.

CONNECTICUT

New London County

New London, *Coit Street Historic District,* Roughly bounded by Coit St., Washington, Tilley St., Bank St., and Reed St.

New London, *Downtown New London Historic District (Boundary Increase),* Along Huntington, Washington and Jay Sts.; SW corner of Meridian and Gov. Winthrop Blvd.; along Bank and Sparyard Sts.

INDIANA

Laporte County

Michigan City, *Michigan City East Pierhead Light Tower and Elevated Walk,* E side of entrance to Michigan City Harbor

KENTUCKY

Hardin County

Fort Knox, *US Bullion Depository, Fort Knox, Kentucky,* Gold Vault Rd. and Bullion Blvd.

MAINE

Hancock County

Islesford vincinty, *Baker Island Light Station (Light Stations of Maine MPS),* Baker Island, Acadia National Park

Northeast Harbor vincity, *Bear Island Light Station (Light Stations of Maine MPS),* Bear Island, Acadia National Park

MICHIGAN

Calhoun County

Albion, *Robertson, Eugene P., House,* 412 S. Clinton St.

Manistee County

Onekama, *Manistee County Courthouse Fountain,* Onekama Village Park

Wayne County

Highland Park, *Highland Heights—Stevens' Subdivision Historic District,* Bounded by Woodard Ave., the alley S of E. Buena Vista Ave., Oakland Ave., and the alley S of Massachusetts Ave.

Highland Park, *Medbury's—Grove Lawn Subdivisions Historic District,* Roughly bounded by Hamilton Ave., the alley S of Louise Ave., Woodward Ave., and the alley S of Puritan Ave.

NEW YORK

Essex County

Willsboro Point vicinity, *Edgewater Farm,* 470 Point Rd.

Livingston County

Sonyea vicinity, *Black and White Farm Barn,* &Resort TR), 375 Littleworth La.

Sea Cliff, *House at 103 Roslyn Avenue (Sea Cliff Summer Resort TR),* 103 Roslyn Ave.

Sea Cliff, *House at 112 Sea Cliff Avenue (Sea Cliff Summer Resort TR),* 112 Sea Cliff Ave.

Sea Cliff, *House at 115 Central Avenue (Sea Cliff Summer Resort TR),* 115 Central Ave.

Sea Cliff, *House at 137 Prospect Avenue (Sea Cliff Summer Resort TR),* 137 Prospect Ave.

Sea Cliff, *House at 173 Sixteenth Avenue (Sea Cliff Summer Resort TR),* 173 Sixteenth Ave.

Sea Cliff, *House at 176 Prospect Avenue (Sea Cliff Summer Resort TR),* 176 Prospect Ave.

Sea Cliff, *House at 18 Seventeenth Avenue (Sea Cliff Summer Resort TR),* 18 Seventeenth Ave.

Sea Cliff, *House at 19 Locust Place (Sea Cliff Summer Resort TR),* 19 Locust Pl.

Sea Cliff, *House at 195 Prospect Avenue (Sea Cliff Summer Resort TR),* 195 Prospect Ave.

Sea Cliff, *House at 199 Prospect Avenue (Sea Cliff Summer Resort TR),* 199 Prospect Ave.

Sea Cliff, *House at 207 Carpenter Avenue (Sea Cliff Summer Resort TR),* 207 Carpenter Ave.

Sea Cliff, *House at 240 Sea Cliff Avenue (Sea Cliff Summer Resort TR),* 240 Sea Cliff Ave.

Sea Cliff, *House at 285 Glen Avenue (Sea Cliff Summer Resort TR),* 285 Glen Ave.

Sea Cliff, *House at 285 Sea Cliff Avenue (Sea Cliff Summer Resort TR),* 285 Sea Cliff Ave.

Sea Cliff, *House at 290 Eighth Avenue (Sea Cliff Summer Resort TR),* 290 Eighth Ave.

Sea Cliff, *House at 332 Franklin Avenue (Sea Cliff Summer Resort TR),* 332 Franklin Ave.

Sea Cliff, *House at 362 Sea Cliff Avenue (Sea Cliff Summer Resort TR),* 362 Sea Cliff Ave.

Sea Cliff, *House at 378 Glen Avenue (Sea Cliff Summer Resort TR),* 378 Glen Ave.

Sea Cliff, *House at 52 Eighteenth Avenue (Sea Cliff Summer Resort TR),* 52 Eighteenth Ave.

Sea Cliff, *House at 58 Eighteenth Avenue (Sea Cliff Summer Resort TR),* 58 Eighteenth Ave.

Sea Cliff, *House at 65 Twentieth Avenue (Sea Cliff Summer Resort TR),* 65 Twentieth Ave.

Sea Cliff, *House at 9 Locust Place (Sea Cliff Summer Resort TR),* 9 Locust Pl.

Sea Cliff, *St. Lukes Protestant Episcopal Church (Sea Cliff Summer Resort TR),* 253 Glen St.

Orange County

West Point vicinity, *US Bullion Depository, West Point, New York,* US Military Academy

Suffolk County

Montauk, *Montauk Tennis Auditorium,* Flamingon Ave. and Edjemere St.

Ulster County

New Paltz vicinity, *DuBois, Josiah, Farm,* Libertyville Rd.

NORTH CAROLINA

Duplin County

Magnolia vicinity, *Dickson, Robert, Farm,* E. side of SR 1917

Wayne County

Mount Olive, *Southerland-Burnette House,* 210 N. Chestnut St.

OHIO

Cuyahoga County

Cleveland, *Glidden, Francis K., House,* 1901 Ford Dr.

Cleveland, *Weizer Building,* 8935 Buckeye Rd.

Franklin County

Columbus, *Berry Brothers Bolt Works,* 350 E. First Ave.

PUERTO RICO

Humacao County

Fajardo, *US Custom House (United States Custom Houses in Puerto Rico MPS),* Calle Union

Mayaguez County

Mayaguez, *US Custom House (United States Custom Houses in Puerto Rico MPS),* Ava. Gonzalez Clemente, esq. McKinley.

Ponce County

Ponce, *US Custom House (United States Custom Houses in Puerto Rico MPS),* Calle Bonaire at Calle Aduana Playa de Ponce

San Juan County

San Juan, *US Custom House (United States Custom Houses in Puerto Rico MPS)*, Calle Puntilla, 1.

SOUTH CAROLINA

Darlington County

Darlington, *Cashua Street—Spring Street Historic District (City of Darlington MRA)*, Cashua St. between Columbian St. and Warley St., and Spring St. between Cashua St. and N. Ervin St.
Darlington, *Dargan, Julius A., House (City of Darlington MRA)*, 488 Pearl St.
Darlington, *Darlington Industrial Historic District (City of Darlington MRA)*, Roughly bounded by Sixth St., Ave. B, Dargan St., and Siskron St.
Darlington, *Deas, Edmund H., House (City of Darlington MRA)*, 229 Ave. E
Darlington, *First Baptist Church (City of Darlington MRA)*, 246 S. Main St.
Darlington, *Hudson, Nelson, House (City of Darlington MRA)*, 521 Pearl St.
Darlington, *Manne Building (City of Darlington MRA)*, 129 Pearl St.
Darlington, *McColl, Clarence, House (City of Darlington MRA)*, 870 Cashua St.
Darlington, *McCullough, Charles S., House (City of Darlington MRA)*, 480 Pearl St.
Darlington, *South Carolina Western Railway Station (City of Darlington MRA)*, 129 Russell St.
Darlington, *West Broad Street Historic District (City of Darlington MRA)*, W. Broad St. between Dargan St. and Player St.
Darlington, *Wilds—Edwards House (City of Darlington MRA)*, 120 Edwards Ave.
Darlington, *Williamson, Mrs. B. F., House (City of Darlington MRA)*, 141 Oak St.

SOUTH DAKOTA

Bon Homme County

Tabor, *Old St. Wenceslaus Catholic Parish House*, 227 Yankton St.

Brookings County

Brookings, *Brookings Commerical Historic District*, Roughly along Main Ave. between the C&NW Railroad and the alley N of Fifth St.

Codington County

Kranzburg vicinity, *Ries, Nicholas T., Farmstead*, Off Codington County Hwy. 3

Custer County

Buffalo Gap vicinity, *Buffalo Gap Cheyenne River Bridge*, CR 656

Day County

Lily vicinity, *Barber, Charles A., Farmstead*, ¼ mi. W of Lily

Douglas County

Delmont, *Lenehan, Thomas, House*, Main St.

Jones County

Murdo vicinity, *Immanuel Lutheran Church*, 14 mi. N of I–90

Yankton County

Yankton, *Pennington, Governor John L., House*, 410 E. Third St.

TEXAS

Harris County

Houston, *San Felipe Courts Historic District*, 1 Allen Pkwy. Village.

[FR Doc. 88–996 Filed 1–19–88; 8:45 am]
BILLING CODE 4310–70–M

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–387 (Preliminary)]

Certain Fabricated Structural Steel From Canada

AGENCY: United States International Trade Commission.

ACTION: Institution of a preliminary antidumping investigation and scheduling of a conference to be held in connection with the investigation.

SUMMARY: The Commission hereby gives notice of the institution of preliminary antidumping investigation No. 731–TA–387 (Preliminary) under section 733(a) of the Tariff Act of 1930 (19 U.S.C. 1673b(a)) to determine whether there is a reasonable indication that an industry in the United States is materially injured, or is threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports from Canada of fabricated structural steel,[1] provided for in items 609.84, 609.86, 652.94, 652.95, 652.96, and 653.00 of the Tariff Schedules of the United States, that are alleged to be sold in the United States at less than fair value. As provided in section 733(a), the Commission must complete preliminary antidumping investigations in 45 days, or in this case by February 25, 1988.

For further information concerning the conduct of this investigation and rules of general application, consult the Commission's Rules of Practice and Procedure, Part 207, Subparts A and B (19 CFR Part 207), and Part 201, Subparts A through E (19 CFR Part 201).

EFFECTIVE DATE: January 11, 1988.

FOR FURTHER INFORMATION CONTACT: Rebecca Woodings (202–252–1192), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–252–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–252–1000.

SUPPLEMENTARY INFORMATION:

Background

This investigation is being instituted in response to a petition filed on January 11, 1988, by counsel on behalf of the American Institute of Steel Construction, Inc. (AISC)., Chicago, Illinois.

Participation in the Investigation

Persons wishing to participate in this investigation as parties must file an entry of appearance with the Secretary to the Commission, as provided in § 201.11 of the Commission's rules (19 CFR 201.11), not later than seven (7) days after publication of this notice in the **Federal Register**. Any entry of appearance filed after this date will be referred to the Chairman, who will determine whether to accept the late entry for good cause shown by the person desiring to file the entry.

Service List

Pursuant to § 201.11(d) of the Commission's rules (19 CFR 201.11(d)), the Secretary will prepare a service list containing the names and addresses of all persons, or their representatives, who are parties to this investigation upon the expiration of the period for filing entries of appearance. In accordance with §§ 201.16(c) and 207.3 of the rules (19 CFR 201.16(c) and 207.3), each document filed by a party to the investigation must be served on all other parties to the investigation (as identified by the service list), and a certificate of service must accompany the document. The Secretary will not accept a document for filing without a certificate of service.

Conference

The Director of Operations of the Commission has scheduled a conference in connection with this investigation for 9:30 a.m., on February 5, 1988, at the U.S. International Trade Commission

[1] For purposes of this investigation, the term "fabricated structural steel" means the following articles suitable for use in erecting or assembling buildings: (1) Angles, shapes, and sections, all of the foregoing of iron or steel; drilled, punched, or otherwise advanced; provided for in Tariff Schedules of the United States (TSUS) items 609.84 and 609.86; (2) columns, pillars, post, beams, girders, and similar structural units, all the foregoing of iron or steel (except non-malleable cast iron articles, rough or advanced), provided for in TSUS items 652.94, 652.95, 652.96; and (3) other structures and parts of structures not specially provided for, all the foregoing of iron or steel, provided for in TSUS item 653.00. The articles covered by this investigation are provided for in subheadings 7216.90.00, 7222.40.60, 7228.70.60, 7301.20.10, 7301.20.50, 7308.90.30, 7308.90.60, and 7308.90.90 of the proposed Harmonized Tariff Schedule of the United States (USITC Pub. 2030).

Building, 500 E Street SW., Washington, DC. Parties wishing to participate in the conference should contact Rebecca Woodings (202–252–1192) not later than February 2, 1988, to arrange for their appearance. Parties in support of the imposition of antidumping duties in this investigation and parties in opposition to the imposition of such duties will each be collectively allocated one hour within which to make an oral presentation at the conference.

Written Submissions

Any person may submit to the Commission on or before February 9, 1988, a written statement of information pertinent to the subject of the investigation, as provided in § 207.15 of the Commission's rules (19 CFR 207.15). A signed original and fourteen (14) copies of each submission must be filed with the Secretary to the Commission in accordance with § 201.8 of the rules (19 CFR 201.8). All written submissions except for confidential business data will be available for public inspection during regular business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary of the Commission.

Any business information for which confidential treatment is desired must be submitted separately. The envelope and all pages of such submissions must be clearly labeled "Confidential Business Information." Confidential submissions and requests for confidential treatment must conform with the requirements of § 201.6 of the Commission's rules (19 CFR 201.6).

Authority: This investigation is being conducted under authority of the Tariff Act of 1930, title VII. This notice is published pursuant to § 207.12 of the Commission's rules (19 CFR 207.12).

By order of the Commission.

Kenneth R. Mason,

Secretary.

Issued: January 14, 1988.

[FR Doc. 88–1039 Filed 1–19–88; 8:45 am]

BILLING CODE 7020–02–M

INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 31202]

Railroad Acquisition and Operation; The Mahoning Valley Railway Co.

The Mahoning Valley Railway Company (MVR) has filed a notice of exemption to lease and acquire through assignment and operate certain rail lines under an agreement with LTV Steel Company, Inc. (LTV), a noncarrier. The lines total 24.07 miles and consist of 15.38 route miles and 8.69 miles of industrial track. The LTV property over which MVR will operate is divided into two sections. No mileposts have been erected yet. (1) The Massillon Line is approximately 8.60 track miles (composed of 6.57 route miles and 2.03 miles of industrial track), beginning at a point approximately 2,300 feet south of Ordbrook Avenue SW., in Perry Township, Stark County, Ohio, and running in a northeasterly direction for a distance of approximately 1.22 miles to a point also in Perry Township, adjacent to Conrail Interchange Yard. The Massillon Line crosses property owned by LTV and Mercury Stainless, Inc. (Mercury). MVR will operate over LTV's property pursuant a lease agreement with LTV. It will operate over Mercury's property as the assignee of the rights held by LTV pursuant to a perpetual easement. MVR will also operate over certain spur and industrial track which connects with the Massillon Line. (2) The Canton Line is approximately 15.47 track miles (composed of 8.81 route miles and 6.66 miles of industrial track), bounded on the north by the line of Conrail and on the south by properties of LTV, and beginning at a point approximately 1,500 feet east of Trump Road in Perry Township, Stark County, and then running in a southwesterly direction approximately 1.44 miles to a point in the city of Canton, OH, approximately 750 feet from the western border of LTV. MVR will also operate over certain spur and industrial track which connects with the Canton Line.

Any comments must be filed with the Commission and served on Kimberly A. Madigan, Weiner, McCaffrey, Brodsky & Kaplan, P.C., Suite 800, 1350 New York Avenue, NW., Washington, DC 20005–4797, (202) 628–2000, as representative of MVR and James J. Corbett, LTV Steel Company, Inc., 25 W. Prospect Avenue., Cleveland, OH 44115, (216) 622–5000, as representative of LTV.

The notice is filed under 49 CFR 1150.31. If the notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

Decided: January 5, 1988.

By the Commission, Jane F. Mackall, Director, Office of Proceedings.

Noreta R. McGee,

Secretary.

[FR Doc. 88–1004 Filed 1–19–88; 8:45 am]

BILLING CODE 7035–01–M

[Finance Docket No. 31197]

Railroad Acquisition and Operation; Saginaw Valley Railway Co., Inc.

Saginaw Valley Railway Company, Inc. (SVRC), a non-carrier, has filed a notice of exemption to acquire and operate approximately 58 and one-half miles of railroad of CSX Transportation, Inc. (CSX), located in Michigan. The line extends from milepost 4.09 east of Saginaw, MI to milepost 62.56 at Bad Axe, MI. The agreement for transfer of the lines between SVRC and CSX was to be consummated on or before December 31, 1987. Any comments must be filed with the Commission and served on Eric D. Gerst, ESQ. c/o Gerst, Heffner, & Foldes, Suite 900, 21 South 5th Street, Philadelphia, PA 19106.

A transaction relating to the control of SVRC is the subject of a petition for exemption filed concurrently in Finance Docket No. 31196, *Saginaw Valley Railway Company—Petition For Exemption and/or Approval of Common Control.*[1]

This transaction will also involve the issuance of securities by SVRC, which will be a class III carrier. The issuance of these securities will be an exempt transaction under 49 CFR 1175.1.

The notice is filed under 49 CFR 1150.31. If the notice contains false or misleading information, the exemption is void *ab initio*. Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

Decided: January 12, 1988.

By the Commission, Jane F. Mackall, Director, Office of Proceedings.

Noreta R. McGee,

Secretary.

[FR Doc. 88–1005 Filed 1–19–88; 8:45 am]

BILLING CODE 7035–01–M

DEPARTMENT OF JUSTICE

Information Collection(s) Under Review

January 11, 1988.

The Office of Management and Budget (OMB) has been sent for review the following proposals for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35) and the Paperwork Reduction Reauthorization Act since the last list was published. Entries are grouped into submission categories.

[1] Informal approval of a voting trust agreement has been granted.

Each entry contains the following information: (1) The name and telephone number of the Department's Clearance Officer from whom a copy of the form and/or supporting documentation is available; (2) the office, board or division of the Department of Justice issuing the form or administering the collection; (3) the title of the form/collection; (4) the agency form number, if any; (5) how often the report must be filled out or the information is to be collected; (6) who will be asked or required to respond, as well as a brief abstract; (7) an estimate of the total number of respondents; (8) an estimate of the total public burden hours associated with the collection; (9) an indication of whether section 3504(h) of Pub. L. 96–511 applies; and, (10) the name and telephone number of the person or office responsible for the OMB review. Comments and/or questions regarding the item(s) contained in this notice should be directed to the OMB reviewer listed at the end of each entry and to the Department's Clearance Officer. If you anticipate commenting on a form/collection, but find that time to prepare such comments will prevent you from prompt submission, you should so advise the OMB reviewer and the Department's Clearance Officer of your intent as early as possible.

The Department of Justice Clearance Officer is Larry E. Miesse and can be reached on (202) 633–4312.

New Collections

(1) Larry E. Miesse, (202) 633–4312.
(2) Immigration and Naturalization Service, Department of Justice.
(3) Immigration User Fee.
(4) No form number.
(5) Quarterly with an annual report.
(6) Businesses or other for-profit. The information requested from commercial airlines, cruise lines and tour operators is generally required by Pub. L. 99–591 and is necessary for monitoring, follow-up and audit of user fee submissions. No form is required, only data basic to collection, payment and remittance of fees.
(7) 625 annual responses, .25 hours burden per response.
(8) 157 estimated public burden hours with estimated 1,250 burden hours for recordkeeping for a total public burden of 1,407 hours.
(9) Not applicable under 3504(h).
(10) Robert Fishman, (202) 395–7340.

(1) Larry E. Miesse, (202) 633–4312.
(2) Immigration and Naturalization Service, Department of Justice.
(3) National Legalization Survey.
(4) No form number.
(5) One-time.
(6) Individuals or households. Section 404 of Pub. L. 99–603 mandates a report to the Congress on legalized aliens to include a description of the demographic characteristics and a general profile of this population. This survey will obtain data for that report.
(7) 7,500 annual responses, .883 hours burden per response.
(8) 6,625 estimated total public burden hours.
(9) Not applicable under 3504(h).
(10) Robert Fishman, (202) 395–7340.

Extension of the Expiration Date of a Currently Approved Collection Without any Change in the Substance or in the Method of Collection

(1) Larry E. Miesse, (202) 633–4312.
(2) Drug Enforcement Administration, Department of Justice.
(3) Piperdine Report.
(4) DEA Form 420.
(5) On occasion.
(6) Businesses or other for-profit, Federal agencies or employees, small businesses or organizations. 21 U.S.C. 830 requires that any person who sells, distributes, or imports piperdine to report via this form to the Drug Enforcement Administration. Information is used to control movement of piperdine and to determine any illicit use made of pipedine for the manufacture of phencyclidine, a Schedule II controlled substance.
(7) 600 annual responses, .167 burden hours per response.
(8) 100 estimated total public burden hours.
(9) Not applicable under 3504(h).
(10) Robert Fishman, (202) 395–7340.

Reinstatement of a Previously Approved Collection for Which Approval Has Expired

(1) Larry E. Miesse, (202) 633–4312.
(2) Criminal Division, Department of Justice.
(3) Foreign Agents Registration Program.
(4) (a) Registration Statement of Individual (Foreign Agents).
(b) Short Form Registration Statement of Individuals (Foreign Agents).
(c) Exhibit A to Registration Statement (Foreign Agents).
(d) Exhibit B to Registration Statement (Foreign Agents).
(e) Supplemental Registration of Individuals (Foreign Agents).
(f) Amendment to Registration or Supplemental Registration Reports (Foreign Agents).
(g) Dissemination Report (Transmittal of Political Propaganda).
(5) (a), (b), (c), (d), (f), and (g) are on occasion, (e) is semiannually.
(6) Individuals or households, businesses or other for-profit, non-profit institutions, small businesses or organization. This program and its associated form are required by the provisions of 22 U.S.C. 611 *et seq.* and filings are maintained in the public office of the Registration Unit, Internal Security Section, Criminal Division, where they are available for public review.
(7) (a) 100 annual respondents at 1.5 burden hours each.
(b) 350 annual respondents at .429 burden hours each.
(c) 75 annual responses at .49 burden hours each.
(d) 75 annual responses at .33 burden hours each.
(e) 2,400 annual respondents at 1.375 burden hours each.
(f) 200 annual respondents at 1.5 burden hours each.
(g) 3,600 annual respondents at .5 burden hours each.
(8)(a) 150 hours annual burden.
(b) 150 hours annual burden.
(c) 38 hours annual burden.
(d) 25 hours annual burden.
(e) 3,300 hours annual burden.
(f) 300 hours annual burden.
(g) 1,800 hours annual burden.
(9) Not applicable under 3504(h).
(10) Robert Fishman, (202) 395–7340

Larry E. Miesse,

Department Clearance Office, Department of Justice.

[FR Doc. 88–1040 Filed 1–19–88; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF LABOR

Office of the Secretary

Agency Recordkeeping/Reporting Requirements Under Review by the Office of Management and Budget (OMB)

Background

The Department of Labor, in carrying out its responsibilities under the Paperwork Reduction Act (44 U.S.C. Chapter 35), considers comments on the reporting and recordkeeping requirements that will affect the public.

List of Recordkeeping/Reporting Requirements Under Review

As necessary, the Department of Labor will publish a list of the Agency recordkeeping/reporting requirements 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 the particular submission they are interested in. Each entry may contain the following information:

The Agency of the Department issuing this recordkeeping/reporting requirement.

The title of the recordkeeping/reporting requirement.

The OMB and Agency identification numbers, if applicable.

How often the recordkeeping/reporting requirement is needed.

Who will be required to or asked to report or keep records.

Whether small businesses or organizations are affected.

An estimate of the total number of hours needed to comply with the recordkeeping/reporting requirements.

The number of forms in the request for approval, if applicable.

An abstract describing the need for and uses of the information collection.

Comments and Questions

Copies of the recordkeeping/reporting requirements 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 N–1301, Washington, DC 20210. Comments should also be sent to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for (BLS/DM/ESA/ETA/OLMS/MSHA/OSHA/PWBA/VETS), Office of Management and Budget, Room 3208, Washington, DC 20503 (Telephone (202) 395–6880).

Any member of the public who wants to comment on a recordkeeping/reporting requirement which has been submitted to OMB should advise Mr. Larson of this intent at the earliest possible date.

New

Occupational Safety and Health Administration
Formaldehyde
Recordkeeping; On occasion
Businesses or other for-profit; Federal agencies or employees;
Small businesses or organizations
112,217 respondents; 955,043 burden hours; 0 forms

This regulation requires employers to train employees about the hazards of formaldehyde, monitor employee exposure, provide medical surveillance, and maintain accurate records of employee exposure. These records will be used by employers, employees, physicians and the Government to ensure that employees are not harmed by exposure to formaldehyde.

Survey to Collect Information on Bloodborne Diseases
Other
Businesses or other for profit; Federal agencies or employees; Non-profit institutions; Small businesses or organizations; State or local governments
260 responses; 108 hours

The information for which this request has been submitted will assist in the determination of whether or not to issue a standard on occupational exposure to Hepatitis B and AIDS. The information will be requested of businesses where employees handle blood and/or body fluids.

Signed at Washington, DC, this fourteenth day of January, 1988.

Paul E. Larson,

Departmental Clearance Officer.

[FR Doc. 88–1021 Filed 1–19–88; 8:45 am]

BILLING CODE 4510–26–M

Employment and Training Administration

[TA–W–19, 925 et al.]

General Motors Corp.; Revised Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In the matter of TA–W–19,925, BOC Orion Assembly, Orion Township, MI; TA–W–19,926, BOC Wentzville Assembly, Wentzville, Mo; TA–W–19,928, CPC Pontiac Fiero, Pontiac, MI; TA–W–19,934, CPC Flint Engine, Flint, MI; TA–W–20,050, BOC Clark Street, Detroit, MI; TA–W–20,051, BOC Fleetwood, Detroit, MI; TA–W–20,054, Truck & Bus Division, Flint, MI; TA–W–20,057, Fisher Guide, Fort Street, Detroit, MI; TA–W–20,035, BOC Conner Street, Detroit, MI.

In accordance with section 223 of the Trade Act of 1974, the Department of Labor issued Certifications Regarding Eligibility to Apply for Worker Adjustment Assistance on September 23, 1987 for workers at CPC Fiero plant in Pontiac, Michigan (TA–W–19,928); on September 25, 1987 for workers at CPC Flint Engine, Flint, Michigan (TA–W–19,934); on October 20, 1987 for workers at BOC Clark Street, Detroit, Michigan and BOC Fleetwood, Detroit, Michigan (TA–W–20,050–51); on October 28, 1987 for workers at Fisher Guide, Fort Street plant, Detroit, Michigan (TA–W–20,057); on October 30, 1987 for workers of utility vehicles and station wagon-type truck assembly line at the Flint, Michigan Truck & Bus Division assembly plant (TA–W–20,054) and on December 29, 1987 for workers at BOC Conner Street, Detroit, Michigan (TA–W–20,235).

The certifications TA–W–19,928 and TA–W–19,934 were published in the **Federal Register** on October 6, 1987 (52 FR 37381); certifications TA–W–20,050 and TA–W–20,051 were published in the **Federal Register** on November 3, 1987 (52 FR 42158); certification TA–W–20,057 was published in the **Federal Register** on November 10, 1987 (52 FR 43257); certification TA–W–20,054 was published in the **Federal Register** on December 22, 1987 (52 FR 48470).

On December 4, 1987 the Department revised the negative determinations for workers at GM's BOC Orion Assembly plant in Orion Township, Michigan and BOC Wentzville Assembly Center in Wentzville, Missouri. The notices were published in the **Federal Register** on December 11, 1987 (52 FR 47063). On December 29, 1987 the Department issued a certification to workers at BOC Conner Street, Detroit, Michigan. This certification will be published shortly in the **Federal Register.**

On the basis of additional information that some workers were employed by more than one of the certified plants in the 52 weeks prior to their layoff, the Office of Trade Adjustment Assistance, on its own motion, revised the certifications to put the following assembly plants under a single certification. This permits workers to use their combined time in adversely affected employment for established eligibility for trade readjustment allowance (TRA) payments.

The separate certifications applicable to GM workers at BOC Orion Assembly; BOC Wentzville Assembly Center; CPC Pontiac Fiero; CPC Flint Engine; BOC Clark Street; BOC Fleetwork; Truck & Bus Division, Flint; Fisher Guide, Fort Street and BOC Conner Street are hereby revised as follows:

All workers at the following facilities of General Motors Corporation who became totally or partially separated from employment on or after the indicated impact dates are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

TA–W–	Plant	Impact date
19,925	BOC Orion Assembly, Orion Township, MI.	7/16/86
19,926	BOC Wentzville, Wentzville, MO.	7/16/86
19,928	CPC Pontiac Fiero, Pontiac, MI.	7/16/86
19,934	CPC Flint Engine, Flint, MI.	7/16/86
20,050	BOC Clark Street, Detroit, MI.	8/17/86
20,051	BOC Fleetwood, Detroit, MI.	8/17/86

TA-W-	Plant	Impact date
20,054	Truck & Bus Division, Flint, MI (utility vehicles and station wagon/type trucks only).	8/17/86
20,057	Fisher Guide, Fort Street, Detroit, MI.	8/17/86
20,235	BOC Conner Street, Detroit, MI.	10/30/86

The expiration dates in the original certifications and termination date in TA-W-19,934 are unchanged.

Signed at Washington, DC., this 6th day of January 1988.

Robert O. Deslongchamps,

Director, Office of Legislation and Actuarial Services, UIS.

[FR Doc. 88-1020 Filed 1-19-88; 8:45 am]

BILLING CODE 4510-30-M

[TA-W-18,474, et al.]

Kerr-McGee Corp., Petroleum Exploration Division, Oil & Gas Production Division, and Transworld Drilling Co., Subsidiary of Kerr-McGee Corp.; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In the matter of TA-W-18,474, Oklahoma City, OK; TA-W-18,474A, all other locations in Oklahoma; TA-W-18,474B, all locations in Louisiana; TA-W-18,474C, all locations in Texas; TA-W-18,474D, all locations in Oklahoma; TA-W-18,474E, all locations in Louisiana; TA-W-18,474F, all locations in Texas; TA-W-18,474G, all locations in Alabama.

In accordance with section 223 of the Trade Act of 1974, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on December 23, 1986 applicable to all workers of Kerr-McGee Corporation, Petroleum Exploration and Production Division, Morgan City, Oklahoma. The Certification was published in the **Federal Register** on January 21, 1987 (52 FR 2306). The certification was amended on January 20, 1987 to properly reflect the correct worker group. The amended notice was published in the **Federal Register** on February 10, 1987 (52 FR 4200). The certification was amended again on November 16, 1987 and the notice was published in the **Federal Register** on November 20, 1987 (52 FR 44646).

The Transworld Drilling Company furnished new information to the Department which showed two additional states where worker separations occurred that were not included in the amended certification. Accordingly, the amended certification is changed to include the states of Alabama and Texas where additional worker separations occurred.

The intent of the certification is to cover all workers Kerr-McGee Corporation's Petroleum Exploration and Oil and Gas Production Divisions and Kerr-McGee's wholly owned drilling subsidiary, Transworld Drilling Company. The amended notice applicable to TA-W-18,474 is hereby issued as follows:

All workers of Kerr-McGee Corporation, Petroleum Exploration and Oil and Gas Production Divisions, Oklahoma City, Oklahoma and all other Kerr-McGee Corporation locations of the Petroleum Exploration and Oil and Gas Production Divisions in Oklahoma, Louisiana and Texas and all workers of the Transworld Drilling Company in Oklahoma, Louisiana, Texas and Alabama who became totally or partially separated from employment on or after September 30, 1985 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington, DC, this 11th day of January 1988.

Robert O. Deslongchamps,

Director, Office of Legislation and Actuarial Services, UIS.

[FR Doc. 88-1019 Filed 1-19-88; 8:45 am]

BILLING CODE 4510-30-M

NATIONAL SCIENCE FOUNDATION

Committee on Equal Opportunities in Science and Engineering Meeting

Name: Committee on Equal Opportunities in Science and Engineering.

Place: Room 540, National Science Foundation 1800 G Street, NW., Washington, DC 20550

Dates: January 27, 28, 29, 1988.

Times: January 27: Subcommittee on Women, 9:00 a.m.-12:00 p.m.; January 27: Subcommittee on the Disabled, 1:30 p.m.-4:30 p.m.; January 28: Full Committee Meeting 9:00 a.m.-4:30 p.m.; January 29: Subcommittee on Minorities 9:00 a.m.-12:00 p.m.

Type of Meeting: Open.

Contact: Mary M. Kohlerman, Executive Secretary of the CEOSE, National Science Foundation, Room 635, Telephone: 202-357-7066

Purpose of Meeting: To provide advice to the Foundation on policies and activities to encourage full participation of groups currently underrepresented in scientific, engineering, professional and technical fields.

Summary Minutes: May be obtained from the Executive Secretary at the above address.

Agenda: To review progress by the subcommittees, become familiar with successful intervention programs, and to meet with the Director and other NSF staff.

M. Rebecca Winkler,

Committee Management Officer.

January 13, 1988.

[FR Doc. 88-1001 Filed 1-19-88; 8:45 am]

BILLING CODE 7555-01-M

NUCLEAR REGULATORY COMMISSION

Relocation of NRC Offices

Effective January 11, 1988, the NRC's Office of Nuclear Material Safety and Safeguards (NMSS) has been relocated at the agency's new office building located at One White Flint North. Effective January 15, 1988, the NRC's Office of Governmental and Public Affairs' (GPA) State, Local, and Indian Tribe Programs and International Programs will be relocated at One White Flint North. The remainder of GPA, including Public Affairs and Congressional Affairs, will relocate at One White Flint North in late February 1988.

One White Flint North is located at 11555 Rockville Pike, Rockville, Maryland. The agency's mailing address remains unchanged—U.S. Nuclear Regulatory Commission, Washington, DC 20555. Specific telephone numbers for the relocated personnel may be obtained from the NRC Operator on 301-492-7000. A new telephone directory (NUREG/BR-0046) is expected to be issued in February 1988.

Dated at Bethesda, Maryland, this 13th day of January 1988.

For the Nuclear Regulatory Commission.

Donnie H. Grimsley,

Director, Division of Rules and Records, Office of Administration and Resources Management.

[FR Doc. 88-1012 Filed 1-19-88; 8:45 am]

BILLING CODE 7590-01-M

[Docket Nos. 50-413 and 50-414]

Duke Power Co. et al.; Denial of Amendments to Facility Operating Licenses and Opportunity for Hearing

The U. S. Nuclear Regulatory Commission (the Commission) has denied a request by the licensee for amendments to Facility Operating Licenses Nos. NPF-35 and NPF-52, issued to Duke Power Company, et al., (the licensee) for operation of the Catawba Nuclear Station, Units 1 and 2, (the facility) located in York County, South Carolina.

The denied amendments, as proposed by the licensee, would modify the Unit 1 and Unit 2 Technical Specifications (TS) to allow additional time to remain in Mode 3 (hot standby) beyond that allowed in the current TS following the licensee's determination that the 1 gpm unidentified leak rate was exceeded but before reaching 3 gpm.

The licensee's application for the amendments was dated June 9, 1986, and supplemented February 18, March 23, and December 2, 1987. Notice of Consideration of issuance of these amendments was published in the **Federal Register** on April 8, 1987 (52 FR 11359).

In the course of its review, the NRC staff requested the licensee to submit a stability analysis of the flaw based on a 3 gpm leak rate utilizing the acceptance criteria defined in NUREG-1061, Volume 3. In lieu of providing such analysis, the licensee stated that they would rely on the leakage detection capability, which is 1 gpm, to negate the need for the flaw stability analysis. The staff has determined that although the leak detection capability is important to support operation, it is not a substitute for the analysis of the pipe toughness capability which may be represented by the stability of a 3 gpm flaw.

The proposed change allowing the leak rate to exceed 1 gpm would reduce the available safety margin. Therefore, extending the time to remain in Mode 3 following the determination that the 1 gpm leak rate was exceeded is unacceptable.

Accordingly the request was denied. The licensee was notified of the Commission's denial of the request by letter dated January 13, 1988.

By February 19, 1988, the licensee may demand a hearing with respect to the denial described above and any person whose interest may be affected by the proceeding may file a written petition for leave to intervene.

A request for a hearing or petition for leave to intervene must be filed with the Secretary of the Commission, U. S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch, or may be delivered to the Commission's Public Document Room, 1717 H Street, NW., Washington, DC, by the above date.

