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

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

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 93

[Docket No. 00–109–1]

Spanish Pure Breed Horses from Spain

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the regulations for the importation of Spanish Pure Breed horses from Spain by removing the requirement that the health certificate accompanying imported Spanish Pure Breed horses from Spain specify that the horses, since reaching breeding age, have not been on breeding premises. In place of that requirement, we will require that the health certificate accompanying Spanish Pure Breed horses certify, among other things, that, since reaching breeding age, the horses have not been on a farm that is exclusively a breeding premises; have not been bred; have not attempted to breed; and have not been commingled and left unattended with adult horses of the opposite sex. We are also correcting the name of the horse breed association of Spain. We believe that this action will relieve unnecessary restrictions on the importation of Spanish Pure Breed horses from Spain while continuing to protect against the introduction and dissemination of contagious equine metritis into the United States.

DATES: This interim rule is effective November 16, 2000. We invite you to comment on this docket. We will consider all comments that we receive by January 16, 2001.

ADDRESSES: Please send four copies of your comment (an original and three copies) to: Docket No. 00–109–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Please state that your comment refers to Docket No. 00–109–1.

You may read any comments that we receive on this docket in our reading room. The reading room is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 690–2817 before coming.

APHIS documents published in the **Federal Register**, and related information, including the names of organizations and individuals who have commented on APHIS dockets, are available on the Internet at http://www.aphis.usda.gov/ppd/rad/webrepor.html.

FOR FURTHER INFORMATION CONTACT: Dr. Karen A. James, Assistant Director, Technical Trade Services Team, National Center for Import and Export, VS, APHIS, 4700 River Road Unit 38, Riverdale, MD 20737–1231; (301) 734–8172.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 9 CFR part 93 (referred to below as the regulations) prohibit or restrict the importation of certain animals into the United States to prevent the introduction of communicable diseases of livestock and poultry. Subpart C—Horses, § § 93.300 through 92.326 of the regulations, pertains to the importation of horses into the United States. Section 93.301 of the regulations contains specific provisions for the quarantine and testing of horses from regions affected with contagious equine metritis (CEM), a highly contagious bacterial venereal disease that affects breeding and fertility. Section 93.301 also identifies regions where CEM exists and regions that trade horses freely with regions where CEM exists without testing for CEM. Section 93.301 prohibits, with certain exceptions, the importation of horses into the United States from those areas. The European Union—of which Spain is a Member State—is listed in § 93.301 as a region where CEM exists or may exist.

On August 1, 2000, we published in the **Federal Register** a final rule (65 FR 46859–46861, Docket No. 99–054–2) that amended the regulations in § 93.301 to allow Spanish Pure Breed stallions and mares that are more than 731 days old that have tested negative for CEM in the country of origin and have undergone Federal quarantine upon arrival in the United States to be imported into the United States without being subject to additional quarantine, testing, and treatment. Essentially, the final rule allowed Spanish Pure Breed Horses from Spain to be imported into the United States under the same preexport testing and quarantine conditions that previously applied only to thoroughbred horses from France, Germany, Ireland, and the United Kingdom.

Under the regulations in § 93.301(d), as amended by our August 1, 2000, final rule, thoroughbred horses from France, Germany, Ireland, and the United Kingdom and Spanish Pure Breed horses from Spain may be imported into the United States under certain conditions. Those conditions include, among other things, a requirement that thoroughbred horses from France, Germany, Ireland, and the United Kingdom and Spanish Pure Breed horses from Spain that are presented for permanent entry into the United States be accompanied by a health certificate.

Under § 93.301(d)(1)(ii), the health certificate accompanying such horses must certify, among other things, that since reaching 731 days of age, the horses have not been on breeding premises in the exporting region. This requirement is intended to protect against the introduction of CEM into the United States by ensuring that only virgin thoroughbred and Spanish Pure Breed horses from countries where CEM exists or may exist are eligible for importation into the United States under the requirements in § 93.301(d). Since CEM is a venereal disease that is spread primarily by sexual contact between horses, we believe that allowing only virgin thoroughbred and Spanish Pure Breed horses to enter the United States greatly reduces the risk that thoroughbred horses from France, Germany, Ireland, and the United Kingdom and Spanish Pure Breed horses from Spain could introduce CEM into the United States.

This requirement has not proven to be burdensome to exporters of thoroughbred horses because thoroughbreds are not, by standard practice, kept on breeding premises. However, we have been informed that Spanish Pure Breed horses in Spain are typically kept on premises where some breeding may occur. Because of this, horses from such premises cannot be certified as not having been on a breeding premises since reaching 731 days of age. The Government of Spain has requested that we amend the regulations in § 93.301(d)(1)(ii) to provide an alternative set of requirements that take into account this standard industry practice in Spain.

After considering the Spanish Government's request, we are removing the requirement that the health certificate accompanying Spanish Pure Breed horses must certify, among other things, that since reaching 731 days of age, the horses have not been on breeding premises in the exporting region. Rather, we will require that the health certificate accompanying Spanish Pure Breed horses specify that, since reaching 731 days of age:

- Each horse has never been on a farm that is exclusively a breeding premises,
- Each horse has never been bred,
- Breeding of each horse has never been attempted, and
- Each horse has never been commingled and left unattended with adult horses of the opposite sex.

We believe that these four requirements are adequate and necessary to ensure that any Spanish Pure Breed horses from Spain that are imported into the United States are virgin horses that present a minimal risk of introducing or disseminating CEM into the United States. Thus, from a disease exclusion and risk reduction standpoint, this change accomplishes what we intended in the August 1, 2000, final rule while making compliance with the regulations easier for persons exporting Spanish Pure Breed horses from Spain to the United States.

This rule will have no effect on the existing requirements for thoroughbred horses imported from France, Germany, Ireland, and the United Kingdom.

In this document, we are also correcting the name of the breed association in Spain that is specifically approved by the U.S. Department of Agriculture to provide factual, current information regarding the activities of Spanish Pure Breed horses for the purposes of § 93.301(d). In the final rule mentioned above, we identified the breed association in Spain as ''Servicio de Cria Caballar y Remonta.'' The correct name of the Spanish breed association is ''Jefatura de Cria Caballar Registro Matricula.''

Immediate Action

Immediate action is necessary to relieve restrictions on the importation of Spanish Pure Breed horses into the United States. When we established the existing requirements for the importation of Spanish Pure Breed horses from Spain, we did not anticipate that compliance with the requirements would be problematic for exporters of those horses. We believe that the changes reflected in this document will relieve unnecessary restrictions while continuing to protect against the introduction of CEM into the United States. Under these circumstances, the Administrator has determined that prior notice and opportunity for public comment are contrary to the public interest and that there is good cause under 5 U.S.C. 553 for making this rule effective less than 30 days after publication in the **Federal Register**.

We will consider comments that are received within 60 days of publication of this rule in the **Federal Register**. After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

On August 1, 2000, we published in the **Federal Register** (65 FR 46859–46861, Docket No. 99–054–2) a final rule that amended the animal importation regulations by allowing Spanish Pure Breed horses to be imported from Spain into the United States under the same conditions that had previously applied only to thoroughbred horses from France, Germany, Ireland, and the United Kingdom. At that time, we conducted a regulatory flexibility analysis for the rule that determined that the rule would not have a significant economic impact on a substantial number of small entities. This rule has the same intended effect as the August 1, 2000, final rule, and simply amends the certification requirements for Spanish Pure Breed horses from Spain by providing a different means of certifying that those horses offered for entry into the United States have not been bred. Therefore, this rule will not result in any economic impacts other than those identified in the August 1, 2000, final rule.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 93

Animal diseases, Imports, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements.

Accordingly, we are amending 9 CFR part 93 as follows:

PART 93—IMPORTATION OF CERTAIN ANIMALS, BIRDS, AND POULTRY, AND CERTAIN ANIMAL, BIRD, AND POULTRY PRODUCTS; REQUIREMENTS FOR MEANS OF CONVEYANCE AND SHIPPING CONTAINERS

1. The authority citation for part 93 continues to read as follows:

Authority: 7 U.S.C. 1622; 19 U.S.C. 1306; 21 U.S.C. 102–105, 111, 114a, 134a, 134b, 134c, 134d, 134f, 136, and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

2. In § 93.301, paragraph (d)(1)(ii) is amended as follows:

a. In paragraph (d)(1)(ii), in the introductory text, second sentence, by removing the word ''shall'' and adding the word ''must'' in its place.

b. By revising paragraph (d)(1)(ii)(B) to read as follows:

§ 93.301 General Prohibitions; exceptions.

* * * * *

(d) * * *

(1) * * *

(ii) * * *

(B) He or she has examined the records of the horse's activities maintained by a breed association

specifically approved by the Department[6] and certified by the breed association to be current, true, and factual for the following information:

(*1*) Identification of the horse by name, sex, age, breed, and all identifying marks;

(*2*) Identification of all premises where the horse has been since reaching 731 days of age and the dates that the horse was at such premises;

(*3*) For thoroughbred horses, that none of the premises where the horse has been since reaching 731 days of age are breeding premises; and

(*4*) For Spanish Pure Breed horses from Spain, that since reaching 731 days of age:

(*i*) The horse has never been on a premises that is exclusively a breeding premises;

(*ii*) The horse has never been bred;

(*iii*) Breeding of the horse has never been attempted; and

(*iv*) The horse has never been commingled and left unattended with adult horses of the opposite sex;

* * * * *

Done in Washington, DC, this 9th day of November 2000.

Craig A. Reed,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 00–29365 Filed 11–15–00; 8:45 am]

BILLING CODE 3410–34–U

[6] The following breed associations and their record systems have been approved by the Department: Jefatura de Cria Caballar Registro Matricula for Spain; Weatherby's Ltd. for the United Kingdom and Ireland; Haras du Pain for France; and Direktorium fur Vollblutzucht und Rennen e.v. for Germany.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NM–325–AD; Amendment 39–11948; AD 2000–22–02 R1]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 737 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; correction.

SUMMARY: This document corrects information in an existing airworthiness directive (AD) that applies to all Boeing Model 737 series airplanes. That AD supersedes AD 99–05–15, amendment 39–11063, to require revising the FAA-approved Airplane Flight Manual (AFM) procedure in the existing AD to simplify the instructions for correcting a jammed or restricted flight control condition. This document corrects the format for certain AFM material described in that AD. This correction is necessary to ensure that the flightcrew is aware of certain critical recall items in the AFM procedure that are necessary to address a condition involving a jammed or restricted rudder.

DATES: Effective November 13, 2000.

FOR FURTHER INFORMATION CONTACT: Steve O'Neal, Aerospace Engineer, Flight Test Branch, ANM–160S, Seattle Aircraft Certification Office, FAA, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2699; fax (425) 227–1181.

SUPPLEMENTARY INFORMATION: On October 20, 2000, the Federal Aviation Administration (FAA) issued AD 2000–22–02, amendment 39–11948 (65 FR 64134, October 26, 2000), which applies to all Boeing Model 737 series airplanes. That AD supersedes AD 96–26–07, amendment 39–9871 (62 FR 15, January 2, 1997), to require revising the FAA-approved Airplane Flight Manual (AFM) procedure in the existing AD to simplify the instructions for correcting a jammed or restricted flight control condition. That AD was prompted by an FAA determination that the procedure currently inserted in the AFM by the existing AD is not defined adequately. The actions required by that AD are intended to ensure that the flight crew is advised of the procedures necessary to address a condition involving a jammed or restricted rudder.

Need for the Correction

Information obtained recently by the FAA indicates that certain AFM material described in AD 2000–22–02 was incorrectly formatted.

The FAA has determined that a correction to the published format of the AFM procedure specified in paragraph (b) of that AD is necessary. The procedure contains critical recall (memory) items. The first two procedural steps, which call for disengagement of the autopilot and autothrottle, and their associated text, are recall items. In standard operational materials, recall items are indicated to the flight crew by specifying the information in a text box. Any duplication of this procedure in operational documentation must reflect the recall nature of these items. Therefore, paragraph (b) of this AD has been revised to reference Figure 1 of this AD, which contains the correct format in order to emphasize these recall items. The correction will ensure that the flightcrew is aware of the critical recall items in the AFM procedure described in that AD that are necessary to address a condition involving a jammed or restricted rudder.

Correction of Publication

This document corrects the error and correctly adds the AD as an amendment to § 39.13 of the Federal Aviation Regulations (14 CFR 39.13).

The AD is reprinted in its entirety for the convenience of affected operators. The effective date of the AD remains November 13, 2000.

Since this action only corrects a formatting error, it has no adverse economic impact and imposes no additional burden on any person. Therefore, the FAA has determined that notice and public procedures are unnecessary.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Correction

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Corrected]

2. Section 39.13 is amended by correctly adding the following airworthiness directive (AD):

2000–22–02 R1 Boeing: Amendment 39–11948. Docket 2000–NM–325–AD.

Applicability: All Model 737 series airplanes, certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To ensure that the flight crew is advised of the procedures necessary to address a condition involving a jammed or restricted rudder, accomplish the following:

Restatement of Certain Requirements of AD 96–26–07

(a) Within 30 days after January 17, 1997 (the effective date of AD 96–26–07, amendment 39–9871): Revise the Emergency Procedures Section of the FAA-approved Airplane Flight Manual (AFM) to include the following recall item, which will enable the flight crew to take appropriate action to maintain control of the airplane during an uncommanded yaw or roll condition. This may be accomplished by inserting a copy of this AD in the AFM.

''UNCOMMANDED YAW OR ROLL RECALL

Maintain control of the airplane with all available flight controls. If roll is uncontrollable, immediately reduce angle of attack and increase airspeed. Do not attempt to maintain altitude until control is recovered. If engaged, disconnect autopilot and autothrottle.''

New Requirements of This AD

(b) Within 30 days after the effective date of this AD: Revise the Normal Procedures Section of the FAA-approved AFM for Model 737–100 and –200 series airplanes or the Non-Normal Procedures Section of the FAA-approved AFM for Model 737–300, –400, –500, –600, –700, and –800 series airplanes, as applicable, to include the procedure specified in Figure 1 of this AD. This may be accomplished by inserting a copy of this AD in the AFM and removing the existing copy (inserted as required by AD 96–26–07), entitled ''Jammed Flight Controls.''

"UNCOMMANDED RUDDER

Condition: Uncommanded rudder pedal displacement or pedal kicks.

AUTOPILOT (if engaged). . . . . DISENGAGE
Maintain control of the airplane with all available flight controls. If roll is uncontrollable, immediately reduce pitch/angle of attack and increase airspeed. Do not attempt to maintain altitude until control is recovered.

AUTOTHROTTLE (if engaged). . . . . DISENGAGE
Verify thrust is symmetrical.