A copy of any petitions should also be sent to the Office of General Counsel-Bethesda, U. S. Nuclear Regulatory Commission, Washington, DC 20555 and to Mr. Albert Carr, Duke Power Company, 422 South Church Street, Charlotte, North Carolina 28242.

For further details with respect to this action, see (1) the application for amendment dated June 9, 1986, and supplemented February 18, March 23, and December 2, 1987, and (2) the Commission's letter to Duke Power Company dated January 13, 1988, which are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, DC, and at the York County Library, 138 East Black Street, Rock Hill, South Carolina 29730. A copy of item (2) may be obtained upon request addressed to the U. S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Director, Division of Reactor Projects I/II.

Dated at Bethesda, Maryland, this 13th day of January 1988.

For the Nuclear Regulatory Commission.

Kahtan N. Jabbour,

Project Manager, Project Directorate II-3, Division of Reactor Projects, I/II.

[FR Doc. 88-1013-Filed 1-19-88; 8:45 am]

BILLING CODE 7590-01-M

[Docket Nos. 50-369 and 50-370]

Duke Power Co.; Denial of Amendments to Facility Operating Licenses and Opportunity for Hearing

The U.S. Nuclear Regulatory Commission (the Commission) has denied a request by the licensee for amendments to Facility Operating Licenses Nos. NPF-9 and NPF-17, issued to Duke Power Company, (the licensee) for operation of the McGuire Nuclear Station, Units 1 and 2, (the facility) located in Mecklenburg County, North Carolina.

The denied amendments, as proposed by the licensee, would modify the Unit 1 and Unit 2 Technical Specifications (TS) to allow additional time to remain in Mode 3 (hot standby) beyond that allowed in the current TS following the licensee's determination that the 1 gpm unidentified leak rate was exceeded but before reaching 3 gpm.

The licensee's application for the amendments was dated June 9, 1986, and supplemented February 18, March 23, and December 2, 1987. Notice of Consideration of issuance of these amendments was published in the **Federal Register** on April 8, 1987 (52 FR 11361).

In the course of its review, the NRC staff requested the licensee to submit a stability analysis of the flaw based on a 3 gpm leak rate utilizing the acceptance criteria defined in NUREG-1061, Volume 3. In lieu of providing such analysis, the licensee stated that they would rely on the leakage detection capability, which is 1 gpm, to negate the need for the flaw stability analysis. The staff has determined that although the leak detection capability is important to support operation, it is not a substitute for the analysis of the pipe toughness capability which may be represented by the stability of a 3 gpm flaw.

The proposed change allowing the leak rate to exceed 1 gpm would reduce the available safety margin. Therefore, extending the time to remain in Mode 3 following the determination that the 1 gpm leak rate was exceeded is unacceptable.

Accordingly the request was denied. The licensee was notified of the Commission's denial of the request by letter dated January 13, 1988.

By February 19, 1988, the licensee may demand a hearing with respect to the denial described above and any person whose interest may be affected by the proceeding may file a written petition for leave to intervene.

A request for a hearing or petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch, or may be delivered to the Commission's Public Document Room, 1717 H Street, NW., Washington, DC, by the above date.

A copy of any petitions should also be sent to the Office of General Counsel-Bethesda, U.S. Nuclear Regulatory Commission, Washington, DC 20555 and to Mr. Albert Carr, Duke Power Company, 422 South Church Street, Charlotte, North Carolina 28242.

For further details with respect to this action, see (1) the application for amendment dated June 9, 1986, and supplemented February 18, March 23, and December 2, 1987, and (2) the Commission's letter to Duke Power Company dated January 13, 1988, which are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, DC, and at the Atkins Library, University of North Carolina, Charlotte (UNCC Station), North Carolina 28230. A copy of item (2) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Director, Division of Reactor Projects I/II.

Dated at Bethesda, Maryland, this 13th day of January 1988.

For the Nuclear Regulatory Commission.

Darl S. Hood, Project Manager

Project Directorate II-3, Division of Reactor Projects, I/II.

[FR Doc. 88-1014-Filed 1-19-88; 8:45 am]

BILLING CODE 7590-01-M

POSTAL SERVICE

Privacy Act of 1974; Systems of Records

AGENCY: Postal Service.

ACTION: Notice of Records System Changes.

SUMMARY: This document gives notice that the Postal Service is revising its system of records, USPS 050.005, Finance Records—Accounts Receivable File Maintenance to add two new routine uses and the general disclosure authority at subsection (b)(12) of the Privacy Act permitting disclosure of information to consumer reporting agencies, and to make related minor editorial changes. The new routine uses authorize disclosure of limited information to (1) private debt collection agencies under contract for collection of debts owed the U.S. Government and (2) the Office of Personnel Management to determine the collectibility of monies owed to the Postal Service by retired annuitants. The intended effect of this notice is to make the public aware that the Postal Service may make such disclosures to collect and service its delinquent accounts receivables.

DATE: The new routine uses will become effective without further notice on February 19, 1988, unless comments are received on or before that date that would result in a contrary determination and a notice is published to that effect.

ADDRESS: Comments may be mailed to the Records Officer, U.S. Postal Service, 475 L'Enfant Plaza, SW., Washington, D.C. 20260–5010, or delivered to Room 8121 at the above address between 8:15 a.m and 4:45 p.m. Comments received may also be inspected during the above hours in Room 8121.

FOR FURTHER INFORMATION CONTACT: Betty Sheriff, Records Office (202) 268–5158.

SUPPLEMENTARY INFORMATION: The Debt Collection Act of 1982 (Pub. L. 97–365) amended the Privacy Act of 1974, 5 USC 552a, to provide a new general disclosure authority, subsection (b)(12), permitting a Federal agency to disclose information about its delinquent debtors to a "consumer reporting agency" (as defined both in the Fair Credit Reporting Act, 15 U.S.C. 168la(f), and the Federal Claims Collection Act of 1966, 31 U.S.C. 3701(a)(3)). Disclosure can only be made if a claim is verified as overdue and certain due process steps have been taken that include validation of the debt and written notice to the debtor of the claim and his rights. Disclosure pursuant to subsection (b)(12) is restricted to information directly related to the identity of the debtor (name, address, social security number, and other information necessary to establish the identity of the debtor) and the history of the claim (amount, status, and history of the debt). To the extent that the Postal Service may wish to make future disclosures pursuant to subsection (b)(12), such disclosures would be made from its records system 050.005. Notice of the Postal Service's intent to disclose information from this system to consumer reporting agencies pursuant to subsection (b)(12) meets a requirement of the Debt Collection Act; advance notice is not required by the Privacy Act.

The Postal Service also intends to use the services of private debt collection agencies to recover debts delinquently owed to it. The Debt Collection Act of 1982 provides the statutory authority to make such disclosure pursuant to subsection (b)(3) of the Privacy Act, i.e., for a routine use. Such disclosures will be made from this system under proposed routine use No. 8 and pursuant to contract provisions that make the debt collection contractor subject to subsection (m) on the Privacy Act.

Proposed routine use No. 9 will permit the Postal Service to provide information about individuals indebted to the Postal Service for the purpose of identifying former Federal employees whose postal debts are collectible from available retirement accounts, or are uncollectible due to present unavailability of an existing account, a lump sum refund, or other reason. These individuals will be identified by conducting a computer matching program comparing the Postal Service's accounts receivable file and the annuitant files of the Office of Personnel Management. The match will be conducted in accordance with the Office of Management and Budget's Revised Supplemental Guidelines for Conducting Matching Programs (47) FR 21656, May 19, 1982) and will be announced in this publication prior to its initiation, as required by the Guidelines.

The addition of subsection (b)(12), the proposed routine uses, and the editorial changes are not within the purview of the provisions of 5 U.S.C. 552a(o) of the Act that require the submission of an altered system report. Accordingly, it is proposed that system 050.005 be amended as follows:

USPS 050.005

SYSTEM NAME:

Finance Records—Accounts Receivable File Maintenance, 050.005.

SYSTEM LOCATION:

CHANGE TO READ, "Postal Data Centers and contractor sites."

* * * * *

CATEGORIES OF RECORDS IN THE SYSTEM:

Invoice number, location name, Social Security Number, employee name, designation code.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

CHANGE TO READ, 39 U.S.C. 401; 5 U.S.C. 552a(b)(12); Debt Collection Act of 1982 (Pub. L. 97–365).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

a. Purpose. CHANGE TO READ: "Records are used to facilitate debt collection, to monitor and record collections made by the USPS, and as a data source for management information for production of summary descriptive statistics and analytical studies."

b. Use

* * * * *

ADD,

8. Disclosure may be made to a debt collection agency for collection of a debtor's account as provided for by contract with the debt collection agency.

9. Disclosure of information about individuals indebted to the Postal Service may be made to the Office of Personnel Management under approved computer matching efforts in which either the Postal Service or OPM acts as the matching agency, but limited to those data elements considered relevant to determining whether the indebted individual has retirement funds available for set-off; collecting debts when funds are available for set-off; and writing off debts determined to be uncollectible.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Disclosures pursuant to U.S.C. 552a(b)(12) may be made from this system to consumer reporting agencies as defined in the Fair Credit Reporting Act (15 U.S.C. 1681(a)(f)) and the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)).

* * * * *

SAFEGUARDS:

CHANGE TO READ: "Access is restricted to personnel of the General Accounting Section within the Postal Service and to contract employees responsible for assigned accounts. Computerized records are subject to the security of the computer room. Contract provisions make the contractor(s)

responsible for complying with the provisions of the Privacy Act (subsection (m)(1)), except in the case of subsection (b)(12) disclosures to consumer reporting agencies (subsection (m)(2)).''

Fred Eggleston,

Assistant General Counsel, Legislative Division.

[FR Doc. 88–1003 Filed 1–19–88; 8:45 am]

BILLING CODE 7710–12–M

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster Loan Area #2303; Amdt. #1]

Arkansas; Declaration of Disaster Loan Area

The above-numbered Declaration (52 FR 650, January 7, 1987) is hereby amended in accordance with the Notice of Amendment to the President's declaration, dated January 6, 1988, to include Mississippi, Monroe, Ouachita, and Pulaski Counties and the adjacent Counties of Arkansas, Cross, Lee, Lonoke, Poinsett, and Woodruff in the State of Arkansas because of damage from severe storms and flooding beginning on December 24, 1987. All other information remains the same; i.e., the termination date for filing applications for physical damage is the close of business on March 3, 1988 and for economic injury until the close of business on October 3, 1988.

(Catalog of Federal Domestic Assistance Programs Nos. 59002 and 59008).

Date: January 12, 1988.

Bernard Kulik,

Deputy Associate Administrator for Disaster Assistance.

[FR Doc. 88–984 Filed 1–19–88; 8:45 am]

BILLING CODE 8025–01–M

[Declaration of Disaster Loan Area #2298; Amdt. #1]

Mississippi; Declaration of Disaster Loan Area

The above-numbered Declaration (52 FR 47987, December 17, 1987) is hereby amended to include Rankin County and the adjacent Counties of Madison and Simpson in the State of Mississippi because of damage from tornadoes and flooding which occurred on November 16, 1987. All other information remains the same; i.e., the termination date for filing applications for physical damage is the close of business on February 9, 1988, and for economic injury until the close of business on September 12, 1988.

(Catalog of Federal Domestic Assistance Programs Nos. 59002 and 59008).

Date: December 23, 1987.

James Abdnor,

Administrator.

[FR Doc. 88–1044 Filed 1–19–88; 8:45 am]

BILLING CODE 8025–01–M

[Declaration of Disaster Loan Area #2301; Amdt. #1]

Puerto Rico; Declaration of Disaster Loan Area

The above-numbered Declaration (52 FR 49243, December 30, 1987) is hereby amended in accordance with the Notice of Amendment to the President's declaration, dated December 18, 1987, to include the Municipality of Lajas in the Commonwealth of Puerto Rico because of damage from severe storms and flooding beginning on November 24, 1987. All other information remains the same; i.e., the termination date for filing applications for physical damage is the close of business on February 16, 1988, and for economic injury until the close of business on September 19, 1988.

(Catalog of Federal Domestic Assistance Programs Nos. 59002 and 59008).

Date: December 22, 1987.

Bernard Kulik,

Deputy Associate Administrator for Disaster Assistance.

[FR Doc. 88–985 Filed 1–19–88; 8:45 am]

BILLING CODE 8025–01–M

[Declaration of Disaster Loan Area #2295; Amdt. #2]

Texas; Declaration of Disaster Loan Area

The above-numbered Declaration (52 FR 45702, December 1, 1987), as amended (52 FR 47071, December 11, 1987), is hereby further amended in accordance with the Notice of Amendment to the President's declaration, dated November 30, 1987, to include Leon and Madison Counties in the State of Texas, because of damage from severe storms and tornadoes on November 15–16, 1987. All other information remains the same; i.e., the termination date for filing applications for physical damage is the close of business on January 21, 1988, and for economic injury until the close of business on August 22, 1988.

(Catalog of Federal Domestic Assistance Programs Nos. 59002 and 59008).

Date: December 7, 1987.

Bernard Kulik,

Deputy Associate Administrator for Disaster Assistance.

[FR Doc. 88–986 Filed 1–19–88; 8:45 am]

BILLING CODE 8025–01–M

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. M–001]

Notification to Interested United States Citizen Bidders of the Intent of NATO To Solicit Bids on a Project Involving Revision to the NATO Interallied Insurance Organization (IIO) Valuation System

The North Atlantic Council agreed in 1984 that a revised NATO War Risk Insurance Scheme would be prepared. The purpose of this scheme (following the outbreak of war or hostilities involving the Alliance) was to insure, on a mutual insurance association basis, ships placed at the disposal of a common pool of NATO shipping. Under the scheme, member governments would pay premiums for their insured values and the overall losses incurred.

It follows from the above that an essential part of the insurance scheme is a uniform system of valuation for the ships to be covered. For various reasons the system of valuation in operation prior to 1984 was regarded as unsatisfactory.

In 1984, it was decided that revision of the valuation system should proceed in two steps:

- Step 1 was to establish the changes required to the earlier structure of the ship valuation scales in order to make their valuations more effective.
- Step 2 was to review the ship valuation system in the light of Step 1.

Step 1 of the revision was carried out by consultants and their report submitted in January 1986. The consultants concluded that the valuation system resulted in price scales that were far removed from the present realities of the shipbuilding industry and made recommendations as to the changes that should be effected.

Following the submission of the consultants' report in January 1986 to the NATO technical group concerned with the development of plans for the IIO, namely the Shipping War Losses Working Group (SWLWG), the report was endorsed and policy approval given for Step 2 to proceed. NATO funding has been requested for work to commence on Step 2 during 1988, to continue over a two or three year period. This work on Step 2 is to be undertaken by consultants selected through a competitive bid process.

The Maritime Administration has been requested by the Planning Board for Ocean Shipping (PBOS), a NATO planning group to which the SWLWG reports, to identify potential United

States contractors who might wish to bid on this project. The same request has been made of other members of NATO. Eventual bidding will be conducted by NATO on an international basis. Potential bidders, who feel that they are qualified and interested in bidding, and who desire that the names be submitted to NATO by the United States Government to be included on a potential bidders list, should identify themselves in writing.

When submitting expressions of interest, potential bidders should supply information concerning their capabilities and experience in the field. Information submitted should be pertinent and specific to the proposal under consideration on the following qualifications: (1) Experience: An outline of previous projects, specific work previously performed or being performed; (2) Personnel: Name professional qualifications and specific experience of technical personnel who may be assigned as principal investigator and/or project officer; (3) Security: A statement regarding industrial security clearance; and (4) Other: Any other specific and pertinent information that would enhance NATO's consideration of the submission.

The Maritime Administration has not been provided with any materials for distribution by NATO. The acquisition will be conducted directly by NATO in the course of this year.

Any person, firm, or corporation in the United States wishing to have its name submitted to NATO must file in writing with the Secretary, Maritime Administration, Room 7300, Nassif Building, 400 Seventh Street, SW., Washington, DC 20590. This submission must be received no later than 5:00 p.m. on February 5, 1988. This notice is published as a matter of discretion.

By Order of the Maritime Administration.

Dated: January 13, 1988.

James E. Sarri,

Secretary.

[FR Doc. 88-1026 Filed 1-19-88; 8:45 am]

BILLING CODE 4910-81-M

DEPARTMENT OF THE TREASURY

Office of the Secretary

[Supplement to Department Circular; Public Debt Series No. 37-87]

Treasury Notes; Series E-1995

Washington, January 7, 1988.

The Secretary announced on January 6, 1988, that the interest rate on the notes designated Series E-1995, described in Department Circular—Public Debt Series—No. 37-87 dated December 30, 1987, will be 8⅝ percent. Interest on the notes will be payable at the rate of 8⅝ percent per annum.

Gerald Murphy

Fiscal Assistant Secretary.

[FR Doc. 88-992 Filed 1-19-88; 8:45 am]

BILLING CODE 4810-40-M

UNITED STATES INFORMATION AGENCY

Advisory Board for Radio Braodcasting to Cuba; Meeting

The Advisory Board for Radio Broadcasting to Cuba will conduct a meeting on January 25, 1988, in Room 3557, 400 Sixth Street SW., Washington, DC. Below is the intended agenda.

Monday, January 25, 1988

Part One—Closed to the Public

10:00 a.m. 1. Report by the Director of Radio Marti
11:00 a.m. 2. Status of selection of executive director

Part Two—Open to the Public

1:00 p.m. 3. Marti TV
2:00 p.m. 4. Marathon transmitter site upgrade status
2:30 p.m. 5. Audience research results
3:00 p.m. 6. Public testimony period.

Items one and two, which will be discussed from 10:00 a.m. to 12:00 noon, will be closed to the public. Item 1 involves discussion of classified information. Closing such deliberations to the public is justified under 5 U.S.C. 552b (c)(1). Item 2 relates solely to internal personnel rules and practices. Authority for closing such deliberations is provided by 5 U.S.C. 552b (c)(2).

Members of the public interested in attending the meeting should contact Peggy Chu (202) 485-7011 to make prior arrangements, as access to the building is controlled.

Dated: January 12, 1988.

Charles Z. Wick,

Director.

[FR Doc. 88-1116 Filed 1-19-88; 8:45 am]

BILLING CODE 8230-01-M

VETERANS ADMINISTRATION

Advisory Committee on Former Prisoners of War; Meeting

The Veterans Administration gives notice under Pub. L. 92-463, section 10(a)(2) that a meeting of the Advisory Committee on Former Prisoners of War will be held at the Paralyzed Veterans of America, 801 18th Street, NW., Washington, DC 20006, from February 17 through February 19, 1988. The purpose of the Committee is to consult with and advise the Administrator of Veterans' Affairs on the administration of benefits under title 38, United States Code, for veterans who are former prisoners of war and on the need of such veterans for compensation, health care and rehabilitation.

The meeting will convene at 9 a.m., each day, and will be open to the public.

Following opening remarks by the Chairman and greetings by Agency management staff, various issues affecting health care and benefit delivery to former prisoners of war will be discussed over the first two days of the meeting. Topics will include community nursing home care, the burden of proof necessary to demonstrate entitlement to compensation and other matters deemed appropriate by the Chairman. The final day of the meeting, February 19, will be devoted to the composition of a report to the Administrator.

Members of the public may direct questions or submit prepared statements for review by the Committee in advance of the meeting, in writing only, to: Mr. David Sturm, Policy Staff, Compensation and Pension Service, Room 416, Veterans Administration Central Office, 810 Vermont Avenue, NW., Washington, DC 20420. Submitted material must be received at least five days prior to the meeting. Such members of the public may be asked to clarify submitted material prior to consideration by the Committee.

A summary report of the meeting and rosters of the Committee members may be obtained from Mr. David Sturm at the aforementioned address.

Dated: January 11, 1988.

By direction of the Administrator.

Rosa Maria Fontanez,

Committee Management Officer.

[FR Doc. 88-982 Filed 1-19-88; 8:45 am]

BILLING CODE 8320-01-M

Veterans' Advisory Committee on Rehabilitation; Meeting

The Veterans Administration gives notice that a meeting of the Veterans' Advisory Committee on Rehabilitation, authorized by 38 U.S.C. 1521, will be held in Room 1010, Veterans Administration Central Office, 810 Vermont Avenue, NW., Washington, DC 20420, February 2 and 3, 1988. The sessions will begin at 8:30 a.m. The purpose of the meeting will be to review the administration of veterans' rehabilitation programs and provide recommendations to the Administrator.

The meeting will be open to the public up to the seating capacity of the conference room. Because of the limited seating capacity, it will be necessary for those wishing to attend to contact Dr. Carole J. Westerman, Executive Secretary, Veterans' Advisory Committee on Rehabilitation (phone 202–233–2886) prior to January 26, 1988.

Interested persons may attend, appear before, or file statements with the Committee. Statements, if in written form, may be filed before or within 10 days after the meeting. Oral statements will be heard at 9:30 a.m. on February 3, 1988.

Dated: January 12, 1988.

By direction of the Administrator.

Rosa Maria Fontanez,

Committee Management Officer.

[FR Doc. 88–1024 Filed 1–19–88; 8:45 am]

BILLING CODE 8320–01–M

Advisory Committee on Readjustment Problems of Vietnam Veterans; Meeting

The Veterans Administration gives notice under Pub. L. 92–463 that a meeting of the Advisory Committee on Readjustment Problems of Vietnam Veterans will be held February 11 and 12, 1988. This is a regularly scheduled meeting for the purpose of reviewing Agency services to Vietnam veterans and to formulate Committee goals and objectives for the next two year period. The meeting will be held in the Omar Bradley Conference Room at VA Central Office, 810 Vermont Avenue, NW., Washington, DC 20420.

The meeting on February 11 will begin at 8:30 a.m. and conclude at 4:15 p.m. The day's agenda will consist of Committee review of goals, objectives, and tasks for the next two years. Also the committee will receive status reports concerning pending legislation that may impact services to Vietnam veterans, the VA/DOL working agreement, and the chief Medical Director's and the Administrator's guidance for future Committee work. The meeting on February 12 will begin at 8:15 a.m. and conclude at 4 p.m. The second day's agenda will consist of a status report on Readjustment Counseling Service, a clinical report of the Committee's field trip to Bay Pines VAMC, a report by VA mental health officials on VA mental health services to Vietnam veterans, and a report by OPM officials on employee assistance programs available to veterans in the federal work force. Both day's meetings will be open to the public to the seating capacity of the rom.

Due to the limited seating capacity of the room, those who plan to attend or who have questions concerning the meeting should contact Arthur S. Blank, Jr., M.D., Director, Readjustment Counseling Service, Veterans Administration Central Office, (phone number 202–233–3317/3303).

Dated: January 12, 1988.

By direction of the Administrator.

Rosa Maria Fontanez,

Committee Management Officer.

[FR Doc. 88–983 Filed 1–19–88; 8:45 am]

BILLING CODE 8320–01–M

Wage Committee Meetings

The Veterans Administration, in accordance with Pub. L. 92–463, gives notice that meetings of the Veterans Administration Wage Committee will be held on:

Thursday, January 28, 1988, at 2:30 p.m.
Thursday, February 11, 1988, at 2:30 p.m.
Thursday, February 25, 1988, at 2:30 p.m.
Thursday, March 10, 1988, at 2:30 p.m.
Thursday, March 24, 1988, at 2:30 p.m.

The meetings will be held in Room 304, Veterans Administration Central Office, 810 Vermont Avenue NW., Washington, DC 20420.

The Committee's purpose is to advise the Chief Medical Director on the development and authorization of wage schedules for Federal Wage System (blue-collar) employees.

At these meetings the Committee will consider wage survey specifications, wage survey data, local committee reports and recommendations, statistical analyses, and proposed wage schedules.

This notice does not appear 15 days prior to the meeting due to delays in administrative processing.

All portions of the meetings will be closed to the public because the matters considered are related solely to the internal personnel rules and practices of the Veterans Administration and because the wage survey data considered by the Committee have been obtained from officials of private business establishments with a guarantee that the data will be held in confidence. Closure of the meetings is in accordance with subsection 10(d) of Pub. L. 92–463, as amended by Pub. L. 94–409, and as cited in 5 U.S.C. 552b(c) (2) and (4).

However, members of the public are invited to submit material in writing to the Chairman for the Committee's attention.

Additional information concerning these meetings may be obtained from the Chairman, Veterans Administration Wage Committee, Room 1175, 810 Vermont Avenue NW., Washington, DC 20420.

Dated: January 6, 1988.

By direction of the Administrator.

Robert W. Schultz,

Associate Deputy Administrator for Public Affairs.

[FR Doc. 88–1101 Filed 1–19–88; 8:45 am]

BILLING CODE 8320–01–M

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Implementation of Amendments to Specialty Steel Import Relief

AGENCY: Office of the United States Trade Representative.

ACTION: Notice.

SUMMARY: This notice establishes an allocation for Austria of the quotas currently applicable to imports of certain stainless steel bar and stainless steel wire rod and makes modifications in the Tariff Schedules of the United States (TSUS) to implement this allocation.

EFFECTIVE DATE: January 20, 1988.

FOR FURTHER INFORMATION CONTACT: Robert Cassidy or Elena Bryan, Office of the United States Trade Representative, (202) 395–4510.

SUPPLEMENTARY INFORMATION: Presidential Proclamation 5679 of July 16, 1987 (58 FR 27308) provided for the temporary imposition of increased tariffs and quantitative restrictions on certain stainless steel and alloy tool steel imported into the United States, pursuant to section 203 of the Trade Act of 1974. Proclamation 5679 authorizes the U.S. Trade Representative to take such actions and perform such functions for the United States as may be necessary to administer and implement the relief, including negotiating orderly marketing agreements and allocating quota quantities on a country-by-country basis. The U.S. Trade Representative is also authorized to make modifications in the TSUS headnote of items proclaimed by the President in order to implement such actions.

Accordingly, the U.S. Trade Representative has determined that items 926.11 through 926.17, inclusive, schedule 9, subpart A, part 2 of the Appendix to the TSUS be modified by adding an allocation for Austria and changing quota quantitive for "Other", as follows:

Item	Articles	Quota quantity (in short tons)	
		If entered during the restrant period	
		July 20 through January 19	January 20 through July 19
926.11	"Austria"	"n/a"	"108"
	Other, except as provided in headnote 10(g)(ii) to this subpart.	"110"	"107"
926.12	"Austria"	"107"	"108"
	Other, except as provided in headnote 10(g)(ii) to this subpart.	"119"	"115"
926.13	"Austria"	"43"	"n/a"
	Other, except as provided in headnote 10(g)(ii) to this subpart.	"49"	"n/a"
926.15	"Austria"	"n/a"	"28"
	Other, except as provided in headnote 10(g)(ii) to this subpart.	"97"	"167"
926.16	"Austria"	"27"	"28"
	Other, except as provided in headnote 10(g)(ii) to this subpart.	"170"	"167"
926.17	"Austria"	"11"	"n/a"
	Other, except as provided in headnote 10(g)(ii) to this subpart.	"70"	"n/a"

I have determined that the above changes in the import relief are appropriate to carry out the authority granted by the President to the U.S. Trade Representative and the obligations of the United States, with due consideration to the interests of the domestic producers of such specialty steel. This action is subject to further modification.

Clayton Yeutter,

United States Trade Representative.

[FR Doc. 88–1178 Filed 1–19–88; 9:50 am]

BILLING CODE 3190–01–M

Sunshine Act Meetings

Federal Register
Vol. 53, No. 12
Wednesday, January 20, 1988

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).

CONSUMER PRODUCT SAFETY COMMISSION

TIME AND DATE: 10:00 a.m., Wednesday, January 20, 1988.

LOCATION: Room 556, Westwood Towers, 5401 Westbard Avenue, Bethesda, Md.

Status:

MATTERS TO BE CONSIDERED:

Open to the Public

1. Small Parts Petition, HP 87-2

The commission will consider Small Parts Petition, HP 87-2, from the Consumer Federation of America and the New York State Attorney General's office, which requests amendment of the small parts regulation.

2. Electrical/Mech./Children Program Status Briefings

The staff will brief the Commission on the progress being made on various projects within the Electrical/Mechanical/Children programs.

Closed to the Public

3. Enforcement Matter OS# 527

The staff will brief the Commission on Enforcement Matter OS# 527.

4. Enforcement Matter OS# 5912

The staff will brief the Commission on Enforcement Matter OS# 5912.

FOR A RECORDED MESSAGE CONTAINING THE LATEST AGENDA INFORMATION, CALL: 301-492-5709.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Sheldon D. Butts, Office of the Secretary, 5401 Westbard Ave., Bethesda, Md. 20207 301-492-6800.

Sheldon D. Butts,

Deputy Secretary.

January 14, 1988.

[FR Doc. 88-1050 Filed 1-15-88; 9:27 am]

BILLING CODE 6355-01-M

FEDERAL COMMUNICATIONS COMMISSION

January 13, 1988.

Additional Item to be Considered at Open Meeting, Thursday, January 14th

The Federal Communications Commission will consider an additional item on the subject listed below at the Open Meeting scheduled for 9:30 a.m., Thursday, January 14, 1988 at 1919 M Street, NW., Washington, DC.

Agenda, Item No., and Subject

Mass Media—2—Title: In re Reexamination of the Commission's Comparative Licensing, Distress Sales and Tax Certificate Policies Premised on Racial, Ethnic or Gender Classifications.

Summary: This Order deals with appropriations legislation, Making Further Continuing Appropriations for Fiscal Year 1988 and for Other Purposes, Pub. L. No.100-202 (signed December 22, 1987), as it relates to the Commission's reexamination of its comparative licensing, distress sales and tax certificate policies premised on racial, ethnic or gender classifications.

The prompt and orderly conduct of Commission business requires that less than 7-days notice be given consideration of this additional item.

Action by the Commission January 12, 1988. Commissioners Patrick, Chairman; Quello, and Dennis voting to consider this item.

Additional information concerning this meeting may be obtained from Sarah Lawrence, Office of Public Affairs, telephone number (202) 632-5050.

Issued: January 13, 1988.

Federal Communications Commission.

H. Walker Feaster III,

Acting Secretary.

[FR Doc. 88-1110 Filed 1-15-88; 2:16 pm]

BILLING CODE 6712-01-M

FEDERAL COMMUNICATIONS COMMISSION

January 7, 1988.

FCC to Hold Open Commission Meeting Thursday, January 14, 1988

The Federal Communications Commission will hold on Open Meeting on the subjects listed below on Thursday, January 14, 1988, which is scheduled to commence at 9:30 a.m., in Room 856, at 1919 M Street, NW., Washington, DC.

Agenda, Item No., and Subject

Private Radio—1—Title: Applications from the Association of American Railroads to use six 900 MHz frequencies for the operation of a nationwide Advanced Train Control System. Summary: The Commission will consider appropriate action on the requests.

Common Carrier—1—Title: Amendment of § 64.702 of the Commission's Rule and Regulations (Third Computer Inquiry) CC Docket No. 85-229, Phase I. Summary: The Commission will consider three petitions for further reconsideration in this proceeding.

Common Carrier—2—Title: Amendment of § 64.702 of the Commission's Rules and Regulations (Third Computer Inquiry) CC Docket No. 85-229, Phase II. Summary: The Commission will consider nine petitions for reconsideration in this proceeding.

Common Carrier—3—Title: In the Matter of Pacific Bell and Nevada Bell Plan for the Provision of Voice Mail Service. Summary: The Commission will consider whether to approve the CEI plan filed by Pacific Bell.

Common Carrier—4—Title: In the Matter of the Bell Atlantic Companies Offer of Comparably Efficient Interconnection to Enhanced Service. Summary: The Commission will consider whether to approve the CEI plan filed by Bell Atlantic.

Common Carrier—5—Title: Prescription of Depreciation Rates for Domestic Telephone Companies. Summary: This Commission will consider the adoption of two Orders modifying the depreciation rates of various accounts for twelve triennial and nineteen annual update domestic telephone companies.

Common Carrier—6—Title: In the Matter of Inquiry into the Policies to be Followed in the Authorization of Common Carrier Facilities to Meet North Atlantic Telecommunications Needs During the 1991-2000 Period, CC Docket No. 79-184. Summary: The Commission will consider whether to adopt a Third Notice of Proposed Rulemaking in this proceeding.

Mass Media—1—Title: AM Stereophonic Broadcasting. Summary: The Commission will consider three petitions for rule making and two reports issued by the National Telecommunications and Information Administration concerning AM stereophonic broadcasting.

This meeting may be continued the following work day to allow the Commission to complete appropriate action.

Additional information concerning this meeting may be obtained from Sarah Lawrence, Office of Public Affairs, telephone number (202) 632-5050.

Issued: January 7, 1988.

Federal Communications Commission.

H. Walker Feaster III,

Acting Secretary.

[FR Doc. 88-1111 Filed 1-15-88; 2:16 pm]

BILLING CODE 6712-01-M

FEDERAL RESERVE SYSTEM BOARD OF GOVERNORS

TIME AND DATE: 11:00 a.m., Monday, January 25, 1988.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any items caried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204. You may call (202) 452–3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Date: January 15, 1988.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 88–1159 Filed 1–15–88; 3:56 pm]

BILLING CODE 6210–01–M

MERIT SYSTEMS PROTECTION BOARD

TIME AND DATE: 10:00 a.m., Monday, January 25, 1988.

PLACE: Eighth Floor, 1120 Vermont Avenue, NW., Washington, DC.

STATUS: Closed.

MATTER TO BE CONSIDERED: Adjudication of Chapter 43 cases which raise questions about the weight to be given to an employee's performance during the Performance Improvement Plan period.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Robert E. Taylor, Clerk of the Board, (202) 653–7200.

Date: January 15, 1988.

Robert E. Taylor,

Clerk of the Board.

[FR Doc. 88–1157 Filed 1–15–88; 3:38 pm]

BILLING CODE 7400–01–M

Corrections

Federal Register
Vol. 53, No. 12
Wednesday, January 20, 1988

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents and volumes of the Code of Federal Regulations. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Implementation of 1988 Import Controls and Visa Arrangements Based on the Harmonized System

Correction

In notice document 87-29627 beginning on page 48859 in the issue of Monday, December 28, 1987, make the following correction:

On page 48859, in the third column, in paragraph 1, in the fifth line, "0.8312736 sm" should read "0.83612736 sm".

BILLING CODE 1505-01-D

GENERAL SERVICES ADMINISTRATION

48 CFR Part 501

[APD 2800.12 CHGE 51]

Acquisition Regulation; Miscellaneous Changes

Correction

In rule document 88-14 beginning on page 130 in the issue of Tuesday, January 5, 1988, make the following correction:

501.170-4 [Corrected]

On page 131, in the first column, in section 501.170-4(a), in the ninth line, "GSA" should read "GSAR".

BILLING CODE 1505-01-D

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AZ-940-08-4212-13; A-13138]

Arizona; Conveyance of Public Land; Order Providing for Opening of Land

Correction

In notice document 87-28304 beginning on page 46847 in the issue of Thursday, December 10, 1987, make the following corrections:

1. On page 46847, in the third column, under T. 20 N., R. 21 W., Sec. 20 should read as follows:
NE¼, NW¼SW¼NE¼NW¼, S½,S½ NE¼NW¼,
NW¼NE¼NW¼NW¼, S½NE¼ NW¼NW¼,
NW¼NW¼NW¼, N½SW¼NW¼NW¼, SE¼NW¼NW¼, E½NE¼SW¼NW¼, S½SW¼NW¼, SE¼NW¼;

2. In the same column, under T. 19 N., R. 15 W., in Sec. 31, "EW½W½" should read "E½W½".

3. On page 46848, in the first column, under T. 20 N., R. 15 W., in the fifth line, "S½" should read "W½" and "NW¼SE½" should read "NW¼SE¼". In the sixth line, "S½W½" should read "W½W½".

4. On the same page, in the third column, in the 11th line, "19 minutes" should read "00 minutes".

5. In the same column, under T. 20 N., R. 15 W., (cont.), in the first line, "W½NW¼" should read "W½NE¼".

BILLING CODE 1505-01-D

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AZ-940-08-4212; A-21081]

Arizona; Opening Order

Correction

In notice document 87-28303 beginning on page 46846 in the issue of Thursday, December 10, 1987, make the following correction:

On page 46846, in the second column, under T. 10 S., R. 27 E., in the first line, "S½NW¼" should read "S½NE¼".

BILLING CODE 1505-01-D

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AZ-940-08-4212-12; A-20347 (B)]

Reconveyed Land Opened to Entry; Pinal County, AZ

Correction

In notice document 87-28930 appearing on page 47978 in the issue of Thursday, December 17, 1987, make the following correction:

In the second column, under **Gila and Salt River Meridian, Arizona**, the first line should read "T. 7 S., R. 18 E.,".

BILLING CODE 1505-01-D

federal register

Wednesday
January 20, 1988

Part II

Office of Management and Budget

Guidelines for Federal Statistical Activities; Notice

OFFICE OF MANAGEMENT AND BUDGET

Guidelines for Federal Statistical Activities

AGENCY: Office of Management and Budget.

ACTION: Notice of a draft circular establishing guidelines for Federal statistical activities.

SUMMARY: The Office of Management and Budget (OMB) is soliciting public comment on a draft OMB Circular that would revise government-wide guidance for planning and conducting statistical surveys, publishing statistical data, documenting statistical methods and procedures, and using standard statistical classifications, definitions, and data sources. The guidance, which applies to all Federal agencies subject to the Paperwork Reduction Act of 1980, is intended to assure that the results of statistical surveys and studies sponsored by the Federal government are as reliable and useful as possible and that statistical activities are conducted as efficiently as possible.

DATE: Comments must be received on or before April 19, 1988.

ADDRESS: Comments are invited on any aspect of the Circular. They should be made in writing and sent to Dorothy M. Tella, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503. The comments will be available for public examination at this address.

FOR FURTHER INFORMATION CONTACT: Dorothy M. Tella, (202) 395–3093.

SUPPLEMENTARY INFORMATION: Statistics collected and published by the Federal government constitute a large part of the available information about the United States economy, population, natural resources, environment, and public and private institutions. These data are used by the Federal government and others as the basis for actions that affect people's lives and well-being. It is essential that they be collected, processed, and published in a manner that guarantees and inspires confidence in their reliability. The statistical programs of the Federal government are decentralized among seventy or more agencies or separate departmental units. It is therefore also essential that, to the extent permitted by law, there be sufficient government-wide uniformity in statistical methods and practices to ensure the maximum usefulness of the statistics produced.

The Paperwork Reduction Act of 1980, as amended (44 U.S.C. 3504), gives the Director of OMB broad responsibility for improving the usefulness of information collected, maintained, and disseminated by the Federal government and for reducing the Federal government's reporting burden on the public. Among the Director's functions under the Act are statistical policy and coordination functions, which include the development and implementation of policies, principles, standards, and guidelines concerning statistical collection procedures and methods, statistical data classification, statistical information presentation and dissemination, and such statistical data sources as may be required for the administration of Federal programs.

This Circular provides revised guidance for designing, conducting, and publishing statistical surveys and studies sponsored by Federal agencies. The guidelines are intended to ensure that such surveys and studies are designed to produce reliable data as efficiently as possible and that methods are documented and results presented in a manner that makes the data as accessible and useful as possible. The Circular would also establish guidelines for the use of standard classifications, definitions, and data sources. The Circular would rescind and replace guidance on the conduct of Federal statistical activities currently contained in 19 statistical policy directives. (Section 2 of the Circular lists the rescinded directives.) The Circular would, however, leave in place Directive No. 19, "Reports of the Department of Commerce on International Transactions" (43 FR 19272, May 4, 1978).

The Circular would for the first time establish guidelines for documenting all methods, procedures, and models used to produce statistical estimates and would revise and strengthen existing guidance on planning of statistical surveys, treatment of respondents, publication of statistical data, and use of standard statistical classifications, definitions, and data sources. The Circular would discontinue certain classifications and definitions as government-wide statistical standards, as indicated below.

The attachments to the Circular address the following subjects:

Planning Statistical Surveys. The OMB paperwork regulation (5 CFR Part 1320) requires that when agencies seek OMB approval to collect information, they demonstrate that they have taken reasonable steps to ensure that the information is useful and that the cost and burden of collecting it have been minimized. Attachment A of the Circular specifies the documentation that the sponsoring agency shall include in its request for OMB approval of a statistical survey to demonstrate that the survey is designed efficiently and will produce reliable, useful results.

Treatment of Respondents. The guidelines in Attachment B are intended to reassure respondents to statistical surveys that the Federal government is dealing with them honestly and forthrightly and that their interests are being protected. For this purpose, agencies that sponsor statistical surveys should provide certain information to potential respondents about the purpose of each survey and the planned use of the survey data, including any matching or combination of individual respondent data with data from administrative sources. Any such match or combination should meet the conditions specified in section 3.c. of the attachment. Matches for statistical purposes, to which the guidance in Attachment B applies, are not covered by the OMB Guidelines for conducting computerized matching programs (47 FR 21656, May 19, 1982). Agencies should take the specific steps outlined in Attachment B to ensure the protection from public disclosure of information collected under a pledge of confidentiality. Attachment B would also establish certain design guidelines for statistical surveys conducted under mandatory reporting authority, in order to minimize the burden of such surveys on individual respondents.

Statistical Publications. Attachment C contains guidelines for the presentation and documentation of the results of statistical surveys and studies. To ensure that other agencies and the public have an opportunity to verify and use the results of all Federally-sponsored statistical surveys and studies, the sponsoring agency should either publish the results or maintain them in an accessible data base such that requests for summary data or tabulations can be met within 90 days. This guidance is based on the presumption that data collected for statistical purposes have practical utility, as defined in 5 CFR Part 1320, only to the extent that they are accessible to potential users within and outside the Federal government. In deciding whether to publish the results or else to maintain them in an accessible data base, agencies will be expected to conform to the policies on the dissemination of government information products and services established in section 8.a.(9) of OMB Circular A–130, Management of Federal Information Resources (50 FR 52730, December 24, 1985).

Documentation of Methods and Procedures. Attachment D contains

guidelines under which agencies would maintain publicly available documentation of all statistical methods, procedures, and models used to produce statistical data and estimates, thereby enabling users to make informed, independent judgments about the quality of data and estimates and to verify that they have been produced by sound, replicable methods.

Compilation, Release, and Evaluation of Principal Federal Economic Indicators. Attachment E contains guidelines for the compilation, release, and evaluation of data series that have been designated as principal economic indicators by the Director of OMB. The provisions in this attachment are the same as those in Statistical Policy Directive No. 3 (50 FR 38932, September 25, 1985), except for the addition, in Section 8, of the provision that agencies inform the public of the uncertainty or probable range of error in preliminary estimates of economic indicators.

Use of Standard Classifications, Data Sources, and Definitions. Attachment F establishes, and prescribes the uses of, certain standard statistical classifications, data sources, and definitions, which have all been previously established in OMB Statistical Policy Directives. Five classifications or definitions would be discontinued as government-wide statistical standards either because the current standards have not proven useful for the statistical purposes intended (standard Federal administrative regions, the standard industrial classification of enterprises, and the standard reference base period for Federal government general-purpose index numbers) or because they are used by only one or two agencies to collect and publish statistics (the standard classification of fields of science and engineering and the standard gas pressure base). In the latter case, OMB believes it is more practical for the principal user agencies to maintain the standards. The Circular makes it clear that the definitions of Metropolitan Statistical Areas (MSAs), the Standard Industrial Classification (SIC), and the Standard Occupational Classification (SOC) are established and maintained by OMB solely for statistical purposes and that agencies that use these statistical standards in nonstatistical programs bear the responsibility for assuring that the standard definitions or classifications are appropriate for those uses.

Provision of Statistical Data to International Organizations. Attachment G provides guidance on the implementation of Executive Order 10033.

In several cases, statistical activities covered by this Circular are also covered by other OMB Circulars. In such cases, this Circular supplements or clarifies the guidance in the other Circulars as it relates to statistical collections and publications. The specific instances of each are noted in the appropriate portions of the Circular.

Wendy L. Gramm,

Administrator for Information and Regulatory Affairs.

OMB Circular No. A-____

To the Heads of Executive Departments and Establishments.

Subject: Guidelines for Federal Statistical Activities.

1. *Purpose.* This Circular revises government-wide guidance for planning and conducting statistical surveys, publishing statistical data, and documenting statistical methods and procedures. These guidelines are intended to assure that all statistical surveys and studies sponsored by the Federal government produce as accurate and useful information as possible, serve their purposes as efficiently as possible, and impose no unnecessary burden on respondents. The Circular also prescribes four standards—a standard data source for population estimates, a standard data source for labor force and unemployment estimates, standard categories for reporting race and ethnic background, and a standard definition of poverty—to be used in the administration of Federal programs, consistent with statutory requirements. It also clarifies the responsibilities of agencies that use the Standard Industrial Classification (SIC), the Standard Occupational Classification (SOC), and the standard definitions of Metropolitan Statistical Areas (MSAs) for nonstatistical purposes.

2. *Rescissions.* This Circular rescinds and replaces Statistical Policy Directives Nos. 1–2 and 5–18 (43 FR 19260, May 4, 1978); Statistical Policy Directive No. 3 (46 FR 3253, January 14, 1981), as revised (50 FR 38932, September 25, 1985); and the directive entitled "Comparability of Statistics on Business Size" (47 FR 21362, May 18, 1982).

3. *Authority.* The Paperwork Reduction Act of 1980, as amended (44 U.S.C. 3504); the Budget and Accounting Procedures Act of 1950, as amended (31 U.S.C. 1104); Executive Order 10253 of June 11, 1951, as amended (see 31 USCA 1104); and Executive Order 10033 of February 8, 1949, as amended (see 22 USCA 286f).

4. *Background.* The Paperwork Reduction Act grants the Director of the Office of Management and Budget (OMB) broad authority to develop and implement government-wide policies, principles, standards, and guidelines concerning statistical collection procedures and methods, statistical data classifications, statistical information presentation and dissemination, and statistical data sources required for the administration of Federal programs. The Act also reassigns to the Director the authority in the Budget and Accounting Procedures Act to develop programs and issue regulations and orders for the improved gathering, compiling, analyzing, publishing, and disseminating of statistical information for any purpose by the various agencies of the executive branch of the Federal government. Since the Paperwork Reduction Act took effect in 1981, OMB has provided government-wide guidance on collecting and publishing statistical data in 19 statistical policy directives: Directives Nos. 1–2 and 5–19 (43 FR 19260, May 4, 1978); Directive No. 3 (46 FR 3253, January 14, 1981), as revised (50 FR 38932, September 25, 1985); and a directive establishing standard business size categories for statistical purposes, "Comparability of Statistics on Business Size" (47 FR 21362, May 18, 1982). This Circular rescinds and replaces all of these directives except Directive No. 19, "Reports of the Department of Commerce on International Transactions" (43 FR 19272, May 4, 1978).

OMB information collection reviews and other evaluations of statistical activities and publications have pointed to a need for more explicit guidance to agencies on (1) planning statistical surveys so that they meet the requirements set forth in 5 CFR Part 1320 for OMB approval under the Paperwork Reduction Act; (2) treating respondents to statistical surveys in a manner that ensures the public's continued willingness to provide accurate, timely information to the Federal government for statistical purposes; and (3) documenting statistical surveys and studies in such a way as to make their results as useful as possible, minimize the risk that statistics may be misinterpreted, and ensure the public that estimates have been produced by sound, replicable methods. The Circular establishes guidelines on these aspects of statistical work, as well as on the use of standard classifications, data sources, and definitions for statistical and administrative purposes; on the

compilation, release, and evaluation of principal Federal economic indicators; and on the provision of statistical data to international organizations, consistent with the requirements of Executive Order 10033.

5. *Coverage.* The provisions of the Circular apply to all Federal agencies subject to the Paperwork Reduction Act of 1980 (see 5 CFR 1320.7(a)), to all statistical surveys and studies sponsored by those agencies, and to all publications resulting from such surveys and studies.

6. *Agency Implementation.* This Circular provides policy guidance on statistical issues. This guidance should be applied to the extent permitted by the laws governing the agency's actions.

7. *Definitions.* For the purposes of this Circular:

a. "Benchmarking" is the reconciliation of one estimate with another that is thought to be more accurate.

b. "Data" is used interchangeably with "information", as defined in 5 CFR 1320.7(k), when referring to information collected in or resulting from statistical surveys and studies.

c. An "estimate" is a numerical value or relationship that is derived from a survey, model, other statistical or mathematical procedures, or professional judgment.

d. "Imputation" means assigning estimated values to fill in missing data on individual statistical records or to replace data supplied by respondents that an agency believes to be in error. Changes to correct obvious coding or recording errors made by the agency are not imputations. Filling in missing data with data that the same respondent has supplied on another statistical or administrative record is not defined as imputation if the data were supplied in response to the same question for the same time period.

e. "Publication" means any release of statistical data or results of a statistical study for distribution or sale to the public on paper, computer tape, disk, or any other semipermanent medium, or by means of electronic data bases.

f. A Federal agency is the "sponsor" of a statistical survey or study if:

(1) That agency conducts the survey or study using funds appropriated to it or available for discretionary use through other means;

(2) That agency provides funds appropriated to it to another Federal agency, other government organization, or a private contractor to conduct the survey or study; or

(3) The survey or study is conducted under a grant from or cooperative agreement with that agency and:

(A) The grantee or cooperating party is conducting the survey or study at the specific request of the agency for the planning, operation, or evaluation of its programs; or

(B) The terms and conditions of the grant or agreement provide for prior or ongoing agency approval of the collection of information or the procedures to be used in the survey or study.

g. "Statistics are the quantitative results of a survey or study. Statistics include both aggregate estimates and the elements of individual data records.

h. Information collected for "statistical purposes" is information collected for the purpose of reporting population characteristics, developing statistical procedures, or constructing sampling frames. Information collected for any other purpose is for "nonstatistical purposes".

i. "Statistical study" means any study that makes use of a survey, model, or statistical or mathematical procedure or of estimates derived by these means.

j. "Statistical survey" means a collection of data from or about any population or group for the purpose of studying characteristics of the population or group. Both collections of data gathered directly from respondents in a census or sample of the study population and compilations of data from administrative records for statistical purposes are defined as statistical surveys.

8. *Contents.* The guidance provided by this Circular is set forth in the attachments:

Attachment A—Planning of statistical surveys
Attachment B—Treatment of respondents
Attachment C—Statistical publications
Attachment D—Documentation of methods and procedures
Attachment E—Compilation, release, and evaluation of principal Federal economic indicators
Attachment F—Use of standard classifications, data sources, and definitions
Attachment G—Provision of statistical information to international organizations

9. *Submission of Agency Plan.* Within 120 days of the publication of this Circular, the head of each agency shall submit to the Director a plan, including completion dates, for bringing all the agency's programs into compliance with the guidelines in the Circular. Where appropriate, these plans shall be coordinated with the anticipated schedule for paperwork clearance reviews.

10. *Judicial Review.* This Circular is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any person.

11. *Information Contact.* Chief, Statistical Policy Office, Office of Information and Regulatory Affairs. Telephone: (202) 395–3093.

ATTACHMENT A—Circular No. A–___

Planning of Statistical Surveys

1. This attachment outlines the documentation that is to accompany statistical surveys when they are submitted to OMB for approval under the Paperwork Reduction Act, in order to demonstrate that the surveys meet the relevant requirements of the Act and its implementing regulation, 5 CFR Part 1320. It replaces guidance on the planning of statistical surveys previously contained in Statistical Policy Directive No. 1, "Standards for Statistical Surveys," which is rescinded by this Circular.

2. With every request for OMB approval of a statistical survey under the Paperwork Reduction Act, the sponsoring agency shall submit supporting documentation to demonstrate that the survey has a useful purpose and is designed to accomplish that purpose as efficiently as possible. That documentation shall include the following information:

a. *The analytical purpose of the survey.* The documentation shall state specifically the analytical problem or research question the survey is expected to solve or answer and shall explain the role the survey is expected to play in the analysis. If the analysis calls for any individual match or combination of data collected directly from respondents in the survey with data from administrative sources, the documentation shall fully describe the purpose of and plans for the match or combination. Any such match or combination should comply with the provisions in Attachment B, Section 3.c. When requesting OMB approval of a pretest, the sponsoring agency shall specify the aspect of the survey that is to be pretested, the design features of the actual survey that will be determined by the results of the pretest, and the agency's plans and timetable for evaluating the pretest results.

b. *The statistical objectives of the survey.* The documentation shall specify the population to be investigated, the variables for which data are to be gathered, the parameters to be estimated on the basis of survey data,

and the accuracy requirements for these estimates. If the survey is to investigate relationships among variables, differences among populations, or changes over time, the documentation shall indicate the necessary accuracy of the estimates of these relationships, differences, or changes.

c. *The need for a survey.* For any survey that involves a new collection of data from the public, the sponsoring agency shall describe its efforts to obtain suitable data from other sources, including existing surveys, administrative records, and model-based estimates, and explain why such alternatives were rejected.

d. *The feasibility of the survey.* The sponsoring agency shall submit documentation to demonstrate that the desired information exists and that it can be obtained through a survey in a sufficiently timely manner and at a sufficient level of accuracy and detail to serve the analytical purposes of the survey.

e. *Justification of the proposed frequency of the survey.* If the survey is to be recurring, the sponsoring agency shall submit documentation to demonstrate that:

(1) Measurable changes in the phenomena being studied are expected to occur in the proposed interval between data collections and that such changes need to be estimated to fulfill the analytical purpose of the survey;

(2) Without a survey at the proposed frequency, changes during this interval could not be estimated with an acceptable degree of accuracy; and

(3) The sponsoring agency is able and intends to collect, process, and publish data promptly if collection is at the frequency proposed.

f. *The survey design.* The sponsoring agency shall submit documentation to demonstrate that:

(1) The survey will collect all data not available from other sources that are necessary for the analyses the survey is intended to support.

(2) The survey is designed to satisfy the accuracy requirements of the analyses it is intended to support. The documentation shall include estimates of the variance of key parameters, including composites and projections, to demonstrate that they are likely to be within acceptable limits. If the survey is intended to measure relationships among variables, differences among populations, or changes over time, the documentation shall also include calculations to demonstrate that the relationships, differences, or changes of interest can probably be measured with the precision required. If the sample design calls for nonprobability sampling, the documentation shall explain the basis for statements about the accuracy of the estimates.

(3) The survey design is operationally feasible. The sponsoring agency shall demonstrate that it is able to carry out the survey as designed.

(4) Adequate steps have been taken to minimize the impact of nonsampling error on the estimates to be derived from survey data. The documentation shall identify the potential sources of error and give the sponsoring agency's projection of the size of such errors and their impact, individually and in the aggregate, on the estimates. All potential sources of nonsampling error shall be analyzed, including:

(A) Any differences between the target population (the universe of study) and the sampling frame;

(B) Any conceptual differences between the parameters to be estimated on the basis of survey data and the parameters desired for the planned analyses;

(C) In statistical studies that involve control groups, dissimilarities between the study group and the control group; and

(D) The expected extent and impact of overall and item nonresponse. The documentation shall include estimates of response rates based on the sponsoring agency's prior experience (or the experience of the organization conducting the survey) with the same survey or similar surveys. If the agency anticipates significantly different rates of nonresponse for different subgroups of the sampled population or for different questions in the survey, it shall provide separate estimates for all such subgroups and questions. If timeliness of response is important (for example, if the sponsoring agency has specified cut-off dates for publishing or using data), it shall indicate the expected response rates by the relevant cut-off dates.

Under 5 CFR 1320.6(g), statistical surveys must be designed to produce results that can be generalized to the universe of study. Accordingly, the sponsoring agency shall submit documentation to demonstrate either that nonsampling error is sufficiently small that it is unlikely to bias estimates derived from survey data, or that effective methods have been developed to adjust for such error. All benchmarking, imputation, and other adjustment methods shall be described in the documentation.

(5) The proposed design satisfies the survey objectives in a way that minimizes the burden on respondents, consistent with sound administrative practices and reasonable cost to the government. In estimating the burden on respondents, agencies shall take into account the amount of time it will take to provide proper responses and the cost of the time of the particular individuals who will be asked to respond, including any time that will be required by agency follow-up. Before submitting a survey to OMB for approval, the sponsoring agency shall analyze the benefits and costs of a range of possible design options, including alternative sample sizes and data collection techniques. The documentation supporting the request for approval shall summarize the results of this analysis.

(6) The survey meets the conditions set forth in Attachment B, Section 4, whenever response to the survey is mandatory. The documentation for surveys that use mandatory reporting authority shall also provide a justification of the use of such authority in terms of its effectiveness in meeting the survey's objectives. The documentation shall include the sponsoring agency's plans for enforcing the penalties for nonresponse.

g. *Performance and Quality Measures.* The documentation shall specify what measures the sponsoring agency will use to evaluate the performance of the survey and the quality of the data collected. It shall list the performance indicators that will be calculated and available after completion of the survey, such as:

(1) Nonresponse rates;

(2) Rates of edit failure;

(3) Percentage of cases requiring follow-up or reinterview; and

(4) Timeliness measures, such as the number of days required to collect data from respondents and the number of days between the reference date of the survey and the date survey results are published.

The documentation shall also include a description of the information validation techniques and quality control procedures that will be used to verify that data in publications or in final data bases are equivalent to the data actually collected.

h. *Disclosure control techniques.* The documentation shall state what disclosure control techniques are to be used in each kind of release of survey data (e.g., summary tabulations and microdata products). If variables or table cells are to be suppressed, the documentation shall indicate what variables will be suppressed and what cross classifications are likely to be lost. The description of disclosure control techniques shall be general enough so that it cannot be used to breach the protection against disclosure. The documentation shall report the

sponsoring agency's efforts to minimize the impact of its disclosure control techniques on the usefulness of the survey data.

i. *Quality standards for publishing data.* The documentation shall specify what quality standards the sponsoring agency will use to determine whether data from the survey are publishable or should be suppressed.

j. *Processing and reporting of survey data.* The documentation shall describe:

(1) The editing and imputation procedures to be used in processing the survey data;

(2) The procedures to be used in preparing estimates based on survey data, including benchmarking and seasonal adjustment methods and methods for creating composite variables; and

(3) The contents of all planned products of the survey, including tabulations to be published, analytical reports to be prepared by the sponsoring agency, and public use data products, with the dates that the sponsoring agency intends to release these products. If the data to be gathered in the survey are likely to be of substantial interest for research purposes, the sponsoring agency should plan to produce a public-use data file. The data file should be offered on a cost-recovery basis, i.e., with the fees for purchase or use of the file set so as to recover the agency's incremental cost of preparing, maintaining, and distributing the file, as provided in OMB Circular A–25. The agency's documentation shall indicate whether the agency plans to release a public-use data file in conformity with the provisions in Attachment C, Section 2.d. The documentation shall also provide a schedule for such release.

k. *The basis for any pledge of confidentiality.* If the sponsoring agency intends to make a pledge of confidentiality covering information collected in the survey, the documentation shall include the statement required by Attachment B, Section 3.b.(1) of this Circular, and shall indicate whether the agency has complied with all the other provisions of Attachment B., Section 3.a. and 3.b.

ATTACHMENT B—Circular No. A-____

Treatment of Respondents

1. This attachment sets forth guidelines for the treatment of respondents to statistical surveys, and replaces guidance on this subject previously contained in section 8 of Statistical Policy Directive No. 1. The guidelines in this attachment are independent of obligations imposed on agencies by the Privacy Act and apply regardless of whether the record systems supporting an agency's statistical programs are exempt from certain provisions of that Act under 5 U.S.C. 552a(k). Moreover, these guidelines are to be applied in addition to all relevant provisions of 5 CFR Part 1320. The guidelines for matching or combining statistical and administrative information (Sections 2.d.(3) and 3.c.) apply only to matches for statistical purposes and therefore do not overlap the OMB Guidelines for conducting computerized matching programs (47 FR 21656, May 19, 1982), which specifically exclude from their coverage matches for statistical purposes.

2. *Informing respondents.* Agencies that sponsor statistical surveys should ensure that potential respondents are provided the following information at the time they are asked to participate in such surveys:

a. The names of all sponsors of the survey, including organizations other than Federal agencies that are providing funding for the survey;

b. The subjects about which respondents will be asked to supply information, in sufficient detail to alert respondents to any sensitive topics in the survey;

c. For surveys in which information is to be collected periodically from the same respondents, the period during which and the frequency with which the respondent will be asked to supply information;

d. The uses that are intended to be made of information from the survey (e.g., to publish statistics on a stated subject or to carry out a particular study). The sponsoring agency should explicitly state:

(1) Whether it intends to use the information exclusively for statistical purposes. In cases for which that is the intent, the sponsoring agency should explicitly state the measures it has taken and its legal authority to prevent nonstatistical uses;

(2) Whether a pledge of confidentiality, made in accordance with the requirements of Section 3.b. of this attachment, covers the information collected and the fact of the respondent's participation in the survey; and

(3) Whether it plans to match or combine survey data with information about survey respondents from administrative sources. If any individual match or combination of survey data and administrative information is intended, the sponsoring agency should explain its nature and purpose to potential respondents; and

e. If the survey uses mandatory reporting authority, a full quotation of the relevant text of the statute(s) and/or regulation(s) that establish the mandatory reporting authority and the penalties for nonresponse.

3. *Protection of confidentiality and privacy.*

a. A Federal agency that collects information for statistical purposes under a pledge of confidentiality should protect that information from public disclosure to the extent permitted by law. Measures to provide this protection should include at a minimum:

(1) Written policies that proscribe the use of such information for nonstatistical purposes;

(2) Written policies and procedures for ensuring the physical security of the information while in the possession of the agency, its contractors, or its grantees. Where appropriate, these should include policies implementing the provisions of Appendix III of OMB Circular A–130 (50 FR 52730, December 24, 1985), on the Security of Automated Information Systems;

(3) A program to ensure that the agency's employees, contractors, and grantees are fully aware of their responsibilities for the safeguarding of confidential information; and

(4) Such other policies, programs, or agency rules as are available and necessary to protect from public disclosure respondent information that the agency believes qualifies for exemption from disclosure under the Freedom of Information Act (5 U.S.C. 552).

Policies, programs, or rules established for this purpose should eliminate any legal or administrative discretion otherwise retained by the agency to make public disclosures that are not consistent with the provisions of this section. Before submitting to OMB for review any proposed information collection for statistical purposes that is to be covered by a pledge of confidentiality, the sponsoring agency shall have resolved any legal questions affecting its ability to prevent public disclosure of the information.

b. To ensure consistent and accurate public understanding of pledges of statistical confidentiality, no agency should make such a pledge of confidentiality unless:

(1) It has provided a statement to OMB that it believes the information covered by the pledge is exempt from disclosure under the Freedom of Information Act, indicating upon what exemption it relies and, if the exemption is by statute, citing the relevant statute;

(2) It has met the requirements of Section 3.a. of this attachment for protecting confidentiality; and

(3) It includes in the information collection the following uniform pledge of confidentiality:

This information collection conforms to legal and administrative standards established by the Federal government to assure confidential treatment of statistical information. The information you provide will be used only for statistical purposes and will not be published or released in any form that would reveal specific information reported by any individually identifiable respondent. The [name of sponsoring agency or department] has determined that the information you provide, as well as the fact that you have participated in this survey, is exempt from public disclosure under the Freedom of Information Act.

In any case where potential respondents might misinterpret agency statements concerning statistical use or confidential treatment, OMB may require the sponsoring agency to display on information collection forms, or otherwise convey to potential respondents, an explicit statement of noncompliance with the confidentiality provisions of this Circular.

c. If information is collected for statistical purposes, as stated to respondents pursuant to Section 2.d.(1) of this attachment, any individual match or combination of that information with information from administrative records should meet the following conditions:

(1) The match or combination is exclusively for statistical purposes;

(2) The sponsor of each statistical survey involved in the match or combination has informed all respondents as required in Section 2.d.(3) of this attachment; and

(3) Any match or combination involving a statistical survey is conducted as described in the sponsoring agency's request for OMB approval of the survey, submitted in accordance with Attachment A, Section 2.a. of this Circular.

4. *Designing and conducting surveys that use mandatory reporting authority.*

Unless there is a statutory requirement that the survey be designed otherwise, any statistical survey that uses mandatory reporting authority should meet the following conditions:

a. The survey is designed so that all units in the population of study, or within each designated sampling stratum of the population, have an equal probability of being included in the survey;

b. If the survey requires periodic responses by the same respondents, the sample is redrawn at regular intervals not to exceed 3 years; and

c. The information that respondents are required to provide includes only factual information that can be obtained from and verified by respondents' records.

ATTACHMENT C—Circular No. A-____

Statistical Publications

1. This attachment sets forth guidelines for publishing the results of statistical surveys and studies. It replaces guidance previously contained in Statistical Policy Directive No. 2, "Standards for the Publication of Statistics," which is rescinded by this Circular.

2. *Obligation to publish.*

a. Agencies that sponsor statistical surveys and studies should either publish the results or else make them available upon request in a form that does not reveal information about any individually-identifiable respondent. Nonpublished results should be maintained in a data base that is sufficiently accessible that requests by other agencies or the public for tabulations or summaries can be met within 90 days.

b. Except as provided in Attachment E of this Circular for principal Federal economic indicators, no data collected in a statistical survey should be suppressed or withheld from release unless:

(1) Suppression is necessary to protect the confidentiality of information provided by individual respondents, or

(2) The data fail to meet the quality standards for publication that the sponsoring agency has specified in its request for OMB approval of the data collection, as required in Attachment A, Section 2.i. of this Circular. If it is necessary to suppress data because they fail to meet these standards, the sponsoring agency shall report to OMB the data items to be suppressed and the basis for suppression, as soon as the agency has that information, and should:

(A) Notify potential users that the data will not be published or otherwise released; and

(B) Make no use of the suppressed data in any published reports or estimates.

c. Agencies should annually publish, either in the **Federal Register** or in an agency publication, a catalog of the statistical data in their files, indicating the form in which they are available to the public (e.g., hardcopy reports, public use tapes, online, tabulations upon request), the period of time for which they will remain available in each form, and the name, address, and telephone number of the office within the issuing agency to which inquiries may be directed.

d. Agencies should provide for the prompt release of public-use data files that enable analysts outside the sponsoring agency to reproduce and verify the sponsoring agency's results, test alternative hypotheses, and develop alternative interpretations. If survey plans submitted to OMB included the preparation of public-use data files (see Attachment A, Section 2.j.(3)), the sponsoring agency should release these files no later than 90 days after the sponsoring agency's first published reports (except for preliminary summary tabulations) based on survey data. If such files are not available when the first reports are issued, the reports should contain a notice regarding their forthcoming availability.

3. *Use of standard statistical classifications and definitions.* Agencies should use the standard classifications and definitions set forth in Attachment F when publishing statistics for which there are such standards. When reporting statistics for which there are no such standards, the classifications and definitions used should support the broadest possible range of analytical uses of the data. Publications should explain all standard classifications and definitions that are used and provide appropriate references.

4. *Presentation of statistics.* The following guidelines apply to the presentation of statistical data in publications.

a. Data tables, charts, and graphs. Tables, charts, and graphs should be designed and labeled so that their meaning is clear and unambiguous. The publication should include an explanation of all technical terms and the definitions of all categorizations or appropriate references for them. Any term whose usage differs from common usage or might otherwise be misconstrued should be clearly defined. Labels should be properly aligned, groups clearly separated, and all group totals included. Labels for subgroups should be sufficiently indented to ensure that relationships among the categories are clear. If all subcategories are not displayed, there should be an explanation of what has been omitted. If tables contain percentages, the population totals that are needed to reproduce the numbers on which the percentages are based should be reported.

b. Complete presentation.

(1) Any publication that contains data tables based on sample surveys should also report estimates of standard deviations or variances. Variances and standard deviations should be directly measured from the sample whenever possible. If generalized variances or other approximations to the variances

are used in the publication, the publication should clearly inform users that the variance estimates are approximations and statistics that rely on these variances may be inaccurate. The publication should fully describe the methods used to estimate variances.

(2) To enable users to evaluate further the reliability of estimates, the agency issuing the publication should publish, or offer and be prepared to provide upon request, the actual number of observations in each published table cell.

(3) To enable users to discern the extent and impact of imputation, agencies should identify imputed data items with separate codes when they publish unsummarized data (as in public-use data files). When they publish summarized data, agencies should report the percentage of observations that are imputed for each variable included in the summary and should indicate (by code or other means) the percentage of data items that are imputed in each published table cell.

c. Discussion of findings. The evidence to support conclusions and statements about causes and effects should be presented in full in the publication. Inferences about differences and changes should be based upon generally accepted statistical techniques, which should be identified and described in the publication.

d. Preliminary and revised estimates. Any data or reports that are released prior to final editing, compilation, or correction should be clearly labeled as preliminary. The release should explain the limitations of the preliminary estimates, describe the nature of future corrections, and provide the scheduled dates for the publication of revisions. When revised data are published, the quantitative difference between the preliminary and revised data should be shown, the revision process described, and the effects of the revisions on the interpretation of the data explained.

5. *Documentation.* All publications of results of a statistical survey or study should include documentation that describes the purpose of and the procedures for conducting the survey or study and the quality and limitations of the results. For reports that are part of a regular series, the required documentation may be published separately but should be kept completely current and accurate. For one-time surveys or studies and for the first publication in a series, the documentation should be available at the same time as the publication. Public-use data files should provide the documentation both in paper form and as part of the file. The documentation should cover:

a. The purpose of the study.

b. A description of the study design. The documentation should explain the rationale for the study design and how the study was conducted. The description should be sufficiently detailed to serve most needs of the principal users of the publication and to ensure that all users are alerted to aspects of the study design that affect the interpretation of results. It should include a brief account of the outcome of the quality control procedures used. The publication should refer the user to the complete documentation of methods and procedures that the sponsoring agency maintains in accordance with Attachment D of this Circular.

c. The sources of all statistical data used in the study. The documentation should clearly identify data that were collected through different surveys or from different administrative record systems and describe how such data were changed through editing and imputation. The documentation should clearly identify constructed and estimated variables and describe the methods used to construct composite variables and the models or statistical procedures used to develop estimates. If data have been subjected to aggregate adjustments, such as benchmarking or seasonal adjustment, this should be clearly noted and the adjustment methods described.

d. A discussion of the limitations of the survey or study results. Sufficient information should be presented to enable the user to judge the accuracy of the reported results of the study and the extent to which the results can be extrapolated or generalized to other populations or circumstances.

6. *Review of publications.* Before releasing any publication, the agency should review it to ensure that it clearly and correctly presents information and that it complies with the standards in this Circular. Agencies that regularly issue statistical publications should establish a formal review process with written procedures and specific assignments of responsibility. The process should provide for independent review of each publication by at least one competent professional who was not involved in the preparation of the publication or the survey or study on which it is based.

7. *Assistance to users.* All publications should contain the name, address, and telephone number of an office within the agency issuing the publication that may be contacted for further information or assistance. The documentation of public-use files should indicate what user services are available for the file and what period of time such services will remain available.

ATTACHMENT D—Circular No. A-____

Documentation of Methods and Procedures

1. Agencies that regularly publish statistics should maintain complete and current documentation of all methods and procedures used to produce these estimates. This documentation should be publicly available in its entirety and therefore should not contain any information that the agency considers to be exempt from disclosure under the Freedom of Information Act (5 U.S.C. 552). The documentation should include, but is not limited to, the areas detailed in this attachment.

2. *Surveys.* Agencies that sponsor statistical surveys should maintain for each survey a file documenting the survey design and the operations used to collect, process, and publish data from the survey. The file should be maintained until the survey is no longer being conducted and demand for the data no longer exists.

The documentation file should include:

a. Descriptions of: the target population; the sampling frame; the correspondence between the target population and the sampling frame; the sample design; collection methods, locations, and dates; follow-up procedures; the methods used to edit and tabulate survey data; any imputation and adjustment procedures applied to survey data; and the procedures used to control the quality of survey operations.

b. Copies of the forms used in the survey, including the survey questionnaire and the instructions to both respondents and interviewers;

c. The performance statistics, such as those presented in Attachment A, Section 2.g. of this Circular, that the sponsoring agency, its contractors, or its grantees have used for management and evaluation of the survey; and

d. The results of any evaluations of survey operations and data, including quality control audits.

3. *All imputation procedures, coding procedures, and procedures used to adjust data acquired through surveys or administrative records.* The documentation of such procedures, including benchmarking, revision, and seasonal adjustment procedures, should be complete enough to enable a competent professional from outside the agency to duplicate the procedures and results.