YAW DAMPER SWITCH. . . . . .OFF

RUDDER TRIM . . . . . .CENTER

RUDDER PEDALS . . . . . .FREE & CENTER
Use maximum force including a combined effort of both pilots, if required to free and center the rudder pedals.

If rudder pedal position or movement is not normal and the condition is not the result of rudder trim:

SYSTEM B FLIGHT
CONTROL SWITCH. . . . . .STBY RUD

A slight rudder deflection may remain, but continued rudder pedal pressure may help maintain an in-trim condition.

Sufficient directional control is available on landing using differential braking and nose wheel steering.

Crosswind capability may be reduced.

Do not use autobrakes.

Consider checking rudder freedom of movement at a safe altitude using slow rudder inputs while in the landing configuration and at approach speed.

If condition was the result of rudder trim or environmental factors:

YAW DAMPER SWITCH . . . . . .ON

Accomplish the normal DESCENT – APPROACH and LANDING checklists."

FIGURE 1

(c) It is acceptable to modify the format of the above procedure to reflect the format used by individual carriers. However, the procedural sequence, memory items, and/or associated text may not be modified, except by submitting a request for an alternative method of compliance (AMOC) as specified in paragraph (d) of this AD.

Alternative Methods of Compliance

(d) An AMOC or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA. Operators shall submit their requests through an appropriate FAA Principal Operations Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 1: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

Special Flight Permits

(e) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Effective Date

(f) The effective date of this amendment remains November 13, 2000.

Issued in Renton, Washington, on November 9, 2000.

Donald L. Riggin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00–29403 Filed 11–15–00; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30214; Amdt. No. 2021]

Standard Instrument Approach Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

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

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

Incorporation by reference—approved by the Director of the Federal Register on December 31, 1980, and reapproved as of January 1, 1982.

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

For Examination—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;

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

3. The National Flight Procedures Office (NFPO) at the Mike Monroney Aeronautical Center in Oklahoma City, OK, which originated the SIAP.

For Purchase—Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or

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

By Subscription—Copies of all SIAP's, mailed once every 2 weeks, are for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

FOR FURTHER INFORMATION CONTACT: Donald P. Pate, Flight Procedure Standards Branch (AMCAFS–420), Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK 73125) telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes SIAP's. The complete regulatory description of each SIAP is contained in official FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 14 CFR 97.20 of the Federal Aviation Regulations (FAR). The applicable FAA Form is identified as FAA Form 8260–3. Materials incorporated by reference are available for examination or purchase as stated above.

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

The Rule

This amendment to part 97 is effective upon publication of each separate SIAP as contained in the transmittal. The SIAP's contained in this amendment are based on the criteria contained in the United States Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports.

The FAA has determined through extensive analysis that current SIAP's intended for use by Area Navigation (RNAV) equipped aircraft can be flown by aircraft utilizing various types of navigational equipment. The techniques used to code these SIAP's into the equipment data base impacts the usability of the procedure when activated. This amendment provides for the revision of the name/title of existing RNAV procedures to ensure coding techniques make the procedure fully available to the user. In consideration of the above, those SIAP's currently designated as ''RNAV'' will be redesignated as ''RNAV (GPS)'' without otherwise reviewing or modifying the SIAP's.

Because of the close and immediate relationship between these SIAP's and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a

''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Navigation (Air).

Issued in Washington, DC on November 9, 2000.

L. Nicholas Lacey,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, part 97 of the Federal Aviation Regulations (14 CFR part 97) is amended as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

1. The authority citation for part 97 is revised to read:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113–40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

§§ 9723, 97.27, 97.33, 97.35 [Amended]

2. Amend 97.23, 97.27, 97.33 and 97.35, as appropriate, by adding, revising, or removing the following SIAP's, effective at 0901 UTC on the dates specified:

** * * Effective January 25, 2001*

Adak Island, AK, Adak NAF, RNAV RWY 23, Orig, CANCELLED
Adak Island, AK, Adak NAF, RNAV (GPS) RWY 23, Orig
Ambler, AK, Ambler, RNAV RWY 36, Orig, CANCELLED
Ambler, AK, Ambler, RNAV (GPS) RWY 36, Orig
Gulkana, AK, Gulkana, RNAV RWY 14, Orig, CANCELLED
Gulkana, AK, Gulkana, RNAV (GPS) RWY 14, Orig
Gulkana, AK, Gulkana, RNAV RWY 32, Orig, CANCELLED
Gulkana, AK, Gulkana, RNAV (GPS) RWY 32, Orig
Albertville, AL, The Albertville Muni-Thomas J. Brumlik Field, RNAV RWY 5, Orig, CANCELLED
Albertville, AL, The Albertville Muni-Thomas J. Brumlik Field, RNAV (GPS) RWY 5, Orig
Albertville, AL, The Albertville Muni-Thomas J. Brumlik Field, RNAV RWY 23, Orig, CANCELLED
Albertville, AL, The Albertville Muni-Thomas J. Brumlik Field, RNAV (GPS) RWY 23, Orig
Decatur, AL, Pryor Field Regional, RNAV RWY 36, Orig, CANCELLED
Decatur, AL, Pryor Field Regional, RNAV (GPS) RWY 36, Orig
Gulf Shores, AL, Jack Edwards, RNAV RWY 9, Orig, CANCELLED
Gulf Shores, AL, Jack Edwards, RNAV (GPS) RWY 9, Orig
Prattville, AL, Autauga County, RNAV RWY 9, Orig, CANCELLED
Prattville, AL, Autauga County, RNAV (GPS) RWY 9, Orig
Glendale, AZ, Glendale Muni, RNAV RWY 19, Orig, CANCELLED
Glendale, AZ, Glendale Muni, RNAV (GPS) RWY 19, Orig
Phoenix, AZ, Phoenix Sky Harbor Intl, RNAV RWY 7L, Orig, CANCELLED
Phoenix, AZ, Phoenix Sky Harbor Intl, RNAV (GPS) RWY 7L, Orig
Phoenix, AZ, Phoenix Sky Harbor Intl, RNAV RWY 8, Orig, CANCELLED
Phoenix, AZ, Phoenix Sky Harbor Intl, RNAV (GPS) RWY 8, Orig
Phoenix, AZ, Phoenix Sky Harbor Intl, RNAV RWY 26, Orig, CANCELLED
Phoenix, AZ, Phoenix Sky Harbor Intl, RNAV (GPS) RWY 26, Orig
Phoenix, AZ, Phoenix Sky Harbor Intl, RNAV RWY 25R, Orig, CANCELLED
Phoenix, AZ, Phoenix Sky Harbor Intl, RNAV (GPS) RWY 25R, Orig
Phoenix, AZ, Williams Gateway, RNAV RWY 12C, Orig, CANCELLED
Phoenix, AZ, Williams Gateway, RNAV (GPS) RWY 12C, Orig
Phoenix, AZ, Williams Gateway, RNAV RWY 12R, Orig, CANCELLED
Phoenix, AZ, Williams Gateway, RNAV (GPS) RWY 12R, Orig
Phoenix, AZ, Williams Gateway, RNAV RWY 30L, Orig, CANCELLED
Phoenix, AZ, Williams Gateway, RNAV (GPS) RWY 30L, Orig
Georgetown, DE, Sussex County, RNAV RWY 4, Orig, CANCELLED
Georgetown, DE, Sussex County, RNAV (GPS) RWY 4, Orig
Georgetown, DE, Sussex County, RNAV RWY 22, Orig, CANCELLED
Georgetown, DE, Sussex County, RNAV (GPS) RWY 22, Orig
Apalachicola, FL, Apalachicola Muni, RNAV RWY 13, Orig, CANCELLED
Apalachicola, FL, Apalachicola Muni, RNAV (GPS) RWY 13, Orig
Apalachicola, FL, Apalachicola Muni, RNAV RWY 31, Orig, CANCELLED
Apalachicola, FL, Apalachicola Muni, RNAV (GPS) RWY 31, Orig
Clearwater, FL, Clearwater Air Park, RNAV RWY 16, Orig, CANCELLED
Clearwater, FL, Clearwater Air Park, RNAV (GPS) RWY 16, Orig
Destin, FL, Destin-Fort Walton Beach, RNAV RWY 14, Orig, CANCELLED
Destin, FL, Destin-Fort Walton Beach, RNAV (GPS) RWY 14, Orig
Destin, FL, Destin-Fort Walton Beach, RNAV RWY 32, Orig, CANCELLED
Destin, FL, Destin-Fort Walton Beach, RNAV (GPS) RWY 32, Orig
Jacksonville, FL, Jacksonville Intl, RNAV RWY 7, Orig, CANCELLED
Jacksonville, FL, Jacksonville Intl, RNAV (GPS) RWY 7, Orig
Jacksonville, FL, Jacksonville Intl, RNAV RWY 13, Orig, CANCELLED
Jacksonville, FL, Jacksonville Intl, RNAV (GPS) RWY 13, Orig
Jacksonville, FL, Jacksonville Intl, RNAV RWY 25, Orig, CANCELLED
Jacksonville, FL, Jacksonville Intl, RNAV (GPS) RWY 25, Orig
Lake City, FL, Lake City Muni, RNAV RWY 10, Orig, CANCELLED
Lake City, FL, Lake City Muni, RNAV (GPS) RWY 10, Orig
Lake City, FL, Lake City Muni, RNAV RWY 28, Orig, CANCELLED
Lake City, FL, Lake City Muni, RNAV (GPS) RWY 28, Orig
Merritt Island, FL, Merritt Island, RNAV RWY 11, Orig, CANCELLED
Merritt Island, FL, Merritt Island, RNAV (GPS) RWY 11, Orig
Naples, FL, Naples Muni, RNAV RWY 5, Orig, CANCELLED
Naples, FL, Naples Muni, RNAV (GPS) RWY 5, Orig
Naples, FL, Naples Muni, RNAV RWY 23, Orig, CANCELLED
Naples, FL, Naples Muni, RNAV (GPS) RWY 23, Orig
Ocala, FL, Ocala Regional/Jim Taylor Field, RNAV RWY 18, Orig, CANCELLED
Ocala, FL, Ocala Regional/Jim Taylor Field, RNAV (GPS) RWY 18, Orig
Ocala, FL, Ocala Regional/Jim Taylor Field, RNAV RWY 36, Orig, CANCELLED
Ocala, FL, Ocala Regional/Jim Taylor Field, RNAV (GPS) RWY 36, Orig
Orlando, FL, Orlando Sanford, RNAV RWY 9L, Orig, CANCELLED
Orlando, FL, Orlando Sanford, RNAV (GPS) RWY 9L, Orig
Orlando, FL, Orlando Sanford, RNAV RWY 27R, Orig, CANCELLED
Orlando, FL, Orlando Sanford, RNAV (GPS) RWY 27R, Orig
Tampa, FL, Tampa Intl, RNAV RWY 9, Orig, CANCELLED
Tampa, FL, Tampa Intl, RNAV (GPS) RWY 9, Orig
Tampa, FL, Tampa Intl, RNAV RWY 27, Orig, CANCELLED
Tampa, FL, Tampa Intl, RNAV (GPS) RWY 27, Orig
Tampa, FL, Tampa Intl, RNAV RWY 36R, Orig, CANCELLED
Tampa, FL, Tampa Intl, RNAV (GPS) RWY 36R, Orig
Vero Beach, FL, Vero Beach Muni, RNAV RWY 11R, Orig, CANCELLED
Vero Beach, FL, Vero Beach Muni, RNAV (GPS) RWY 11R, Orig
Vero Beach, FL, Vero Beach Muni, RNAV RWY 29L, Orig, CANCELLED
Vero Beach, FL, Vero Beach Muni, RNAV (GPS) RWY 29L, Orig
Blakely, GA, Early County, RNAV RWY 5, Orig, CANCELLED
Blakely, GA, Early County, RNAV (GPS) RWY 5, Orig
Blakely, GA, Early County, RNAV RWY 23, Orig, CANCELLED
Blakely, GA, Early County, RNAV (GPS) RWY 23, Orig
Marietta, GA, Cobb County-McCollum Field, RNAV RWY 9, Orig, CANCELLED

Marietta, GA, Cobb County-McCollum Field, RNAV (GPS) RWY 9, Orig
Marietta, GA, Cobb County-McCollum Field, RNAV RWY 27, Orig, CANCELLED
Marietta, GA, Cobb County-McCollum Field, RNAV (GPS) RWY 27, Orig
Ames, IA, Ames Muni, RNAV RWY 1, Orig, CANCELLED
Ames, IA, Ames Muni, RNAV (GPS) RWY 1, Orig
Burlington, IA, Burlington Regional, RNAV RWY 36, Orig, CANCELLED
Burlington, IA, Burlington Regional, RNAV (GPS) RWY 36, Orig
Estherville, IA, Estherville Muni, RNAV RWY 16, Orig, CANCELLED
Estherville, IA, Estherville Muni, RNAV (GPS) RWY 16, Orig
Estherville, IA, Estherville Muni, RNAV RWY 34, Orig, CANCELLED
Estherville, IA, Estherville Muni, RNAV (GPS) RWY 34, Orig
Hampton, IA, Hampton Muni, RNAV RWY 17, Orig, CANCELLED
Hampton, IA, Hampton Muni, RNAV (GPS) RWY 17, Orig
Hampton, IA, Hampton Muni, RNAV RWY 35, Orig, CANCELLED
Hampton, IA, Hampton Muni, RNAV (GPS) RWY 35, Orig
Mason City, IA, Mason City Muni, RNAV RWY 30, Orig, CANCELLED
Mason City, IA, Mason City Muni, RNAV (GPS) RWY 30, Orig
Hailey, ID, Friedman Memorial, RNAV RWY 31, Orig, CANCELLED
Hailey, ID, Friedman Memorial, RNAV (GPS) RWY 31, Orig
Belleville, IL, Scott AFB/Midamerica, RNAV RWY 14R, Orig, CANCELLED
Belleville, IL, Scott AFB/Midamerica, RNAV (GPS) RWY 14R, Orig
Belleville, IL, Scott AFB/Midamerica, RNAV RWY 32L, Orig. CANCELLED
Belleville, IL, Scott AFB/Midamerica, RNAV (GPS) RWY 32L, Orig
Chicago, IL, Chicago O'Hare Intl, RNAV RWY 9r, Orig, CANCELLED
Chicago, IL, Chicago O'Hare Intl, RNAV (GPS) RWY 9R, Orig
Chicago, IL, Chicago O'Hare Intl, RNAV RWY 14L, Orig, CANCELLED
Chicago, IL, Chicago O'Hare Intl, RNAV (GPS) RWY 14L, Orig
Chicago, IL, Chicago O'Hare Intl, RNAV RWY 14R, Orig, CANCELLED
Chicago, IL, Chicago O'Hare Intl, RNAV (GPS) RWY 14R, Orig
Chicago/Aurora, IL, Aurora Muni, RNAV RWY 15, Orig, CANCELLED
Chicago/Aurora, IL, Aurora Muni, RNAV (GPS) RWY 15, Orig
Chicago/Aurora, IL, Aurora Muni, RNAV RWY 33, Orig, CANCELLED
Chicago/Aurora, IL, Aurora Muni, RNAV (GPS) RWY 33, Orig
Chicago/Lake In The Hills, IL, Lake In The Hills, RNAV RWY 8, Orig, CANCELLED
Chicago/Lake In The Hills, IL, Lake In The Hills, RNAV (GPS) RWY 8, Orig
Chicago/Lake In The Hills, IL, Lake In The Hills, RNAV RWY 26, Orig, CANCELLED
Chicago/Lake In The Hills, IL, Lake In The Hills, RNAV (GPS) RWY 26, Orig
Grayslake, IL, Campbell, RNAV–B, Orig, CANCELLED
Grayslake, IL, Campbell, RNAV–B (GPS), Orig
Greenwood/Wonder Lake, IL, Galt Field, RNAV–B, Orig, CANCELLED
Greenwood/Wonder Lake, IL, Galt Field, RNAV–B (GPS), Orig
Lawrenceville, IL, Lawrenceville-Vincennes Intl, RNAV RWY 9, Orig, CANCELLED
Lawrenceville, IL, Lawrenceville-Vincennes Intl, RNAV (GPS) RWY 9, Orig
Lawrenceville, IL, Lawrenceville-Vincennes Intl, RNAV RWY 18, Orig, CANCELLED
Lawrenceville, IL, Lawrenceville-Vincennes Intl, RNAV (GPS) RWY 18, Orig
Lawrenceville, IL, Lawrenceville-Vincennes Intl, RNAV RWY 27, Orig, CANCELLED
Lawrenceville, IL, Lawrenceville-Vincennes Intl, RNAV (RPS) RWY 27, Orig
Lawrenceville, IL, Lawrenceville-Vincennes Intl, RNAV RWY 36, Orig, CANCELLED
Lawrenceville, IL, Lawrenceville-Vincennes Intl, RNAV (GPS) RWY 36, Orig
Connersville, IN, Mettel Field, RNAV RWY 18, Orig, CANCELLED
Connersville, IN, Mettel Field, RNAV (GPS) RWY 18, Orig
Connersville, IN, Mettel Field, RNAV RWY 36, Orig, CANCELLED
Connersville, IN, Mettel Field, RNAV (GPS) RWY 36, Orig
Lafayette, IN, Purdue University, RNAV RWY 10, Orig, CANCELLED
Lafayette, IN, Purdue University, RNAV (GPS) RWY 10, Orig
Lafayette, IN, Purdue University, RNAV RWY 28, Orig, CANCELLED
Lafayette, IN, Purdue University, RNAV (GPS) RWY 28, Orig
Winamac, IN, Arens Field RNAV RWY 9, Orig, CANCELLED
Winamac, IN, Arens Field RNAV (GPS) RWY 9, Orig
Winamac, IN, Arens Field RNAV RWY 27, Orig, CANCELLED
Winamac, IN, Arens Field RNAV (GPS) RWY 27, Orig
Hays, KS, Hays Regional, RNAV RWY 34, Orig, CANCELLED
Hays, KS, Hays Regional, RNAV (GPS) RWY 34, Orig
Olathe, KS, New Century Aircenter, RNAV RWY 17, Orig, CANCELLED
Olathe, KS, New Century Aircenter, RNAV (GPS) RWY 17, Orig
Olathe, KS, New Century Aircenter, RNAV RWY 35, Orig, CANCELLED
Olathe, KS, New Century Aircenter, RNAV (GPS) RWY 35, Orig
Georgetown, KY, Georgetown Scott County-Marshall Field, RNAV RWY 3, Orig, CANCELLED
Georgetown, KY, Georgetown Scott County-Marshall Field, RNAV (GPS) RWY 3, Orig
Georgetown, KY, Georgetown Scott County-Marshall Field, RNAV RWY 21, Orig, CANCELLED
Georgetown, KY, Georgetown Scott County-Marshall Field, RNAV (GPS) RWY 21, Orig
Pikeville, KY, Pike County-Hatcher Field, RNAV RWY 9, Orig, CANCELLED
Pikeville, KY, Pike County-Hatcher Field, RNAV (GPS) RWY 9, Orig
Pikeville, KY, Pike County-Hatcher Field, RNAV RWY 27, Orig, CANCELLED
Pikeville, KY, Pike County-Hatcher Field, RNAV (GPS) RWY 27, Orig
Alexandria, LA, Alexandria Intl, RNAV RWY 14, Orig, CANCELLED
Alexandria, LA, Alexandria Intl, RNAV (GPS) RWY 14, Orig
Tallulah/Vicksburg, LA, Vicksburg Tallulah Regional, RNAV RWY 18, Orig, CANCELLED
Tallulah/Vicksburg, LA, Vicksburg Tallulah Regional, RNAV (GPS) RWY 18, Orig
Tallulah/Vicksburg, LA, Vicksburg Tallulah Regional, RNAV RWY 36, Orig, CANCELLED
Tallulah/Vicksburg, LA, Vicksburg Tallulah Regional, RNAV (GPS) RWY 36, Orig
Boston, MA, General Edward Lawrence Logan Intl, RNAV RWY 4R, Orig, CANCELLED
Boston, MA, General Edward Lawrence Logan Intl, RNAV (GPS) RWY 4R, Orig
Hyannis, MA, Barnstable Muni-Boardman/Polando Field, RNAV RWY 24, Orig, CANCELLED
Hyannis, MA, Barnstable Muni-Boardman/Polando Field, RNAV (GPS) RWY 24, Orig
Baltimore, MD, Baltimore-Washington Intl, RNAV RWY 4, Orig, CANCELLED
Baltimore, MD, Baltimore-Washington Intl, RNAV (GPS) RWY 4, Orig
Baltimore, MD, Baltimore-Washington Intl, RNAV RWY 10, Orig, CANCELLED
Baltimore, MD, Baltimore-Washington Intl, RNAV (GPS) RWY 10, Orig
Baltimore, MD, Baltimore-Washington Intl, RNAV RWY 15L, Orig, CANCELLED
Baltimore, MD, Baltimore-Washington Intl, RNAV (GPS) RWY 15L, Orig
Baltimore, MD, Baltimore-Washington Intl, RNAV Y RWY 15R, Orig, CANCELLED
Baltimore, MD, Baltimore-Washington Intl, RNAV (GPS) Y RWY 15R, Orig
Baltimore, MD, Baltimore-Washington Intl, RNAV Z RWY 15R, Orig, CANCELLED
Baltimore, MD, Baltimore-Washington Intl, RNAV (GPS) Z RWY 15R, Orig
Baltimore, MD, Baltimore-Washington Intl, RNAV RWY 22, Orig, CANCELLED
Baltimore, MD, Baltimore-Washington Intl, RNAV (GPS) RWY 22, Orig
Baltimore, MD, Baltimore-Washington Intl, RNAV Y RWY 28, Orig, CANCELLED
Baltimore, MD, Baltimore-Washington Intl, RNAV (GPS) Y RWY 28, Orig
Baltimore, MD, Baltimore-Washington Intl, RNAV Z RWY 28, Orig, CANCELLED
Baltimore, MD, Baltimore-Washington Intl, RNAV (GPS) Z RWY 28, Orig
Baltimore, MD, Baltimore-Washington Intl, RNAV RWY 33L, Orig, CANCELLED
Baltimore, MD, Baltimore-Washington Intl, RNAV (GPS) RWY 33L, Orig
Baltimore, MD, Baltimore-Washington Intl, RNAV RWY 33R, Orig, CANCELLED
Baltimore, MD, Baltimore-Washington Intl, RNAV (GPS) RWY 33R, Orig
Baltimore, MD, Martin State, RNAV RWY 15, Orig, CANCELLED
Baltimore, MD, Martin State, RNAV (GPS) RWY 15, Orig
Baltimore, MD, Martin State, RNAV RWY 33, Orig, CANCELLED
Baltimore, MD, Martin State, RNAV (GPS) RWY 33, Orig
College Park, MD, College Park, RNAV RWY 15, Orig, CANCELLED
College Park, MD, College Park, RNAV (GPS) RWY 15, Orig

Cumberland, MD, Greater Cumberland Regional, RNAV RWY 5, Orig, CANCELLED
Cumberland, MD, Greater Cumberland Regional, RNAV (GPS) RWY 5, Orig
Gaithersburg, MD, Montgomery County Airpark, RNAV RWY 14, Orig, CANCELLED
Gaithersburg, MD, Montgomery County Airpark, RNAV (GPS) RWY 14, Orig
Ocean City, MD, Ocean City Muni, RNAV RWY 14, Orig, CANCELLED
Ocean City, MD, Ocean City Muni, RNAV (GPS) RWY 14, Orig
Salisbury, MD, Salisbury-Ocean City Wicomico Regional, RNAV RWY 5, Orig, CANCELLED
Salisbury, MD, Salisbury-Ocean City Wicomico Regional, RNAV (GPS) RWY 5, Orig
Salisbury, MD, Salisbury-Ocean City Wicomico Regional, RNAV RWY 14, Orig, CANCELLED
Salisbury, MD, Salisbury-Ocean City Wicomico Regional, RNAV (GPS) RWY 14, Orig
Salisbury, MD, Salisbury-Ocean City Wicomico Regional, RNAV RWY 23, Orig, CANCELLED
Salisbury, MD, Salisbury-Ocean City Wicomico Regional, RNAV (GPS) RWY 23, Orig
Salisbury, MD, Salisbury-Ocean City Wicomico Regional, RNAV RWY 32, Orig, CANCELLED
Salisbury, MD, Salisbury-Ocean City Wicomico Regional, RNAV (GPS) RWY 32, Orig
Stevensville, MD, Bay Bridge, RNAV RWY 11, Orig, CANCELLED
Stevensville, MD, Bay Bridge, RNAV (GPS) RWY 11, Orig
Stevensville, MD, Bay Bridge, RNAV RWY 29, Orig, CANCELLED
Stevensville, MD, Bay Bridge, RNAV (GPS) RWY 29, Orig
Westminster, MD, Carroll County Reg/Jack B. Poage Field, RNAV RWY 16, Orig, CANCELLED
Westminster, MD, Carroll County Reg/Jack B. Poage Field, RNAV (GPS) RWY 16, Orig
Westminster, MD, Carroll County Reg/Jack B. Poage Field, RNAV RWY 34, Orig, CANCELLED
Westminster, MD, Carroll County Reg/Jack B. Poage Field, RNAV (GPS) RWY 34, Orig
Westminster, MD, Clearview Airpark, RNAV RWY 14, Orig, CANCELLED
Westminster, MD, Clearview Airpark, RNAV (GPS) RWY 14, Orig
Frenchville, ME, Northern Aroostook Regional, RNAV RWY 14, Orig, CANCELLED
Frenchville, ME, Northern Aroostook Regional, RNAV (GPS) RWY 14, Orig
Frenchville, ME, Northern Aroostook Regional, RNAV RWY 32, Orig, CANCELLED
Frenchville, ME, Northern Aroostook Regional, RNAV (GPS) RWY 32, Orig
Princeton, ME, Princeton Muni, RNAV RWY 15, Orig, CANCELLED
Princeton, ME, Princeton Muni, RNAV (GPS) RWY 15, Orig
Coldwater, MI, Branch County Memorial, RNAV RWY 6, Orig, CANCELLED
Coldwater, MI, Branch County Memorial, RNAV (GPS) RWY 6, Orig
Detroit/Grosse Ile, MI, Grosse Ile Muni, RNAV RWY 22, Orig, CANCELLED
Detroit/Grosse Ile, MI, Grosse Ile Muni, RNAV (GPS) RWY 22, Orig
Frankfort, MI, Frankfort Dow Memorial Field, RNAV RWY 15, Orig, CANCELLED
Frankfort, MI, Frankfort Dow Memorial Field, RNAV (GPS) RWY 15, Orig
Frankfort, MI, Frankfort Dow Memorial Field, RNAV RWY 33, Orig, CANCELLED
Frankfort, MI, Frankfort Dow Memorial Field, RNAV (GPS) RWY 33, Orig
Harbor Springs, MI, Harbor Springs, RNAV RWY 10, Orig, CANCELLED
Harbor Springs, MI, Harbor Springs, RNAV (GPS) RWY 10, Orig
Harbor Springs, MI, Harbor Springs, RNAV RWY 28, Orig, CANCELLED
Harbor Springs, MI, Harbor Springs, RNAV (GPS) RWY 28, Orig
Ionia, MI, Ionia County, RNAV RWY 27, Orig, CANCELLED
Ionia, MI, Ionia County, RNAV (GPS) RWY 27, Orig
Marlette, MI, Marlette, RNAV RWY 9, Orig, CANCELLED
Marlette, MI, Marlette, RNAV (GPS) RWY 9, Orig
Marlette, MI, Marlette, RNAV RWY 27, Orig, CANCELLED
Marlette, MI, Marlette, RNAV (GPS) RWY 27, Orig
Marquette, MI, Sawyer Intl, RNAV RWY 19, Orig, CANCELLED
Marquette, MI, Sawyer Intl, RNAV (GPS) RWY 19, Orig
Saginaw, MI, Saginaw County H. W. Browne, RNAV RWY 27, Orig, CANCELLED
Saginaw, MI, Saginaw County H. W. Browne, RNAV (GPS) RWY 27, Orig
Three Rivers, MI, Three Rivers Muni Dr Haines, RNAV RWY 27, Orig, CANCELLED
Three Rivers, MI, Three Rivers Muni Dr Haines, RNAV (GPS) RWY 27, Orig
Troy, MI, Oakland/Troy, RNAV RWY 9, Orig, CANCELLED
Troy, MI, Oakland/Troy, RNAV (GPS) RWY 9, Orig
Bemidji, MN, Bemidji-Beltrami County, RNAV RWY 31, Orig, CANCELLED
Bemidji, MN, Bemidji-Beltrami County, RNAV (GPS) RWY 31, Orig
Minneapolis, MN, Flying Cloud, RNAV RWY 36, Orig, CANCELLED
Minneapolis, MN, Flying Cloud, RNAV RWY (GPS) 36, Orig
Olivia, MN, Olivia Regional, RNAV RWY 29, Orig, CANCELLED
Olivia, MN, Olivia Regional, RNAV (GPS) RWY 29, Orig
Owatonna, MN, Owatonna Degner Regional, RNAV RWY 12, Orig, CANCELLED
Owatonna, MN, Owatonna Degner Regional, RNAV (GPS) RWY 12, Orig
Pine River, MN, Pine River Regional, RNAV RWY 34, Orig, CANCELLED
Pine River, MN, Pine River Regional, RNAV (GPS) RWY 34, Orig
Cameron, MO, Cameron Memorial, RNAV RWY 17, Orig, CANCELLED
Cameron, MO, Cameron Memorial, RNAV (GPS) RWY 17, Orig
Cameron, MO, Cameron Memorial, RNAV RWY 35, Orig, CANCELLED
Cameron, MO, Cameron Memorial, RNAV (GPS) RWY 35, Orig
Fredericktown, MO, Fredericktown Regional, RNAV RWY 1, Orig, CANCELLED
Fredericktown, MO, Fredericktown Regional, RNAV (GPS) RWY 1, Orig
Fredericktown, MO, Fredericktown Regional, RNAV RWY 19, Orig, CANCELLED
Fredericktown, MO, Fredericktown Regional, RNAV (GPS) RWY 19, Orig
Marshall, MO, Marshall Meml Muni, RNAV RWY 18, Orig, CANCELLED
Marshall, MO, Marshall Meml Muni, RNAV (GPS) RWY 18, Orig
Marshall, MO, Marshall Meml Muni, RNAV RWY 36, Orig, CANCELLED
Marshall, MO, Marshall Meml Muni, RNAV (GPS) RWY 36, Orig
Picayune, MS, Picayune Muni, RNAV RWY 18, Orig, CANCELLED
Picayune, MS, Picayune Muni, RNAV (GPS) RWY 18, Orig
Picayune, MS, Picayune Muni, RNAV RWY 36, Orig, CANCELLED
Picayune, MS, Picayune Muni, RNAV (GPS) RWY 36, Orig
Poplar, MT, Poplar, RNAV RWY 9, Orig, CANCELLED
Poplar, MT, Poplar, RNAV (GPS) RWY 9, Orig
Poplar, MT, Poplar, RNAV RWY 27, Orig, CANCELLED
Poplar, MT, Poplar, RNAV (GPS) RWY 27, Orig
Edenton, NC, Northeastern Regional, RNAV RWY 1, Orig, CANCELLED
Edenton, NC, Northeastern Regional, RNAV (GPS) RWY 1, Orig
Edenton, NC, Northeastern Regional, RNAV RWY 5, Orig, CANCELLED
Edenton, NC, Northeastern Regional, RNAV RWY 5, Orig
Edenton, NC, Northeastern Regional, RNAV RWY 19, Orig, CANCELLED
Edenton, NC, Northeastern Regional, RNAV (GPS) RWY 19, Orig
Gastonia, NC, Gastonia Muni, RNAV RWY 3, Orig, CANCELLED
Gastonia, NC, Gastonia Muni, RNAV (GPS) RWY 3, Orig
Kinston, NC, Kinston Regional Jetport at Stallings Fld, RNAV RWY 5, Orig, CANCELLED
Kinston, NC, Kinston Regional Jetport at Stallings Fld, RNAV (GPS) RWY 5, Orig
Silver City, NC, Silver City Municipal, RNAV RWY 22, Orig, CANCELLED
Silver City, NC, Silver City Municipal, RNAV (GPS) RWY 22, Orig
Bismarck, ND, Bismarck Muni, RNAV RWY 3, Orig, CANCELLED
Bismarck, ND, Bismarck Muni, RNAV (GPS) RWY 3, Orig
Bismarck, ND, Bismarck Muni, RNAV RWY 21, Orig, CANCELLED
Bismarck, ND, Bismarck Muni, RNAV (GPS) RWY 21, Orig
Dickinson, ND, Dickinson Muni, RNAV RWY 14, Orig, CANCELLED
Dickinson, ND, Dickinson Muni, RNAV (GPS) RWY 14, Orig
Dickinson, ND, Dickinson Muni, RNAV RWY 32, Orig, CANCELLED
Dickinson, ND, Dickinson Muni, RNAV (GPS) RWY 32, Orig
Fargo, ND, Hector Intl, RNAV RWY 8, Orig, CANCELLED