4. *Models.* The documentation of models used to generate estimates should be complete enough to enable a competent professional from outside the agency to use the model and duplicate the sponsoring agency's results. Model documentation should include the following: a model specification; a summary of the purpose of the model, including its principles, structure, and assumptions; a complete mathematical statement of the model; a description of any data base used with the model; a description of the validation, verification, and audit record associated with the model; and the results of using the model, including both the raw outputs and analysis based on those outputs.

If the documentation is for a computer model, it should also include a user's guide explaining how to run the model.

5. *The procedures used to generate statistical estimates that are required by statute or by this Circular to be used by Federal agencies in making determinations about the benefits, obligations, privileges, or rights of specific individuals or entities.* Complete, current documentation of all procedures, including specific assumptions and decision rules, should be available in published form at the time such estimates are released. All statistical estimates used in making such determinations should themselves be published.

ATTACHMENT E—Circular No. A-____

Compilation, Release, and Evaluation of Principal Federal Economic Indicators

1. This attachment replaces Statistical Policy Directive No. 3, "Compilation, Release and Evaluation of Principal Federal Economic Indicators," which this Circular rescinds.

2. Agencies that publish statistical estimates that have been designated by the Director of OMB as principal Federal economic indicators should follow the procedures prescribed in this attachment for the compilation, release, and evaluation of these estimates.

3. *Designation of Principal Indicators.* The Director of OMB shall determine, after consultation with the affected Federal agencies, the statistics and estimates to be designated as principal Federal economic indicators and covered by this attachment to the Circular. At the beginning of each calendar year, OMB will publish the list of indicators covered and the scheduled dates for release of each indicator during the year.

4. *Prompt Release.* The interval between the end of the period to which the statistics refer and the date when the data or estimates are released to the public should be as short as practicable. Agencies should compile and release series that are issued quarterly or more frequently within 22 working days of the end of the reference period.

5. *Release Schedule.* The releasing agency is responsible for ensuring that the interested public is aware of the release time and date. The last report of each calendar year should contain the time and date of all reports in the upcoming year. In addition, each release should include an announcement of the time and date of the next release. The releasing agency shall provide a schedule of releases for the upcoming calendar year to the Statistical Policy Office, Office of Information and Regulatory Affairs, OMB, by November 30th of each year. Changes in the release schedule may occur only if special, unforeseen circumstances arise. The releasing agency should announce and fully explain any schedule changes as soon as it has determined they are unavoidable.

There should be one office in the agency that can provide the release schedule of all the agency's principal economic indicators. The name, address, and telephone number of this office should be readily available to the public. Agencies should establish and maintain no more than two specific times of day for the release of their principal economic indicators and should only release indicators at such designated times.

6. *Announcement of Changes.* Agencies should announce any planned change in data collection, analysis, or estimation methods that may affect the interpretation of a principal economic indicator as far in advance of the change as possible. The agency should include the announcement in a regular report of the economic indicator. When possible, a period for public comment should be provided between the announcement of an intended change and its implementation. At a minimum, for quarterly and monthly series, the agency should announce the change at least three reports before the first report affected by the change. For weekly and annual series, the announcement should precede the first report affected by the change by at least three months. In the first report affected by the change, the agency should include a complete description of the change and its impact.

Agencies should fully explain unforeseeable changes due to special circumstances as soon as they are known and in the first report affected by the change.

7. *Release Procedure.* The statistical agency that produces each principal economic indicator should issue it in a press release or other printed report. The agency should issue a press release where this will significantly speed up the dissemination of data to the public.

Each statistical agency is responsible for establishing procedures to ensure that there is no premature release of information or data estimates during the time required for preparation of the public report. This includes the protection of public-use data banks, which should not receive any data or estimates until they are officially released. As soon as copies of materials for public release have been prepared, the agency should physically secure them.

Except for the authorized distribution described in this section, agencies should ensure that no information or data estimates are released before the official release time.

The agency shall provide prerelease information to the President, through the Chairman of the Council of Economic Advisers, as soon as it is available. The agency should grant prerelease access to others only under the following conditions:

a. The agency head has established whatever security arrangements, and imposed whatever conditions on the granting of access, that are necessary to prevent unauthorized dissemination or use.

b. The agency head will ensure that any person granted access has been fully informed of, and has agreed to, these conditions.

c. Any prerelease of information under an embargo will not precede the official release time by more than 30 minutes.

d. In all cases, prerelease access will precede the official release time only to the extent necessary for an orderly review of the data.

All employees of the Executive Branch who receive prerelease distribution of information and data estimates as authorized above are responsible for ensuring that no release occurs prior to the official release time. Except for members of the staff of the agency issuing the principal economic indicator who have been designated by the agency head to provide technical explanations of the data, employees of the Executive Branch should not comment publicly on the data until at least one hour after the official release time.

8. *Preliminary Estimates and Revisions.* Deciding when to release a principal economic indicator requires the balancing of accuracy and timeliness. Agencies should not

withhold information needed to evaluate current economic conditions by imposing unnecessarily stringent accuracy requirements on preliminary estimates. They should, however, fully inform the public of the degree of inaccuracy that is accepted to accommodate timely release.

In the case of estimates based on probability samples, agencies should publish measures of uncertainty based on the sampling variance and consideration of nonsampling errors, e.g., a root-mean-square error estimate or its equivalent. In cases where the confidence interval about any single point estimate cannot be estimated, results should be presented only in the form of an interval estimate. Methods used to estimate upper and lower bound values that define the interval estimate should be designed to meet three objectives: (1) Preliminary interval estimates should include the final point estimate with high probability; (2) the width of the interval should be consistent with the error history of the indicator being estimated; and (3) the bound values should be consistent with any confidence intervals that can be estimated for components of the indicator.

For either point or interval estimates, agencies shall apply the following guidelines when issuing and evaluating preliminary data and revisions:

a. Agencies should clearly identify estimates as preliminary or revised;

b. If the difference between preliminary and final aggregate estimates, or the width of a preliminary interval estimate, is large relative to average period-to-period differences, the agency should either take steps to improve the accuracy of preliminary estimates or delay the release of estimates until a reliable estimate can be made;

c. If preliminary estimates show signs of a consistent bias (for example, if revisions are consistently in the same direction), the agency should take steps to eliminate this bias;

d. Revisions occurring for routine reasons, such as benchmarking and updating of seasonality factors, should be consolidated and released simultaneously;

e. Agencies should release routine revisions of a principal economic indicator only as part of the regular reporting schedule; and

f. Revisions occurring for other than routine reasons should be fully explained and should be released as soon as adjustments can be completed.

9. *Granting of Exceptions.* Prior to taking any action that may be contrary to the provisions of Attachment E, the head of a releasing agency shall consult with the Director of OMB. If the Director determines that the action is contrary to the provisions of this attachment, the head of the agency may apply for an exception. Any agency requesting an exception shall demonstrate that the proposed exception is necessary and consistent with the purposes of the Circular.

10. *Performance Evaluation.* Each agency that issues a principal Federal economic indicator shall submit a performance evaluation of that indicator to the Statistical Policy Office, Office of Information and Regulatory Affairs, OMB, every three years. A schedule for the performance evaluation of data series or estimates designated as principal Federal economic indicators will be prepared by the Statistical Policy Office. The evaluation shall address the following issues:

a. The accuracy and reliability of the series, e.g., the magnitude and direction of all revisions, the performance of the series relative to established benchmarks, and the proportion and effect of nonresponses or responses received after the publication of preliminary estimates;

b. The accuracy, completeness, and accessibility of documentation describing the methods used in compiling and revising the indicator;

c. The agency's performance in meeting the designated release schedule and the prompt release objective of this Circular;

d. The agency's ability to avoid disclosure prior to the scheduled release time; and

e. Any additional issues that the Director may specify in writing to the agency at least 6 months in advance of the scheduled submission date.

The Director will review the evaluation to determine whether the indicator is prepared and published in conformity with all OMB statistical policies, standards, and guidelines. OMB will include a summary of the year's evaluations and their reviews in the annual report to Congress required by 44 U.S.C. 3514.

ATTACHMENT F—Circular No. A-____

Use of Standard Classifications, Data Sources, and Definitions

1. This attachment replaces guidance on the use of standard classifications, data sources, and definitions previously contained in Statistical Policy Directives 5–17 and in the directive on "Comparability of Statistics on Business Size" (47 FR 21362, May 18, 1982), all of which this Circular rescinds. Nine of the standards established in these directives are retained in the Circular. Five others have been discontinued as government-wide statistical standards, either because they have not proven useful for the statistical purposes intended or because they are used by only one or two agencies in collecting and publishing statistics and can effectively be maintained by these agencies. The discontinued standards are a standard reference base period for Federal government general-purpose index numbers; standard Federal administrative regions; the standard industrial classification of enterprises; the standard classification of fields of science and engineering; and the standard gas pressure base.

2. Agencies should use standard statistical classifications, data sources, and definitions for the purposes and in the manner specified in this section.

a. *Metropolitan Statistical Areas*

All agencies that conduct statistical programs to collect and publish data for Metropolitan Statistical Areas (MSAs) should use the most recent definitions of Metropolitan Statistical Areas established by the Office of Management and Budget.

OMB establishes and maintains the definitions of Metropolitan Statistical Areas solely for statistical purposes. In periodically reviewing and revising the MSA definitions, OMB does not take into account or attempt to anticipate any nonstatistical uses that may be made of the definitions, nor will OMB modify the definitions to meet the requirements of any nonstatistical program.

Therefore, if an agency uses the MSA definitions in a nonstatistical program, it is that agency's responsibility to ensure that the definitions are appropriate for such use. In cases where an agency is publishing for comment a proposed regulation that would use the MSA definitions for a nonstatistical purpose, the agency should seek public comment on the proposed use of the MSA definitions. Agencies that use the MSA definitions in a nonstatistical program may modify the MSA definitions, exclusively for the purposes of that program. However, in order to avoid confusion with the standard statistical definitions, all such modifications should be clearly identified as deviations from the OMB standard definitions of Metropolitan Statistical Areas.

b. *Standard Industrial Classification*

All agencies that conduct statistical programs to collect and publish establishment data by industry type should use the Standard Industrial Classification (SIC), as published in the

most recent edition of the *Standard Industrial Classification Manual.*

OMB establishes and maintains the Standard Industrial Classification solely for statistical purposes. In periodically reviewing and revising the SIC, OMB does not take into account or attempt to anticipate any nonstatistical uses that may be made of the classification, nor will OMB modify the classification to meet the requirements of any nonstatistical program.

Therefore, if an agency uses the SIC in a nonstatistical program, it is that agency's responsibility to ensure that the classification is appropriate for such use. In cases where an agency is publishing for comment a proposed regulation that would use the SIC for a nonstatistical purpose, the agency should seek public comment on the proposed use of the SIC. Agencies that use the SIC in a nonstatistical program may modify the SIC, exclusively for the purposes of that program. However, in order to avoid confusion with the standard statistical classification, all such modifications should be clearly identified as deviations from the Standard Industrial Classification.

Any agency requesting or requiring an establishment to provide its SIC code as part of an information collection shall clearly identify within the information collection instrument or its directions the name, address, and telephone number of a unit within that agency that will assist respondents in determining their appropriate SIC code. When submitting any such information collection request to OMB for clearance, the agency shall disclose any modifications it has made in the SIC for the purposes of any nonstatistical program of which the information collection is a part and shall demonstrate that it has sufficient and appropriately-trained personnel to assist its respondents in determining their SIC codes.

c. *Standard Occupational Classification*

All agencies that conduct statistical programs to collect and publish data by occupation should use the Standard Occupational Classification (SOC), as published in the most recent edition of the *Standard Occupational Classification Manual.*

OMB establishes and maintains the Standard Occupational Classification solely for statistical purposes. In periodically reviewing and revising the SOC, OMB does not take into account or attempt to anticipate any nonstatistical uses that may be made of the classification, nor will OMB modify the classification to meet the requirements of any nonstatistical program.

Therefore, if an agency uses the SOC in a nonstatistical program, it is that agency's responsibility to ensure that the classification is appropriate for such use. In cases where an agency is publishing for comment a proposed regulation that would use the SOC for a nonstatistical purpose, the agency should seek public comment on the proposed use of the SOC. Agencies that use the SOC in a nonstatistical program may modify the SOC, exclusively for the purposes of that program. However, in order to avoid confusion with the standard statistical classification, all such modifications should be clearly identified as deviations from the Standard Occupational Classification.

Any agency requesting or requiring respondents to provide SOC codes as part of an information collection shall clearly identify within the information collection instrument or its directions the name, address, and telephone number of a unit within that agency that will assist respondents in determining their appropriate SOC codes. When submitting any such information collection request to OMB for clearance, the agency shall disclose any modifications it has made in the SOC for the purposes of any nonstatistical program of which the information collection is a part and shall demonstrate that it has sufficient and appropriately-trained personnel to assist its respondents in determining their SOC codes.

d. *Standard Business Size Categories*

When publishing statistics, agencies should use the size categories in the table below to classify reporting businesses by number of employees, revenues, or assets. Tabulations based on these categories should be accompanied by precise definitions of the variables used to measure size and of the type of reporting unit tabulated.

BUSINESS SIZE CATEGORIES

[Revenues or assets (dollars)]

	under	$25,000.
$25,000	under	$50,000.
$50,000	under	$100,000.
$100,000	under	$250,000.
$250,000	under	$500,000.
$500,000	under	$1 million.
$1 million	under	$2.5 million.
$2.5 million	under	$5 million.
$5 million	under	$10 million.
$10 million	under	$25 million.
$25 million	under	$50 million.
$50 million	under	$100 million.
$100 million	under	$250 million.
$250 million	under	$500 million.
$500 million	under	$1 billion.
$1 billion	under	$2.5 billion.
$2.5 billion	under	$5 billion.
$5 billion	or more	

BUSINESS SIZE CATEGORIES

[Employment (number of employees)]

0	(none)	
1	under	5
5	under	10
10	under	20
20	under	50
50	under	100
100	under	250
250	under	500
500	under	1,000
1,000	under	2,500
2,500	under	10,000
10,000	or more	

Agencies may combine adjacent size categories or truncate the size scale, if the limited scope of the data, the need to ensure the confidentiality of individual responses, or very large sampling variability makes it undesirable to publish data at the recommended level of detail. The reasons for such actions should be noted in the affected publication. Unless the categories are combined to ensure confidentiality of individual responses, agencies should, when they publish data that combine size categories, maintain unpublished estimates or internal documentation sufficient to allow reasonable retrospective estimates of the unpublished detail. Agencies may define additional partitions within the standard categories to meet particular analytical needs, but these should be in addition to, not in lieu of, the standard categories.

e. *Standard Payroll Reporting Period*

Agency requests to employers for data from their payroll records to be used for statistical purposes should refer to the payroll period that includes the twelfth day of the month.

f. *Source of Population Data for Use in the Administration of Federal Programs*

Agencies that are required by law to allocate Federal funds or determine eligibility for participation in a Federal program on the basis of the total population of State, county, or local units of government should use—to the extent permitted by law—the most current population estimates of the Bureau of the Census that have been published for all units of the relevant levels of government. If total population is used with other variables in a ratio or formula that is the basis of allocating Federal funds or determining eligibility for participation in a Federal program, unless otherwise required by law all the variables shall refer to the same year, which shall be the most recent year for which all data are available.

g. *Standard Source of Labor Force and Unemployment Estimates for Use in the Administration of Federal Programs*

Agencies that are required by law to allocate Federal funds or determine eligibility for participation in a Federal program on the basis of the employment, unemployment, or labor force participation levels or rates in the population or any subgroups of the population of State, county, or local units of government, should use—to the extent permitted by law—the most current estimates published by the Bureau of Labor Statistics that are available for all units of the relevant levels of government.

h. *Definition of Poverty*

Agencies that are required by law to use the definition of poverty established by the Office of Management and Budget, and agencies that publish statistical estimates of the number of persons, families, or households in poverty, should continue to use as the definition of poverty the annual income thresholds that for 1986 and prior years have been published by the Bureau of the Census in its Current Population Reports, P–60 series. For 1987 and subsequent years, the definition of poverty shall be the 1986 thresholds adjusted annually by the year-over-year change in the Consumer Price Index for all urban consumers.

i. *Racial and Ethnic Categories*

To the extent permitted by law, agencies should use the following categories for all purposes that require classifying people by racial and/or ethnic background. A person's racial and/or ethnic background is determined by the way in which the person chooses to be identified in his/her community.

Racial Categories:

American Indian or Alaska Native

Asian or Pacific Islander

Black

White

In establishing reporting systems and collecting data, agencies should permit individuals to identify themselves as "other" if they believe they do not fall into any of the categories listed above.

Ethnic Categories:

Hispanic

Not of Hispanic origin

Agencies may use other, more detailed categories as long as such categories can be aggregated into the basic categories listed in this section.

ATTACHMENT G—Circular No. A-___

Provision of Statistical Information to International Organizations

1. This attachment replaces Statistical Policy Directive No. 18, "Providing of Statistical Information to International Organizations," which this Circular rescinds.

2. In accordance with Section 1 of Executive Order 10033 of February 8, 1949, as amended (see 22 USCA 286f), the Director of OMB will determine, with the concurrence of the Secretary of State, what statistical information shall be provided in response to official requests received by the United States Government from any international organization of which the United States is a member, and will determine which agency or agencies shall prepare the statistical information to be provided. Agencies that have not been previously designated by the Director to prepare such information shall notify the Director and receive his concurrence before compiling or providing any statistical information for publication or use by any international organization of which the United States is a member.

[FR Doc. 88–696 Filed 1–19–88; 8:45 am]

BILLING CODE 3110–01–M

federal register

Wednesday
January 20, 1988

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 884 and 892

Radiology Devices; General Provisions and Classifications of 59 Devices; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 884 and 892

[Docket No. 78N-2742]

Radiology Devices; General Provisions and Classifications of 59 Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying 59 generic types of radiology devices. The preamble to this rule responds to comments received on the proposed regulations classifying these devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: February 19, 1988.

FOR FURTHER INFORMATION CONTACT: Harvey Rudolph, Center for Devices and Radiological Health (HFZ-83), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION:

Table of Contents

A. Background

In the **Federal Register** of January 29, 1982 (47 FR 4406), FDA published a proposed rule containing general provisions applicable to the classification of radiology devices and individual proposed regulations to classify 73 devices. FDA has withdrawn the proposals to classify 2 of the 73 proposed devices (September 17, 1982; 47 FR 41139) because FDA's Center for Drug Evaluation and Research regulates the radionuclide generator as a radiopharmaceutical drug, and the automatic contrast medium injector is essentially the same as, or is included in, the angiographic injector and syringe that has been classified into class II as a cardiovascular device (21 CFR 890.1650).

As to the remaining 71 proposed regulations, in this final rule FDA is classifying 59 devices, as follows: 13 devices into class I, 44 devices into class II, 1 device into class III, and, depending upon its intended use, 1 device into class I or class III. FDA is postponing classifications of certain versions or all versions of 14 devices, as described below under "D. Devices Not Being Classified at this Time."

FDA provided a period of 60 days, later extended to 90 days (March 19, 1982; 47 FR 11879), for interested persons to submit written comments on the proposed regulations. The comments received and FDA's responses are discussed below.

Classification of medical devices in commercial distribution is required by section 513 of the Medical Device Amendments of 1976 (Pub. L. 94-295) (the amendments) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c). The effect of classifying a device into class I is to require that the device continue to meet only the general controls applicable to all devices. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application that includes information concerning safety and effectiveness tests for the device. For a class III device not considered a new drug before the amendments that either was in commercial distribution before May 28, 1976, or that is substantially equivalent to a device that was in commercial distribution before that date, each application for premarket approval must be submitted to FDA on or before July 31, 1990, or within 90 days after promulgation of a separate regulation requiring premarket approval of the device, whichever occurs later. Devices that FDA previously regarded as new drugs, or newly offered devices that are not substantially equivalent to a device that was in commercial distribution before the amendments, are classified by statute into class III and already are required to have in effect an approved application for premarket approval. See section 520(1) of the act (21 U.S.C. 360j(1)).

The preamble to proposed regulations described the development of the general provisions and the proposed regulations classifying radiology devices and the activities of the Radiology Devices Panel, an FDA advisory committee that makes recommendations to FDA concerning the classification of radiology devices.

In April 1985, H.R. 2177 (99th Cong., 1st Sess.) was introduced in the U.S. House of Representatives. The bill was a legislative proposal of the Department of Health and Human Services. Among other things, the bill would have (1) amended the act to eliminate the statutory category of class II, (2) and the establishment of a performance standard one of the several general controls that may be made applicable to a device, and (3) streamlined the procedure for establishing standards set out in section 514 of the act. If legislation comparable to this bill becomes law, there will be two categories of devices, class I (general controls) and class II (premarket approval, currently class III). Class II devices would be redesignated as class I devices. Because this legislation included transitional provisions that translate classifications under the current law to classifications under the proposed law, FDA is continuing its issuance of classification rules under the current law.

B. FDA's Priorities for Establishing Performance Standards

In the **Federal Register** of October 23, 1985 (50 FR 43060), FDA published a notice, "Policy Statement; Class II Medical Devices," announcing its policy for setting priorities for initiating proceedings to establish performance standards for medical devices classified into class II. Under the amendments, FDA is required to establish performance standards for class II devices. At this time, however, FDA does not have the resources to establish performance standards for all of the devices already classified (or being classified) in class II. Under the amendments, FDA is using the regulatory controls of class I to regulate a device classified into class II until a performance standard is established under section 514 of the act (21 U.S.C. 360d) for the class II device.

In that notice, FDA announced it will consider the following factors when setting priorities for establishing performance standards for class II devices.

A. The seriousness of questions concerning the safety and effectiveness of the device; the risks associated with use of the device; the significance of a device to the public health; and the present and projected use of the device.

b. The recommendations of FDA's advisory committees.

c. The impact of an FDA guidelines or recommendation.

d. The effect of a Federal standard or other regulatory controls under an authority other than the act.

e. The impact of voluntary standards.

f. The impact of activities authorized under the general controls provisions of the act.

g. The effect of dissemination of information and education efforts.

h. The sufficiency of voluntary corrective actions.

i. Valid scientific evidence developed since classification.

j. The existence of a petition for reclassification.

k. The impact of any other factors that affect a device's safety or effectiveness.

C. Changes in the Name of the Radiology Device Advisory Committee

FDA has periodically reorganized its advisory panels for device classification. Most recently, on April 14, 1984, FDA established the Radiologic Devices Panel (the Panel) (see 49 FR 17446; April 24, 1984). The new panel performs the same functions with respect to radiology devices as did its predecessors, the Radiologic Devices Panel (1982–1984), the Obstetrics-Gynecology and Radiologic Devices Panel (1978–1982), and the Radiological Devices Classification Panel (1976–1978). Also, the charter for the new panel has been amended to include the functions of the Medical Radiation Advisory Committee.

D. Devices Not Being Classified at This Time

FDA is postponing classification of certain versions or all versions of the 14 AC-powered radiology devices listed below, to give the agency time to review additional data on the safety of electrically powered devices. Although FDA proposed to classify these devices into class II, it now is considering placing them in class I. When FDA does classify the devices not being classified at this time, it plans to use the same docket numbers.

Note that, as a result of postponing classifications of certain versions of two proposed thermographic devices and classifying other versions of these two devices in this final rule, each of these devices is counted twice—once as a device with classification postponed and also as a device now being classified.

FDA proposed to classify the AC-powered telethermographic system (§ 892.1450) into class II for certain intended uses and into class III for other intended uses. The agency is postponing the classification of this device intended for adjunctive diagnostic use and, in this final rule, is classifying the device intended for use as a sole diagnostic screening tool.

FDA proposed to classify the AC-powered versions of the liquid crystal thermographic system into class II or class III, depending upon the intended use of the device. FDA is postponing the classification of the AC-powered versions of the device intended for adjunctive diagnostic use. In this final rule, FDA is classifying all non-AC-powered versions of the device and is classifying the AC-powered versions of the device intended for use as a sole diagnostic screening tool.

Further, in this final rule, FDA is codifying classifications of the telethermographic system and the liquid crystal thermographic system in 21 CFR Part 884—Obstetrical and Gynecological Devices, because FDA believes this part to be a more appropriate place to publish these classifications in the Code of Federal Regulations.

The 14 devices whose classifications are being postponed are listed below.

Section No.	Device	Docket No.
1. 892.1100	Scintillation gamma camera.	78N-2743
2. 892.1110	Positron camera.	78N-2744
3. 892.1130	Nuclear whole body counter.	78N-2745
4. 892.1300	Nuclear rectilinear scanner.	78N-2750
5. 892.1320	Nuclear uptake probe.	78N-2752
6. 892.1330	Nuclear whole body scanner.	78N-2753
7. 892.1350	Nuclear scanning bed.	78N-2754
8. 892.1410	Nuclear electrocardiograph synchronizer.	78N-2760
9. 884.2980 (formerly 892.1450).	AC-powered telethermographic system.	78N-2762
10. 884.2982 (formerly 892.1480).	AC-powered liquid crystal thermographic system.	78N-2763
11. 892.1640	Radiographic film marking system.	78N-2773
12. 892.1890	Radiographic film illuminator.	78N-2795
13. 892.1900	Automatic radiographic film processor.	78N-2796
14. 892.1970	Radiographic ECG/respirator synchronizer.	78N-2803

E. Changes in Classifications of Devices

Based on the comments received and upon additional consideration of all information before the agency, FDA has placed each of the six devices listed below in a different class from that proposed. The agency's specific reasons for changing the classifications of these devices are provided in this preamble under "G. Summary of Comments On Classifications and FDA's Responses" in the respective paragraph number noted below after the name of the devices.

Section No.	Device	Proposed class	Final class
892.1370	Nuclear anthropomorphic phantom (see paragraph 3).	II	I
892.1380	Nuclear flood source phantom (see paragraph 3).	II	I
892.1400	Nuclear sealed calibration source (see paragraph 3).	II	I
892.1420	Radionuclide test pattern phantom (see paragraph 3).	II	I
892.5740	Radionuclide teletherapy source (see paragraph 3).	II	I
892.6500	Personnel protective shield (see paragraph 15).	II	I

FDA does not believe that it is necessary to issue new proposed regulations regarding these decisions. The purpose of publishing a proposed regulation and soliciting comments is to enable the agency to determine whether its proposed classification of a device was correct. After reviewing the comments submitted on a proposed regulation, the agency may be persuaded that its proposed classification is incorrect. Persons interested in the classification process should, therefore, anticipate that in a

final regulation a device may be placed in a class different from the one originally proposed. This possibility was specifically identified in the proposed general regulation for radiology devices (see 47 FR 4406; January 29, 1982). Persons who disagree with the final classification of a device may petition for reclassification of the device under Subpart C of Part 860 (21 CFR Part 860).

F. List of Radiology Devices

The list below shows for each radiology device the section of the Code of Federal Regulations at which classification of that device is being codified, the docket number of the corresponding proposed classification regulation, and the classification of each device in the final rule. The list includes the radiology devices for which final classifications are being postponed. For each of these devices, the section number of the Code of Federal Regulations is in parentheses, the name of the device is identified with footnote [1] and no classification is provided. See "D. Devices Not Being Classified At This Time" for a description of FDA's reasons for postponing classifications of these devices. The names of six devices on the list whose final classifications are different from the classifications proposed for these devices are identified by an asterisk (*). If no comments were received on a proposed regulation, FDA is adopting the proposed regulation without a change in classification of the device unless specified otherwise in this rule.

SUBPART B—DIAGNOSTIC DEVICES

Section No.	Device	Docket No.	Classification
(892.1100)	Scintillation (gamma) camera [1]	78N-2743	
(892.1110)	Positron camera [1]	78N-2744	
(892.1130)	Nuclear whole body counter [1]	78N-2745	
892.1170	Bone densitometer	78N-2746	II
892.1200	Emission computed tomography system	78N-2747	II
892.1220	Fluorescent scanner	78N-2748	II
(892.1300)	Nuclear rectilinear scanner [1]	78N-2750	
892.1310	Nuclear tomography system	78N-2751	II
(892.1320)	Nuclear uptake probe [1]	78N-2752	
(892.1330)	Nuclear whole body scanner [1]	78N-2753	
(892.1350)	Nuclear scanning bed [1]	78N-2754	
892.1360	Radionuclide dose calibrator	78N-2755	II
892.1370	Nuclear anthropomorphic phantom*	78N-2756	I
892.1380	Nuclear flood source phantom*	78N-2757	I
892.1390	Radionuclide rebreathing system	78N-2758	II
892.1400	Nuclear sealed calibration source*	78N-2759	I
(892.1410)	Nuclear electrocardiograph synchronizer [1]	78N-2760	
892.1420	Radionuclide test pattern phantom*	78N-2761	I
884.2980	Telethermographic system (proposed as § 892.1450)	78N-2762	III
(884.2980)	Telethermographic system, AC-powered, if intended for adjunctive diagnostic use (proposed as § 892.1450) [1].	78N-2762	
884.2982	Liquid crystal thermographic system (proposed as § 892.1480)	78N-2763	I, III
(884.2982)	Liquid crystal thermographic system, AC-powered, if intended for adjunctive diagnostic use (proposed as § 892.1480) [1].	78N-2763	
892.1540	Nonfetal ultrasonic monitor	78N-2765	II
892.1550	Ultrasonic pulsed doppler imaging system	78N-2766	II
892.1560	Ultrasonic pulsed echo imaging system	78N-2767	II
892.1570	Diagnostic ultrasonic transducer	78N-2768	II
892.1600	Angiographic X-ray system	78N-2769	II
892.1610	Diagnostic X-ray beam-limiting device	78N-2770	II
892.1620	Cine or spot fluorographic X-ray camera	78N-2771	II
892.1630	Electrostatic X-ray imaging system	78N-2772	II
(892.1640)	Radiographic film marking system [1]	78N-2773	
892.1650	Image-intensified fluoroscopic X-ray system	78N-2774	II
892.1660	Non-image-intensified fluoroscopic X-ray system	78N-2775	II
892.1670	Spot-film device	78N-2776	II
892.1680	Stationary X-ray system	78N-2777	II
892.1700	Diagnostic X-ray high voltage generator	78N-2778	II
892.1710	Mammographic X-ray system	78N-2779	II
892.1720	Mobile X-ray system	78N-2780	II
892.1730	Photofluorographic X-ray system	78N-2781	II
892.1740	Tomographic X-ray system	78N-2782	II
892.1750	Computed tomography X-ray system	78N-2783	II
892.1760	Diagnostic X-ray tube housing assembly	78N-2784	II
892.1770	Diagnostic X-ray tube mount	78N-2785	II
892.1820	Pneumoencephalographic chair	78N-2788	II
892.1830	Radiologic patient cradle	78N-2789	II
892.1840	Radiographic film	78N-2790	I
892.1850	Radiographic film cassette	78N-2791	II
892.1860	Radiographic film/cassette changer	78N-2792	II

[1] Classification postponed.

SUBPART B—DIAGNOSTIC DEVICES—Continued

Section No.	Device	Docket No.	Classification
892.1870	Radiographic film/cassette changer programmer	78N-2793	II
892.1880	Wall-mounted radiographic cassette holder	78N-2794	II
(892.1890)	Radiographic film illuminator[1]	78N-2795	
(892.1900)	Automatic radiographic film processor[1]	78N-2796	
892.1910	Radiographic grid	78N-2797	I
892.1920	Radiographic head holder	78N-2798	I
892.1940	Radiologic quality assurance instrument	78N-2800	I
892.1950	Radiographic anthropomorphic phantom	78N-2801	I
892.1960	Radiographic intensifying screen	78N-2802	I
(892.1970)	Radiograpic ECG/respirator synchronizer[1]	78N-2803	
892.1980	Radiologic table	78N-2804	II

[1] Classification postponed.

SUBPARTS C-E—[RESERVED]

SUBPART F.—THERAPEUTIC DEVICES

892.5050	Medical charged-particle radiation therapy system	78N-2806	II
892.5300	Medical neutron radiation therapy system	78N-2810	II
892.5650	Manual radionuclide applicator system	78N-2813	I
892.5700	Remote controlled radionuclide applicator system	78N-2814	II
892.5710	Radiation therapy beamshaping block	78N-2815	II
892.5730	Radionuclide brachytherapy source	78N-2817	II
892.5740	Radionuclide teletherapy source*	78N-2818	I
892.5750	Radionuclide radiation therapy system	78N-2819	II
892.5770	Powered radiation therapy patient support assembly	78N-2820	II
892.5780	Light beam patient position indicator	78N-2821	II
892.5840	Radiation therapy simulation system	78N-2822	II
892.5900	X-ray radiation therapy system	78N-2823	II
892.5930	Therapeutic X-ray tube housing assembly	78N-2826	II
892.6500	Personnel protective shield*	78N-2827	I

[1] Classification postponed.

G. Summary of Comments on Classifications and FDA's Responses

1. In FDA's proposed regulations, FDA proposed to classify most of the radiology devices into class II. Comments argued (arguments 1a through 1h) that FDA should classify into class I many of the radiology devices that it proposed be in class II. FDA's responses to each of these arguments follow:

1a. Some comments said that electrical shock from devices was not a significant risk to health. These comments said that electrically powered radiology devices should be classified into class I instead of class II as proposed.

FDA currently is reviewing additional data on safety of electrically powered devices. The agency is postponing classifications of those AC-powered radiology devices it proposed be in class II, if FDA believes that the general controls of class I alone are sufficient to control all risks to health presented by the AC-powered devices, including the risks of electrical shock. Thus, FDA tentatively agrees that it should consider classifying certain AC-powered devices into class I. However, as to those devices for which FDA believes that the general controls of class I alone are insufficient to control any risks to health presented by an AC-powered radiology device in addition to the risk of electrical shock, FDA believes that they should not be classified into class I. Accordingly, FDA is postponing classifications of the 14 proposed radiology devices listed earlier in this preamble under "D. Devices Not Being Classified At This Time" while the agency reviews additional data on safety of electrically powered devices. Also, in this final rule FDA is classifying certain AC-powered devices into class II or class III to control risks to health other than electrical shock presented by these devices.

1b. Some comments said that voluntary standards exist for many radiology devices. The comments requested that FDA classify devices subject of such voluntary standards into class I, instead of class II as proposed.

FDA disagrees with the comments. FDA classifies devices using statutory criteria in section 513 of the act. These statutory criteria do not include reliance on voluntary standards. In the Federal Register of October 23, 1985 (50 FR 43060), FDA published a final policy statement regarding class II devices. This statement identifies the factors that FDA takes into account in setting priorities for initiating proceedings to establish performance standards under section 514 of the act for class II devices. Among the factors FDA considers is the existence of an adequate adhered-to voluntary standard. FDA's final policy statement does not include a provision for reliance on voluntary standards, nor does it provide for promotion of such standards. See "B. FDA's Priorities for Establishing Performance Standards" at the beginning of this preamble.

1c. A comment said that, when FDA classifies a device into class II, this constitutes a formal determination by FDA that without a performance standard there is not reasonable assurance that a device is safe and effective. The comment said that many devices that FDA proposed be in class II should be classified into class I until a mandatory standard is available. The comment suggested that, when a mandatory standard is available for

such a device, FDA could change the classification of the device to class II.

FDA agrees that classification of a device into class II is a formal determination by FDA that a mandatory performance standard is necessary (in addition to the requirements of general controls) to provide reasonable assurance of the safety and effectiveness of a device. However, FDA disagrees that the agency could classify a device that meets the statutory criteria for class II into class I until a mandatory performance standard is available and then place the device into class II. Such a temporary classification is unnecessary because the act provides that, until a standard for a class II device is established under section 514 of the act, the device may be marketed subject only to the general controls of the act. Thus, the act provides for the same marketing conditions that would apply if FDA temporarily classified a proposed class II device in class I.

1d. Several general comments stated that FDA proposed to classify too many radiology devices in class II and requested that FDA place more devices in class I.

FDA agrees that certain of the devices that it proposed to classify in class II should be in class I. These devices are identified earlier in this preamble under "E. Changes in Classifications of Devices." FDA's reasons for making these changes are provided below in paragraphs 3 and 15. FDA's reasons for classifying other radiology devices into class II as proposed are provided in FDA's responses below to comments on specific devices. In "A. Background" above, this preamble describes the Department of Health and Human Services' legislative proposal to amend the act to eliminate the statutory category of class II.