Fargo, ND, Hector Intl, RNAV (GPS) RWY 8, Orig
Fargo, ND, Hector Intl, RNAV RWY 26, Orig, CANCELLED
Fargo, ND, Hector Intl, RNAV (GPS) RWY 26, Orig
Mohall, ND, Mohall Muni, RNAV RWY 31, Orig, CANCELLED
Mohall, ND, Mohall Muni, RNAV (GPS) RWY 31, Orig
Albion, NE, Albion Muni, RNAV RWY 15, Orig. CANCELLED
Albion, NE, Albion Muni, RNAV (GPS) RWY 15, Orig
Albion, NE, Albion Muni, RNAV RWY 33, Orig, CANCELLED
Albion, NE, Albion Muni, RNAV (GPS) RWY 33, Orig
Grand Island, NE, Central Nebraska Regional, RNAV RWY 13, Orig, CANCELLED
Grand Island, NE, Central Nebraska Regional, RNAV (GPS) RWY 13, Orig
Grand Island, NE, Central Nebraska Regional, RNAV RWY 17, Orig, CANCELLED
Grand Island, NE, Central Nebraska Regional, RNAV (GPS) RWY 17, Orig
Grand Island, NE, Central Nebraska Regional, RNAV RWY, Orig, CANCELLED
Grand Island, NE, Central Nebraska Regional, RNAV (GPS) RWY 31, Orig
Grand Island, NE, Central Nebraska Regional, RNAV RWY 35, Orig, CANCELLED
Grand Island, NE, Central Nebraska Regional, RNAV (GPS) RWY 35, Orig,
McCook, NE, McCook Muni, RNAV RWY 21, Orig. CANCELLED
McCook, NE, McCook Muni, RNAV (GPS) RWY 21, Orig
Norfolk, NE, Karl Stefan Memorial, RNAV RWY 1, Orig, CANCELLED
Norfolk, NE, Karl Stefan Memorial, RNAV (GPS) RWY 1, Orig,
Norfolk, NE, Karl Stefan Memorial, RNAV RWY 19, Orig, CANCELLED
Norfolk, NE, Karl Stefan Memorial, RNAV (GPS) RWY 19, Orig
Norfolk, NE, Karl Stefan Memorial, RNAV RWY 13, Orig, CANCELLED
Norfolk, NE, Karl Stefan Memorial, RNAV (GPS) RWY 13, Orig
Norfolk, NE, Karl Stefan Memorial, RNAV RWY 31, Orig, CANCELLED
Norfolk, NE, Karl Stefan Memorial, RNAV (GPS) RWY 31, Orig
O'Neill, NE, The O'Neill Muni-John L. Baker Field, RNAV RWY 13, Orig, CANCELLED
O'Neill, NE, The O'Neill Muni-John L. Baker Field, RNAV (GPS) RWY 13, Orig
O'Neill, NE, The O'Neill Muni-John L. Baker Field, RNAV (GPS) RWY 31, Orig, CANCELLED
O'Neill, NE, The O'Neill Muni-John L. Baker Field, RNAV (GPS) RWY 31, Orig
Valentine, NE, Miller Field, RNAV RWY 32, Orig, CANCELLED
Valentine, NE, Miller Field, RNAV (GPS) RWY 32, Orig
Wayne, NE, Wayne Muni, RNAV RWY 17, Orig, CANCELLED
Wayne, NE, Wayne Muni, RNAV (GPS) RWY 17, Orig
Wayne, NE, Wayne Muni, RNAV RWY 35, Orig, CANCELLED
Wayne, NE, Wayne Muni, RNAV (GPS) RWY 35, Orig
Atlantic City, NJ, Atlantic City Intl, RNAV RWY 13, Orig, CANCELLED
Atlantic City, NJ, Atlantic City Intl, RNAV (GPS) RWY 13, Orig
Atlantic City, NJ, Atlantic City Intl, RNAV RWY 22, Orig, CANCELLED
Atlantic City, NJ, Atlantic City Intl, RNAV (GPS) RWY 22, Orig
Newark, NJ, Newark Intl, RNAV RWY 22L, Orig, CANCELLED
Newark, NJ, Newark Intl, RNAV (GPS) RWY 22L, Orig
Montgomery, NY Orange County, RNAV RWY 3, Orig, CANCELLED
Montgomery, NY Orange County, RNAV (GPS) RWY 3, Orig
Montgomery, NY Orange County, RNAV RWY 8, Orig, CANCELLED
Montgomery, NY Orange County, RNAV (GPS) RWY 8, Orig
Montgomery, NY Orange County, RNAV RWY 21, Orig, CANCELLED
Montgomery, NY Orange County, RNAV (GPS) RWY 21, Orig
Montgomery, NY Orange County, RNAV RWY 26, Orig, CANCELLED
Montgomery, NY Orange County, RNAV (GPS) RWY 26, Orig
Monticello, NY, Sullivan County Intl, RNAV RWY 33, Orig, CANCELLED
Monticello, NY, Sullivan County Intl, RNAV (GPS) RWY 33, Orig
New York, NY, La Guardia, Copter RNAV 250, Orig, CANCELLED
New York, NY, La Guardia, Copter RNAV (GPS) 250, Orig
Niagara Falls, NY, Niagara Falls Intl, RNAV RWY 10L, Orig, CANCELLED
Niagara Falls, NY, Niagara Falls Intl, RNAV (GPS) RWY 10L, Orig
Sidney, NY, Sidney Muni, RNAV RWY 25, Orig, CANCELLED
Sidney, NY, Sidney Muni, RNAV (GPS) RWY 25, Orig
Lebanon, OH, Lebanon-Warren County, RNAV RWY 1, Orig, CANCELLED
Lebanon, OH, Lebanon-Warren County, RNAV (GPS) RWY 1, Orig
Lebanon, OH, Lebanon-Warren County, RNAV RWY 19, Orig, CANCELLED
Lebanon, OH, Lebanon-Warren County, RNAV RWY 19, Orig
Ardmore, OK, Ardmore Muni, RNAV RWY 31, Orig, CANCELLED
Ardmore, OK, Ardmore Muni, RNAV (GPS) RWY 31, Orig
Oklahoma City, OK, Sundance Airpark, RNAV RWY 17, Orig, CANCELLED
Oklahoma City, OK, Sundance Airpark, RNAV (GPS) RWY 17, Orig
Oklahoma City, OK, Sundance Airpark, RNAV RWY 35, Orig, CANCELLED
Oklahoma City, OK, Sundance Airpark, RNAV (GPS) RWY 35, Orig
Tillamook, OR, Tillamook, RNAV RWY 13, Orig, CANCELLED
Tillamook, OR, Tillamook, RNAV (GPS) RWY 13, Orig
Pittsburgh, PA, Allegheny County, RNAV RWY 5, Orig, CANCELLED
Pittsburgh, PA, Allegheny County, RNAV RWY 5, Orig
Pittsburgh, PA, Allegheny County, RNAV RWY 10, Orig, CANCELLED
Pittsburgh, PA, Allegheny County, RNAV RWY 10, Orig
Pittsburgh, PA, Allegheny County, RNAV RWY 28, Orig, CANCELLED
Pittsburgh, PA, Allegheny County, RNAV RWY 28, Orig
Pittsburgh, PA, Pittsburgh Intl, RNAV RWY 10R, Orig, CANCELLED
Pittsburgh, PA, Pittsburgh Intl, RNAV (GPS) RWY 10R, Orig
Pittsburgh, PA, Pittsburgh Intl, RNAV RWY 10L, Orig, CANCELLED
Pittsburgh, PA, Pittsburgh Intl, RNAV (GPS) RWY 10L, Orig
Pittsburgh, PA, Pittsburgh Intl, RNAV RWY 10C, Orig, CANCELLED
Pittsburgh, PA, Pittsburgh Intl, RNAV (GPS) RWY 10C, Orig
Pittsburgh, PA, Pittsburgh Intl, RNAV RWY 14, Orig, CANCELLED
Pittsburgh, PA, Pittsburgh Intl, RNAV (GPS) RWY 14, Orig
Pittsburgh, PA, Pittsburgh Intl, RNAV RWY 28R, Orig, CANCELLED
Pittsburgh, PA, Pittsburgh Intl, RNAV (GPS) RWY 28R, Orig
Pittsburgh, PA, Pittsburgh Intl, RNAV RWY 28L, Orig, CANCELLED
Pittsburgh, PA, Pittsburgh Intl, RNAV (GPS) RWY 28L, Orig
Pittsburgh, PA, Pittsburgh Intl, RNAV RWY 28C, Orig, CANCELLED
Pittsburgh, PA, Pittsburgh Intl, RNAV (GPS) RWY 28C, Orig
Pittsburgh, PA, Pittsburgh Intl, RNAV RWY 32, Orig, CANCELLED
Pittsburgh, PA, Pittsburgh Intl, RNAV (GPS) RWY 32, Orig
Pottsville, PA, Schuylkill County/Joe Zerbey, RNAV RWY 11, Orig, CANCELLED
Pottsville, PA, Schuylkill County/Joe Zerbey, RNAV (GPS) RWY 11, Orig
Pottsville, PA, Schuylkill County/Joe Zerbey, RNAV RWY 29, Orig, CANCELLED
Pottsville, PA, Schuylkill County/Joe Zerbey, RNAV (GPS) RWY 29, Orig, CANCELLED
Pottsville, PA, Schuylkill County/Joe Zerbey, RNAV (GPS) RWY 29, Orig
San Juan, PR Luis Munoz Marin Intl, RNAV RWY 8, Orig, CANCELLED
San Juan, PR Luis Munoz Marin Intl, RNAV (GPS) RWY 8, Orig
San Juan, PR Luis Munoz Marin Intl, RNAV RWY 10, Orig, CANCELLED
San Juan, PR Luis Munoz Marin Intl, RNAV RWY 10, Orig
Anderson, SC, Anderson Regional, RNAV RWY 5, Orig, CANCELLED
Anderson, SC, Anderson Regional, RNAV (GPS) RWY 5, Orig
Myrtle Beach, SC, Myrtle Beach Intl, RNAV RWY 35, Orig, CANCELLED
Myrtle Beach, SC, Myrtle Beach Intl, RNAV (GPS) RWY 35, Orig
Myrtle Beach, SC, Myrtle Beach Intl, RNAV RWY 17, Orig, CANCELLED
Myrtle Beach, SC, Myrtle Beach Intl, RNAV (GPS) RWY 17, Orig
Rapid City, SD, Rapid City Regional, RNAV RWY 32, Orig, CANCELLED
Rapid City, SD, Rapid City Regional, RNAV (GPSA) RWY 32, Orig
Murfreesboro, TN, Murfreesboro Muni, RNAV RWY 18, Orig, CANCELLED
Murfreesboro, TN, Murfreesboro Muni, RNAV (GPS) RWY 18, Orig
Murfreesboro, TN, Murfreesboro Muni, RNAV RWY 36, Orig, CANCELLED
Murfreesboro, TN, Murfreesboro Muni, RNAV (GPS) RWY 36, Orig