1e. Some comments argued that FDA proposed to classify too many radiology devices in class II, because FDA failed to weigh probable benefit against probable risk during its preparation of proposed classification regulations for radiology devices. The comments requested that FDA place more devices in class I. These comments said that FDA's proposed regulations unfairly required manufacturers to prove that their devices do not present health risks.

FDA disagrees with the comments' argument that the proposed classifications of certain radiology devices into class II are unfair and unreasonable. FDA also disagrees that it failed to weigh the probable benefits from the use of devices against the probable risks of these devices. FDA believes that the criteria it uses to determine the safety of a device, which criteria are found in section 513(a)(2) of the act and in 21 CFR 860.7, are required by law and are reasonable.

Further, FDA believes that any risk of injury or illness is unreasonable when no evidence is available of probable benefit to the health of those persons for whose use the device is intended. This conclusion is supported by the legislative history of the Medical Device Amendments of 1976 (Pub. L. 94–295). In its report, the House Committee on Interstate and Foreign Commerce explained the meaning of "potential unreasonable risk" as follows:

> The phrase 'presents a potential unreasonable risk of illness or injury' has two significant features. First, the requirement that a risk be unreasonable contemplates a balancing of the possibility that illness or injury will occur against benefits from use. Second, the risk need only be a potential one. The risk may be one demonstrated by reported injuries or it may simply be foreseeable. The fact that a device is being marketed without sufficient testing is an adequate basis for the Secretary's conclusion that the device presents a potential unreasonable risk to health.

H. Rept. 94–853, 94th Cong., 2d Sess. 36 (1976).

Further, the following language in 21 CFR 860.7(d)(1) describes the criteria FDA uses to determine the safety of a device:

> There is reasonable assurance that a device is safe when it has been determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions of use.

1f. As is clear, Congress contemplated imposition of the burden of proof of safety on the manufacturer. Some comments said that most of the radiology devices that FDA proposed be in class II should be in class I because manufacturers' compliance with the general controls of class I, such as the requirements of the current good manufacturing practice (CGMP) regulations (21 CFR Part 820), would provide reasonable assurance of the safety and effectiveness of the devices. It is unnecessary, the comments argued, to establish performance standards for these devices.

FDA disagrees that manufacturers' compliance with general controls would provide reasonable assurance of the safety and effectivness of many of the radiology devices that FDA proposed be in class II. FDA believes that, for certain devices, performance standards to control biocompatibility, electrical safety, sterility, radiation emission, or other characteristics sometimes are necessary to provide reasonable assurance of the safety and effectiveness of such devices. Also, FDA believes that certain devices should be classified into class III under the relevant statutory criteria.

1g. A number of comments requested that FDA classify more radiology devices into class I, because classifying such devices into class II would slow development of new devices.

FDA disagrees with the comments. Classification regulations have little immediate impact on device development because they apply only to already developed and marketed products. See the discussion under "N. Economic Impact" later in this preamble.

1h. Some comments requested that many devices that FDA proposed be in class II instead be placed in class I because these devices are intended for use by health care professionals, and establishment of mandatory performance standards for these radiology devices is unnecessary.

FDA disagrees with the comments. The agency bases its classifications of devices on characteristics of the devices themselves under criteria established in the statute. FDA's classifications are intended to assure that the radiology devices being used by health care professionals perform as intended, and otherwise provide reasonable assurance of the safety and effectiveness of devices. FDA's criteria and process for classifying devices are described earlier in this paragraph.

2. Some comments argued that several diagnostic X-ray systems or components of diagnostic X-ray systems that are listed below and that FDA proposed to be in class II are adequately regulated by the performance standard for diagnostic X-ray systems and their major components (21 CFR 1020.30 through 1020.32) promulgated under the Radiation Control for Health and Safety Act of 1968 (RCHSA) (Pub. L. 90–602, 42 U.S.C. 263f). The comments noted that all of the risks to health identified in the proposed regulations are addressed by the performance standard for such devices. The comments also argued that additional standards issued under section 514 of the act would be unnecessary, duplicative, and would not improve the safety and effectiveness of such devices. These comments recommended that FDA classify the radiology devices listed below (all of

which are subject to the performance standards in 21 CFR 1020.30 through 1020.32 and 21 CFR 1040.10) in class I rather than class II.

Section No.	Device	Proposed rule: FR page No.
892.1600...	Angiographic X-ray system.	4423
892.1610...	Diagnostic X-ray beam-limiting device.	4424
892.1630...	Electrostatic X-ray imaging system.	4424
892.1650...	Image-intensified fluoroscopic X-ray system.	4425
892.1660...	Non-image-intensified fluoroscopic X-ray system.	4425
892.1670...	Spot-film device	4426
892.1680...	Stationary X-ray system	4426
892.1700...	Diagnostic X-ray high voltage generator.	4427
892.1710...	Mammographic X-ray system.	4427
892.1720...	Mobile X-ray system	4428
892.1730...	Photofluorographic X-ray system.	4428
892.1740...	Tomographic X-ray system.	4428
892.1750...	Computed tomography X-ray system.	4429
892.1760...	Diagnostic X-ray tube housing assembly.	4429
892.1830...	Radiologic patient cradle.	4430
892.1860...	Radiographic film/cassette changer.	4432
892.1870...	Radiographic film/cassette changer programmer.	4433
892.1880...	Wall-mounted radiographic cassette holder.	4433
892.5780...	Light beam patient position indicator.	4441

FDA believes that performance standards under section 514 of the act are necessary (in addition to those under the Radiation Control for Health and Safety Act) to control the risks to health presented by the 19 devices listed above that were identified in the proposed regulations (47 FR 4406 at the page numbers shown above). FDA also believes that sufficient information is available to establish such standards. Accordingly, FDA is adopting the proposed regulations for the devices listed above with minor clarifying changes.

3. A number of comments requested that FDA classify the 13 devices listed below in this paragraph into class I instead of class II as proposed, arguing that the risks to health presented by these devices are adequately controlled through the licensing requirements of the Nuclear Regulatory Commission (NRC) and the Agreement States. "Agreement States" are those states which have entered into an effective agreement with the NRC or its predecessor, the Atomic Energy Commission, under section 247b of the Atomic Energy Act of 1954, as amended (73 Stat. 689).

FDA agrees in part and disagrees in part with these comments, as shown below in responses 3a and 3c.

Response 3a. FDA agrees with the comments regarding the five devices listed below.

Section No.	Device
892.1370...	Nuclear anthropomorphic phantom.
892.1380...	Nuclear flood source phantom.
892.1400...	Nuclear sealed calibration source.
892.1420...	Readionuclide test pattern phantom.
892.5740...	Radionuclide teletherapy source.

The establishment of performance standards under section 514 of the act for the devices listed above is unnecessary, because the general controls of class I, particularly the controls of the current good manufacturing practices regulations in 21 CFR Part 820, in conjunction with the regulatory controls of NRC and the Agreement States, provide reasonable assurance of the safety and effectiveness of the devices. NRC and agreement states ensure that sources are encapsulated, sealed, and accurately calibrated. Sealing of sources and compliance with CGMP's provide adequate assurance of safety. Accordingly, FDA is adopting the proposed regulations for each of the five devices listed above with changes in classification from class II into class I and minor clarifying changes.

Response 3b. FDA disagrees with the comments regarding the five devices listed below.

Section No.	*Device*
892.1200...	Emission computed tomography system.
892.1220...	Fluorescent scanner.
892.1310...	Nuclear tomography system.
892.1360...	Radionuclide dose calibrator.
892.5710...	Radiation therapy beam shaping block.

Neither NRC nor the governments of the states regulate the five devices listed above. FDA believes that performance standards under section 514 of the act are necessary to control the risks to health presented by these devices that were identified in the proposed regulations. FDA also believes that sufficient information is available to establish such standards. Accordingly, FDA is adopting the proposed regulations for the five devices listed above with minor clarifying changes.

Response 3c. FDA disagrees with the comments regarding the three devices listed below.

Section No.	*Device*
892.1170...	Bone densitometer.
892.5700...	Remote controlled radionuclide applicator system.
892.5730...	Radionuclide brachytherapy source.

Although NRC and agreement states do regulate the radionuclides that may be contained in, or used with, these devices, NRC does not control the overall safety or effectiveness of these devices, and there is no uniformity among the states in the degree of regulatory control provided regarding these three devices. In addition, the radionuclide brachytherapy source is intended to be occasionally implanted in the human body. Section 513(d)(2)(B) of the act (21 U.S.C. 360c(d)(2)(B)) requires that FDA classify all implants into class III unless the agency determines that, for a particular implant, premarket approval is unnecessary to provide reasonable assurance of its safety and effectiveness. FDA believes that insufficient evidence of safety and effectiveness is now available to classify into class I any radiology device intended to be implanted. Therefore, performance standards under section 514 of the act are necessary for all three devices to control the risks to health identified in the proposed regulations for these devices. FDA also believes that sufficient information is available to establish such standards. Accordingly, FDA is adopting the proposed regulations for the three devices listed above with minor clarifying changes.

4. Other comments requested that FDA classify the 11 devices listed below into class I instead of class II as proposed, arguing that the devices could safely be placed in class I, because voluntary standards exist for these devices.

Section No.	Device	Proposed rule; FR page No.
892.1310...	Nuclear tomography system.	4415
892.1540...	Nonfetal ultrasonic monitor.	4421
892.1550...	Ultrasonic pulsed doppler imaging system.	4422
892.1560...	Ultrasonic pulsed echo imaging system.	4422
892.1570...	Diagnostic ultrasonic transducer.	4423
892.5050...	Medical charged particle therapy system.	4438
892.5300...	Medical neutron radiation therapy system.	4438
892.5700...	Remote controlled radionuclide applicator system.	4439
892.5710...	Radiation therapy beam shaping block.	4439
892.5730...	Radionuclide brachytherapy source.	4440
892.5750...	Radionuclide teletherapy system.	4440

FDA disagrees with the comments for the reasons given in paragraph 1b. See also the discussion at the beginning of this preamble under "B. FDA's Priorities For Establishing Performance Standards." FDA believes that performance standards under section 514 of the act are necessary to control the risks to health presented by these 11 devices that were identified in the proposed regulations (47 FR 4406 and at page numbers shown above). FDA also believes that sufficient information is available to establish such standards. Accordingly, FDA is adopting the proposed regulations for the 11 devices listed above with minor clarifying changes.

5. Yet more comments requested that FDA classify the 14 devices listed below into class I instead of class II as proposed, arguing that these electrically powered devices do not present a significant risk to health from electrical shock.

Section No.	Device
892.1170...	Bone densitometer.
892.1200...	Emission computed tomography system.
892.1220...	Fluorescent scanner.
892.1310...	Nuclear tomography system.
892.1540...	Nonfetal ultrasonic monitor.
892.1550...	Ultrasonic pulsed doppler imaging system.
892.1560...	Ultrasonic pulsed echo imaging system.
892.1570...	Diagnostic ultrasonic transducer.
892.1620...	Cine or spot fluorographic X-ray camera.
892.1630...	Electrostatic X-ray imaging system.
892.1640...	Radiologic film marking X-ray system.
892.1770...	Diagnostic X-ray tube mount.
892.1820...	Pneumoencephalographic chair.
892.5700...	Remote controlled radionuclide applicator system.

FDA believes that 13 of the devices listed above present risks to health in addition to the risk of electrical shock that require establishment of performance standards. Except for the radiologic film marking X-ray system (§ 892.1640), FDA believes that all of the devices listed above are intended for use during application of radiation to the body for diagnostic or therapeutic purposes. FDA believes that performance standards under section 514 of the act are necessary to control the risks to health presented by these devices. FDA also believes that sufficient information is available to establish such standards.

In the case of the radiologic film marking X-ray system (§ 892.1640), FDA is not aware of any currently marketed system which uses other than a visible light source to place identification information on X-ray film. Thus, the radiation risk to health identified by the panel no longer exists. Accordingly, FDA is postponing classification of the device, as it presents only the risk of electrical shock. The agency will repropose to classify this device as the radiologic film marking system with clarifying changes in its identification. See "D. Devices Not Being Classified at This Time." However, FDA is adopting the proposed regulations for the 13 other devices listed above with minor clarifying changes.

6. Some other comments requested that FDA classify the two devices named below into class I instead of class II as proposed, because, the comments said, classification into class II would inhibit the development of new phantoms by increasing development costs: § 892.1370 *Nuclear anthropomorphic phantom* and § 892.1420 *Radionuclide test pattern phantom.*

As to the comments' request that the two devices be in class I, FDA agrees but not for the reasons given by the comments. (See paragraphs 1g and 3a.)

7. Some comments requested that FDA classify the three devices listed below into class I instead of class II as proposed, arguing that the RCHSA performance standard (21 CFR 1020.30 through 1020.33) and the Occupational Safety and Health Administration's (OSHA) standards regarding safety in the workplace provide adequate regulatory control of the safety of the devices. The comments said that section 514 standards for the three devices would be unnecessary.

Section No.	Device
892.5840...	Radiation therapy simulation system.
892.5900...	X-ray radiation therapy system.
892.5930...	Therapeutic X-ray tube housing assembly.

FDA disagrees with the comments. FDA has recognized the importance of the safety and effectiveness of the radiation therapy simulation system and has amended the diagnostic X-ray equipment performance standard specifically to exclude this device from radiation safety performance requirements that are inappropriate or that would hamper the effectiveness of this device. The accuracy of the simulation, which includes accurate positioning, determines the effectiveness of the subsequent therapy, which was the concern of the Panel. Improper function of this device may result in excessive patient exposure and tissue damage. The comment mistakenly states that the RCHSA standard addresses this risk. The RCHSA performance standard at 21 CFR 1020.30 through 1020.33 does apply to a radiation therapy simulation system, but this standard only addresses radiation safety and does not assure that the radiation therapy simulation system is safe and effective for its intended uses. FDA believes that a performance standard under section 514 of the act is necessary for the radiation therapy simulation system.

The RCHSA performance standard does not apply to the other two devices named above: The X-ray radiation therapy system and the therapeutic X-ray tube housing assembly. Further, the OSHA standards do not control the safety and effectiveness of the three devices regarding application of radiation to patients. For these reasons, FDA believes that a performance standard under section 514 of the act is necessary for each of the three devices

to provide reasonable assurance of the safety and effectiveness of the devices and to control the risk to health of excessive radiation from improper function presented by the devices. FDA believes that sufficient information is available to establish such performance standards. Accordingly, FDA is adopting the proposed regulations for the three devices listed above with minor clarifying changes.

8. A comment said that the radionuclide dose calibrator (§ 892.1360) is not a medical device and should not be classified.

FDA disagrees with the comment. FDA believes that the radionuclide dose calibrator meets the definition of a device in section 201(h) of the act (21 U.S.C. 321(h)), because it is intended for medical purposes. Radionuclide dose calibrators are used to determine the dosage strength of a radionuclide before the radionuclide is administered to a patient. Therefore, a radionuclide dose calibrator is a component, part, or accessory to a medical device and is, thus, itself a device as defined by section 201(h) of the act. Accordingly, FDA is adopting the proposed regulation for the radionuclide dose calibrator with minor clarifying changes.

9. A comment requested that FDA classify the nuclear anthropomorphic phantom into class I instead of class II as proposed, because many different versions of the device are being used, and the device is intended for use with other devices that emit radiation throughout a large range of frequencies.

Unlike the comment, FDA believes that it would be possible to establish a performance standard for the device under section 514 of the act. However, FDA has decided that such a standard would be unnecessary. FDA is classifying the device into class I rather than class II, for the reasons provided in paragraph 3a.

10. Section 892.1480; Liquid crystal thermographic system—non-AC-powered and AC-powered.

If the device is intended for adjunctive use in diagnostic screening for detection of breast cancer or other uses, FDA proposed that the device be classified as follows: If non-AC-powered, class I; if AC-powered, class II. If the device (non-AC-powered or AC-powered) is intended for use alone in diagnostic screening for detection of breast cancer, FDA proposed that the device be classified into class III.

10a. Some comments requested that (1) the non-AC-powered device be classified into class I as proposed if it is used in diagnostic evaluations as an adjunct to other clinically accepted techniques and (2) the non-AC-powered device be classified into class II instead of class III as proposed if it is used alone in diagnostic evaluations. These comments gave no reasons for the suggested change in classification.

FDA agrees that the general controls of class I by themselves would provide reasonable assurance of the safety and effectiveness of the non-AC-powered liquid crystal thermographic system if the device is intended for diagnostic use as an adjunct to other generally accepted diagnostic procedures. Thus, FDA agrees that the device should be placed in class I if it is intended for adjunctive diagnostic use for various conditions or uses, e.g., in the diagnosis of breast cancer if the device is intended as an adjunct to clinical physical examinations including breast palpation and X-ray mammography.

However, FDA disagrees that the non-AC-powered liquid crystal thermographic system should be classified into class II if it is intended as a sole diagnostic tool (including screening tool) for diagnosis of breast cancer and other diseases. If the device is intended to be used as a sole diagnostic tool, FDA believes that the device cannot be classified as a class II device because there is insufficient information for the establishment of performance standards to provide reasonable assurance of the safety and effectiveness of the device.

10b. One comment suggested that FDA not classify the liquid crystal thermographic system in Part 892 with radiology devices because the device does not emit radiation.

FDA agrees that, for the reason given in the comment, the device should not be codified in Part 892. In this final rule, FDA is codifying the classification of certain versions of the device in 21 CFR Part 884—Obstetrical and Gynecological Devices (§ 884.2982). FDA also is postponing classification of the AC-powered version of the liquid crystal thermographic system intended for certain uses. See "D. Devices Not Being Classified At This Time." When FDA classifies the proposed but postponed versions of the device, the agency will codify its classification in Part 884 using the same docket number.

10c. Comments said that the risk to health of electrical shock is not a significant risk for the AC-powered device. These comments said that the AC-powered and non-AC-powered versions of the device should be placed in class I because no meaningful differences in risks to health exist between the non-AC-powered and AC-powered versions of the device.

FDA tentatively agrees that it is unnecessary to establish performance standards under section 514 of the act to control the risk to health of electrical shock presented by the AC-powered version of the liquid crystal thermographic system intended for certain adjunctive uses. Thus, FDA is postponing classification of the AC-powered version of the device if it is intended for certain uses, and the agency is considering classifying the device intended for these uses into class I. See "D. Devices Not Being Classified At this Time." For the reasons provided below, FDA disagrees that the proposed device should be classified into class I for all intended uses.

10d. Several comments stated that the efficacy of thermography in early detection of breast cancer can be significantly influenced by the degree of expertise and experience of the users. These comments said that the device should be in class I because the skill of the users assured safe and effective performance of the device.

FDA disagrees with the comments. Under the statute, FDA classifies devices based on attributes of the devices, including adequacy of labeling for their intended uses. Although user skill may enhance results obtained for use of a device, in determining the safety and effectiveness of a device for purposes of classification, FDA assumes that the users possess average skills.

10e. One comment requested that FDA classify both the non-AC-powered and the AC-powered versions of the liquid crystal thermographic system into class I for all intended uses instead of into class I, class II, or class III as proposed, depending upon certain intended uses of the device. The comment said that classification of the device, if it is intended for use as the only screening tool in the early detection of breast cancer, into class III would essentially eliminate its use.

FDA disagrees with the comment. Classification of a preamendments device into class II or class III under section 513 (c) and (d) of the act (21 U.S.C. 360c (c) and (d)) has no immediate impact on the commercial availability of the device. For each device classified into class II or class III under these sections of the act, FDA must publish an additional proposed and final regulation allowing further public comment before the agency can establish a performance standard (21 U.S.C. 360d) or require premarket approval (21 U.S.C. 360e) for the device. See the discussion later in this preamble entitled "N. Economic Impact." Further, the essential purpose of the classification procedures provided by Congress is to provide reasonable

assurance of the safety and effectiveness of devices. Continued commercial availability of devices is not one of the criteria that FDA may consider when classifying devices.

10f. Some comments recommended that the liquid crystal thermographic system intended for consumer use, whether over-the-counter or prescription, be classified into class III.

FDA agrees with the comment. The agency is unaware that anyone has ever marketed the liquid crystal thermographic system for diagnostic use by consumers. If such a device were considered for marketing for diagnostic use by consumers, it would not be substantially equivalent to the preamendments device subject to the proposed rulemaking. Accordingly, FDA believes that a liquid crystal thermographic system intended for diagnostic use by consumers would be a new, not substantially equivalent device, classified by statute into class III. Further, before testing a liquid crystal thermographic system with such new intended uses on humans for purposes of gathering data to submit to FDA to obtain premarket approval, manufacturers should obtain from FDA an investigational device exemption for the device as specified in 21 CFR Part 812.

10g. Other comments indicated that FDA's statements in the proposed regulations about the unacceptably high levels of false-negative and false-positive results from using the liquid crystal thermographic system for diagnosing breast cancer were not accurate. One comment said that the false-negative rate for breast cancer detection using thermography is less than the false-negative rate using X-ray mammography. Another comment said that the high false-positive rate for breast cancer detection using thermography is of greater significance than the false-negative rate.

Some comments stated that the device should be in class I instead of class III when it is intended only for screening and detection of breast cancer. The comments stated that there is adequate evidence to show the safety and effectiveness of the device for this intended use. The comments submitted (or cited) a number of published studies to support their requests that the device be in class I.

FDA acknowledges the importance of both the false-negative and the false-positive rates when evaluating the efficacy of any cancer detection method. FDA is concerned that (1) based upon a false-negative thermogram, a woman may not seek proper medical attention, and (2) a false-positive result may cause a woman to lose faith in medicine and not participate in further routine clinical screening programs for cancer. Therefore, both the false-negative and the false-positive rates are important in evaluating the safety and effectiveness of thermographic devices. FDA has reviewed the data submitted and cited by the comments and other data and available information and has observed no scientific consensus regarding the safety and effectiveness of thermography when used alone in diagnosis of cancer. Based upon available data, FDA believes that thermography in the detection of breast cancer is appropriate only as an adjunct to other clinically accepted independent screening techniques, i.e., a clinical physical examination including palpation and X-ray mammography. Thermography may be useful to detect breast temperature variations which may be indicative of abnormalities. But its effectiveness, when used alone in the specific detection of breast cancer, has not been demonstrated.

To summarize, FDA is adopting the proposed regulation for the nonelectrically powered liquid crystal thermographic system intended for adjunctive use in diagnostic screening for detection of breast cancer or other diagnostic uses without a change in classification of the device from that proposed. Although FDA tentatively agrees that the AC-powered version of the liquid crystal thermographic system should be placed in class I if it is intended for adjunctive diagnostic use, for the reasons given above in paragraph 10c, FDA is postponing classification of the AC-powered version of the device if it is intended for adjunctive diagnostic use.

FDA believes that there is insufficient information to determine whether or not the general controls of class I by themselves are sufficient to provide reasonable assurance of the safety and effectiveness of the non-AC-powered or AC-powered liquid crystal thermographic system intended for use as the sole diagnostic tool in screening for breast cancer or other conditions and that insufficient information exists for the establishment of performance standards to provide such assurance. FDA believes that this device, when used as the only screening tool for the diagnosis of breast cancer or other conditions, is of substantial importance in preventing impairment of human health. Because of the potential for high levels of false-negative and false-positive test results, the device presents a potential unreasonable risk of illness or injury. Accordingly, FDA is adopting the proposed regulation classifying the nonelectrically powered and the electrically powered liquid crystal thermographic system intended as the only screening tool for the diagnosis of breast cancer or other conditions into class III with clarifying change in the identification of the device.

10h. FDA recognizes that the liquid crystal thermographic system is being commercially distributed for use in a wide range of diagnostic applications where variations in skin temperature may occur, such as (a) peripheral vascular disease, (b) musculoskeletal disorders, (c) extracranial cerebral vascular disease, (d) abnormalities of the thyroid gland, and (e) various neoplastic and inflammatory conditions. FDA believes that the liquid crystal thermographic system (non-AC-powered and AC-powered) intended for adjunctive use in diagnostic screening for breast cancer or other uses is a preamendments device. FDA believes that this preamendments device, if intended for use as the sole screening tool in diagnostic screening for breast cancer or other uses, has been substantially altered and has undergone a major change or modification of its intended use (see 21 CFR 807.85) and is not substantially equivalent to the liquid crystal thermographic system in commercial distribution on the enactment date of the amendments.

Because FDA believes that the liquid crystal thermographic system is being commercially distributed while intended for a new use, i.e., use unaided in diagnostic screening, FDA is codifying the statutory classification of the new device into class III for such new use. See § 884.3(b). Accordingly, the regulation classifying this class III device states that, as of the enactment date of the amendments, May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed.

11. Section 892.1450; Telethermographic System—AC-powered.

If the device is intended for adjunctive use in diagnostic screening for detection of breast cancer, FDA proposed that the device be classified in class II. If the device is intended for use alone in diagnostic screening for detection of breast cancer, FDA proposed that the device be classified in class III.

11a. One comment suggested that FDA not classify the telethermographic system in Part 892 with radiology devices because the device does not emit radiation.

FDA agrees that, for the reason given in the comment, the device should not be codified in Part 892. In this final rule, FDA is codifying the classification of

one version of the proposed device in 21 CFR Part 884—Obstetrical and Gynecological Devices (§ 884.2980). FDA also is postponing classification of the telethermographic system intended for certain uses. See "D. Devices Not Being Classified At This Time." When FDA classifies the proposed but postponed version of the device, the agency will codify its classification in Part 884 using the same docket number.

11b. Some comments on the proposed regulation said that the device should be placed in class I for all intended uses, because the risk to health of electric shock is not a significant risk for this device.

FDA tentatively agrees that it is unnecessary to establish performance standards under section 514 of the act to control the risk to health of electric shock presented by the telethermographic system. Thus, FDA is postponing classification of the telethermographic system, if the device is intended for certain uses, and the agency is considering classifying the device intended for these uses into class I. See "D. Devices Not Being Classified At This Time." For the reasons provided below, FDA disagrees that the proposed device should be classified into class I for all intended uses.

11c. Several comments stated that the efficacy of thermography in early detection of breast cancer can be significantly influenced by the degree of expertise and experience of the users. These comments said that the device should be in class I because the skill of the users assured safe and effective performance of the device.

FDA disagrees with the comments. Under the statute, FDA classifies a device based on attributes of the device, including adequacy of labeling for its intended uses. Although user skill may enhance results obtained from use of a device, in determining the safety and effectiveness of a device for purposes of classification, FDA assumes that users possess average skills.

11d. One comment requested that FDA classify the telethermographic system into class I for all intended uses instead of into class II or class III as proposed, depending upon certain intended uses of the device. The comment said that classification of the device into class III if it is intended for use as the only screening tool in the early detection of breast cancer would essentially eliminate its use.

FDA disagrees with the comment. Classification of a preamendments device into class II or class III under section 513 (c) and (d) of the act has no immediate impact on the commercial availability of the device. For each device classified into class II or class III under this section of the act, FDA must publish and additional proposed and final regulation allowing further public comment before the agency can establish a performance standard (21 U.S.C. 360d) or require premarket approval (21 U.S.C. 360e) for the device. See the discussion later in this preamble entitled "N. Economic Impact." Further, the essential purpose of the classification procedures provided by Congress is to provide reasonable assurance of the safety and effectiveness of the devices. Continued commerical availability of devices is not one of the criteria that FDA may consider when classifying devices.

11e. Some comments recommended that the telethermographic system intended for consumer use, whether over-the-counter or prescription, be classified into class III.

FDA agrees with the comment. The agency believes that the telethermographic system intended for diagnostic use by consumers has never been marketed and that, if the device is intended for diagnostic use by consumers, it would not be substantially equivalent to the preamendments device subject to the proposed rulemaking. Accordingly, FDA believes that a telethermographic system intended for diagnostic use by consumers would be a new significant risk device. Before testing a telethermographic device with such new intended uses on humans for purposes of gathering data to submit to FDA to obtain premarket approval, manufacturers should obtain from FDA an investigational device exemption for the device as specified in 21 CFR Part 812.

11f. Other comments indicated that FDA's statements in the proposed regulations about the unacceptably high levels of false-negative and false-positive results from using the telethermographic system for diagnosing breast cancer were not accurate. One comment said that the false-negative rate for breast cancer detection using thermography is less than the false-negative rate using X-ray mammography. Another comment said that the high false-positive rate for breast cancer detection using thermography is of greater significance than the false-negative rate.

Some comments stated that the device should be in class I instead of class III when it is intended only for screening and detection of breast cancer. The comments stated that adequate evidence exists to show the safety and effectiveness of the device for this intended use. The comments submitted (or cited) a number of published studies to support their requests that the device be in class I.

FDA acknowledges the importance of both the false-negative and the false-positive rates when evaluating the efficacy of any cancer detection method. FDA is concerned that (1) based upon a false-negative thermogram, a woman may not seek proper medical attention, and (2) a false-positive result may cause a woman to lose faith in medicine and not participate in further routine clinical screening programs for cancer. Therefore, both the false-negative and the false-positive rates are important in evaluating the safety and effectiveness of thermographic devices. FDA has reviewed the data submitted and cited by the comments and other data and information available and has observed a lack of scientific consensus regarding the safety and effectiveness of thermography when used along in diagnosis of cancer. Based upon available data, FDA believes that thermography in the detection of breast cancer is appropriate only as an adjunct to other clinically accepted independent screening techniques, i.e., a clinical physical examination including palpation and X-ray mammography. Thermography may be useful to detect breast temperature variations which may be indicative of abnormalities. Thermography's effectiveness, when used alone in the specific detection of breast cancer, has not been demonstrated.

To summarize, although FDA tentatively agrees that the telethermographic system should be placed in class I if it is intended for adjuctive diagnostic use, for the reasons given above in paragraph 11b, FDA is postponing classification of the device if it is intended for adjunctive diagnostic use. Further, FDA believes that there is insufficient information to determine whether or not the general controls of class I by themselves are sufficient to provide reasonable assurance of the safety and effectiveness of the telethermographic system intended for use as the sole diagnostic tool in screening for breast cancer or other conditions and that insufficient information exists for the establishment of performance standards to provide such assurance. FDA believes that this device, when used as the only screening tool for the diagnosis of breast cancer or other conditions, is of substantial importance in preventing impairment of human health. Because of the potential for high levels of false-negative and false-positive test results, the device presents a potential unreasonable risk of illness or injury. Accordingly, FDA is

adopting the proposed regulation classifying the telethermographic system intended as the only screening tool for the diagnosis of breast cancer or other conditions into class III with clarifying changes in the identification of the device.

11g. FDA recognizes that the telethermographic system is being commercially distributed for use in a wide range of diagnostic applications where variations in skin temperature may occur, such as (a) peripheral vascular disease, (b) musculoskeletal disorders, (c) extracranial cerebral vascular disease, (d) abnormalities of the thyroid gland, and (e) various neoplastic and inflammatory conditions. FDA believes that the telethermographic system intended for adjunctive use in diagnostic screening for breast cancer or other uses is a preamendments device. FDA believes that this preamendments device, if intended for use as the sole tool in diagnostic screening for breast cancer or other uses, has been substantially altered and has undergone a major change or modification of its intended use (see 21 CFR 807.85) and is not substantially equivalent to the telethermographic system in commercial distribution on the enactment date of the amendments.

Because FDA believes that the telethermographic system is being commercially distributed while intended for a new use, i.e., used unaided in diagnostic screening, FDA is codifying the statutory classification of the new device into class III for such new use. See § 884.3(b). Accordingly, the regulation classifying this class III device states that, as of the enactment date of the amendments, May 28, 1976, an approval under section 515 of the act is required before this device may be commercially distributed.

12. Section 892.1820; Pneumoencephalographic chair; proposed class II.

A comment on the proposed regulation requested that FDA classify the device into class I instead of class II, arguing that the adjustment of the tension of the restraint straps to prevent constriction of the patient's blood vessels is under control of the medical staff while the device is in use and that structural or control mechanism failure is not a significant hazard for this device.

FDA believes that, whether or not the comment is correct, the agency must classify the device into class II because the Panel cited additional risks to health, i.e., electromechanical malfunction or difficulties in administering contrast agents, in addition to the risk of vascular constriction. FDA believes that the identified risks would be minimized by establishing a performance standard for the device and that general controls alone are insufficient to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that sufficient information is available to develop a performance standard for the device. Accordingly, FDA is adopting the proposed regulation classifying the pneumoencephalographic chair with minor clarifying changes.

13. Section 892.1850; Radiographic film cassette; proposed class II.

Some comments on the proposed regulation requested that FDA classify the device into class I instead of class II as proposed, arguing that the risk to health of misdiagnosis from poor contact of the radiographic film with the intensifying screen would be minimized if the user of the device employed readily available quality assurance tests.

FDA disagrees with the comments. Data collected by FDA indicate that significant differences in patient exposure can result from the choice of cassette used in a radiographic examination (Refs. 1 and 3). The aluminum equivalence of cassette front panels range from 0.06 to 1.7 millimeters. These thicknesses result in X-ray transmissions ranging from 98 to 61 percent of the incident beam and a worst-case difference in exposure to the patient of 1 to 1.6. In addition to direct exposure differences, the differences between cassettes can result in degradation of image quality and increased repeat rates. The agency believes that this information provides both a basis for and data to support development of a standard for the device. Accordingly, FDA is adopting the proposed regulation for the radiographic film cassette with a minor clarifying change.

14. Section 892.5770; Powered radiation therapy patient support assembly; proposed class II.

A comment on the proposed regulation requested that FDA classify the device into class I instead of class II, arguing that the risk to patients from failure of the device's structural integrity or control mechanism is not a significant risk.

FDA disagrees with the comment. FDA has received reports of patients being injured due to failures of this device. FDA believes that a performance standard is necessary for the powered radiation therapy patient support assembly to control the risk to patients' health from trauma resulting from failure of the structural or control mechanisms of the device. FDA also believes that sufficient information is available to develop a performance standard for the device. The agency further believes that general controls alone are insufficient to provide reasonable assurance of the safety and effectiveness of the device. Accordingly, FDA is adopting the proposed regulation for the powered radiation therapy patient support assembly with a minor clarifying change.

15. Section 892.6500; Personnel protective shield; proposed class II.

Some comments on the proposed regulation requested that FDA classify the device into class I instead of class II, arguing that performance standards are unnecessary to control the risk to health of excessive radiation exposure of patients from improper function of the device. The comments said that exposure to unnecessary radiation is a potential hazard but that unnecessary radiation exposure is unlikely to result from improper functioning of the device. The comments further stated that manufacturers' adherence to the requirements of the current good manufacturing practice (CGMP) regulations and testing by users before acceptance of the devices would provide a reasonable assurance of the safety and effectiveness of the personnel protective shield. One comment argued that the establishment of performance standards for all of the various kinds of shields encompassed in this generic type of device would not be cost effective.

FDA agrees with the comments. The general controls of class I alone for the personnel protective shield, particularly the requirements of the CGMP regulations in 21 CFR Part 820, would provide reasonable assurance of the safety and effectiveness of the device. The personnel protective shield is intended to protect the patient, the operator of radiation emitting medical devices, or other persons from any unnecessary radiation. The amount of shielding required varies (a) with the levels of radiation emitted, and (b) with the distance between the radiation source and the person being protected. FDA believes that users of radiation-emitting devices are essentially responsible for the amount and placement of shielding needed to prevent unnecessary or excessive radiation exposure from these devices. FDA now believes that the general controls of class I would provide reasonable assurance that the personnel protective shield is constructed properly and that it is unnecessary to establish performance standards for the device under section 514 of the act. Accordingly, FDA is adopting the

proposed regulation for the personnel protective shield with a change in classification from class II to class I and minor clarifying changes.

H. Exemptions For Class I Devices

16. The various panels reviewing radiology devices recommended that FDA exempt the five radiology devices listed below from certain requirements of the act. In the preamble to the proposed regulations, the agency provided its reasons for agreeing or disagreeing with the panels' recommendations regarding exemptions (47 FR 4406 at 4410 and 4436).

In response to the panels' recommendations, FDA proposed that the first four radiology devices listed below be exempt from most requirements of the CGMP regulations (21 CFR Part 820) and the requirement of premarket notification (section 510(k) of the act and Subpart E of 21 CFR Part 807). FDA proposed to classify the radiographic intensifying screen into class I with no exemptions.

Section No.	Device
892.1840	Radiographic film.
892.1920	Radiographic head holder.
892.1940	Radiologic quality assurance instrument.
892.1950	Radiographic anthropomorphic phantom.
892.1960	Radiographic intensifying screen.