Smithville, TN, Smithville Muni, RNAV RWY 24, Orig, CANCELLED
Smithville, TN, Smithville Muni, RNAV (GPS) RWY 24, Orig
Somerville, TN, Fayette County, RNAV RWY 19, Orig, CANCELLED
Somerville, TN, Fayette County, RNAV (GPS) RWY 19, Orig
Anahuac, TX, Chambers County, RNAV RWY 12, Orig, CANCELLED
Anahuac, TX, Chambers County, RNAV (GPS) RWY 12, Orig
Baytown, TX, RWJ Airpark, RNAV RWY 26, Orig. CANCELLED
Baytown, TX, RWJ Airpark, RNAV (GPS) RWY 26, Orig
Bonham, TX, Jones Field, RNAV RWY 17, Orig, CANCELLED
Bonham, TX, Jones Field, RNAV (GPS) RWY 17, Orig
Brownwood, TX, Brownwood Regional, RNAV RWY 17, Orig, CANCELLED
Brownwood, TX, Brownwood Regional, RNAV (GPS) RWY 17, Orig
Brownwood, TX, Brownwood Regional, RNAV RWY 35, Orig, CANCELLED
Brownwood, TX, Brownwood Regional, RNAV (GPS) RWY 35, Orig
Corsicana, TX, C. David Campbell Field-Corsicana Muni, RNAV RWY 14, Orig, CANCELLED
Corsicana, TX, C. David Campbell Field-Corsicana Muni, RNAV (GPS) RWY 14, Orig
Corsicana, TX, C. David Campbell Field-Corsicana Muni, RNAV RWY 32, Orig, CANCELLED
Corsicana, TX, C. David Campbell Field-Corsicana Muni, RNAV (GPS) RWY 32, Orig
Eastland, TX, Eastland Muni, RNAV RWY 35, Orig, CANCELLED
Eastland, TX, Eastland Muni, RNAV (GPS) RWY 35, Orig
Fort Stockton, TX, Fort Stockton-Pecos County, RNAV RWY 12, Orig, CANCELLED
Fort Stockton, TX, Fort Stockton-Pecos County, RNAV (GPS) RWY 12, Orig
Fort Stockton, TX, Fort Stockton-Pecos County, RNAV RWY 30, Orig, CANCELLED
Fort Stockton, TX, Fort Stockton-Pecos County, RNAV (GPS) RWY 30, Orig
Fort Worth, TX, Fort Worth Alliance, RNAV RWY 16L, Orig, CANCELLED
Fort Worth, TX, Fort Worth Alliance, RNAV (GPS) RWY 16L, Orig
Fort Worth, TX, Fort Worth Alliance, RNAV RWY 34R, Orig, CANCELLED
Fort Worth, TX, Fort Worth Alliance, RNAV (GPS) RWY 34R, Orig
La Grange, TX, Fayette Regional Air Center, RNAV RWY 16, Orig, CANCELLED
La Grange, TX, Fayette Regional Air Center, RNAV (GPS) RWY 16, Orig
La Grange, TX, Fayette Regional Air Center, RNAV RWY 34, Orig, CANCELLED
La Grange, TX, Fayette Regional Air Center, RNAV (GPS) RWY 34, Orig
Liberty, TX, Liberty Muni, RNAV RWY 16, Orig, CANCELLED
Liberty, TX, Liberty Muni, RNAV (GPS) RWY 16, Orig
Livingston, TX, Livingston Muni, RNAV RWY 30, Orig, CANCELLED
Livingston, TX, Livingston Muni, RNAV (GPS) RWY 30, Orig
Lufkin, TX, Angelina County, RNAV RWY 25, Orig, CANCELLED
Lufkin, TX, Angelina County, RNAV (GPS) RWY 25, Orig
Lufkin, TX, Angelina County, RNAV RWY 33, Orig, CANCELLED
Lufkin, TX, Angelina County, RNAV (GPS) RWY 33, Orig
Nacogdoches, TX, A L Mangham Jr Regional, RNAV RWY 15, Orig, CANCELLED
Nacogdoches, TX, A L Mangham Jr Regional, RNAV (GPS) RWY 15, Orig
Nacogdoches, TX, A L Mangham Jr Regional, RNAV RWY 18, Orig, CANCELLED
Nacogdoches, TX, A L Mangham Jr Regional, RNAV (GPS) RWY 18, Orig
Palestine, TX, Palestine Muni, RNAV RWY 35, Orig, CANCELLED
Palestine, TX, Palestine Muni, RNAV (GPS) RWY 35, Orig
Port Lavaca, TX, Calhoun County, RNAV RWY 14, Orig, CANCELLED
Port Lavaca, TX, Calhoun County, RNAV (GPS) RWY 14, Orig
Rockport, TX, Aransas Co, RNAV RWY 14, Orig, CANCELLED
Rockport, TX, Aransas Co, RNAV (GPS) RWY 14, Orig
Seminole, TX, Gaines County, RNAV (GPS) RWY 35, Orig, CANCELLED
Seminole, TX, Gaines County, RNAV (GPS) RWY 35, Orig
Uvalde, TX, Garner Field, RNAV RWY 33, Orig, CANCELLED
Uvalde, TX, Garner Field, RNAV (GPS) RWY 33, Orig
Wendover, UT, Wendover, RNAV RWY-A, Orig, CANCELLED
Wendover, UT, Wendover, RNAV (GPS)-A, Orig
Wendover, UT, Wendover, RNAV RWY 26, Orig, CANCELLED
Wendover, UT, Wendover, RNAV (GPS) RWY 26, Orig
Charlottesviklle, VA, Charlottesville-Albermarle, RNAV RWY 3, Orig, CANCELLED
Charlottesviklle, VA, Charlottesville-Albermarle, RNAV (GPS) RWY 3, Orig
Norfolk, VA, Norfolk Intl, RNAV RWY 23, Orig, CANCELLED
Norfolk, VA, Norfolk Intl, RNAV (GPS) RWY 23, Orig
Charlotte Amalie, VI, Cyril E King, RNAV RWY 10, Orig, CANCELLED
Charlotte Amalie, VI, Cyril E King, RNAV (GPS) RWY 10, Orig
Christiansted, VI, Henry E. Rohlsen, RNAV RWY 9, Orig, CANCELLED
Christiansted, VI, Henry E. Rohlsen, RNAV (GPS) RWY 9, Orig
Black River Falls, WI, Black River Falls Area, RNAV RWY 8, Orig, CANCELLED
Black River Falls, WI, Black River Falls Area, RNAV (GPS) RWY 8, Orig
Green Bay, WI, Austin Straubel Intl, RNAV RWY 6, Orig, CANCELLED
Green Bay, WI, Austin Straubel Intl, RNAV (GPS) RWY 6, Orig
Green Bay, WI, Austin Straubel Intl, RNAV RWY 36, Orig, CANCELLED
Green Bay, WI, Austin Straubel Intl, RNAV (GPS) RWY 36, Orig
Morgantown, WV, Morgantpwn Muni-WAalter L. Bill Hart Field, RNAV RWY 18, Orig, CANCELLED
Morgantown, WV, Morgantpwn Muni-WAalter L. Bill Hart Field, RNAV (GPS) RWY 18, Orig

[FR Doc. 00–29321 Filed 11–15–00; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30213; Amdt. No. 2020]

Standard Instrument Approach Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

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

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

Incorporation by reference—approved by the Director of the Federal Register on December 31, 1980, and reapproved as of January 1, 1982.

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

For Examination—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;

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

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

For Purchase—Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or

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

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

FOR FURTHER INFORMATION CONTACT: Donald P. Pate, Flight Procedure Standards Branch (AMCAFS–420), Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082, Oklahoma City, OK 73125), telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs). The complete regulatory description on each SIAP is contained in the appropriate FAA Form 8260 and the National Flight Data Center (FDC)/Permanent (P) Notices to Airmen (NOTAM) which are incorporated by reference in the amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of the Federal Aviation's Regulations (FAR). Materials incorporated by reference are available for examination or purchase as stated above.

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

The Rule

This amendment to part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes SIAPs. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained in the content of the following FDC/P NOTAMs for each SIAP. The SIAP information in some previously designated FDC/Temporary (FDC/T) NOTAMs is of such duration as to be permanent. With conversion to FDC/P NOTAMs, the respective FDC/T NOTAMs have been canceled.

The FDC/P NOTAMs for the SIAPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these chart changes to SIAPs by FDC/P NOTAMs, the TERPS criteria were applied to only these specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a National Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for all these SIAP amendments requires making them effective in less than 30 days.

Further, the SIAPs contained in this amendment are based on the criteria contained in the TERPS. Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are impractical and contrary to the public interest and, where applicable, that good cause exists for making these SIAPs effective in less than 30 days.

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Navigation (Air).

Issued in Washington, DC on November 9, 2000.

L. Nicholas Lacey,

Director, Flight Standards Service.

Adoption of the Amendment

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

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

1. The authority citation for part 97 is revised to read as follows:

Authority: 49 U.S.C. 40103, 40113, 40120, 44701; 49 U.S.C. 106(g); and 14 CFR 11.49(b)(2).

2. Part 97 is amended to read as follows:

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPS; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

** * * Effective Upon Publication*

FDC date	State	City	Airport	FDC No.	SIAP
09/21/00	AZ	Kingman	Kingman	FDC 0/1580	VOR/DME Rwy 21 Amdt 6A... This corrects FDC 0/1580 IN TL 00–22.
10/11/00	WI	Mosinee	Central Wisconsin	FDC 0/2658	ILS RWY 8, Amdt 1A...
10/17/00	VA	Suffolk	Suffolk Muni	FDC 0/2868	GPS RWY 7 Orig–A...
10/17/00	WI	Ladysmith	Rusk County	FDC 0/2839	NDB or GPS Rwy 32, Amdt 2A...
10/20/00	VA	Richmond/Ashland	Hanover County Muni	FDC 0/2998	VOR Rwy 16 Orig–D...
10/25/00	WI	Eau Claire	Chippewa Valley Regional	FDC 0/3230	LOC/DME BC Rwy 4, Amdt 8...
10/26/00	IA	Boone	Boone Muni	FDC 0/3295	GPS Rwy 32, Orig...
10/26/00	IA	Boone	Boone Muni	FDC 0/3296	GPS Rwy 14, Amdt 1...
10/26/00	NM	Santa Fe	Sante Fe Muni	FDC 0/3274	VOR/DMR or GPS–A, Amdt 1...
10/26/00	NM	Socorro	Socorro Muni	FDC 0/3273	GPS Rwy 33, Orig–A...

FDC date	State	City	Airport	FDC No.	SIAP
10/26/00	NM	Truth or Consequences	Truth or Consequences Muni	FDC 0/3275	VOR or GPS–A, Amdt 9A...
10/26/00	NV	Las Vegas	McCarran Intl	FDC 0/3308	GPS Rwy 1R Orig–A...
10/27/00	AK	Fort Yukon	Fort Yukon	FDC 0/3362	VOR/DME or TACAN Rwy 21, Amdt 1B... Replaces 0/2899
10/27/00	AZ	Prescott	Ernest A. Love Field	FDC 0/3372	VOR/DME RNAV Rwy 21L Amdt 3...
.					
10/27/00	AZ	Prescott	Ernest A. Love Field	FDC 0/3375	VOR Rwy 12 Amdt 2...
10/27/00	ND	Grand Forks	Grand Forks Intl	FDC 0/3367	ILS Rwy 35L, Amdt 11A... Replaces 0/3225
10/27/00	TX	Conroe	Conroe/Montgomery County	FDC 0/3345	GPS Rwy 32, Orig–B...
10/27/00	TX	Conroe	Conroe/Montgomery County	FDC 0/3346	VOR/DME RNAV Rwy 32, Amdt 1B...
10/27/00	TX	Conroe	Conroe/Montgomery County	FDC 0/3347	NDB Rwy 14, Amdt 1B...
10/27/00	TX	Greenville	Majors	FDC 0/3387	ILS 2 Rwy 17, Amdt 4...
10/27/00	TX	Greenville	Majors	FDC 0/3391	ILS Rwy 17, Amdt 5...
10/27/00	TX	Greenville	Majors	FDC 0/3398	VOR/DME Rwy 17, Orig–A...
10/27/00	VA	Leesburg	Leesburg Executive	FDC 0/3339	GPS Rwy 17 Amdt 1...
10/27/00	VA	Leesburg	Leesburg Executive	FDC 0/3342	LOC Rwy 17 Amdt 2...
10/27/00	VA	Leesburg	Leesburg Executive	FDC 0/3343	VOR or GPS–A Amdt 1...
10/27/00	WI	Mosinee	Central Wisconsin	FDC 0/3330	ILS/DME Rwy 35, Orig...
10/30/00	GA	Valdosta	Valdosta Regional	FDC 0/3471	ILS Rwy 35, Amdt 5B...
10/30/00	IL	Chicago/Aurora	Aurora Muni	FDC 0/3465	ILS Rwy 9, Amdt 1B...
10/30/00	NE	Albion	Albion Muni	FDC 0/3484	RNAV Rwy 33, Orig...
10/30/00	NE	Albion	Albion Muni	FDC 0/3485	RNAV Rwy 15, Orig....
10/30/00	TX	Conroe	Conroe/Montgomery County	FDC 0/3470	ILS Rwy 14, Amdt 1C...
10/30/00	TX	Greenville	Majors	FDC 0/3445	NDB or GPS Rwy 35, Amdt 1A...
10/30/00	TX	Sherman/Denison	Grayson County	FDC 0/3441	NDB or GPS Rwy 17L, Amdt 9...
10/31/00	IL	Chicago/Aurora	Aurora Muni	FDC 0/3520	VOR/DME RNAV or GPS Rwy 27, Orig–A...
10/31/00	MO	St Louis	Lambert-St Louis Intl	FDC 0/3540	ILS Rwy 30L, Amdt 11...
10/31/00	SD	Rapid City	Rapid City Regional	FDC 0/3523	RNAV Rwy 32, Orig...
10/31/00	TX	Greenville	Majors	FDC 0/3515	NDB or GPS Rwy 17, Amdt 5A...
10/31/00	WI	Richland Center	Richland	FDC 0/3546	VOR or GPS–A, Amdt 4...
11/2/00	NC	Monroe	Monroe	FDC 0/3665	ILS Rwy 5 Orig–C...
11/2/00	NC	Monroe	Monroe	FDC 0/3666	VOR/DME or GPS–B Amdt 6B...
11/2/00	NC	Monroe	Monroe	FDC 0/3667	VOR or GPS–A Amdt 11B...
11/2/00	NC	Monroe	Monroe	FDC 0/3669	NDB or GPS Rwy 5, Amdt 2B...
11/01/00	AZ	Prescott	Ernest A. Love Field	FDC 0/3570	ILS/DME Rwy 21L Amdt 3...
11/02/00	AR	Ash Flat	Sharp County Regional	FDC 0/3634	NDB Rwy 3, Amdt 1B...
11/02/00	AR	Camden	Harrell Field	FDC 0/3619	VOR/DME or GPS Rwy 36, Amdt 8A...
11/02/00	MO	Kansas City	Kansas City Downtown	FDC 0/3685	ILS Rwy 3, Amdt 1D...
11/02/00	MO	Kansas City	Kansas City Intl	FDC 0/3684	ILS Rwy 9, Amdt 11B...
11/02/00	TX	Kerrville	Kerrville Muni/Louis Scheriner Field	FDC 0/3663	VOR/DME RNAV or GPS Rwy 12, Amdt 2A...
11/02/00	TX	Wichita Falls	Wichita Valley	FDC 0/3638	VOR–B, Amdt 5...
11/02/00	TX	Wichita Falls	Wichita Valley	FDC 0/3639	VOR/DME–C, Amdt 1...
11/03/00	FL	Fort Myers	Southwest Florida Intl	FDC 0/3749	VOR/DME or TACAN Rwy 24, Amdt 1...
11/03/00	LA	New Iberia	Acadiana Regional	FDC 0/3744	VOR or TACAN or GPS Rwy 16, Orig–A...
11/03/00	OH	Tiffin	Seneca County	FDC 0/3752	NDB Rwy 24, Amdt 7...
11/03/00	OR	Medford	Rouge Valley Intl-Medford	FDC 0/3741	ILS Rwy 14, Orig...
11/03/00	TX	Dalhart	Dalhart Muni	FDC 0/3718	VOR Rwy 17, Amdt 12B...
11/06/00	NV	Las Vegas	North Las Vegas	FDC 0/3819	GPS Rwy 12 Orig...
11/07/00	AK	Anchorage	Anchorage Intl	FDC 0/3850	VOR Rwy 6R, Amdt 12B...
11/07/00	AR	Lake Village	Lake Village Muni	FDC 0/3860	GPS Rwy 1, Orig...
11/07/00	FL	Fort Myers	Southwest Florida Intl	FDC 0/3864	RADAR–1 Amdt 5...
11/07/00	TX	Houston	Ellington Field	FDC 0/3834	ILS Rwy 17R, Amdt 4A...
11/07/00	TX	Houston	Ellington Field	FDC 0/3835	GPS Rwy 17R, Orig...