However, as stated in the proposed rule, the agency has determined that exemption of manufacturers of any device from §§ 820.180 and 820.198 of the CGMP regulations would not be in the public interest. Moreover, compliance with these sections is not unduly burdensome for device manufacturers. The complaint file requirements of § 820.198 ensure that device manufacturers have adequate systems for complaint investigation and followup. The general requirements in § 820.180 concerning records ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, can determine whether the manufacturer's corrective actions are adequate, and can determine whether an exemption from other sections of the CGMP regulations, if one has been granted, is still appropriate.

FDA has determined that no device that is labeled or otherwise represented as sterile will be exempted from the device CGMP regulations. A sterile device must be subject to all of the CGMP regulations to ensure that manufacturers adequately reduce the bioburden (number of microorganisms) on the device and its components during manufacturing processes. This reduction is accomplished through adherence to a comprehensive quality assurance program, as is required by the CGMP regulations, including adequate environmental controls, trained personnel, appropriate maintenance and calibration of sterilization equipment, recordkeeping concerning lot sterility, strict packaging and labeling controls, and other quality assurance measures.

16a. Exemptions from CGMP regulations.

Many general comments on the proposed regulations for radiology devices requested that the agency grant all of the exemptions that the panels had recommended.

FDA agrees that it should grant to the manufacturers of three of the five radiology devices listed in paragraph 16 above an exemption from most requirements of the CGMP regulations, as FDA proposed (§§ 892.1920, 892.1940, and 892.1950).

FDA disagrees that the agency should grant to manufacturers of the radiographic intensifying screen an exemption from the CGMP regulations. FDA believes that, in order to control the risks to health that may result from unnecessary radiation exposure from repreated radiographs or loss of diagnostic information due to the use of a substandard product and thereby to provide reasonable assurance of the safety and effectiveness of the device, this device should be subject to all of the requirements of the CGMP regulations.

FDA now believes that radiographic film should not be exempt from CGMP requirements because of wide variations in the amount of X-rays transmitted to patients and in the image quality produced by various types of film which is affected by the manufacturing process.

Accordingly, FDA is adopting the proposed regulations classifying the radiographic head holder, radiologic quality assurance instrument, and radiographic anthropomorphic phantom into class I with the exemptions from CGMP that were proposed.

16b. Exemptions from premarket notification procedures.

Many comments requested that FDA grant the exemptions from premarket notification procedures in section 510(k) of the act and Subpart E of 21 CFR Part 807 that the panels had recommended.

In this final rule, FDA is granting the exemption from the requirement of premarket notification for manufacturers of each of the four radiology devices that were proposed (§§ 892.1840, 892.1920, 892.1940, and 892.1950). Elsewhere in this issue of the **Federal Register**, FDA is proposing to grant an exemption from the requirement of premarket notification for six additional class I radiology devices. In that proposed rule, FDA explains its recently developed policy on granting such exemptions.

I. Minor Changes or Clarifications

Occasionally, the agency has made minor changes in the name of a generic type of device or its identification to clarify the final regulation. Also, the agency is adding new §§ 884.3 and 892.3 in Subpart A of each part to explain the various effective dates for premarket approval requirements for devices classified into class III. FDA also is adding a new paragraph in the classification regulation for each device classified into class III to declare, where applicable, the effective date of premarket approval requirements for the device.

J. Guidelines For Measuring and Reporting Acoustic Output of Diagnostic Ultrasound Devices

FDA has developed guidelines to assist diagnostic ultrasound manufacturers prepare 510(k) premarket notifications on their devices. A copy of these guidelines, entitled "510(k) Guide for Measuring and Reporting Acoustic Output of Diagnostic Ultrasound Devices," can be obtained upon request from: Lillian L. Yin, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7555.

K. Classification Regulations Published to Date

The following table shows the current structure of the advisory committees involved with the classification of medical devices and a list of all proposed and final classification regulations, published to date:

Panel name	Publication date in **Federal Register**
Circulatory Systems Devices Panel	March 9, 1979; 44 FR 13284–13434 (proposals); February 5, 1980, 45 FR 7904–7971 (final regulations).
Clinical Chemistry and Clinical Toxicology Devices Panel	February 2, 1982; 47 FR 4802–4929 (proposals); May 1, 1987; 52 FR 16102–16138 (final regulations).
Hematology and Pathology Devices Panel	September 11, 1979; 44 FR 52950–53063 (proposals); September 12, 1980; 45 FR 60576–60651 (final regulations).
General Hospital and Personal Use Devices Panel	August 24, 1979; 44 FR 49844–49954 (proposals); October 21, 1980; 45 FR 69678–69737 (final regulations).

Panel name	Publication date in Federal Register
Gastroenterology-Urology Devices Panel	January 23, 1981; 46 FR 7562-7641 (proposals); November 23, 1983; 48 FR 53012-53029 (final regulations).
Immunology Devices Panel	April 22, 1980; 45 FR 27204-27359 (proposals); November 9, 1982; 47 FR 50814-50840 (final regulations).
Microbiology Devices Panel	April 22, 1980; 45 FR 27204-27359 (proposals); November 9, 1982; 47 FR 50814-50840 (final regulations).
Obstetrics-Gynecology Devices Panel	April 3, 1979; 44 FR 19894-19971 (proposals); February 26, 1980; 45 FR 12682-12720 (final regulations).
Radiologic Devices Panel	January 29, 1982; 47 FR 4406-4451 (proposals); January 20, 1988 (final regulations).
Ophthalmic Devices Panel	January 26, 1982; 47 FR 3694-3749 (proposals); September 2, 1987; 52 FR 33346-33363 (final regulations).
Ear, Nose, and Throat Devices Panel	January 22, 1982; 47 FR 3280-3325 (proposals); November 6, 1986; 51 FR 40378-40393 (final regulations).
Dental Devices Panel	December 30, 1980; 45 FR 85962-86168 (proposals); August 12, 1987; 52 FR 30082-30106 (final regulations).
Anesthesiology and Respiratory Therapy Devices Panel	November 2, 1979; 44 FR 63292-63426 (proposals); July 16, 1982; 47 FR 31130-31150 (final regulations).
Neurological Devices Panel	November 23, 1978; 43 FR 54640-55732 (proposals); September 4, 1979; 44 FR 51726-51778 (final regulations).
Orthopedic and Rehabilitation Devices Panel (Physical Medicine Devices)	August 28, 1979; 44 FR 50458-50537 (proposals); November 23, 1983; 48 FR 53032-53054 (final regulations).
Orthopedic and Rehabilitation Devices Panel (Orthopedic Devices)	July 2, 1982; 47 FR 29052-29140 (proposals); September 4, 1987; 52 FR 33686-33711 (final regulations).
General and Plastic Surgery Devices Panel	January 19, 1982; 47 FR 2810-2853 (proposals).

L. Reference

The following information has been placed on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

Schuping, R. E., et al., "Dose Reduction Potential of Carbon Fiber Material in Diagnostic Radiology," *Proceedings of the Society of Photo-Optical Instrumentation Engineers*, Vol. 233 (1980).

M. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

N. Economic Impact

The agency has carefully analyzed the economic effects of this final rule and has determined that the rule will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act. In accordance with section 3(g)(1) of the Executive Order 12291, the agency has carefully analyzed the impact of this final rule and it has determined that the final rule does not constitute a major rule as defined in section 1(b) of the Exeuctive Order. Rules classifying devices into class I generally maintain the status quo: These devices are now subject only to the general controls provisions of the act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j) and under the final rule remain subject only to such controls either in their entirety or with certain exemptions. Devices classified into class II also remain subject only to the general controls provisions of the act unless and until an applicable performance standard is established. Similarly, devices classified into class III remain subject only to the general controls provisions of the act until an additional regulation is promulgated pursuant to section 515(b) of the act (21 U.S.C. 360e(b)) requiring that such devices have in effect approved applications for premarket approval. In accordance with section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)), devices classified by regulation into class III may remain in commercial distribution without an approved premarket approval application for 30 months following the effective date of classification of the device into class III, or for 90 days following the promulgation of a regulation under section 515(b) of the act (21 U.S.C. 360e(b)), whichever occurs later. In sum, device classification rules do not have a significant impact on a substantial number of small entities and are not major rules.

List of Subjects

21 CFR Part 884

Medical devices.

21 CFR Part 892

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Chapter I of Title 21 of the Code of Federal Regulations is amended in Part 884 and Part 892 as follows:

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

1. The authority citation for 21 CFR Part 884 continues to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794-795 as amended, 90 Stat. 540-546, 552-559, 565-574, 576-577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

2. By adding new § 884.2980, to read as follows:

§ 884.2980 Telethermographic system.

(a) [Reserved]

(b) *Telethermographic system intended for use alone in diagnostic screening for detection of breast cancer or other uses*—(1) *Identification.* A telethermographic system for use as the sole diagnostic screening tool for detection of breast cancer or other uses is an electrically powered device with a detector that is intended to measure, without touching the patient's skin, the self-emanating infrared radiation that reveals the temperature variations of the surface of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(2) *Classification.* Class III.

(3) *Date PMA or notice of completion of a PDP is required.* As of the enactment date of the amendments, May 28, 1976, an approval under section 515 of the act is required before the device described in paragraph (b)(1) may be commercially distributed. See § 884.3.

3. By adding new § 884.2982, to read as follows:

§ 884.2982 Liquid crystal thermographic system.

(a) *A nonelectrically powered liquid crystal thermographic system intended for adjunctive use in diagnostic screening for detection of breast cancer or other uses*—(1) *Identification.* A nonelectrically powered liquid crystal thermographic system intended for use as an adjunct to physical palpation or mammography in diagnostic screening for detection of breast cancer or other uses is a nonelectrically powered device applied to the skin that displays the color patterns of heat sensitive cholesteric liquid crystals that respond to temperature variations of the surface of the body. This generic type of device may include patient and equipment supports, a means to ensure thermal contact between the patient's skin and the liquid crystals, component parts, and accessories.

(2) *Classification.* Class I.

(b) *A nonelectrically powered or an AC-powered liquid crystal thermographic system intended for use alone in diagnostic screening for detection of breast cancer or other uses*—(1) *Identification.* A nonelectrically powered or an AC-powered liquid crystal thermographic

system intended for use as the sole diagnostic screening tool for detection of breast cancer or other uses is a nonelectrically powered or an AC-powered device applied to the skin that displays the color patterns of heat sensitive cholesteric liquid crystals that respond to temperature variations of the surface of the body. This generic type of device may include image display and recording equipment, patient and equipment supports, a means to ensure thermal contact between the patient's skin and the liquid crystals, component parts, and accessories.

(2) *Classification.* Class III.

(3) *Date PMA or notice of completion of a PDP is required.* As of the enactment date of the amendments, May 28, 1976, an approval under section 515 of the act is required before the device described in paragraph (b)(1) may be commercially distributed. See § 884.3.

4. By adding new Part 892 to read as follows:

PART 892—RADIOLOGY DEVICES

Subpart A—General Provisions

Sec.

Subpart B—Diagnostic Devices

Subparts C–E—[Reserved]

Subpart F—Therapeutic Devices

Subpart G—Miscellaneous Devices

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

Subpart A—General Provisions

§ 892.1 Scope.

(a) This part sets forth the classification of radiology devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, a radiology device that has two or more types of uses (e.g., use both as a diagnostic device and a therapeutic device) is listed in one subpart only.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of this Title 21, unless otherwise noted.

§ 892.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act, FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class III in this part, the device may be commercially distributed without FDA's issuance of an order approving a PMA or declaring completed a PDP for the device. If FDA promulgates a regulation under section 515(b) of the act requiring premarket approval for a device, section 501(f)(1)(A) of the act applies to the device.

(b) Any new, not substantially equivalent, device introduced into commercial distribution on or after May 28, 1976, including a device formerly marketed that has been substantially altered, is classified by statute (section 513(f) of the act) into class III without

any grace period and FDA must have issued an order approving a PMA or declaring completed a PDP for the device before the device is commercially distributed unless it is reclassified. If FDA knows that a device being commerically distributed may be a "new" device as defined in this section because of any new intended use or other reasons, FDA may codify the statutory classification of the device into class III for such new use. Accordingly, the regulation for such a class III device states that as of the enactment date of the amendments, May 28, 1976, the device must have an approval under section 515 of the act before commercial distribution.

Subpart B—Diagnostic Devices

§ 892.1170 Bone densitometer.

(a) *Identification.* A bone densitometer is a device intended for medical purposes to measure bone density and mineral content by X-ray or gamma ray transmission measurements through the bone and adjacent tissues. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1200 Emission computed tomography system.

(a) *Identification.* An emission computed tomography system is a device intended to detect the location and distribution of gamma ray- and positron-emitting radionuclides in the body and produce cross-sectional images through computer reconstruction of the data. This generic type of device may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1220 Fluorescent scanner.

(a) *Identification.* A fluorescent scanner is a device intended to measure the induced fluorescent radiation in the body by exposing the body to certain X-rays or low-energy gamma rays. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts and accessories.

(b) *Classification.* Class II.

§ 892.1310 Nuclear tomography system.

(a) *Identification.* A nuclear tomography system is a device intended to detect nuclear radiation in the body and produce images of a specific cross-sectional plane of the body by blurring or eliminating detail from other planes. This generic type of devices may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1360 Radionuclide dose calibrator.

(a) *Identification.* A radionuclide dose calibrator is a radiation detection device intended to assay radionuclides before their administration to patients.

(b) *Classification.* Class II.

§ 892.1370 Nuclear anthropomorphic phantom.

(a) *Identification.* A nuclear anthropomorphic phantom is a human tissue facsimile that contains a radioactive source or a cavity in which a radioactive sample can be inserted. It is intended to calibrate nuclear uptake probes or other medical instruments.

(b) *Classification.* Class I.

§ 892.1380 Nuclear flood source phantom.

(a) *Identification.* A nuclear flood source phantom is a device that consists of a radiolucent container filled with a uniformly distributed solution of a desired radionuclide. It is intended to calibrate a medical gamma camera-collimator system for uniformity of response.

(b) *Classification.* Class I.

§ 892.1390 Radionuclide rebreathing system.

(a) *Identification.* A radionuclide rebreathing system is a device intended to be used to contain a gaseous or volatile radionuclide or a radionuclide-labeled aerosol and permit it to be respired by the patient during nuclear medicine ventilatory tests (testing process of exchange between the lungs and the atmosphere). This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1400 Nuclear sealed calibration source.

(a) *Identification.* A nuclear sealed calibration source is a device that consists of an encapsulated reference radionuclide intended for calibration of medical nuclear radiation detectors.

(b) *Classification.* Class I.

§ 892.1420 Radionuclide test pattern phantom.

(a) *Identification.* A radionuclide test pattern phantom is a device that consists of an arrangement of radiopaque or radioactive material sealed in a solid pattern intended to serve as a test for a performance characteristic of a nuclear medicine imaging device.

(b) *Classification.* Class I.

§ 892.1540 Nonfetal ultrasonic monitor.

(a) *Identification.* A nonfetal ultrasonic monitor is a device that projects a continuous high-frequency sound wave into body tissue other than a fetus to determine frequency changes (doppler shift) in the reflected wave and is intended for use in the investigation of nonfetal blood flow and other nonfetal body tissues in motion. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1550 Ultrasonic pulsed doppler imaging system.

(a) *Identification.* An ultrasonic pulsed doppler imaging system is a device that combines the features of continuous wave doppler-effect technology with pulsed-echo effect technology and is intended to determine stationary body tissue characteristics, such as depth or location of tissue interfaces or dynamic tissue characteristics such as velocity of blood or tissue motion. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1560 Ultrasonic pulsed echo imaging system.

(a) *Identification.* An ultrasonic pulsed echo imaging system is a device intended to project a pulsed sound beam into body tissue to determine the depth or location of the tissue interfaces and to measure the duration of an acoustic pulse from the transmitter to the tissue interface and back to the receiver. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1570 Diagnostic ultrasonic transducer.

(a) *Identification.* A diagnostic ultrasonic transducer is a device made of a piezoelectric material that converts electrical signals into acoustic signals and acoustic signals into electrical signals and intended for use in diagnostic ultrasonic medical devices. Accessories of this generic type of device may include transmission media for acoustically coupling the transducer to the body surface, such as acoustic gel, paste, or a flexible fluid container.

(b) *Classification.* Class II.

§ 892.1600 Angiographic X-ray system.

(a) *Identification.* An angiographic X-ray system is a device intended for radiologic visualization of the heart, blood vessels, or lymphatic system during or after injection of a contrast medium. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1610 Diagnostic X-ray beam-limiting device.

(a) *Identification.* A diagnostic X-ray beam-limiting device is a device such as a collimator, a cone, or an aperture intended to restrict the dimensions of a diagnostic X-ray field by limiting the size of the primary X-ray beam.

(b) *Classification.* Class II.

§ 892.1620 Cine or spot fluorographic X-ray camera.

(a) *Identification.* A cine or spot fluorographic X-ray camera is a device intended to photograph diagnostic images produced by X-rays with an image intensifier.

(b) *Classification.* Class II.

§ 892.1630 Electrostatic X-ray imaging system.

(a) *Identification.* An electrostatic X-ray imaging system is a device intended for medical purposes that uses an electrostatic field across a semiconductive plate, a gas-filled chamber, or other similar device to convert a pattern of X-radiation into an electrostatic image and, subsequently, into a visible image. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1650 Image-intensified fluoroscopic X-ray system.

(a) *Identification.* An image-intensified fluroscopic X-ray system is a device intended to visualize anatomical structures by converting a pattern of X-radiation into a visible image through electronic amplification. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1660 Non-image-intensified fluroscopic X-ray system.

(a) *Identification.* A non-image-intensified fluoroscopic X-ray system is a device intended to be used to visualize anatomical structures by using a fluorescent screen to convert a pattern of X-radiation into a visible image. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1670 Spot-film device.

(a) *Identification.* A spot-film device is an electromechanical component of a fluoroscopic X-ray system that is intended to be used for medical purposes to position a radiographic film cassette to obtain radiographs during fluoroscopy.

(b) *Classification.* Class II.

§ 892.1680 Stationary X-ray system.

(a) *Identification.* A stationary X-ray system is a permanently installed diagnostic system intended to generate and control X-rays for examination of various anatomical regions. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1700 Diagnostic X-ray high voltage generator.

(a) *Identification.* A diagnostic X-ray high voltage generator is a device that is intended to supply and control the electrical energy applied to a diagnostic X-ray tube for medical purposes. This generic type of device may include a converter that changes alternating current to direct current, filament transformers for the X-ray tube, high voltage switches, electrical protective devices, or other appropriate elements.

(b) *Classification.* Class II.

§ 892.1710 Mammographic X-ray system.

(a) *Identification.* A mammographic X-ray system is a device intended to be used to produce radiographs of the breast. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1720 Mobile X-ray system.

(a) *Identification.* A mobile X-ray system is a transportable device system intended to be used to generate and control X-ray for diagnostic procedures. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1730 Photofluorographic X-ray system.

(a) *Identification.* A photofluorographic X-ray system is a device that includes a fluoroscopic X-ray unit and a camera intended to be used to produce, then photograph, a fluoroscopic image of the body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1740 Tomographic X-ray system.

(a) *Identification.* A tomographic X-ray system is an X-ray device intended to be used to produce radiologic images of a specific cross-sectional plane of the body by blurring or eliminating detail from other planes. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1750 Computed tomography X-ray system.

(a) *Identification.* A computed tomography X-ray system is a diagnostic X-ray system intended to produce cross-sectional images of the body by computer reconstruction of X-ray transmission data from the same axial plane taken at different angles. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.1760 Diagnostic X-ray tube housing assembly.

(a) *Identification.* A diagnostic X-ray tube housing assembly is an X-ray generating tube encased in a radiation-shielded housing that is intended for diagnostic purposes. This generic type of device may include high voltage and filament transformers or other appropriate components.

(b) *Classification.* Class II.

§ 892.1770 Diagnostic X-ray tube mount.

(a) *Identification.* A diagnostic X-ray tube mount is a device intended to support and to position the diagnostic X-ray tube housing assembly for a medical radiographic procedure.

(b) *Classification.* Class II.

§ 892.1820 Pneumoencephalographic chair.

(a) *Identification.* A pneumoencephalographic chair is a chair intended to support and position a patient during pneumoencephalography (X-ray imaging of the brain).

(b) *Classification.* Class II.

§ 892.1830 Radiologic patient cradle.

(a) *Identification.* A radiologic patient cradle is a support device intended to be used for rotational positioning about the longitudinal axis of a patient during radiologic procedures.

(b) *Classification.* Class II.

§ 892.1840 Radiographic film.

(a) *Identification.* Radiographic film is a device that consists of a thin sheet of radiotransparent material coated on one or both sides with a photographic emulsion intended to record images during diagnostic radiologic procedures.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

§ 892.1850 Radiographic film cassette.

(a) *Identification.* A radiographic film cassette is a device intended for use during diagnostic X-ray procedures to hold a radiographic film in close contact with an X-ray intensifying screen and to provide a light-proof enclosure for direct exposure of radiographic film.

(b) *Classification.* Class II.

§ 892.1860 Radiographic film/cassette changer.

(a) *Identification.* A radiographic film/cassette changer is a device intended to be used during a radiologic procedure to move a radiographic film or cassette between X-ray exposures and to position it during the exposure.

(b) *Classification.* Class II.

§ 892.1870 Radiographic film/cassette changer programmer.

(a) *Identification.* A radiographic film/cassette changer programmer is a device intended to be used to control the operations of a film or cassette changer during serial medical radiography.

(b) *Classification.* Class II.

§ 892.1880 Wall-mounted radiographic cassette holder.

(a) *Identification.* A wall-mounted radiographic cassette holder is a device that is a support intended to hold and position radiographic cassettes for a radiographic exposure for medical use.

(b) *Classification.* Class II.

§ 892.1910 Radiographic grid.

(a) *Identification.* A radiographic grid is a device that consists of alternating radiolucent and radiopaque strips intended to be placed between the patient and the image receptor to reduce the amount of scattered radiation reaching the image receptor.

(b) *Classification.* Class I.

§ 892.1920 Radiographic head holder.

(a) *Identification.* A radiographic head holder is a device intended to position the patient's head during a radiographic procedure.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 892.1940 Radiologic quality assurance instrument.

(a) *Identification.* A radiologic quality assurance instrument is a device intended for medical purposes to measure a physical characteristic associated with another radiologic device.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 892.1950 Radiographic anthropomorphic phantom.

(a) *Identification.* A radiographic anthropomorphic phantom is a device intended for medical purposes to simulate a human body for positioning radiographic equipment.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 892.1960 Radiographic intensifying screen.

(a) *Identification.* A radiographic intensifying screen is a device that is a thin radiolucent sheet coated with a luminescent material that transforms incident X-ray photons into visible light and intended for medical purposes to expose radiographic film.

(b) *Classification.* Class I.

§ 892.1980 Radiologic table.

(a) *Identification.* A radiologic table is a device intended for medical purposes to support a patient during radiologic procedures. The table may be fixed or tilting and may be electrically powered.

(b) *Classification.* Class II.

Subparts C–E—[Reserved]

Subpart F—Therapeutic Devices

§ 892.5050 Medical charged-particle radiation therapy system.

(a) *Identification.* A medical charged-particle radiation therapy system is a device that produces by acceleration high energy charged particles (e.g., electrons and protons) intended for use in radiation therapy. This generic type of device may include signal analysis and display equipment, patient and equipment supports, treatment planning computer programs, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.5300 Medical neutron radiation therapy system.

(a) *Identification.* A medical neutron radiation therapy system is a device intended to generate high-energy neutrons for radiation therapy. This generic type of device may include signal analysis and display equipment, patient and equipment support, treatment planning computer programs, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.5650 Manual radionuclide applicator system.

(a) *Identification.* A manual radionuclide applicator system is a manually operated device intended to apply a radionuclide source into the body or to the surface of the body for radiation therapy. This generic type of device may include patient and equipment supports, component parts, treatment planning computer programs, and accessories.

(b) *Classification.* Class I.

§ 892.5700 Remote controlled radionuclide applicator system.

(a) *Identification.* A remote controlled radionuclide applicator system is an electromechanical or pneumatic device intended to enable an operator to apply, by remote control, a radionuclide source into the body or to the surface of the body for radiation therapy. This generic type of device may include patient and equipment supports, component parts, treatment planning computer programs, and accessories.

(b) *Classification.* Class II.

§ 892.5710 Radiation therapy beam-shaping block.

(a) *Identification.* A radiation therapy beam-shaping block is a device made of a highly attenuating material (such as lead) intended for medical purposes to

modify the shape of a beam from a radiation therapy source.

(b) *Classification.* Class II.

§ 892.5730 Radionuclide brachytherapy source.

(a) *Identification.* A radionuclide brachytherapy source is a device that consists of a radionuclide which may be enclosed in a sealed container made of gold, titanium, stainless steel, or platinum and intended for medical purposes to be placed onto a body surface or into a body cavity or tissue as a source of nuclear radiation for therapy.

(b) *Classification.* Class II.

§ 892.5740 Radionuclide teletherapy source.

(a) *Identification.* A radionuclide teletherapy source is a device consisting of a radionuclide enclosed in a sealed container. The device is intended for radiation therapy, with the radiation source located at a distance from the patient's body.

(b) *Classification.* Class I.

§ 892.5750 Radionuclide radiation therapy system.

(a) *Identification.* A radionuclide radiation therapy system is a device intended to permit an operator to administer gamma radiation therapy, with the radiation source located at a distance from the patient's body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, treatment planning computer programs, component parts (including beam-limiting devices), and accessories.

(b) *Classification.* Class II.

§ 892.5770 Powered radiation therapy patient support assembly.

(a) *Identification.* A powered radiation therapy patient support assembly is an electrically powered adjustable couch intended to support a patient during radiation therapy.

(b) *Classification.* Class II.

§ 892.5780 Light beam patient position indicator.

(a) *Identification.* A light beam patient position indicator is a device that projects a beam of light (incoherent light or laser) to determine the alignment of the patient with a radiation beam. The beam of light is intended to be used during radiologic procedures to ensure proper positioning of the patient and to monitor alignment of the radiation beam with the patient's anatomy.

(b) *Classification.* Class II.

§ 892.5840 Radiation therapy simulation system.

(a) *Identification.* A radiation therapy simulation system is a fluoroscopic or radiographic X-ray system intended for use in localizing the volume to be exposed during radiation therapy and confirming the position and size of the therapeutic irradiation field produced. This generic type of device may include signal analysis and display equipment, patient and equipment supports, treatment planning computer programs, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.5900 X-ray radiation therapy system.

(a) *Identification.* An X-ray radiation therapy system is a device intended to produce and control X-rays used for radiation therapy. This generic type of device may include signal analysis and display equipment, patient and equipment supports, treatment planning computer programs, component parts, and accessories.

(b) *Classification.* Class II.

§ 892.5930 Therapeutic X-ray tube housing assembly.

(a) *Identification.* A therapeutic X-ray tube housing assembly is an X-ray generating tube encased in a radiation-shielded housing intended for use in radiation therapy. This generic type of device may include high-voltage and filament transformers or other appropriate components when contained in radiation-shielded housing.

(b) *Classification.* Class II.

Subpart G—Miscellaneous Devices

§ 892.6500 Personnel protective shield.

(a) *Identification.* A personnel protective shield is a device intended for medical purposes to protect the patient, the operator, or other persons from unnecessary exposure to radiation during radiologic procedures by providing an attenuating barrier to radiation. This generic type of device may include articles of clothing, furniture, and movable or stationary structures.

(b) *Classification.* Class I.

Dated: December 24, 1987.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 88-857 Filed 1-19-88; 8:45am]

BILLING CODE 4160-01-M

federal register

Wednesday
January 20, 1988

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 864 et al.

Medical Devices; Proposed Exemptions From Premarket Notification for Certain Classified Devices; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 864, 866, 868, 870, 876, 880, 882, 884, and 890

[Docket No. 87N-0005]

Medical Devices; Proposed Exemptions From Premarket Notification for Certain Classified Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to exempt from the requirement of premarket notification, with limitations, 110 generic types of class I devices. The devices that are the subjects of this proposed rule have been classified for several years. These actions are being taken under the Medical Device Amendments of 1976 and are a step in implementing one of the goals in FDA's plan for action.

DATES: Comments by March 21, 1988. FDA is proposing that the final rule based on this proposed rule become effective 30 days after the date of publication of the final rule in the Federal Register.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4874.

SUPPLEMENTARY INFORMATION: The Medical Device Amendments of 1976 (Pub. L. 94-295, hereinafter called the amendments) establish a comprehensive system for the regulation of medical devices intended for human use. One provision of the amendments, section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), establishes three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness: Class I, general controls; class II, performance standards; and class III, premarket approval.

Section 513(d)(2)(A) of the act (21 U.S.C. 360c(d)(2)(A)) authorizes FDA to exempt, by regulation, a generic type of class I device from the requirement of, among other things, premarket notification in section 510(k) of the act (21 U.S.C. 360(k)) and Subpart E of 21 CFR Part 807. Such an exemption permits manufacturers to introduce into commercial distribution generic types of devices without first submitting to FDA a premarket notification. When FDA was publishing its proposed classification regulations for preamendment devices, the agency did not routinely evaluate whether it should grant to manufacturers of devices placed in class I an exemption from the requirement of premarket notification. Generally, FDA considered such exemptions only when the advisory panels included them in recommendations to the agency.

Recently, FDA developed criteria for exempting certain class I devices from the requirement of premarket notification, to reduce the number of unnecessary premarket notifications thereby freeing agency resources for the review of more complex notifications. The development of these criteria and the issuance of proposed and final rules exempting appropriate devices from the requirement of premarket notification will help implement a goal of FDA's July 1985 "A Plan for Action" (Ref. 1).

Criteria for 510(K) Exemptions

FDA is proposing to exempt a generic type of class I device from the requirement of premarket notification with the limitations described below, if FDA determines that premarket notification is unnecessary for the protection of the public health. FDA may propose to grant an exemption if both of the following criteria are met:

1. FDA has determined that the device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device such as device design or materials. When making these determinations, FDA may consider the frequency, persistence, cause, or seriousness of such claims or risks, or other factors.

2. FDA has determined that: (a) Characteristics of the device necessary for its safe and effective performance are well established; (b) anticipated changes in the device that are of the type that could affect safety and effectiveness will (1) be readily detectable by users by visual examination or other means, such as routine testing, e.g., testing of a clinical laboratory reagent with positive and negative controls, before causing harm; or (2) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (c) that any changes in the device will not be likely to result in a change in the device's classification.

FDA will make the determinations above based on its knowledge of the device, including past experience and relevant reports or studies on device performance.

FDA may, if it has concerns only about certain types of changes in a class I device, grant a limited exemption from premarket notification for the generic type of device. A limited exemption will specify what types of changes manufacturers must continue to report to FDA in the context of premarket notification. For example, FDA may exempt a device except when a manufacturer intends to use a different material.

FDA's decision to grant an exemption from the requirement of premarket notification for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic of a device that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

Application of the Criteria to Already Classified Devices

On the dates listed, FDA published final regulations classifying among others, the devices listed below. When FDA classified these devices, the agency did not propose exemptions from the

requirement of premarket notification for them. The panels charged with making classification recommendations on the devices did not focus on exempting them, and did not recommend exemption from premarket notification for them. After reviewing all of the types of devices subject to this notice, and in light of FDA's 510(k) guidance to its reviewers, FDA has determined that premarket notification with respect to the devices listed below is unnecessary for the protection of the public health. FDA believes that exempting these devices will allow the agency to make better use of its resources and thus better serve the public. In other words, the process of exempting these devices from the 510(k) premarket notification program, where premarket notification will not advance FDA's public health mission, will free resources available to address pressing regulatory concerns and make the agency more efficient.

No. of devices proposed to be exempt	CFR Part No., title, and publication dates of final rules
24	864—Hematology and pathology devices; September 12, 1980 (45 FR 60576).
38	866—Immunology and microbiology devices; November 9, 1982 (47 FR 50814).
18	868—Anesthesiology devices; July 16, 1982 (47 FR 31142).
3	870—Cardiovascular devices; February 5, 1980 (45 FR 7904).
9	876—Gastroenterology-urology devices; November 23, 1983 (48 FR 53012).
6	880—General hospital and personal use devices; October 21, 1980 (45 FR 69678).
7	882—Neurological devices; September 4, 1979 (44 FR 51726).
3	884—Obstetrical and gynecological devices; February 26, 1980 (45 FR 12682).
2	890—Physical medicine devices; November 23, 1983 (48 FR 53032).
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Hematology and Pathology Devices

Section	Device
864.1850...	Dye and chemical solution stains.
864.2220...	Synthetic cell and tissue culture media and components.
864.2240...	Cell and tissue culture supplies and equipment.
864.2260...	Chromosome culture kit.
864.2360...	Mycoplasma detection media and components.
864.2800...	Animal and human sera.
864.2875...	Balanced salt solutions or formulations.
864.3010...	Tissue processing equipment.
864.3250...	Specimen transport and storage container.
864.3300...	Cytocentrifuge.
864.3400...	Device for sealing microsections.
864.3600...	Microscopes and accessories.
864.3800...	Automated slide stainer.
864.3875...	Automated tissue processor.
864.4010...	General purpose reagent.
864.4400...	Enzyme preparations.
864.5800...	Automated sedimentation rate device.
864.5850...	Automated slide spinner.
864.6150...	Capillary blood collection tube.
864.6160...	Manual blood cell counting device.
864.6600...	Osmotic fragility test.
864.6700...	Erythrocyte sedimentation rate test.
864.8200...	Blood cell diluent.
864.8540...	Red cell lysing reagent.

FDA is proposing in this document to grant an exemption from the requirement of premarket notification for each of the devices above. However, the proposed exemptions for the specimen transport and storage container (§ 864.3250) and the capillary blood collection tube (§ 864.6150) are limited and would apply only to those products intended for other than over-the-counter (OTC) distribution.

Immunology and Microbiology Devices

Section	Device
866.2050...	Staphylococcal typing bacteriophage.
866.2170...	Automated colony counter.
866.2300...	Multipurpose culture medium.
866.2320...	Differential culture medium.
866.2330...	Enriched culture medium.
866.2350...	Microbiological assay culture medium.
866.2360...	Selective culture medium.
866.2450...	Supplement for culture media.
866.2480...	Quality control kit for culture media.
866.2500...	Microtiter diluting and dispensing device.
866.2560...	Microbial growth monitor.
866.2580...	Gas-generating device.
866.2660...	Microorganism differentiation and identification device.
866.3010...	*Acinetobacter calcoaceticus* serological reagents.
866.3020...	Adenovirus serological reagents.
866.3035...	*Arizona* spp. serological reagents.
866.3065...	*Bordetella* spp. serological reagents.
866.3125...	*Citrobacter* spp. serological reagents.
866.3205...	Echovirus serological reagents.
866.3250...	*Erysipelothrix rhusiopathiae* serological reagents.
866.3255...	*Escherichia coli* serological reagents.
866.3270...	*Flavobacterium* spp. serological reagents.
866.3330...	Influenza virus serological reagents.
866.3340...	*Klebsiella* spp. serological reagents.
866.3400...	Parainfluenza virus serological reagents.
866.3410...	*Proteus* spp. (Weil-Felix) serological reagents.
866.3470...	Reovirus serological reagents.
866.3490...	Rhinovirus serological reagents.
866.3520...	Rubeola (measles) virus serological reagents.
866.3630...	*Serratia* spp. serological reagents.
866.3700...	*Staphylococcus aureus* serological reagents.
866.4500...	Immunoelectrophoresis equipment.
866.4520...	Immunofluorometer equipment.
866.4540...	Immunonephelometer equipment.
866.4600...	Ouchterlony agar plate.
866.4830...	Rocket immunoelectrophoresis equipment.
866.4900...	Support gel.
866.5800...	Seminal fluid (sperm) immunological test system.

FDA is proposing in this document to grant an exemption from the requirement of premarket notification for each of the devices above.

Anesthesiology Devices

Section	Device
868.1030...	Manual algesimeter.
868.1910...	Esophageal stethoscope.
868.1930...	Stethoscope head.
868.1965...	Switching valve (ploss).
868.5220...	Blow bottle.
868.5280...	Breathing tube support.
868.5340...	Nasal oxygen cannula.
868.5365...	Posture chair for cardiac or pulmonary treatment.
868.5420...	Ether hook.
868.5560...	Gas mask head strap.
868.5620...	Breathing mouthpiece.
868.5640...	Medicinal nonventilatory nebulizer (atomizer).
868.5760...	Cuff spreader.
868.6100...	Anesthetic cabinet, table, or tray.
868.6175...	Cardiopulmonary emergency cart.
868.6225...	Nose clip.
868.6700...	Anesthesia stool.
868.6810...	Tracheobronchial suction catheter.

FDA is proposing in this document to grant an exemption from the requirement of premarket notification for each of the devices listed above.

However, the proposed exemption for the medicinal nonventilatory nebulizer (atomizer) (§ 868.5640) would apply only when no curative labeling claims (e.g., "cures the common cold") are made. The proposed exemption for the tracheobronchial suction catheter (§ 868.6810) would apply only when no antichoke or food removal labeling claims are made.

Cardiovascular Devices

Section	Device
870.3730...	Pacemaker service tools.
870.4200...	Cardiopulmonary bypass accessory equipment.
870.4500...	Cardiovascular surgical instruments.

FDA is proposing in this document to grant an exemption from the requirement of premarket notification for each of the devices above.

Gastroenterology-Urology Devices

Section	Device
876.4370...	Gastroenterology-urology evacuator.
876.4530...	Gastroenterology-urology fiberoptic retractor.
876.4560...	Ribdam.
876.4730...	Manual gastroenterology-urology surgical instrument and accessories.
876.4890...	Urological table and accessories.
876.5030...	Continent ileostomy catheter.
876.5820...	Hemodialysis system and accessories.
876.5900...	Ostomy pouch and accessories.
876.5920...	Protective garment for incontinence.

FDA is proposing in this document to grant an exemption from the requirement of premarket notification for each of the devices above. However, the proposed exemptions for the gastroenterology-urology evacuator (§ 876.4370) and urological table and accessories (§ 876.4890) are limited and would apply only to those devices which are manually powered. The proposed exemption is also limited to those accessories of the hemodialysis system (§ 876.5820) that are remote from the extracorporeal blood system and the dialysate delivery system.

General Hospital and Personal Use Devices

Section	Device
880.5110...	Hydraulic adjustable hospital bed.
880.5120...	Manual adjustable hospital bed.
880.5510...	Non-AC-powered patient lifts.
880.6150...	Ultrasonic cleaner for medical instruments.
880.6280...	Medical insole.
880.6970...	Liquid crystal vein locator.

FDA is proposing in this document to grant an exemption from the requirement of premarket notification for each of the devices above. The proposed exemption for the ultrasonic cleaner for medical instruments (§ 880.6150) does not apply to any solutions intended for use with the device for cleaning or sanitizing the instruments.

Neurological Devices

Section	Device
882.1200...	Two-point discriminator.
882.1500...	Esthesiometer.
882.1525...	Tuning fork.
882.1700...	Percussor.
882.1750...	Pinwheel.
882.4215...	Clip rack.
882.4650...	Neurosurgical suture needle.

FDA is proposing in this document to grant an exemption from the requirement of premarket notification for each of the devices listed above. However, the proposed exemptions for the two-point discriminator (§ 882.1200) and the neurosurgical suture needle (§ 882.4650) are limited and would apply only to those devices made of the same material (single, surgical-grade, stainless steel alloy) that was used in the devices before May 28, 1976. The proposed exemption for the pinwheel (§ 882.1750) is limited and would apply only if (1) the device is made of the same material (single, surgical-grade, stainless steel alloy) that was used in the device before May 28, 1976, and (2) it is manually operated. The proposed exemption for the esthesiometer (§ 882.1500) is also limited and would apply only if the device is composed of a single material. The proposed exemption for the percussor (§ 882.1700) would apply only to a small hand-held hammer with a rubber head, and the proposed exemptions for the clip rack (§ 882.4215) would apply only when the device is composed entirely of a single metal alloy having the same composition as the clips it is intended to hold.

Obstetrical and Gynecological Devices

Section	Device
884.2900...	Fetal stethoscope.
884.4520...	Obstetric-gynecologic general manual instrument.
884.5920...	Vaginal insufflator.

FDA is proposing in this document to grant an exemption from the requirement of premarket notification for each of the devices above.

Physical Medicine Devices

Section	Device
890.3700...	Nonpowered communication system.
890.5125...	Nonpowered sitz bath.

FDA is proposing in this document to grant an exemption from the requirement of premarket notification for each of the devices above.

Reference

The following information has been placed in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. "Food and Drug Administration—A Plan for Action," Public Health Service, Department of Health and Human Services, July 1985, p. 18.

Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Economic Impact

FDA has carefully analyzed the economic effects of this proposed rule and has determined that the proposed rule will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act. In accordance with section 3(g)(1) of Executive Order 12291, the impact of this proposed rule has been carefully analyzed, and it has been

determined that the proposed rule does not constitute a major rule as defined in section 1(b) of the Executive Order. The devices subject to this proposed rule are now subject only to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j), with certain exemptions. Under any final rule based on this proposal, the devices would remain subject to such controls, other than premarket notification.

Request for Comments

Interested persons may, on or before March 21, 1988, submit to the Dockets Management Branch (address above) written comments regarding this proposal. 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.

List of Subjects

21 CFR Part 864

Hematology and pathology devices, Medical devices.

21 CFR Part 866

Immunology and microbiology devices, Medical devices.

21 CFR Part 868

Anesthesiology devices, Medical devices.

21 CFR Part 870

Cardiovascular devices, Medical devices.

21 CFR Part 876

Gastroenterology-urology devices, Medical devices.

21 CFR Part 880

General hospital and personal use devices, Medical devices.

21 CFR Part 882

Medical devices, Neurological devices.

21 CFR Part 884

Medical devices, Obstetrical and gynecological devices.

21 CFR Part 890

Medical devices, Physical medicine devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that Parts 864, 866, 868, 870, 876, 880, 882, 884, and 890 be amended as follows:

S-021999 0005(00)(19-JAN-88-10:25:34)

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

1. The authority citation for 21 CFR Part 864 continues to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

2. Part 864 is amended by adding new § 864.9 to read as follows:

§ 864.9 Limitations of exemptions from section 510(k) of the act.

FDA's decision to grant an exemption from the requirement of premarket notification for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976, e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

3. In § 864.1850 by revising paragraph (b) to read as follows:

§ 864.1850 Dye and chemical solution stains.

* * * * *

(b) *Classification.* Class I. The devices are exempt from the premarket notification procedures in Subpart E of Part 807. The devices also are exempt from the good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

4. In § 864.2220 by revising paragraph (b) to read as follows:

§ 864.2220 Synthetic cell and tissue culture media and components.

* * * * *

(b) *Classification.* Class I. The devices are exempt from the premarket notification procedures in Subpart E of Part 807.

5. In § 864.2240 by revising paragraph (b) to read as follows:

§ 864.2240 Cell and tissue culture supplies and equipment.

* * * * *

(b) *Classification.* Class I. The devices are exempt from the premarket notification procedures in Subpart E of Part 807. If the devices are not labeled or otherwise represented as sterile, they are exempted from the good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

6. In § 864.2260 by revising paragraph (b) to read as follows:

§ 864.2260 Chromosome culture kit.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

7. In § 864.2360 by revising paragraph (b) to read as follows:

§ 864.2360 Mycoplasma detection media and components.

* * * * *

(b) *Classification.* Class I. The devices are exempt from the premarket notification procedures in Subpart E of Part 807.

8. In § 864.2800 by revising paragraph (b) to read as follows:

§ 864.2800 Animal and human sera.

* * * * *

(b) *Classification.* Class I. The devices are exempt from the premarket notification procedures in Subpart E of Part 807.

9. In § 864.2875 by revising paragraph (b) to read as follows:

§ 864.2875 Balanced salt solutions or formulations.

* * * * *

(b) *Classification.* Class I. The devices are exempt from the premarket

notification procedures in Subpart E of Part 807.

10. In § 864.3010 by revising paragraph (b) to read as follows:

§ 864.3010 Tissue processing equipment.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

11. In § 864.3250 by revising paragraph (b) to read as follows:

§ 864.3250 Specimen transport and storage container.

* * * * *

(b) *Classification.* Class I. If the device is not intended for over-the-counter (OTC) distribution, it is exempt from the premarket notification procedures in Subpart E of Part 807.

12. In § 864.3300 by revising paragraph (b) to read as follows:

§ 864.3300 Cytocentrifuge.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

13. In § 864.3400 by revising paragraph (b) to read as follows:

§ 864.3400 Device for sealing microsections.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

14. In § 864.3600 by revising paragraph (b) to read as follows:

§ 864.3600 Microscopes and accessories.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807. The devices also are exempt from the good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

15. In § 864.3800 by revising paragraph (b) to read as follows:

§ 864.3800 Automated slide stainer.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

16. In § 864.3875 by revising paragraph (b) to read as follows:

§ 864.3875 Automated tissue processor.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

17. In § 864.4010 by revising paragraph (b) to read as follows:

§ 864.4010 General purpose reagent.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807. If the device is not labeled or otherwise represented as sterile, it is exempt from the good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

18. In § 864.4400 by revising paragraph (b) to read as follows:

§ 864.4400 Enzyme preparations.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

19. In § 864.5800 by revising paragraph (b) to read as follows:

§ 864.5800 Automated sedimentation rate device.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

20. In § 864.5850 by revising paragraph (b) to read as follows:

§ 864.5850 Automated slide spinner.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

21. In § 864.6150 by revising paragraph (b) to read as follows:

§ 864.6150 Capillary blood collection tube.

* * * * *

(b) *Classification.* Class I. If the device is not intended for over-the-counter (OTC) distribution, it is exempt from the premarket notification procedures in Subpart E of Part 807.

22. In § 864.6160 by revising paragraph (b) to read as follows:

§ 864.6160 Manual blood cell counting device.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

23. In § 864.6600 by revising paragraph (b) to read as follows:

§ 864.6600 Osmotic fragility test.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

24. In § 864.6700 by revising paragraph (b) to read as follows:

§ 864.6700 Erythrocyte sedimentation rate test.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

25. In § 864.8200 by revising paragraph (b) to read as follows:

§ 864.8200 Blood cell diluent.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

26. In § 864.8540 by revising paragraph (b) to read as follows:

§ 864.8540 Red cell lysing reagent.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

27. The authority citation for 21 CFR Part 866 continues to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

28. Part 866 is amended by adding new § 866.9 to read as follows:

§ 866.9 Limitations of exemptions from section 510(k) of the act.

FDA's decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use

or characteristic that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

29. In § 866.2050 by revising paragraph (b) to read as follows:

§ 866.2050 Staphylococcal typing bacteriophage.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

30. In § 866.2170 by revising paragraph (b) to read as follows:

§ 866.2170 Automated colony counter.

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(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

31. In § 866.2300 by revising paragraph (b) to read as follows:

§ 866.2300 Multipurpose culture medium.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

32. In § 866.2320 by revising paragraph (b) to read as follows:

§ 866.2320 Differential culture medium.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

33. In § 866.2330 by revising paragraph (b) to read as follows:

§ 866.2330 Enriched culture medium.

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(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

34. In § 866.2350 by revising paragraph (b) to read as follows:

§ 866.2350 Microbiological assay culture medium.

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(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

35. In § 866.2360 by revising paragraph (b) to read as follows:

§ 866.2360 Selective culture medium.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

36. In § 866.2450 by revising paragraph (b) to read as follows:

§ 866.2450 Supplement for culture media.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

37. In § 866.2480 by revising paragraph (b) to read as follows:

§ 866.2480 Quality control kit for culture media.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

38. In § 866.2500 by revising paragraph (b) to read as follows:

§ 866.2500 Microtiter diluting and dispensing device.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

39. In § 866.2560 by revising paragraph (b) to read as follows:

§ 866.2560 Microbial growth monitor.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

40. In § 866.2580 by revising paragraph (b) to read as follows:

§ 866.2580 Gas-generating device.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

41. In § 866.2660 by revising paragraph (b) to read as follows:

§ 866.2660 Microorganism differentiation and identification device.

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(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

42. In § 866.3010 by revising paragraph (b) to read as follows:

§ 866.3010 Acinetobacter calcoaceticus serological reagents.

* * * * *

(b) *Classification.* Class I. These devices are exempt from the premarket notification procedures in Subpart E of Part 807.

43. In § 866.3020 by revising paragraph (b) to read as follows:

§ 866.3020 Adenovirus serological reagents.

* * * * *

(b) *Classification.* Class I. These devices are exempt from the premarket notification procedures in Subpart E of Part 807.

44. In § 866.3035 by revising paragraph (b) to read as follows:

§ 866.3035 Arizona spp. serological reagents.

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(b) *Classification.* Class I. These devices are exempt from the premarket notification procedures in Subpart E of Part 807.

45. In § 866.3065 by revising paragraph (b) to read as follows:

§ 866.3065 Bordetella spp. serological reagents.

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(b) *Classification.* Class I. These devices are exempt from the premarket notification procedures in Subpart E of Part 807.

46. In § 866.3125 by revising paragraph (b) to read as follows:

§ 866.3125 Citrobacter spp. serological reagents.

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(b) *Classification.* Class I. These devices are exempt from the premarket notification procedures in Subpart E of Part 807.

47. In § 866.3205 by revising paragraph (b) to read as follows:

§ 866.3205 Echovirus serological reagents.

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(b) *Classification.* Class I. These devices are exempt from the premarket notification procedures in Subpart E of Part 807.

48. In § 866.3250 by revising paragraph (b) to read as follows:

§ 866.3250 Erysipelothrix rhusiopathiae serological reagents.

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(b) *Classification.* Class I. These devices are exempt from the premarket notification procedures in Subpart E of Part 807.

49. In § 866.3255 by revising paragraph (b) to read as follows:

§ 866.3255 Escherichia coli serological reagents.

* * * * *

(b) *Classification.* Class I. These devices are exempt from the premarket notification procedures in Subpart E of Part 807.

50. In § 866.3270 by revising paragraph (b) to read as follows:

§ 866.3270 Flavobacterium spp. serological reagents.

* * * * *

(b) *Classification.* Class I. These devices are exempt from the premarket notification procedures in Subpart E of Part 807.

51. In § 866.3330 by revising paragraph (b) to read as follows:

§ 866.3330 Influenza virus serological reagents.

* * * * *

(b) *Classification.* Class I. These devices are exempt from the premarket notification procedures in Subpart E of Part 807.

52. In § 866.3340 by revising paragraph (b) to read as follows:

§ 866.3340 Klebsiella spp. serological reagents.

* * * * *

(b) *Classification.* Class I. These devices are exempt from the premarket notification procedures in Subpart E of Part 807.

53. In § 866.3400 by revising paragraph (b) to read as follows:

§ 866.3400 Parainfluenza virus serological reagents.

* * * * *

(b) *Classification.* Class I. These devices are exempt from the premarket notification procedures in Subpart E of Part 807.

54. In § 866.3410 by revising paragraph (b) to read as follows:

§ 866.3410 Proteus spp. (Weil-Felix) serological reagents.

* * * * *

(b) *Classification.* Class I. These devices are exempt from the premarket notification procedures in Subpart E of Part 807.

55. In § 866.3470 by revising paragraph (b) to read as follows:

§ 866.3470 Reovirus serological reagents.

* * * * *

(b) *Classification.* Class I. These devices are exempt from the premarket notification procedures in Subpart E of Part 807.

56. In § 866.3490 by revising paragraph (b) to read as follows:

§ 866.3490 Rhinovirus serological reagents.

* * * * *

(b) *Classification.* Class I. These devices are exempt from the premarket notification procedures in Subpart E of Part 807.

57. In § 866.3520 by revising paragraph (b) to read as follows:

§ 866.3520 Rubeola (measles) virus serological reagents.

* * * * *

(b) *Classification.* Class I. These devices are exempt from the premarket notification procedures in Subpart E of Part 807.

58. In § 866.3630 by revising paragraph (b) to read as follows:

§ 866.3630 Serratia spp. serological reagents.

* * * * *

(b) *Classification.* Class I. These devices are exempt from the premarket notification procedures in Subpart E of Part 807.

59. In § 866.3700 by revising paragraph (b) to read as follows:

§ 866.3700 Staphylococcus aureus serological reagents.

* * * * *

(b) *Classification.* Class I. These devices are exempt from the premarket notification procedures in Subpart E of Part 807.

60. In § 866.4500 by revising paragraph (b) to read as follows:

§ 866.4500 Immunoelectrophoresis equipment.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

61. In § 866.4520 by revising paragraph (b) to read as follows:

§ 866.4520 Immunofluorometer equipment.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

62. In § 866.4540 by revising paragraph (b) to read as follows:

§ 866.4540 Immunonephelometer equipment.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

63. In § 866.4600 by revising paragraph (b) to read as follows:

§ 866.4600 Ouchterlony agar plate.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

64. In § 866.4830 by revising paragraph (b) to read as follows:

§ 866.4830 Rocket immunoelectrophoresis equipment.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

65. In § 866.4900 by revising paragraph (b) to read as follows:

§ 866.4900 Support gel.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

66. In § 866.5800 by revising paragraph (b) to read as follows:

§ 866.5800 Seminal fluid (sperm) immunological test system.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

PART 868—ANESTHESIOLOGY DEVICES

67. The authority citation for 21 CFR Part 868 continues to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

68. Part 868 is amended by adding new § 868.9 to read as follows:

§ 868.9 Limitations of exemptions from section 510(k) of the act.

FDA's decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

69. In § 868.1030 by revising paragraph (b) to read as follows:

§ 868.1030 Manual algesimeter.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

70. In § 868.1910 by revising paragraph (b) to read as follows:

§ 868.1910 Esophageal stethoscope.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

71. In § 868.1930 by revising paragraph (b) to read as follows:

§ 868.1930 Stethoscope head.

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(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

72. In § 868.1965 by revising paragraph (b) to read as follows:

§ 868.1965 Switching valve (ploss).

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

73. In § 868.5220 by revising paragraph (b) to read as follows:

§ 868.5220 Blow bottle.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807. If the device is not labeled or otherwise represented as sterile, it is exempt from the good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

74. In § 868.5280 by revising paragraph (b) to read as follows:

§ 868.5280 Breathing tube support.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

75. In § 868.5340 by revising paragraph (b) to read as follows:

§ 868.5340 Nasal oxygen cannula.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

76. In § 868.5365 by revising paragraph (b) to read as follows:

§ 868.5365 Posture chair for cardiac or pulmonary treatment.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

77. In § 868.5420 by revising paragraph (b) to read as follows:

§ 868.5420 Ether hook.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807. If the device is not labeled or otherwise represented as sterile, it is exempt from the good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

78. In § 868.5560 by revising paragraph (b) to read as follows:

§ 868.5560 Gas mask head strap.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

79. In § 868.5620 by revising paragraph (b) to read as follows:

§ 868.5620 Breathing mouthpiece.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

80. In § 868.5640 by revising paragraph (b) to read as follows:

§ 868.5640 Medicinal nonventilatory nebulizer (atomizer).

* * * * *

(b) *Classification.* Class I. If no curative labeling claims are made (e.g., "cures the common cold"), the device is exempt from the premarket notification procedures in Subpart E of Part 807.

81. In § 868.5760 by revising paragraph (b) to read as follows:

§ 868.5760 Cuff spreader.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807. If the device is not labeled or otherwise represented as sterile, it is exempt from the good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

82. In § 868.6100 by revising paragraph (b) to read as follows:

§ 868.6100 Anesthetic cabinet, table, or tray.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

83. In § 868.6175 by revising paragraph (b) to read as follows:

§ 868.6175 Cardiopulmonary emergency cart.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulations in Part 820, with the exception of § 868.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

84. In § 868.6225 by revising paragraph (b) to read as follows:

§ 868.6225 Nose clip.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

85. In § 868.6700 by revising paragraph (b) to read as follows:

§ 868.6700 Anesthesia stool.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

86. In § 868.6810 by revising paragraph (b) to read as follows:

§ 868.6810 Tracheobronchial suction catheter.

* * * * *

(b) *Classification.* Class I. If no antichoke or food removal labeling claims are made, the device is exempt from the premarket notification procedures in Subpart E of Part 807.

PART 870—CARDIOVASCULAR DEVICES

87. The authority citation for 21 CFR Part 870 continues to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10

88. Part 870 is amended by adding new § 870.9 to read as follows:

§ 870.9 Limitations of exemptions from section 510(k) of the act.

FDA's decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

89. In § 870.3730 by revising paragraph (b) to read as follows:

§ 870.3730 Pacemaker service tools.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures of Subpart E of Part 807.

90. In § 870.4200 by revising paragraph (b) to read as follows:

§ 870.4200 Cardiopulmonary bypass accessory equipment.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

91. In § 870.4500 by revising paragraph (b) to read as follows:

§ 870.4500 Cardiovascular surgical instruments.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

92. The authority citation for 21 CFR Part 876 continues to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

93. Part 876 is amended by adding new § 876.9 to read as follows:

§ 876.9 Limitations of exemptions from section 510(k) of the act.

FDA's decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

94. In § 876.4370 by revising paragraph (b)(2) to read as follows:

§ 876.4370 Gastroenterology-urology evacuator.

* * * * *

(b) * * *

(2) Class I for the gastroenterology-urology evacuator when manually powered. The device subject to this

paragraph (b)(2) is exempt from the premarket notification procedures in Subpart E of Part 807.

95. In § 876.4530 by revising paragraph (b) to read as follows:

§ 876.4530 Gastroenterology-urology fiberoptic retractor.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

96. In § 876.4560 by revising paragraph (b) to read as follows:

§ 876.4560 Ribdam.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

97. In § 876.4730 by revising paragraph (b) to read as follows:

§ 876.4730 Manual gastroenterology-urology surgical instrument and accessories.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

98. In § 876.4890 by revising paragraph (b)(2) to read as follows:

§ 876.4890 Urological table and accessories.

* * * * *

(b) * * *

(2) Class I for the manually powered table and accessories. The device subject to this paragraph (b)(2) is exempt from the premarket notification procedures in Subpart E of Part 807.

99. In § 876.5030 by revising paragraph (b) to read as follows:

§ 876.5030 Continent ileostomy catheter.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

100. In § 876.5820 by revising paragraph (b)(2) to read as follows:

§ 876.5820 Hemodialysis system and accessories.

* * * * *

(b) * * *

(2) Class I for other accessories of the hemodialysis system remote from the extracorporeal blood system and the dialysate delivery system, such as the unpowered dialysis chair, hemodialysis start/stop tray, dialyzer holder set, and dialysis tie gun and ties. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in Subpart E of Part 807.

101. In § 876.5900 by revising paragraph (b) to read as follows:

§ 876.5900 Ostomy pouch and accessories.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

102. In § 876.5920 by revising paragraph (b) to read as follows:

§ 876.5920 Protective garment for incontinence.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

103. The authority citation for 21 CFR Part 880 continues to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

104. Part 880 is amended by adding new § 880.9 to read as follows:

§ 880.9 Limitations of exemptions from section 510(k) of the act.

FDA's decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

105. In § 880.5110 by revising paragraph (b) to read as follows:

§ 880.5110 Hydraulic adjustable hospital bed.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

106. In § 880.5120 by revising paragraph (b) to read as follows:

§ 880.5120 Manual adjustable hospital bed.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the current good manufacturing practice regulations in Part 820 with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

107. In § 880.5510 by revising paragraph (b) to read as follows:

§ 880.5510 Non-AC-powered patient lifts.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

108. In § 880.6150 by revising paragraph (b) to read as follows:

§ 880.6150 Ultrasonic cleaner for medical instruments.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807, except that any solutions intended for use with the device for cleaning or sanitizing the instruments are not exempt.

109. In § 880.6280 by revising paragraph (b) to read as follows:

§ 880.6280 Medical insole.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of part 807.

110. In § 880.6970 by revising paragraph (b) to read as follows:

§ 880.6970 Liquid crystal vein locator.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

PART 882—NEUROLOGICAL DEVICES

111. The authority citation for 21 CFR Part 882 continues to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

112. Part 882 is amended by adding new § 882.9 to read as follows:

§ 882.9 Limitations of exemptions from section 510(k) of the act.

FDA's decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectivenes, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

113. In § 882.1200 by revising paragraph (b) to read as follows:

§ 882.1200 Two-point discriminator.

* * * * *

(b) *Classification.* Class I. If the device is made of the same material (single, surgical-grade, stainless steel alloy) that was used in the device before May 28, 1976, the device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

114. In § 882.1500 by revising paragraph (b) to read as follows:

§ 882.1500 Esthesiometer.

* * * * *

(b) *Classification.* Class I. If the device is composed entirely of a single material, the device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

115. In § 882.1525 by revising paragraph (b) to read as follows:

§ 882.1525 Tuning fork.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the current good manufacturing practice regulations in Part 820, with the exception of §820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

116. In § 882.1700 by revising paragraph (b) to read as follows:

§ 882.1700 Percussor.

* * * * *

(b) *Classification.* Class I. If the device is a small, hand-held hammer with a rubber head, the device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

117. In § 882.1750 by revising paragraph (b) to read as follows:

§ 882.1750 Pinwheel.

* * * * *

(b) *Classification.* Class I. If the device is made of the same material (single, surgical-grade, stainless steel alloy) that was used in the device before May 28, 1976, and it is manually operated, the device is exempt from the premarket notification procedures in Subpart E of Part 807.

118. In § 882.4215 by revising paragraph (b) to read as follows:

§ 882.4215 Clip rack.

* * * * *

(b) *Classification.* Class I. If the device is composed entirely of a single metal alloy having the same composition as the clips it is intended to hold, the device is exempt from the premarket notification procedures in Subpart E of Part 807.

119. In § 882.4650 by revising paragraph (b) to read as follows:

§ 882.4650 Neurosurgical suture needle.

* * * * *

(b) *Classification.* Class I. If the device is made of the same material (single, surgical-grade, stainless steel alloy) that was used in the device before May 28, 1976, the device is exempt from the premarket notification procedures in Subpart E of Part 807.

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

120. The authority citation for 21 CFR Part 884 continues to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

121. Part 884 is amended by adding new § 884.9 to read as follows:

§ 884.9 Limitations of exemptions from section 510(k) of the act.

FDA's decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

122. In § 884.2900 by revising paragraph (b) to read as follows:

§ 884.2900 Fetal stethoscope.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

123. In § 884.4520 by revising paragraph (b) to read as follows:

§ 884.4520 Obstetric and gynecologic general manual instrument.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

124. In § 884.5920 by revising paragraph (b) to read as follows:

§ 884.5920 Vaginal insufflator.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

PART 890—PHYSICAL MEDICINE DEVICES

125. The authority citation for 21 CFR Part 890 continues to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

126. Part 890 is amended by adding new § 890.9 to read as follows:

§ 890.9 Limitations of exemptions from section 510(k) of the act.

FDA's decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

127. In § 890.3700 by revising paragraph (b)(2) to read as follows:

§ 890.3700 Nonpowered communication system.

* * * * *

(b) * * *

(2) Class I., The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the current good manufacturing practice regulations in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

128. In § 890.5125 by revising paragraph (b) to read as follows:

§ 890.5125 Nonpowered sitz bath.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the current good manufacturing regulations in Part 820, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

Dated: December 24, 1987.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 88–858 Filed 1–19–88; 8:45 am]

BILLING CODE 4160-01-M

federal register

Wednesday
January 20, 1988

Part V

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 892

Radiology Devices; Proposed Exemptions From Premarket Notification; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 892

[Docket No. 86N-0014]

Radiology Devices; Proposed Exemptions From Premarket Notification

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to exempt from the requirement of premarket notification, with limitations, six class I generic types of radiology devices. Elsewhere in this issue of the **Federal Register**, FDA is issuing a final rule classifying these and other radiology devices. These actions are being taken under the Medical Device Amendments of 1976 and are a step in implementing one of the goals in FDA's plan for action.

DATES: Comments by March 21, 1988. FDA is proposing that the final rule based on this proposed rule become effective 30 days after its date of publication in the **Federal Register**.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Harvey Rudolph, Center for Devices and Radiological Health (HFZ-83), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3426.

SUPPLEMENTARY INFORMATION: The Medical Device Amendments of 1976 (Pub. L. 94-295, hereinafter called the amendments) establish a comprehensive system for the regulation of medical devices intended for human use. One provision of the amendments, section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), establishes three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness: Class I, general controls; class II, performance standards; and class III, premarket approval.

Section 513(d)(2)(A) of the act (21 U.S.C. 360c(d)(2)(A) authorizes FDA to exempt, by regulation, a generic type of class I device from the requirement of, among other things, premarket notification in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR Part 807, Subpart E. Such an exemption permits manufacturers to introduce into commercial distribution generic types of devices without first submitting to FDA a premarket notification. When FDA was publishing its proposed classification regulations for preamendment devices, the agency did not routinely evaluate whether it should grant to manufacturers of devices placed in class I an exemption from the requirement of premarket notification. Generally, FDA considered such exemptions only when the advisory panels included them in recommendations to the agency.

Recently, FDA developed criteria for exempting certain class I devices from the requirement of premarket notification, to reduce the number of unnecessary premarket notifications thereby freeing agency resources for the review of more complex notifications. FDA believes that exempting these devices will allow the agency to make better use of its resources and thus better serve the public. In other words, the process of exempting these devices from the section 510(k) premarket notification program, where premarket notification will not advance FDA's public health mission, will free resources available to address pressing regulatory concerns and make the agency more efficient.

The development of these criteria and the issuance of proposed and final rules exempting appropriate devices from the requirement of premarket notification in section 510(k) of the act will help implement a goal of FDA's Plan for Action Phase II (Ref. 1).

Criteria for 510(k) Exemptions

FDA is proposing to exempt a generic type of class I device from the requirement of premarket notification with the limitations described below, if FDA determines that premarket notification is not necessary for the protection of the public health. FDA may propose to grant an exemption if both of the following criteria are met:

1. FDA has determined that the device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device such as device design or materials. When making these determinations, FDA may consider the frequency, persistence, cause, or seriousness of such claims or risks, or other factors.

2. FDA has determined that: (a) Characteristics of the device necessary for its safe and effective performance are well established; (b) anticipated changes in the device that are of the type that could affect safety and effectiveness will (1) be readily detectable by users by visual examination or other means, such as routine testing, e.g., testing of a clinical laboratory reagent with positive and negative controls, before causing harm; or (2) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment, and (c) that any changes in the device will not be likely to result in a change in the device's classification.

FDA will make the determinations above based on its knowledge of the device, including past experience and relevant reports or studies on device performance. Based on the above criteria, FDA will place the exempted device into the same class as the class I device to which it would be substantially equivalent.

FDA may, if it has concerns only about certain types of changes in a class I device, grant a limited exemption from premarket notification for the generic type of device. A limited exemption will specify what types of changes manufacturers must continue to report to FDA in the context of premarket notification. For example, FDA may exempt a device except when a manufacturer intends to use a different material.

FDA's decision to grant an exemption from the requirement of premarket notification for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic of a device that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution of the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device

detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

Application of the Criteria to Class I Radiology Devices

In the proposed regulations of January 29, 1982 (47 FR 4406), FDA proposed to classify preamendments radiology devices in accordance with amendments. When FDA proposed to classify the six devices below, the agency did not propose exemptions from the requirement of premarket notification for these devices. The Panel did not recommend exemptions from the requirement of premarket notification for certain of these devices. FDA agrees that full exemption from premarket notification is unjustified for these devices; however, for the efficient enforcement of the act and consistent with its policy regarding exemptions from premarket notification, FDA now is proposing to exempt from the requirement of premarket notification, with limitations, the six devices below.

Section	Device
892.1370...	Nuclear anthropomorphic phantom.
892.1380...	Nuclear flood source phantom.
892.1400...	Nuclear sealed calibration source.
892.1420...	Radionuclide test pattern phantom.
892.1880...	Wall mounted radiographic cassette holder.
892.6500...	Personnel protective shield.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying the devices above in class I. FDA is proposing in this document to grant an exemption from the requirement of premarket notification for each of the devices above.

Reference

The following information has been placed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. "Food and Drug Administration—A Plan for Action," Public Health Service, Department of Health and Human Services, July 1985, p. 18.

Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) (April 26, 1985; 50 FR 16636) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact is required.

Economic Impact

FDA has carefully analyzed the economic effects of this proposed rule and has determined that the proposed rule will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act. In accordance with section 3(g)(1) of Executive Order 12291, the impact of this proposed rule has been carefully analyzed, and it has been determined that the proposed rule does not constitute a major rule as defined in section 1(b) of the Executive Order. The devices subject to this proposed rule are now subject only to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j). Under any final rule based on this proposal, the devices would remain subject to such controls, other than premarket notification.

Interested persons may, on or before March 21, 1988, submit to the Dockets Management Branch (address above) written comments regarding this proposal. 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.

List of Subjects in 21 CFR Part 892

Radiology devices, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that Part 892 be amended as follows:

PART 892—RADIOLOGY DEVICES

1. The authority citation for 21 CFR Part 892 continues to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

2. Part 892 is amended by adding new § 892.9, to read as follows:

§ 892.9 Limitations of exemptions from section 510(k) of the act.

FDA's decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

3. In § 892.1370 by revising paragraph (b), to read as follows:

§ 892.1370 Nuclear anthropomorphic phantom.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

4. In § 892.1380 by revising paragraph (b), to read as follows:

§ 892.1380 Nuclear flood source phantom.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

5. In § 892.1400 by revising paragraph (b), to read as follows:

§ 892.1400 Nuclear sealed calibration source.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

6. In § 892.1420 by revising paragraph (b), to read as follows:

§ 892.1420 Radionuclide test pattern phantom.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

7. In § 892.1880 by revising paragraph (b), to read as follows:

§ 892.1880 Wall mounted radiographic cassette holder.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

8. In § 892.6500 by revising paragraph (b), to read as follows:

§ 892.6500 Personnel protective shield.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807.

Dated: December 24, 1987.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 88–859 Filed 1–19–88; 8:45 am]

BILLING CODE 4160–01–M

federal register

Wednesday
January 20, 1988

Part VI

Department of Education

Invitation for New Applications for Certain Programs Under the Rehabilitation Services Administration; Notice

DEPARTMENT OF EDUCATION

Invitation for New Applications for Certain Programs Under the Rehabilitation Services Administration

In the matter of invitation for new applications for two programs under the Rehabilitation Services Administration for Fiscal Year 1988: (1) Special Projects and Demonstrations for Providing Vocational Rehabilitation Services to Severely Disabled Individuals, and (2) Projects with Industry (CFDA Nos. 84.128A and 84.128B).

Purpose: Provide support to State and other public agencies and private agencies and organizations to expand or otherwise improve rehabilitation services leading to the placement of individuals with severe handicaps in employment.

Deadline for Transmittal of Applications: March 15, 1988.

Applications Available: January 29, 1988.

Available Funds: It is estimated that $730,000 will be available for the support of new projects under the Program of Special Projects and Demonstrations for Providing Vocational Rehabilitation Services to Severely Disabled Individuals and $930,000 for new projects under Projects with Industry.

Applicable Regulations: (a) Education Department General Administrative Regulations (EDGAR), 34 CFR Parts 74, 75, 77, and 78; (b) Rehabilitation Services Administration Regulations, 34 CFR Parts 369, 373, and 379; and (c) when adopted in final form, the Notice of Proposed Priorities for these programs published in the **Federal Register** on January 4, 1988 (53 FR 104). Applicants should prepare their applications based on the proposed priorities. If there are any significant changes in the final priorities, applicants will be given the opportunity to amend or resubmit their applications.

For Applications or Information Contact: The contact person listed in the Notice of Proposed Priorities, or for applications only, Mary V. Vest, Rehabilitation Services Administration, U.S. Department of Education, 400 Maryland Avenue SW., Room 3332—Switzer Building, Mailstop 2312, Washington, DC 20202 (Telephone: (202) 732–1343).

Program Authority: 29 U.S.C. 777a(a)(1), and 795g.

Dated: January 14, 1988.

Madeleine Will,

Assistant Secretary for Special Education and Rehabilitative Services.