[FR Doc. 00–29320 Filed 11–15–00; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30212; Amdt. No. 2019]

Standard Instrument Approach Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

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

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

Incorporation by reference-approved by the Director of the Federal Register on December 31, 1980, and reapproved as of January 1, 1982.

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

For Examination—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;

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

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

For Purchase—Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or

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

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

FOR FURTHER INFORMATION CONTACT: Donald P. Pate, Flight Procedure Standards Branch (AMCAFS–420), Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK. 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK. 73125) telephone: (405) 954–4164.

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

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

The Rule

This amendment to part 97 is effective upon publication of each separate SIAP as contained in the transmittal. Some SIAP amendments may have been previously issued by the FAA in a National Flight Data Center (NFDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP amendments may require making them effective in less than 30 days. For the remaining SIAPs, an effective date at least 30 days after publication is provided.

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

Conclusion

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Navigation (Air).

Issued in Washington, DC on November 9, 2000.

L. Nicholas Lacey,

Director, Flight Standards Service.

Adoption of the Amendment

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

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

1. The authority citation for part 97 is revised to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120, 44701; and 14 CFR 11.49(b)(2).

2. Part 97 is amended to read as follows:

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME,

LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

** * * Effective November 30, 2000*

Philadelphia, PA, Philadelphia Intl, ILS RWY 26, Amdt 1
Philadelphia, PA, Philadelphia Intl, ILS PRM, RWY 26, Orig (Simultaneous Close Parallel)
Philadelphia, PA, Philadelphia Intl, ILS RWY 27L, Amdt 11
Philadelphia, PA, Philadelphia Intl, ILS PRM, RWY 27L, Orig (Simultaneous Close Parallel)
Memphis, TN, Memphis Intl, ILS RWY 36C, Amdt 1

** * * Effective December 28, 2000*

Talladega, AL, Talladega Muni, VOR/DME–B, Orig
Palmer, MA, Metropolitan, NDB RWY 4, Orig, CANCELLED

** * * Effective January 25, 2001*

Destin, FL, Destin-Fort Walton Beach, RADAR–1, Amdt 8
Perry, FL, Perry-Foley, NDB RWY 36, Amdt 4
Perry, FL, Perry-Foley, RNAV (GPS) RWY 18, Orig
Perry, FL, Perry-Foley, RNAV (GPS) RWY 36, Orig
Perry, FL, Perry-Foley, VOR/DME RNAV OR GPS RWY 18, Amdt 1, CANCELLED
Atlanta, GA, The William B. Hartsfield Atlanta Intl, ILS RWY 27L, Amdt 14
Winamac, IN, Arens Field, NDB OR GPS RWY 9, Amdt 1, CANCELLED
Lexington, KY, Blue Grass, NDB RWY 4, Amdt 21
Lexington, KY, Blue Grass, ILS RWY 22, Amdt 18
Owatonna, MN, Owatonna Degner Regional, ILS RWY 30, Amdt 1
Atlantic City, NJ, Atlantic City Muni/Bader Field, VOR OR GPS–B, Amdt 1A, CANCELLED
Atlantic City, NJ, Ocean City Muni, VOR RWY 6, Amdt 1, CANCELLED
Erwin, NC, Harnett County, VOR/DME RWY 5, Amdt 2
Erwin, NC, HARNETT County, NDB RWY 23, Amdt 1
Erwin, NC, Harnett County, GPS RWY 5, Orig-B, CANCELLED
Erwin, NC, Harnett County, RNAV (GPS) RWY 5, Orig
Erwin, NC, Harnett County, RNAV (GPS) RWY 23, Orig
Saranac Lake, NY, Adirondack Regional, VOR/DME RWY 5, Amdt 3
Saranac Lake, NY, Adirondack Regional, VOR OR GPS RWY 9, Amdt 1
Saranac Lake, NY, Adirondack Regional, RNAV (GPS) RWY 5, Orig
Selinsgrove, PA, Penn Valley, VOR–A, Amdt 6
Selinsgrove, PA, Penn Valley, RNAV (GPS) RWY 17, Orig
Richmond/Ashland, VA, Hanover County Muni, VOR RWY 16, Amdt 1
Richmond/Ashland, VA, Hanover County Muni, LOC RWY 16, Amdt 2
Clarksburg, WV, Benedum, ILS RWY 21, Amdt 1

The FAA published an Amendment in Docket 30210, Amdt No. 2017 to Part 97 Of the Federal Aviation Regulations, Volume 65 FR No. 213, Pages 65733 dated Thursday, November 2, 2000 under section 97.29 effective January 25, 2001 which is hereby rescinded:

Jackson, WY, Jackson Hole, ILS RWY 18, Amdt 7

[FR Doc. 00–29319 Filed 11–15–00; 8:45 am]
BILLING CODE 4910–13–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 125, 225, and 356

[Docket No. RM99–8–001; Order No. 617–A]

Preservation of Records of Public Utilities and Licensees, Natural Gas Companies, and Oil Pipeline Companies; Order Denying Rehearing

Issued November 9, 2000.

AGENCY: Federal Energy Regulatory Commission, DOE

ACTION: Order denying rehearing.

SUMMARY: Edison Electric Institute (EEI) filed a request for rehearing seeking revision of the Commission's Final Rule in Order No. 617, *Preservation of Records of Public Utilities and Licensees, Natural Gas Companies, and Oil Pipeline Companies.* The Commission denies rehearing.

ADDRESSES: Office of the Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

FOR FURTHER INFORMATION CONTACT:
Mary C. Lauermann (Technical Information), Office of the Executive Director, 888 First Street, NE., Washington, D.C. 20426, (202) 208–0087
Julia A. Lake (Legal Information), Office of the General Counsel, 888 First Street, NE., Washington, DC 20426, (202) 208–2019.

SUPPLEMENTARY INFORMATION:

I. Introduction

In this order, the Commission addresses a request for rehearing of Order No. 617, the final rule on the preservation of records of public utilities and licensees, natural gas companies, and oil pipeline companies.[1] In Order No. 617, the Commission amended Parts 125, 225, and 356[2] of its regulations in order to update, reduce, and clarify records retention requirements for jurisdictional public utilities and licensees, natural gas companies and oil pipeline companies. Order No. 617 is part of the Commission's ongoing program to update and eliminate burdensome and unnecessary requirements. These changes significantly reduce the burden of maintaining records for regulated companies.

For the reasons stated below, the Commission denies rehearing.

II. Background

On July 27, 2000, the Commission issued Order No. 617, revising the Commission's records retention regulations, which included revising the general instructions, revising the records retention periods, and removing all but two retention reserve items. Order No. 617, effective January 1, 2001, is part of the Commission's ongoing program to update and eliminate burdensome and unnecessary requirements.

A timely request for rehearing was filed by Edison Electric Institute (EEI) requesting: (1) Reduction of one retention period, and (2) revision of one section of regulatory text. These issues are addressed separately below.

III. Discussion

1. Reduction of Retention Period

Under the final rule, utilities and licensees must maintain plant records for as long as the plant is included in the company's accounting records.[3] EEI argues that the new record retention period for schedule item 8(b)(1) of 25 years represents an increase in the retention period. EEI requests the Commission to reduce the record retention period for schedule item 8(b)(1) back to 6 years, as required under the prior regulations.

The Commission has not increased the record retention period for schedule item 8(b)(1). The record retention period has always been a minimum of 25 years.[4] The revised schedule item 8(b)(1) clarifies this 25-year retention period. The Commission recognized, however, that many plant items have a useful life longer than 25 years, and that other plant items are sold or retired in less than 25 years. The Commission is

[1] 65 FR 48148 (Aug. 7, 2000); III FERC Stats. & Regs. ¶ 31,105 (Jul. 21, 2000). The Commission issued a correction notice on August 15, 2000. *See* 65 FR 50638 (Aug. 21, 2000).

[2] 18 CFR Parts 125, 225, and 356.

[3] 18 CFR 125.2(g) and 18 CFR 125.3 item 8(b)(1).

[4] *See* former 17 CFR 125.2(j) ("* * * records related to plant shall be retained a minimum of 25 years.").

requiring companies to keep plant records until the facilities are permanently removed from service and retired from the accounting records. This revision recognizes that it is possible for companies to maintain plant records for shorter or longer periods than 25 years. The Commission, therefore, denies EEI's request for a reduction of the retention period for schedule item 8(b)(1).

2. Revision of New § 125.2(i)

Section 125.2(i) of the final rule requires public utilities and licensees to assure that supporting cost information is available for services performed by or for associated or affiliated companies, including detailed information regarding the nature of the transaction, the amounts involved, and the accounts used to record the transaction. EEI continues to be concerned that the language in this section could be interpreted to expand the Commission's authority to records of utility affiliates in general, instead of just to records that relate to utility-affiliate transactions. EEI stated that the Commission's clarification provided in the preamble of the final rule was ''very useful and informative,'' and that the ''clarification is valuable because it reduces .* * * ambiguity'' and ''reflects the 'utility-affiliate' focus of the records to be maintained.'' However, EEI's concern is that the clarification provided in the preamble should be incorporated into the regulatory text at § 125.2(i), and requests that the text be amended to include the clarification. EEI proposed the following revision to § 125.2(i):

Public utilities and licensees must assure the availability of records, *to be retained by the originating entity,* of services performed by *a utility or licensee* for associated or affiliated companies *and vice versa,* with supporting cost information for the periods indicated in section 125.3 as necessary, *as they pertain to the cost of the services performed.*

The Commission believes that EEI's suggested revision to the regulatory language in § 125.2(i) is unnecessary. We find that EEI's suggested revision, in fact, deletes clarifying language identifying the kind of information public utilities and licensees must retain. The regulatory text in the final rule clearly states the Commission's needs related to records retention for transactions between utilities and affiliates. The Commission, therefore, denies the request for this revision.

IV. Document Availability

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the Internet through FERC's Home Page (*http://www.ferc.fed.us*) and in FERC's Public Reference Room during normal business hours (8:30 A.M. to 5:00 P.M. Eastern time) at 888 First Street, NE., Room 2A, Washington, DC 20426.

From FERC's Home Page on the Internet, this information is available in both the Commission's Issuance Posting System (CIPS) and the Records and Information Management System (RIMS).

—CIPS provides access to the texts of formal documents issued by the Commission since November 14, 1994.

—CIPS can be accessed using the CIPS link or the Energy Information Online icon. The full text of this document will be available on CIPS in ASCII and WordPerfect 8.0 format for viewing, printing, and/or downloading.

—RIMS contains images of documents submitted to and issued by the Commission after November 16, 1981. Documents from November 1995 to the present can be viewed and printed from FERC's Home Page using the RIMS link or the Energy Information Online icon. Descriptions of documents back to November 16, 1981, are also available from RIMS-on-the-Web; requests for copies of these and other older documents should be submitted to the Public Reference Room.

User assistance is available for RIMS, CIPS, and the Website during normal business hours from our Help line at (202) 208–2222 (e-mail to *Webmaster@ferc.fed.us)* or the Public Reference Room at (202) 208–1371 (e-mail to *public.referenceroom@ferc.fed.us*).

During normal business hours, documents can also be viewed and/or printed in FERC's Public Reference Room, where RIMS, CIPS, and the FERC Website are available. User assistance is also available.

By the Commission.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 00–29330 Filed 11–15–00; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Parts 4, 9, 24, 70 and 275

[T.D. ATF–432]

RIN 1512–AC25

Technical Amendments

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

ACTION: Final rule: Treasury decision.

SUMMARY: This Treasury decision makes technical amendments and corrects typographical errors in various regulations of the ATF. All changes are to provide clarity and uniformity throughout the regulations.

DATES: Effective November 16, 2000.

FOR FURTHER INFORMATION CONTACT: Nancy Kern, Regulations Division, (202) 927–8210, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue, NW., Washington, DC 20226.

SUPPLEMENTARY INFORMATION:

Background

The Bureau of Alcohol, Tobacco and Firearms (ATF) administers regulations published in title 27, Code of Federal Regulations. These regulations are updated April 1 of each year to incorporate new or revised regulations that were published by ATF in the **Federal Register** during the preceding year. ATF identified several amendments that are needed to provide clarity and uniformity to the regulations in 27 CFR.