APPLICATION NOTICES FOR FISCAL YEAR 1988

Title and CFDA No.	Deadline for transmittal of applications	Deadline for intergovernmental review	Available funds	Estimated range of awards	Estimated size of awards	Estimated No. of awards	Project period (Months)
Special projects and demonstrations for providing vocational rehabilitation services to severely disabled individuals, 84.128A.	3/15/88	N/A	730,000	100,000–150,000	146,000	5	Up to 36.
Projects with industry, 84.128B	3/15/88	N/A	930,000	100,000–200,000	155,000	6	Up to 36.

[FR Doc. 88–1016 Filed 1–19–88; 8:45 am]

BILLING CODE 4000–01–M

federal register

Wednesday
January 20, 1988

Part VII

Department of Energy

Office of Nuclear Energy

10 CFR Part 730

Petitions Requesting Disposal Capacity for Unusual or Unexpected Volumes of Low-Level Radioactive Waste; Submission and Evaluation Requirements; Notice of Proposed Rulemaking and Public Hearing

DEPARTMENT OF ENERGY

Office of Nuclear Energy

10 CFR Part 730

Petitions Requesting Disposal Capacity for Unusual or Unexpected Volumes of Low-Level Radioactive Waste; Submission and Evaluation Requirements

AGENCY: Office of Remedial Action and Waste Technology, Office of Nuclear Energy (NE), DOE.

ACTION: Notice of proposed rulemaking and public hearing.

SUMMARY: The Department of Energy (DOE) is issuing a notice of proposed rulemaking in order to implement section 5(c)(5) of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (the Act). This section authorizes DOE to grant to commercial nuclear power reactors allocations of disposal capacity for low-level radioactive waste resulting from unusual or unexpected operations or maintenance activities. The proposed regulation sets forth informational requirements applicable to petitioners for such allocations, as well as the criteria DOE will use to evaluate such petitions.

DATES: Written comments (6 copies) on this proposed rule must be received by March 21, 1988, in order to ensure their consideration.

A public hearing will be held on this proposed rule in Washington, DC, beginning at 10:00 a.m., e.s.t., on February 25, 1988, at the location specified in the addresses section. Requests to speak at the hearing must be received no later than 4:00 p.m. on February 23. Please bring at least 6 copies of the oral statement to the hearing.

ADDRESSES: All written comments (6 copies) and requests to speak at the public hearing should be addressed to: Mr. Jeffrey L. Smiley, NE-24, U.S. Department of Energy, Washington, DC 20545, (301-353-4216). Envelopes should include the notation, "Rulemaking Comment." The public hearing will begin at 10:00 a.m. and will be held in Washington, DC, at: U.S. Department of Energy, Forrestal Building, Room 1E-245, 1000 Independence Avenue, SW., 20585. Each person to be heard is requested to bring 6 copies of his/her statement. In the event any person wishing to testify cannot meet this requirement, alternative arrangements can be made with Mr. Jeffrey L. Smiley in advance by so indicating in the letter requesting to make an oral presentation.

FOR FURTHER INFORMATION CONTACT: Jeffrey L. Smiley, Low-Level Waste Management Program, NE-24, U.S. Department of Energy, Washington, DC 20545, (301-353-4216); or Sandra Sherman, GC-31, Office of General Counsel, 1000 Independence Avenue, SW., Room 6B-256, Washington, DC 20585, (202-586-6972).

SUPPLEMENTARY INFORMATION:

I. Introduction and Background

The Low-Level Radioactive Waste Policy Amendments Act of 1985 (Pub. L. 99-240) (the Act) was enacted January 15, 1986. Subsections (1) and (2) of section 5(c) of the Act contain a formula for allocating to each commercial nuclear power reactor specific volumes of disposal capacity. Under the formula, a reactor may receive an allocation for the "transition period" between January 1, 1986, and December 31, 1989, and another allocation for the "licensing period" between January 1, 1990, and December 31, 1992 (together the "interim access period"). These "regular" allocations of disposal capacity, which do not require petitions to DOE, may be used to dispose of low-level waste at any of the three currently operating disposal sites at Barnwell, South Carolina; Richland, Washington; and Beatty, Nevada, during the interim access period, of January 1, 1986, through December 31, 1992. In addition to these regular allocations, section 5 of the Act authorizes DOE to grant to reactors, upon petition to DOE, additional allocations of disposal capacity for low-level waste which may result from "unusual" or "unexpected" operating and maintenance activities ("Unusual Volume allocations").

Section 5 provides that the total disposal capacity allocated by DOE under the Unusual Volumes procedure cannot exceed 800,000 cubic feet, or result in total allocations of disposal capacity to commercial nuclear power reactors in excess of 11,900,000 cubic feet.

On January 26, 1987, DOE published in the **Federal Register** a Notice of Inquiry soliciting public comment on issues that it considered central to its management of the Unusual Volumes procedure (52 FR 2792). These issues included the definition of "unusual or unexpected" activities; the availability of the 800,000 cubic feet capacity (depending on the rate that full-power operating licenses are granted); the petition process; informational requirements; and decision criteria for evaluating petitions. DOE expressed its intent to provide guidance for submitting, and criteria for evaluating petitions, upon consideration of the comments. Today, DOE responds to the comments received on the Notice of Inquiry and proposes rules for the petition process.

II. Analysis of Comments and Proposed Rules

Thirteen sources provided comments on the Notice of Inquiry. There was an overriding concern expressed by the commenters that a process should be implemented for equitably managing the Unusual Volumes procedure. The comments received and DOE's response to these comments are discussed below.

A. Definition of "Unusual" and "Unexpected" Activities

Section 5(c)(5) of the Act authorizes the Secretary to grant supplemental allocations of disposal capacity to commercial nuclear power reactors if such capacity is necessary to permit unusual or unexpected operating, maintenance, repair or safety activities. The Notice of Inquiry proposed a list of "unusual or unexpected" low-level waste generating activities and invited suggestions for other appropriate activities. Commenters supported the proposed list of activities, but cautioned that any such list should be illustrative, and not exclude other unforeseen activities.

DOE recognizes that other unforeseen operational or maintenance activities could be required over the 7-year interim access period. The definition of unusual or unexpected activities in § 730.2 is intended, therefore, as non-exclusive guidance to petitioners as to the type of low-level waste generating activities eligible for Unusual Volume allocations. As such, the list of examples is illustrative rather than prescriptive, and DOE will consider other activities not typically associated with day-to-day plant operations as eligible for allocations. However, DOE retains discretion regarding whether actually to grant an allocation for any such activity.

B. Availability of the 800,000 Cubic Feet of Capacity

The Act provides that DOE may not make Unusual Volume allocations that would result in total allocations to commercial power reactors in excess of 11,900,000 cubic feet. The 800,000 cubic feet of Unusual Volume disposal capacity is available, subject to further reduction, within this overall limitation. Congress derived the 800,000 cubic foot figure, in part, from estimates of the dates that commercial nuclear power reactors, planned or under construction, would receive their full-power operating licenses. The amount represents the

difference between total estimated regular allocations, and the 11,900,000 cubic feet ceiling on all reactor low-level waste that can be disposed at the three operating disposal sites.

DOE expressed concern in the Notice of Inquiry that the entire 800,000 cubic feet may have to be scaled back if new reactors are licensed ahead of the projections used by the congressional committees in developing the allocation provision. However, commenters pointed out that licensing dates for new reactors will often be delayed, most likely ensuring that the entire 800,000 cubic feet will be available over the interim access period for distribution as Unusual Volume allocations. DOE will proceed on this basis, and has incorporated this assumption at § 730.8, *Schedule for Distributing Allocations*, of the proposed regulation. However, DOE will continue to monitor the licensing dates of new reactors in order to assess the impact on the continued availability of disposal capacity for Unusual Volume allocations, and to determine whether the amount should be reduced to reflect any projected shortfalls.

C. Petition Process

Since the Act does not prescribe procedures for administering the Unusual Volumes provision, the Notice of Inquiry contained five options for managing allocations over the interim access period. In assessing these options, and the comments thereon, DOE's objective was to fashion a method of allocation that would balance the need for equitable distribution during any one year, with the equally important necessity of preventing the premature depletion of the available disposal capacity prior to expiration of the interim access period.

Option 1, Petition as Needed: DOE would evaluate petitions as they were received on a case-by-case basis, until the 800,000 cubic feet of capacity was depleted.

Option 2, Annual Petitions: DOE would establish an annual deadline for submitting petitions for the upcoming year, and would simultaneously issue all allocations each year.

Option 3, One Time Petition: DOE would establish a deadline for submitting petitions covering the entire interim access period, and would issue allocations for each eligible petition on a one-time basis.

Option 4, Allocation Schedule: DOE would provide a disbursement schedule for allocating disposal capacity evenly over the interim access period.

Option 5, Combination of Options: DOE would select elements from the foregoing options.

The majority of commenters supported the establishment of a schedule for disbursement of allocations over the entire interim access period, as proposed under Option 4. Some comments supported Option 1, allowing petitions to be submitted as needed, but noted that this approach should nonetheless promote equity among petitioners by ensuring access to disposal capacity throughout the interim access period. In view of the convergence of concerns around the long-term availability of Unusual Volume allocations, DOE proposes to combine Options 1 and 4. Accordingly, the proposed rule at § 730.4(b) permits petitions to be submitted as needed, but § 730.8 requires DOE to disburse available disposal capacity evenly over the interim access period, and to proportionately limit, if necessary in any particular year, the volumes awarded in response to petitions.

To ensure the availability of capacity over the interim access period, DOE proposes to divide the 800,000 cubic feet equally among the 7 years of the interim access period. The resulting 114,286 cubic feet is the "yearly base volume" for Unusual Volumes allocations. Any capacity not allocated during a year will be applied in equal portions to each subsequent year. Since no allocations were granted in 1986, the 114,286 cubic feet available in 1986 would be distributed equally among the remaining 6 years of the interim access period, resulting in a new yearly base volume of 133,333 cubic feet for the years 1987 through 1992.

The proposed rules provide that DOE will not allocate more than the yearly base volume in any year, unless it determines that (1) the cumulative capacity to be allocated does not significantly exceed the yearly base volume, and a significant number of petitions would be affected by limiting the allocations, or (2) it is substantially likely that the Unusual Volume capacity available for the remainder of the interim access period will exceed the volume for which petitions may be submitted.

The proposed rules contain a mechanism for reconciling the limitation on total capacity issued each year with the flexibility granted to petitioners to file petitions as needed. The rules would permit DOE to (1) limit the capacity issued in response to any petition (or multiple petitions in a single year from the same petitioner) to 25 percent of the yearly base volume applicable on the date of the petition, and (2) reduce the capacity available for allocation if the total capacity that may be issued for that year may exceed the yearly base volume. Under the latter provision, DOE assumes that as the year advances, petitions submitted respecting activities occurring in that year may face an increasing likelihood of capacity reductions. This is because, as petitions are granted, DOE will have a firmer basis upon which to determine whether the yearly base volume for that year may be exceeded. Correspondingly, however, it is likely that a petition submitted later in a calendar year will request disposal capacity for an activity scheduled for the next calendar year; any Unusual Volume allocation in response to such a petition is less likely to be reduced, since it will be made against the yearly base volume available for that year's activities.

Under the proposed rules, DOE will not issue an allocation prior to 6 months before the start of the activity for which it is sought, which should also, promote a relatively even distribution over the interim access period. Moreover, in the event that the capacity allocated in response to a petition is reduced under either of the provisions above, or the volume of waste generated by the activity otherwise exceeds the volume allocated, a petition requesting an additional allocation may be submitted in a subsequent year.

Option 2 in the Notice of Inquiry would have obviated the need for capacity reductions on a case-by-case basis toward the end of the year. However, to reach this result, all petitions for an upcoming calendar year would have been required to be submitted well in advance of that year, allowing DOE to reduce each allocation proportionally if the capacity available for disbursement was not sufficient to satisfy each request in full. However, the commenters felt that this method would have required the petitions to be submitted too far in advance to allow petitioners to properly estimate the allocation that would have been needed to permit activity. Commenters also pointed out that, unlike most "unusual" activities, "unexpected" activities, by definition, cannot be anticipated in this manner.

A procedure using an annual deadline for submission of petitions would also require that some portion of the volume be set aside for unexpected activities that could not have been foreseen, and a set of rules for distinguishing between unusual and unexpected activities. Absent statutory direction, DOE believes that such a procedure would be cumbersome to administer, and that any potential benefit to petitioners would be outweighed by the inconvenience. Because of this, and because DOE

believes that, notwithstanding yearly fluctuations in the capacity awarded, the available capacity will be sufficient to accommodate petitions throughout the interim access period, DOE decided not to propose a process requiring an annual deadline. For the same reasons, DOE also rejected Option 3, requiring a one-time petition from each reactor for the entire interim access period.

In considering the proposed rules and the comments received on the Notice of Inquiry, it has become apparent to DOE that estimates of the volume of waste that will result from an unusual or unexpected activity may not match the volume ultimately generated. In the interest of equitable distribution of available capacity, DOE encourages conservative estimates of the volume of waste to be produced. (As noted, DOE will at any time accept petitions for additional capacity with respect to an activity for which an Unusual Volume allocation has already been granted). In this regard, the rules also provide that Unusual Volume capacity is granted conditionally upon use of the volume allocated for the activity stated in the petition. After completion of the activity and disposal of the resulting waste, it is the petitioner's responsibility promptly to report to DOE the volume of waste from the activity actually disposed. Any Unusual Volume capacity that has been awarded in excess of the volume of waste disposed will revert to DOE for redistribution.

D. Petition Information

The Notice of Inquiry proposed certain mandatory information requirements to be included in each petition, and also proposed certain "discretionary" elements in addition to the minimum requirements. The mandatory requirements proposed in the Notice of Inquiry were: (a) Name, address, and telephone number of the petitioner and point of contact; (b) name of reactor and utility; (c) description of the waste; (d) explanation of the need for an allocation; (e) description of the activity generating the waste; and (f) certification that the waste does not constitute a health or safety hazard and that the utility has not petitioned the Nuclear Regulatory Commission (NRC) for Emergency Access under section 6 of the Act. The proposed rule at § 730.5, *Contents of Petitions*, further elaborates the mandatory informational requirements in order to provide the level of detail necessary to make a proper evaluation of petitions. DOE will use the information to (1) identify the petitioner, (2) determine if and when the petitioner may be eligible for an Unusual Volumes allocation, and (3) determine the volume to be issued.

With the exceptions of item (d), explanation of need for the allocation, and item (f), "health and safety" certification, the commenters generally concurred in the mandatory informational requirements in the Notice of Inquiry.

A number of commenters requested that DOE demonstrate a legal basis for, and clarify, item (d), explanation of the need for the allocation. Section 5(c)(5)(A) of the Act requires the Secretary to state in writing his reasons for "so finding that making additional capacity available for such reactor through this paragraph is *required* to permit" the unusual or unexpected activity (emphasis added). The Act, then, suggests that an Unusual Volume allocation is not an entitlement comparable to the regular allocation that is granted as of right under section 5(c)(1). Instead, an Unusual Volume allocation is granted only upon demonstration of a need for additional capacity in order to permit activities that do not occur on a day-to-day basis.

One commenter suggested that a showing of need might discriminate in favor of reactors that had not made conservative use of their regular allocations, and against reactors that had implemented aggressive volume reduction programs. While recognizing this concern, DOE decided to retain the showing of need because (1) it is required by the Act, and (2) the high cost of disposal itself provides incentive for reactors to reduce waste volumes in spite of the availability of Unusual Volume allocations through the Unusual Volumes provision. DOE believes that Unusual Volume allocations should not be considered automatic, and will evaluate each petition based on its demonstration of need.

The mandatory information requirement, "Need for Allocation," has been further elaborated in the proposed rule to provide additional guidance to petitioners. Each category of information under this item now corresponds to a category of the decision criteria for determining eligibility and making volume determinations.

The commenters also requested clarification of item (f), which required that petitioners certify that the waste "does *not* constitute a health or safety hazard and that the utility has not petitioned the NRC for Emergency Access" (emphasis added). As proposed in the Notice of Inquiry, the "health and safety" certification was intended to be a corollary of the provision in section 6 (c)(1) of the Act that requires the NRC to determine that waste for which it grants emergency access does pose "an immediate and serious threat to the public health and safety."

In contrast to the Emergency Access provision, which provides a last resort for access to disposal facilities only if the waste poses a serious eminent danger, the risk posed by waste for which Unusual Volume petitions are submitted may vary widely, if the waste remains undisposed. One of the purposes of the Unusual Volumes procedure is to ensure that whatever potential risk the waste may pose is eliminated through properly regulated disposal. Therefore, upon further consideration, DOE has deleted the requirement that petitioners certify that the waste does not constitute a health and safety hazard.

The proposed rule retains the requirement that petitioners state that they have not also requested Emergency Access for the waste through the NRC. DOE believes that this procedure does not conflict with the NRC's proposed rules for Emergency Access (52 FR 47587), which require petitioners to demonstrate that waste for which emergency access is requested would not otherwise qualify for Unusual Volume capacity. DOE also believes that this modest requirement will serve to draw a distinction between these two provisions of the Act.

Requirement (c), "description of the waste," has been changed to require that petitions verify that waste for which the petition is submitted is suitable for disposal in at least one of the three currently operating disposal facilities. DOE will not distinguish between different types of waste eligible for Unusual Volume allocations as long as the waste is suitable for disposal in a currently operating site.

The proposed rule also contains two mandatory informational requirements not originally included in the Notice of Inquiry. The proposed rule would require petitions to include (1) the dates over which the activity occurred or will occur, and (2) the dates over which the waste will be shipped for disposal. This information will be necessary in order to determine when an unusual volume allocation may be issued in response to a petition, in view of the requirement that no allocation may be issued prior to 6 months before the commencement of the activity.

The discretionary information suggested in the Notice of Inquiry included: (a) Other utility management options; (b) impacts of denial of all or a portion of the request; (c) description of the utility's waste management plan and

volume reduction program; and (d) projected allocation requirements during the interim access period. Item (d) has been incorporated into the proposed rule for *Contents of Petitions* at § 730.5(a)(6), which requires petitioners to indicate their requirements for disposal capacity over the interim access period.

Comments concerning DOE's use of discretionary information were divided. Some commenters recommended that the information be required, while others suggested that it was not germaine. Under the proposed rule, DOE would require the petition to contain only the mandatory information specified in § 730.5(a), *Contents of Petitions*. However, a petitioner could still include any of the discretionary information elements proposed in the earlier Notice, or any other information that it believed might be useful to DOE in evaluating the petition.

E. Decision Criteria

The Notice of Inquiry proposed five decision criteria that would be used to evaluate the eligibility of petitions for Unusual Volume allocations and, for each eligible petition, to determine the volume to be allocated. The proposed rule more clearly distinguishes these two processes by dividing them into separate sections, *Eligibility Criteria* (§ 730.6), and *Volume Determination* (§ 730.7), and including the applicable decision criteria under each.

The Notice of Inquiry proposed the following decision criteria: (a) The number of applications, (b) activity which generated the waste, (c) consequences of denial of the application, (d) other management options available to the petitioner, and (e) waste volume reduction performed on the waste.

A number of commenters suggested that item (a), the number of applications, was less important in determining the volume to be allocated than the sum of the volumes requested in the petitions. As described in the discussion under subsection C of this Notice, the proposed rule, at § 730.7(b), would require DOE to limit the capacity allocated if the total exceeds the volume available for disbursement in that year.

Item (b), activity which generated the waste, is included in the criteria for determining eligibility of petitions at § 730.6(a). DOE will consider whether the waste is the result of an unusual or unexpected operating, maintenance, repair or safety activity as defined in the proposed rule.

In response to comments, the decision criteria (c), consequences of denial of the application, and (d), other management options available to the petitioner, are not included in the proposed rule as evaluation criteria. Upon further consideration, DOE determined that both of these draft criteria were too speculative or subjective to provide a useful basis for evaluation.

Instead, the proposed *Eligibility Criteria* at § 730.6(b), and criteria for *Volume Determination* at § 730.7 (a), prescribe a more quantitative evaluation of the information required under *Contents of Petitions* to demonstrate the need for the Unusual Volume allocation (§ 730.5(a)(6)). These decision criteria call for a comparison of the capacity available from the petitioner's regular allocation, with the capacity requested in the petition. A petition would be ineligible where the reactor's regular allocation is or will be sufficient to accommodate the additional waste from the unusual or unexpected activity. Where the regular allocation provides partial relief, the petition would be eligible for an Unusual Volume allocation, but only to the extent that the capacity needed for the unusual activity cannot be offset by the petitioner's regular allocation.

Item (e) in the Notice of Inquiry, "waste volume reduction performed on the waste," is not included in the criteria for Volume Determination in the proposed rule. Because of increasing costs of disposal and the accessibility of volume reduction technology, DOE considers that the waste will most likely undergo volume reduction to the extent practicable.

As discussed earlier in this Notice, the proposed rule for Volume Determination at § 730.7(b), (c) and (d) also includes criteria requiring DOE to reduce allocations for which a petition is otherwise eligible if (1) the disposal capacity requested exceeds or may exceed the capacity available for distribution; (2) the capacity requested exceeds 25 percent of the capacity available for distribution; or (3) licensing of new reactors earlier than expected may result in the sum of regular allocations and Unusual Volumes allocation exceeding 11,900,000 cubic feet.

III. Procedural Requirements

A. Executive Order 11291

Under Executive Order 12291 agencies are required to determine whether proposed rules are major rules as defined in the Order. DOE has reviewed this proposed rule and has determined that it is not a major rule because: Issuing Unusual Volume allocations, as proposed in this rule will not have an annual effect on the economy of $100 million or more; will not result in a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will not have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises.

B. Regulatory Flexibility Act

In accordance with section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, DOE finds that sections 603 and 604 of the said Act do not apply to this rule because, if promulgated, the rule will affect only electrical utilities that own nuclear power reactors, and will not affect small entities.

C. National Environmental Policy Act

Issuing Unusual Volume allocations under this proposed rule will not result in any effect on the quality of the human environment because (1) the total capacity for disposal of low-level waste from commercial power reactors is limited to 11,900,000 cubic feet, irrespective of Unusual Volume allocations; (2) each disposal facility may limit the volume of waste disposed, regardless of the availability of reactor allocations; and (3) the types of waste for which Unusual Volume allocations are granted must be suitable for disposal at one of the currently operating disposal facilities. Therefore, DOE has concluded that the rulemaking is not a major Federal action significantly affecting the quality of the human environment. Accordingly, preparation of neither an environmental assessment nor an environmental impact statement is required. However, petitions that meet eligibility requirements will be subject to review under the National Environmental Policy Act.

D. Paperwork Reduction Act

The Department of Energy has submitted the information collection listed at the end of this section to the Office of Management and Budget (OMB) for approval under provisions of the Paperwork Reduction Act (44 U.S.C. 35).

Comments pertaining to the Paperwork Reduction Act aspects of this proposed information collection must be filed within 30 days of publication of this Notice. Address Paperwork Reduction Act comments to: Mr. Vartkes Broussalian, Department of Energy Desk Officer, Office of Management and Budget, 726 Jackson Place, NW., Washington, DC 20503 (202-395-3084). If

you plan to submit comments but require additional time, please notify Mr. Broussalian at the address above as soon as possible.

A copy of your comments should also be sent to: Mr. William A. Hambley, U.S. Department of Energy, MA-213.3, Organization and Management Systems, Mail Stop MA-21, Room 4D-035, 1000 Independence Avenue SW., Washington, DC 20585 (202-586-3292). For further information about Paperwork Reduction Act requirements, and for copies of relevant materials, please contact Mr. Hambley at the address above.

The following information was submitted to OMB concerning this information collection:

1. *Sponsor of the collection (DOE component)*: Office of Assistant Secretary for Nuclear Energy.
2. *Collection number*: Nuclear Materials 116.
3. *Current OMB docket number (if applicable)*: N/A.
4. *Collection title*: Unusual Volume Disposal Capacity Petitions.
5. *Type of request, e.g., new, revision or extension*: New.
6. *Frequency of collection*: This collection has no fixed frequency. Petitions will be filed by petitioners as needed.
7. *Response obligation, i.e., mandatory, voluntary or required to obtain or retain benefit*: Required to obtain benefit (i.e., Unusual Volume allocation).
8. *Affected public*: Utilities operating commercial nuclear power reactors.
9. *An estimate of the number of respondents per report period*: 5 respondents per report period (Fiscal year).
10. *An estimate of the number of respondents annually*: 5 annual responses.
11. *Annual respondent burden, i.e., an estimate of the total number of hours needed to respond to the collection*: 400 burden hours per fiscal year (i.e., 5 petitions at 80 burden hours per petition).
12. *A brief abstract describing the proposed collection and the respondents*: This information collection is necessary in order to allow DOE to implement its responsibilities under section 5(c)(5) of the Low-Level Radioactive Waste Policy Amendments Act of 1985 (Pub. L. 99-240) (the Act). This section authorizes DOE to grant to commercial nuclear power reactors allocations of disposal capacity in order to permit the disposal of low-level waste generated by unusual or unexpected activities. Without the information, DOE would be unable to determine whether the activity was eligible for such an allocation or how much additional disposal capacity would be required to allow the activity to take place.

IV. Opportunity for Public Comment

A. Written Comments

Interested persons are invited to participate in this rulemaking by submitting data, views, or arguments, with respect to the proposal set forth in this notice. Comments should be submitted to the address indicated in the addresses section of this notice and should be identified on the envelope with the designation, "Rulemaking Comment". Six copies should be submitted. All written comments received on or before the date specified in the beginning of this notice and all other relevant information will be considered by DOE before taking final action on this rule. All written comments received on the proposed rule will be available for public inspection in the DOE Freedom of Information Reading Room, Room 1E-190, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC, between the hours of 9:00 a.m. and 4:00 p.m., Monday through Friday.

Any person submitting information which that person believes to be confidential and which may be exempt by law from public disclosure should submit 1 complete copy, as well as 6 copies from which the information claimed to be confidential has been deleted. DOE reserves the right to determine the confidential status of the information or data and treat it according to its determination. This procedure is set forth in 10 CFR 1004.11, 44 FR 1908, January 8, 1979.

B. Public Hearing

The time and place of the public hearing are indicated in the date and addresses sections of this notice. DOE invites any person who has an interest in the proposed rulemaking issued today, or who is representing a group or class of persons that has an interest in the proposed rulemaking, to make a request for an opportunity to make an oral presentation. Such a request should be directed to the person indicated in the addresses section of this notice, and must be received by the date indicated in the dates section of this notice. A request to make an oral presentation should be identified on the envelope with the designation, "Rulemaking public hearing." The person making the request should briefly describe the interest concerned and provide a telephone number where he or she may be contacted during the day.

C. Conduct of Hearing

DOE reserves the right to arrange the schedule of oral presentations and to establish the procedures governing the conduct of the hearing. The length of each presentation is limited to 20 minutes, but may be increased or reduced based on the number of persons requesting to be heard. A DOE official will preside at the hearing. This will not be a judicial or evidentiary-type hearing. Questions may be asked only by those conducting the hearing, and there will be no cross-examination of persons presenting statements. Any participant who wishes to ask a question at the hearing may submit the question, in writing, at the registration desk. The presiding officer will determine whether the question is relevant, and whether time limitations permit it to be presented for answer. Any further procedural rules needed for the proper conduct of the hearing will be announced by the presiding officer. A transcript of the hearing, as well as the entire rulemaking record will be retained by DOE and made available for inspection at the DOE Freedom of Information Reading Room, Room 1E-190, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585, between the hours of 9:00 a.m. and 4:00 p.m., Monday through Friday. Any person may purchase a transcript from the reporter. If DOE must cancel the hearing, DOE will make every effort to publish an advance notice of such cancellation in the Federal Register. Direct notice of cancellation will also be given to all persons scheduled to speak at the hearing.

List of Subjects in 10 CFR Part 730

Nuclear power plants and reactors, Waste treatment and disposal.

Issued in Washington DC on December 11, 1987.

William R. Voigt, Jr.

Director, Office of Remedial Action and Waste Technology, Office of Nuclear Energy.

For the reasons set out in the preamble, Chapter III of Title 10 of the Code of Federal Regulations is proposed to be amended as set forth below.

Part 730 is proposed to be added as set forth below.

PART 730—UNUSUAL VOLUMES ALLOCATION PETITION PROCEDURES

Subpart A—General Provisions

Sec.
730.1 Purpose and scope.
730.2 Definitions.
730.3 Communications.

Subpart B—Allocation Petitions

730.4 Filing.
730.5 Contents of petitions.
730.6 Eligibility criteria.
730.7 Volume determination.
730.8 Schedule for distributing allocations.

Authority: Sec. 5(c)(5), Pub. L. 99-240, 99 Stat. 1842 (42 U.S.C. 2021b-j).

Subpart A—General Provisions

§ 730.1 Purpose and scope.

The regulations in this part establish procedures for submitting petitions and for allocating disposal capacity under section 5(c)(5) of the Low-Level Radioactive Waste Policy Amendments Act of 1985, and prescribe criteria for determining eligibility for such allocations. The regulations in this part apply to all operators of commercial nuclear power reactor units possessing a full-power operating license (pursuant to 10 CFR Part 50).

§ 730.2 Definitions.

As used in this part:

"Act" means the Low-Level Radioactive Waste Policy Amendments Act of 1985 (Pub. L. 99-240);

"Department" means the U.S. Department of Energy

"Interim Access Period" means the 7-year period beginning January 1, 1986 and ending December 31, 1992;

"Licensing Period" means the 3-year period within the interim access period beginning January 1, 1990 and ending December 31, 1992;

"Regular Activity" means an event at a commercial nuclear power reactor associated with day-to-day plant operations;

"Regular Allocation" means the issuance of a specific volume of low-level radioactive waste disposal capacity made to each commercial nuclear power reactor based on the formula in section 5(c)(1) and (2) of the Act for use at any of the currently operating commercial disposal sites.

"Transition Period" means the 4-year period within the interim access period beginning January 1, 1986 and ending December 31, 1989;

"Unusual or Unexpected Activity" means an event at a commercial nuclear reactor not typically associated with day-to-day plant operations, including but not limited to steam generator repair, primary coolant recirculation pipe repair or replacement, operation as a "dry site" reactor with no off-site radioactive liquid discharge, major equipment or hardware repair, removal, modification, or replacement, major equipment modification under the Nuclear Regulatory Commission's backfit rule (10 CFR 50.109), and activities designed to increase the capacity for spent nuclear fuel storage at power reactors.

"Unusual Volume Allocation" means an issuance of a specific volume of low-level radioactive waste disposal capacity to a commercial nuclear power reactor by the Secretary of Energy under section 5(c)(5) of the Act for disposal of waste from unusual or unexpected activities.

"Yearly Base Volume" is the total of Unusual Volume capacity in cubic feet that may be allocated by the Department for any calendar year.

§ 730.3 Communications.

Any communication or report concerning the regulation in this part and any petition filed under these regulations may be submitted to the Assistant Secretary for Nuclear Energy, U.S. Department of Energy, Washington, DC 20585.

Subpart B—Allocation Petitions

§ 730.4 Filing.

(a) Petitions for Unusual Volume allocations should be filed in triplicate with the Assistant Secretary for Nuclear Energy, U.S. Department of Energy, Washington, DC 20585. Written notification will be provided to the petitioner acknowledging receipt of the petition.

(b) Petitions may be filed as needed, i.e., before, during or after the activity for which the request is made.

(c) No Unusual Volume allocation will be made earlier than 6 months before the start of the unusual or unexpected activity for which an allocation is requested.

(d) A petition may be submitted for additional capacity for disposal of waste resulting from an unusual or unexpected activity for which an Unusual Volume allocation has already been made.

(e) Petitions are granted conditionally upon use of the volume allocated for the activity stated in the grant. Within 30 days after all waste resulting from such activity has been disposed, the recipient of an Unusual Volume allocation shall report to the Department the volume of waste resulting from the activity that has been disposed. The excess of any Unusual Volume capacity allocated for the activity will thereupon revert to DOE.

§ 730.5 Contents of petitions.

(a) Each petition for an Unusual Volume allocation shall contain the following information:

(1) Name, address and telephone number of point of contact;

(2) Name of the reactor and utility requesting an allocation;

(3) Detailed description of the activity generating the waste;

(4) Dates during which the activity occurred or will occur;

(5) Estimated dates (months and years) during which the waste will be shipped for disposal;

(6) Explanation of the need for the Unusual Volume allocation. This explanation shall include:

(i) The reactor's regular allocation for the period in which the unusual or unexpected activity occurred or will occur;

(ii) The volume of waste generated or estimated to be generated by the unusual or unexpected activity;

(iii) Explanation of the extent to which the reactor's regular allocation for the period in which the unusual or unexpected activity occurred or will occur can accommodate the waste generated by the unusual or unexpected activity;

(iv) The volume of disposal capacity requested, expressed in cubic feet.

(7) Statement that the petitioner has not applied to the Nuclear Regulatory Commission for emergency access under section 6 of the Act;

(8) Statement that the waste for which the petition is submitted is suitable for disposal at at least one of the operating disposal sites identified in the Act.

(9) Any other information the petitioner believes will assist in evaluating the petition.

(b) After the petition has been submitted, the Department may seek additional information from the petitioner in order to enable the Department to determine eligibility for an allocation, or to determine the capacity to be allocated.

§ 730.6 Eligibility criteria.

The Department will use the following criteria to determine whether a petition is eligible for an allocation.

(a) The activity for which the petition is submitted should be an unusual or unexpected activity, as defined in § 730.2.

(b) The petition should demonstrate that the balance of a reactor's regular allocation at the time the unusual or unexpected activity occurred or will occur, plus the balance of any Unusual Volume allocation the reactor has received, will not exceed the sum of the volume that will be needed for regular activities during the transition period or the licensing period, as applicable, and the volume that is needed during the period for the unusual or unexpected activity.

(c) The waste resulting from the activity for which the petition is

submitted should be suitable for disposal at at least one of the operating disposal sites identified in the Act.

§ 730.7 Volume determination.

(a) Except as adjusted under paragraphs (b), (c) or (d) of this section, the allocation issued in response to a petition shall be the difference between the volume that the Department determines to be required to dispose of waste from the unusual or unexpected activity, and that portion of total allocations received by the reactor (regular and Unusual Volume allocations) that will be available for application toward disposal of waste from the activity. The allocation volume that will be available for disposal of this waste is the difference between the total allocation volume that the reactor has received, and the sum of:

(1) The reactor's regular allocation volume already used for disposal of waste from regular activities;

(2) The reactor's regular allocation volume that is expected to be required for disposal of waste from regular activities through the remainder of the transition period or licensing period, as applicable;

(3) Any portion of the reactor's regular allocation volume that will have been used at the time the Unusual Volume allocation is issued to dispose of waste from the activity for which the petition is submitted; and

(4) Any portion of any previous Unusual Volume allocation that will have been used at the time the Unusual Volume allocation is issued to dispose of waste from the activity for which the petition is submitted.

(b) Except as provided in § 730.8, if the Department determines that the total Unusual Volume awarded for any year, as determined under paragraph (a) of this section, may exceed the yearly base volume for that year, as determined under § 730.8, the Department shall reduce pending and subsequent allocations for that year so that the sum of the volumes awarded does not exceed the yearly base volume.

(c) The capacity allocated to any single reactor shall not exceed 25 percent of the yearly base volume, as determined under § 730.8, during the year for which the allocation is made.

(d) If the Department determines that licensing of new reactors will result in the sum of regular reactor allocations and Unusual Volume allocations exceeding 11,900,000 cubic feet, then pending and subsequent allocations will be reduced so that the sum of all allocations does not exceed 11,900,000 cubic feet.

§ 730.8 Schedule for distributing allocations

(a) The yearly base volume that is available for disbursement by the Department during a calendar year in response to Unusual Volume petitions shall be determined as follows: The 800,000 cubic feet of capacity available shall be divided equally among the 7 years. Any capacity not allocated in a year shall be distributed in equal portions among subsequent years.

(b) Any excess disposal capacity conveyed to the Department under § 730.4(e) shall be distributed in equal portions to the yearly base volumes for subsequent years.

(c) The Department shall not allocate more than the yearly base volume in any year, unless it determines that:

(1)(i) The volume capacity to be issued does not significantly exceed the yearly base volume, and

(ii) A significant number of petitions would be affected by so limiting allocations; or

(2) It is substantially likely that the Unusual Volume capacity available for the remainder of the interim access period will exceed the capacity for which petitions will be submitted.

[FR Doc. 88-757 Filed 1-19-88; 8:45 am]
BILLING CODE 6450-01-D

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