These amendments do not make any substantive changes and are only intended to improve the clarity of title 27.

Paperwork Reduction Act

The provisions of the Paperwork Reduction Act of 1995, Public Law 104–13, 44 U.S.C. Chapter 35, and its implementing regulations, 5 CFR 1320, do not apply to this final rule because there are no recordkeeping or reporting requirements.

Regulatory Flexibility Act

The provisions of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) do not apply to this rule because no notice of proposed rulemaking is necessary.

Executive Order 12866

This final rule is not subject to the requirements of Executive Order 12866 because the regulations make nonsubstantive technical corrections to previously published regulations.

Administrative Procedure Act

Because this final rule merely makes technical corrections to improve the clarity of the regulations, it is unnecessary to issue this final rule with notice and public procedure under 5 U.S.C. 553(b), or subject to the effective date limitation in section 553(d).

Drafting Information

The author of this document in Nancy Kern, Regulations Division, Bureau of Alcohol, Tobacco and Firearms.

List of Subjects

27 CFR Part 4

Advertising, Consumer protection, Customs duties and inspection, Imports, Labeling, Liquors, Packaging and Containers.

27 CFR Part 9

Administrative practices and procedures, Consumer protection, Viticultural areas. Wine.

27 CFR Part 24

Administrative practice and procedure, Authority delegations, Claims, Electronic fund transfers, Excise taxes, Exports, Food additives, Fruit juices, Labeling, Liquors, Packaging and containers, Reporting and recordkeeping requirements, Research, Scientific equipment, Spices and flavoring, Surety bonds, Taxpaid wine bottling house, Transportation, Vinegar, Warehouses, Wine.

27 CFR Part 70

Administrative practice and procedure, Alcohol and alcoholic beverages, Authority delegations, Bankruptcy, Claims, Disaster assistance, Excise taxes, Firearms and ammunition, Government employees, Law enforcement, Law enforcement officers, Penalties, Reporting and recordkeeping requirements, Seizures and forfeitures, Surety bonds, Tobacco.

27 CFR Part 275

Administrative practice and procedure, Authority delegations, Cigars and cigarettes, Claims, Customs duties and inspections, Electronic fund transfers, Excise taxes, Imports, Labeling, Packaging and containers, Penalties, Reporting and recordkeeping requirements, Seizures and forfeitures, Surety bonds, Tobacco.

Authority and Issuance

Accordingly, for the reason set out in the preamble, Title 27, Code of Federal Regulations is amended as follows:

PART 4—LABELING AND ADVERTISING OF WINE

Paragraph 1. The authority citation for part 4 continues to read as follows:

Authority: 17 U.S.C. 205

Par. 2. In § 4.21, revise the cross reference at the end of the section to read as follows:

§ 4.21 The standards of identity.

* * * * *

Cross Reference: For regulations relating to the use of spirits in wine, see part 24 of this chapter.

Par. 3. Section 4.25a(e)(2) is revised to read as follows:

§ 4.25a Appellations of origin.

* * * * *

(e) * * *

(2) *Establishment of American viticultural areas.* Petitions for establishment of American viticultural areas may be made to the Director by any interested party, pursuant to the provisions of § 70.701(c) of this title. The petition may be in the form of a letter, and should contain the following information referred to in § 9.3(b) of this title.

* * * * *

PART 9—AMERICAN VITICULTURAL AREAS

Par. 4. The authority citation for part 9 continues to read as follows:

Authority: 27 U.S.C. 205.

Par. 5. In § 9.3, revise the section heading and paragraphs (a) and (b)(3) to read as follows:

§ 9.3 Relation to parts 4 and 70 of this chapter.

(a) Procedure. In accordance with §§ 4.25a(e)(2) and 70.701(c) of this chapter, the Director shall receive petitions to establish American viticultural areas and shall use the informal rulemaking process, under 5 U.S.C. 553, in establishing viticultural areas in this part.

(b) * * *

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

* * * * *

PART 24—WINE

Par. 6. The authority citation for part 24 continues to read as follows:

Authority: 5 U.S.C. 552(a); 26 U.S.C. 5001, 5008, 5041, 5042, 5044, 5061, 5062, 5081, 5111–5113, 5121, 5122, 5142, 5143, 5173, 5206, 5214, 5215, 5351, 5353, 5354, 5356, 5357, 5361, 5362, 5364–5373, 5381–5388, 5391, 5392, 5511, 5551, 5552, 5661, 5662, 5684, 6065, 6091, 6109, 6301, 6302, 6311, 6651, 6676, 7011, 7302, 7342, 7502, 7503, 7606, 7805, 7851; 31 U.S.C. 9301, 9303, 9304, 9306.

Par. 7. In § 24.265, remove the word ''bail'' and add the wrod ''bailee'' in place thereof.

PART 70—PROCEDURE AND ADMINISTRATION

Par. 8. The authority citation for part 70 continues to read as follows:

Authority: 5 U.S.C. 301 and 552; 26 U.S.C. 4181, 4182, 5146, 5203, 5207, 5275, 5367, 5415, 5504, 5555, 5684(a), 5741, 5761(b), 5802, 6020, 6021, 6064, 6102, 6155, 6159, 6201, 6203, 6204, 6301, 6303, 6311, 6313, 6314, 6321, 6323, 6325, 6326, 6331–6343, 6401–6404, 6407, 6416, 6423, 6501–6503, 6511, 6513, 6514, 6532, 6601, 6602, 6611, 6621, 6622, 6651, 6653, 6656–6658, 6665, 6671, 6672, 6701, 6723, 6801, 6862, 6863, 6901, 7011, 7101, 7102, 7121, 7122, 7207, 7209, 7214, 7304, 7401, 7403, 7406, 7423, 7424, 7425, 7426, 7429, 7430, 7432, 7502, 7503, 7505, 7506, 7513, 7601–7606, 7608–7610, 7622, 7623, 7653, 7805.

Par. 9. In § 70.411, revise paragraph (c)(2) to read as follows:

§ 70.411 Imposition of taxes, qualification requirements, and regulations.

* * * * *

(c) * * *

(2) *Miscellaneous liquor transactions.* Part 170 of 27 CFR contains miscellaneous regulations relative to the manufacture, removal, and use of stills and condensers, and to the notice, registration, and recordkeeping requirements therefor.

* * * * *

Par. 10. Remove the reference ''§ 71.26(h)'' each place it appears and add, in its place, the reference ''§ 70.802(g)'' in the following places;

(a) § 70.701(a)(3)(iv); and

(b) § 70.701(b).

PART 275—IMPORTATION OF TOBACCO PRODUCTS AND CIGARETTE PAPERS AND TUBES

Par. 10a. The authority citation for part 275 continues to read as follows:

Authority: 18 U.S.C. 2342; 26 U.S.C. 5701, 5703, 5704, 5705, 5708, 5712, 5713, 5721, 5722, 5723, 5741, 5754, 5761, 5762, 5763, 6301, 6302, 6313, 6404, 7101, 7212, 7342, 7606, 7652, 7805; 31 U.S.C. 9301, 9303, 9304, 9306.

Par. 11. In § 275.105, revise the first sentence to read as follows:

§ 275.105 Prepayment of tax.

To prepay, in Puerto Rico, the internal revenue tax imposed by 26 U.S.C.

7652(a), on tobacco products and cigarette paper and tubes of Puerto Rican manufacture which are to be shipped to the United States, the shipper shall file, or cause to be filed, with the Chief, Puerto Rico Operations, a tax return, ATF Form 5000.25, in duplicate, with full remittance of tax which will become due on such tobacco products and cigarette papers and tubes.* * *

Signed: October 16, 2000.

Bradley A. Buckles,

Director.

Approved: October 25, 2000.

John P. Simpson,

Deputy Assistant Secretary, (Regulatory, Tariff and Trade Enforcement).

[FR Doc. 00–29409 Filed 11–15–00; 8:45 am]

BILLING CODE 4810–13–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MA–081–7211a; A–1–FRL–6897–4]

Approval and Promulgation of Air Quality Implementation Plans; Massachusetts; Enhanced Motor Vehicle Inspection and Maintenance Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: We are converting our limited approval under the Clean Air Act of the Commonwealth of Massachusetts State Implementation Plan (SIP) revision for an enhanced vehicle inspection and maintenance program to a full approval. In our limited approval, we said Massachusetts needed to submit revisions to its SIP to address four sections of EPA's enhanced I/M regulation for full approval. We have determined that on October 20, 2000 Massachusetts submitted revisions that meet all of the conditions for full approval. Additionally, we are also approving an interim level of emission reduction credit for the inspection and maintenance program that can be utilized by Massachusetts in attainment planning. The intent of this action is to convert our limited approval of Massachusetts' enhanced vehicle I/M program SIP to a full approval and to approve an interim level of emission reduction credit for attainment planning purposes.

DATES: This direct final rule is effective on January 16, 2001 without further notice, unless EPA receives relevant adverse comment by December 18, 2000. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Comments may be mailed to David Conroy, Unit Manager, Air Quality Planning , Office of Ecosystem Protection (mail code CAQ), U.S. Environmental Protection Agency, EPA-New England, One Congress Street, Suite 1100, Boston, MA 02114–2023. Copies of the documents relevant to this action are available for public inspection during normal business hours, by appointment at the Office Ecosystem Protection, U.S. Environmental Protection Agency, EPA-New England, One Congress Street, 11th floor, Boston, MA; Air and Radiation Docket and Information Center, U.S. Environmental Protection Agency, Room M–1500, 401 M Street, (Mail Code 6102), SW., Washington, DC; and Division of Air Quality Control, Department of Environmental Protection, One Winter Street, 8th Floor, Boston, MA 02108.

FOR FURTHER INFORMATION CONTACT: Peter Hagerty, (617) 918–1049.

SUPPLEMENTARY INFORMATION:

This Supplementary Information section is organized as follows:

I. What action is EPA taking today?
II. What Massachusetts SIP revision is the topic of this action?
III. What were the requirements for full approval of the Massachusetts inspection and maintenance program?
IV. How did Massachusetts fulfill these requirements for full approval?
V. What action did EPA take to defer sanctions in Massachusetts?
VI. What credit may Massachusetts assume in the interim until the correlation study is complete?
VII. EPA Action
VIII. Administrative Requirements

I. What Action Is EPA Taking Today?

In this action, we are converting our limited approval of Massachusetts' enhanced motor vehicle inspection and maintenance (I/M) SIP to a full approval.

We are also approving Massachusetts to use ASM credits for future planning purposes until the correlation study to compare IM240 with the Massachusetts 31 second test (MA31 test) is completed. Note: The full approval of the Massachusetts I/M program is based on the ability of the program to achieve the low-enhanced performance standard, and EPA has already determined that the program meets the low-enhanced standard in its limited approval of the program.

II. What Massachusetts SIP Revision Is the Topic of This Action?

This notice deals with a revision to the State of Massachusetts' Clean Air Act SIP submitted by Massachusetts on October 20, 2000 for certain program elements necessary to complete the I/M program. Today we are acting only upon this October 20, 1999 submittal to determine that Massachusetts submitted revisions meeting all of the conditions necessary to convert the limited approval of the enhanced I/M plan to a full approval. In so doing we are not reopening our final rulemaking granting limited approval of the Massachusetts enhanced I/M SIP submitted on May 14, 1999 and approved at 40 CFR 52.1120(c)(122).

III. What Were the Requirements for Full Approval of the Massachusetts Inspection and Maintenance Program?

Approval of Massachusetts' I/M program SIP required submission of information to meet the requirements of the following sections of EPA's I/M regulations: Network type and program evaluation—40 CFR 51.353; Quality control—40 CFR 51.359; Quality assurance—40 CFR 51.363; and On-road testing—40 CFR 51.371.

IV. How Did Massachusetts Fulfill These Requirements for Full Approval?

On October 20, 2000, Massachusetts submitted revisions to its enhanced I/M SIP to EPA in order to meet the conditions for full approval. The following is a description of the measures which Massachusetts has submitted to meet each of the deficient areas described in the limited approval approved at 40 CFR 52.1120(c)(122).

1. *Network type and program evaluation—40 CFR 51.353*—As part of its October 20, 2000 submittal, Massachusetts submitted a document entitled ''Program Evaluation Plans For the Enhanced Inspection and Maintenance Program,'' dated October 2000. The Program Evaluation Plans contained a final ''MA31-to-IM240 Correlation Study.'' The protocol for the correlation study was developed with EPA input and is acceptable to establish final emission reduction credit for the Massachusetts I/M program. A task assignment has been signed by Massachusetts to gather data to conduct the study described in the protocol. A copy of that task assignment was included in the October 20, 2000 submittal.

The Program Evaluation Plans, dated October 2000, also contained a ''Phase 2 Program Evaluation Plan for the Massachusetts I&M Program.'' The

phase 2 program evaluation will begin after the MA31-to-IM240 correlation study is complete. The phase 2 program will evaluate the Massachusetts I/M program using a modified method of the EPA/Sierra Research Method. On January 9, 1998 (63 FR 1362), EPA finalized revisions to its program evaluation requirements allowing this methodology to be utilized. This section of the SIP now meets the requirements of EPA's I/M rule.

2. *Quality control—40 CFR 51.359*—As part of its October 20, 2000 submittal, Massachusetts submitted a document entitled ''Quality Assurance and Quality Control Plan For the Massachusetts Enhanced Emissions and Safety Inspection Program,'' dated October 16, 2000. This plan contains the needed quality control procedures. This section of the SIP now meets the requirements of EPA's I/M rule.

3. Quality assurance—40 CFR 51.363—As part of its October 20, 2000 submittal, Massachusetts submitted a document entitled ''Quality Assurance and Quality Control Plan For the Massachusetts Enhanced Emissions and Safety Inspection Program,'' dated October 16, 2000. This plan contains the needed quality assurance measures and provisions. This section of the SIP now meets the requirements of EPA's I/M rule.

4. *On-road testing—40 CFR 51.371*—In the October 20, 2000 submittal letter, Massachusetts has committed to conducting on-road testing with remote sensing and has shown that resources are available to do the testing. Data will be analyzed and a report submitted to EPA. This section of the SIP now meets the requirements of EPA's I/M rule.

V. What Action Did EPA Take To Defer Sanctions in Massachusetts?

Due to the disapproval of an earlier I/M SIP submitted by the Commonwealth of Massachusetts, the Clean Air Act's offset sanction was applicable in Massachusetts beginning May 15, 1999 and the Clean Air Act's highway sanction was applicable beginning November 15, 1999. On November 30, 1999 (64 FR 66775), EPA published an interim final rule in the **Federal Register** which deferred the application of those sanctions beginning on December 15, 1999. Our interim final rule was based on a finding that Massachusetts had more likely than not implemented an approvable enhanced I/M program that was to take effect on December 15, 1999. In that action EPA said that the implementation of sanctions will be deferred until EPA takes final action on the I/M SIP.

Today EPA is taking final, full approval of Massachusetts' submitted enhanced I/M program SIP revision. Accordingly, all sanctions and FIP clocks related to approval of Massachusetts' I/M program are terminated upon the effective date of today's action.

VI. What Credit May Massachusetts Assume in the Interim Until the Correlation Study Is Complete?

In EPA's supplementary proposed rule on the Massachusetts I/M SIP published on November 30, 1999 (64 FR 66829), EPA stated that there was no data available at the time to assign the exact emission reduction credit for the combination of test type and equipment that the Commonwealth was implementing (*i.e.*, a 31 second transient test utilizing the BAR 31 trace and NYTEST equipment). We did state that, even if one makes extremely conservative assumptions about the efficacy of the Massachusetts test, EPA's mobile modeling shows that the I/M program demonstrates compliance with EPA's performance standard for a low enhanced program. We also acknowledged that Massachusetts will conduct necessary comparison testing to determine the appropriate emission reduction for SIP credit using the combination of the BAR 31 transient trace with NYTEST equipment and stated that this would be important for purposes of approving the ozone attainment demonstration for the one-hour ozone standard submitted by the Commonwealth on July 27, 1998.

On December 16, 1999 (64 FR 70319), EPA proposed approval of the Massachusetts attainment demonstration for the Springfield (Western Massachusetts) ozone nonattainment area. EPA stated that unless Massachusetts submitted a demonstration which would substantiate the level of credit claimed for their I/M program, EPA would disapprove the attainment demonstration. *Id.* at 70329–30. In the meantime, while Massachusetts has pursued such a test program and has in fact signed a work order to execute this program, additional information has become available which allows the Agency to exercise engineering judgement in estimating the credit level of the MA31 test program. The MA 31 test program combines use of the NYTEST equipment used in New York with the BAR 31 test cycle used in Oregon.

The additional information EPA has received is a test program which resulted in an evaluation of the difference in effectiveness between EPA's IM240 equipment and NYTEST equipment which is utilized by Massachusetts. This test program quantified the effectiveness of NYTEST and granted it 95% of the IM240 hydrocarbon (HC) reduction credit and 99% of the IM240 reduction credit for both carbon monoxide (CO) and nitrogen oxides (NO_X).

In November 25, 1996, EPA had quantified the BAR31 cycle currently run in Oregon (OR31) as receiving 90% of the IM240 HC credit and 95% of the IM240 CO and NO_X credit. Although the OR31 uses the same cycle as the MA31 test, the OR31 employs IM240 equipment, which is more accurate than the BAR97 equipment specified in the MA31 test. Therefore, the credit afforded the MA31 at this time has been slightly reduced to reflect this equipment discrepancy. The NYTEST equipment analysis taken in concert with the earlier information defining the relationship between OR31 and IM240 cycles results in the Agency agreeing, based on our best engineering judgment, that the level of credit Massachusetts needs to support their attainment demonstration for their currently operating I/M program is acceptable. Massachusetts needs a level of credit equivalent to ASM2 at final cut points. The level of credit granted the MA31 as compared to the IM240 is 85% for HC, 87% for CO and 85% for NO_X.

At this time, EPA believes Massachusetts will continue work on two related but distinct efforts. The first is to obtain and analyze MA31/IM240 correlation data, and the second is that Massachusetts will also perform a program evaluation to quantify the emissions benefits achieved by the program. EPA will review the correlation data as well as the program evaluation data, and take notice and comment as appropriate on whether the data bears out our current determination with regard to the level of credit granted to the program. If it does not, we will take appropriate action to correct any SIP shortfall.

VII. EPA Action

EPA is converting its limited approval of Massachusetts' enhanced I/M program to a full approval. Accordingly, all sanctions and FIP clocks related to approval of Massachusetts' I/M program are terminated upon the effective date of today's action. An extensive discussion of Massachusetts' enhanced I/M program and our rationale for our limited approval action was provided in the previous final rule for the Massachusetts enhanced I/M program approved at 40 CFR 52.1120(c)(122).

Additionally, we are also approving an interim level of emission reduction credit for the inspection and maintenance program that can be utilized by Massachusetts in attainment planning.

The EPA is publishing this action without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the SIP revision should relevant adverse comments be filed. This rule will be effective January 16, 2001 without further notice unless the Agency receives relevant adverse comments by December 18, 2000.

If the EPA receives such comments, then EPA will publish a notice withdrawing the final rule and informing the public that the rule will not take effect. All public comments received will then be addressed in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period on the proposed rule. Any parties interested in commenting on the proposed rule should do so at this time. If no such comments are received, the public is advised that this rule will be effective on January 16, 2001 and no further action will be taken on the proposed rule.

Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

VIII. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and therefore is not subject to review by the Office of Management and Budget. This action merely approves state law as meeting Federal requirements and imposes no additional requirements beyond those imposed by state law. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). For the same reason, this rule also does not significantly or uniquely affect the communities of tribal governments, as specified by Executive Order 13084 (63 FR 27655, May 10, 1998). This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it merely approves a state rule implementing a Federal standard, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. This rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a SIP submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a SIP submission, to use VCS in place of a SIP submission that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the ''Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings'' issued under the executive order. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Congressional Review Act, 5 U.S.C. section 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. section 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 16, 2001. Interested parties should comment in response to the proposed rule rather than petition for judicial review, unless the objection arises after the comment period allowed for in the proposal. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements.

Dated: October 27, 2000.

Mindy S. Lubber,

Regional Administrator, EPA—New England.

Part 52 of chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart W—Massachusetts

2. Section 52.1159 is added to read as follows:

§ 52.1159 Enhanced Motor Vehicle Inspection and Maintenance.

(a) Revisions submitted by the Massachusetts Department of Environmental Protection on October 20, 2000, to the motor vehicle inspection and maintenance program are approved:

(1) Letter from the Massachusetts Department of Environmental Protection dated October 20, 2000 submitting a revision to the Massachusetts State Implementation Plan.

(2) Document entitled ''Quality Assurance and Quality Control Plan For the Massachusetts Enhanced Emissions and Safety Inspection Program,'' dated October 16, 2000.

(3) Document entitled ''Program Evaluation Plans For the Enhanced Inspection and Maintenance Program,'' dated October 2000, and supporting contracts.

[FR Doc. 00–29220 Filed 11–15–00; 8:45 am]

BILLING CODE 6560–50–P

Proposed Rules

Federal Register
Vol. 65, No. 222
Thursday, November 16, 2000

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2000–NE–24–AD]

RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney Canada (P&WC) Model PW305 and PW305A Turbofan Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to Pratt & Whitney Canada (P&WC) Model PW305 and PW305A turbofan engines. This proposal would require removing stage 4 low pressure turbine (LPT) disks from service before exceeding new, lower cyclic life limits. This proposal is prompted by the results of a spin pit test analysis which indicate that the stage 4 LPT disk does not have full published life. The actions specified by the proposed AD are intended to prevent LPT disk failure resulting from premature cracking of the LPT disks, which could result in an uncontained engine failure and damage to the airplane.

DATES: Comments must be received by December 18, 2000.

ADDRESSES: Submit comments to the Federal Aviation Administration (FAA), New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 2000–NE–24–AD, 12 New England Executive Park, Burlington, MA 01803–5299. Comments may also be sent via the Internet using the following address: ''9-ane-adcomment@faa.gov''. Comments sent via the Internet must contain the docket number in the subject line. Comments may be inspected at this location between 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

This information may be examined at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA.

FOR FURTHER INFORMATION CONTACT: James Rosa, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803–5299; telephone: (781) 238–7152; fax (781) 238–7199.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this action may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2000–NE–24–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRM's

Any person may obtain a copy of this NPRM by submitting a request to the FAA, New England Region, Office of the Regional Counsel, Attention: Rules Docket No. 2000–NE–24–AD, 12 New England Executive Park, Burlington, MA 01803–5299.

Discussion

Transport Canada, which is the airworthiness authority for Canada, recently notified the FAA that an unsafe condition may exist on P&WC model PW305 and PW305A turbofan engines. P&WC ran a spin test and found earlier than expected indications of crack initiation. As a result of this test, Transport Canada advises that there is a possibility of premature failure of the stage 4 LPT disks, part numbers (P/N's) 30A1457 and 30A1499. This condition, if not corrected, could cause a failure of the stage 4 LPT disk, that could result in an uncontained engine failure and damage to the airplane. To prevent a premature failure of the stage 4 LPT disk, this proposal would decrease the current life limit of these disks from 5,000 to 4,000 cycles-in-service (CIS).

Bilateral Airworthiness Agreement

This engine model is manufactured in Canada and is type certificated for operation in the United States under the provisions of § 21.29 of the Federal Aviation Regulations (14 CFR 21.29) and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, Transport Canada has kept the FAA informed of the situation described above. The FAA has examined the findings of Transport Canada, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States. To prevent premature failure of the stage 4 LPT disk used in the model PW305 and PW305A engines, Transport Canada issued airworthiness directive (AD) CF–99–28 in order to ensure the airworthiness of these P&WC engines in Canada.

Proposed Actions

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require removing certain stage 4 LPT disk P/N's 30A1457 and 30A1499 from service, before exceeding new lower cyclic life limit of 4000 CIS, and replacing them with serviceable parts. The new life limits are based on spin test analysis results that indicate that the LPT disks do not have full published lives.

Economic Analysis

There are currently 358 engines in the domestic fleet containing the affected stage 4 LPT disks, P/N's 30A1457 and

30A1499, and a total of 484 engines in the worldwide fleet. The total cost to the domestic fleet to remove and replace these disks at the new life limit of 4000 CIS, rather than the former life limit of 5000 CIS, is estimated to be $6,331,015.

Regulatory Impact

This proposed rule does not have federalism implications, as defined in Executive Order 13132, because it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the FAA has not consulted with state authorities prior to publication of this proposed rule.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, 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 draft regulatory evaluation prepared for this action is contained in the Rules 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, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Pratt & Whitney Canada: Docket No. 2000–NE–24–AD.

Applicability: Pratt & Whitney Canada (P&WC) Model PW305 and PW305A turbofan engines, with stage 4 low pressure turbine (LPT) disks, part numbers (P/N's) 30A1457 and 30A1499. These engines are installed on but not limited to British Aerospace BAe. 125 1000A, BAe. 125 1000B, Hawker 1000 and Learjet 60 series airplanes.

Note 1: This airworthiness directive (AD) applies to each engine identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For engines that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent premature LPT disk failure due to cracking of the LPT disks, which could result in an uncontained engine failure and damage to the airplane, accomplish the following:

New Stage 4 LPT Life Limit

(a) Remove stage 4 LPT disks, P/N's 30A1457 and 30A1499, prior to exceeding the new life limit of 4000 cycles-in-service (CIS).

(b) Except for the provisions of paragraph (c) of this AD, no parts, identified by P/N in paragraph (a) of this AD, that exceed the new life limit of 4000 CIS, may be installed.

Alternative Method of Compliance

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Engine Certification Office (ECO). Operators shall submit their request through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, ECO.

Note 2: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the ECO.

Ferry Flights

(d) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Burlington, MA, on November 9, 2000.

David A. Downey,

Assistant Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 00–29379 Filed 11–15–00; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 203

RIN 1010–AC71

Relief or Reduction in Royalty Rates—Deep Water Royalty Relief for OCS Oil and Gas Leases Issued After 2000

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Proposed rule.

SUMMARY: This proposed rule revises regulations on royalty relief for oil and gas producers on the Outer Continental Shelf (OCS). It provides for suspension or reduction of royalty on a case-by-case basis for certain additional categories of OCS leases. Also, it identifies circumstances when we may consider special royalty relief outside our established end-of-life and deep water royalty relief (DWRR) programs.

DATES: We will consider all comments we receive by December 18, 2000. We will begin reviewing comments then and may not fully consider comments we receive after December 18, 2000.

ADDRESSES: If you wish to comment, you may mail or hand-carry comments to the Department of the Interior, Minerals Management Service; Mail Stop 4024; 381 Elden Street; Herndon, Virginia 20170–4817; Attention: Rules Processing Team (RPT). The RPT's e-mail address is: *rules.comments@MMS.gov.*

FOR FURTHER INFORMATION CONTACT: Marshall Rose, Economics Division, at (703) 787–1536.

SUPPLEMENTARY INFORMATION: The OCS Lands Act (43 U.S.C. 1337 *et seq.*) is the basis for our regulations on suspending or lowering royalties on OCS leases. This rule describes how certain new deep water leases may qualify for royalty suspensions and what circumstances might cause us to grant royalty relief outside normal procedures.

Background

The regulations at 30 CFR part 203 implement the Secretary of the Interior's (Secretary) authority to grant royalty relief to OCS leases. Section 302 of the Outer Continental Shelf Deep Water Royalty Relief Act of 1995 (Pub. L. 104–58) (the Act), gave us the authority to promote development and production of marginal resources in certain areas by suspending royalties. Existing regulations describe our programs in three discretionary relief situations—leases nearing the end of their life, new

developments in water 200 meters or deeper (deep water) in the Gulf of Mexico (GOM), or deep water expansion projects in the GOM. Our programs balance the effectiveness of royalty relief to encourage production that otherwise would not occur with receipt of fair market value for public resources in the specific circumstances of the individual leases.

Discretionary Relief To Promote Future Deep Water Development

Promotion of development with discretionary royalty relief serves several public purposes. In marginal circumstances, royalty suspension can encourage development of resources that otherwise might be bypassed. Royalty suspension can also lead to new production that uses existing infrastructure. Further, making relief discretionary avoids the need to offer blanket relief to whole categories of leases, many of which do not need it to attract exploration or development interest.

The Act contained the following provisions relating to DWRR:

- It authorized granting royalty relief both to nonproducing leases and to expansion projects on producing leases issued before adoption of royalty suspension in lease terms (pre-Act leases).
- It directed that we implement this authority in deep water (200 meters and greater water depth) because of the greater costs and economic risks involved in operating at those depths than in shallower water.
- It set out a qualification test intended to grant relief only when development otherwise would not make economic sense.

Based on the Act, our current regulations governing pre-Act leases oblige us to consider each field in its entirety. That approach commits us to evaluating all the resources that the field may contain. To improve the assumptions that we have to make, we propose to add language to invite applicants to share information they may have on other leases that may eventually become part of the field. (See clarifications we propose in § 203.63) Also, we propose to add language to clarify the reservoir and well data we are looking for in the geological and geophysical (G&G) report part of the application. (See changes proposed to § 203.86) Both of these proposed changes reflect additional information we have requested from previous applicants.

After November 2000, we will issue new deep water leases. Some will be like pre-Act leases in that we will issue them with no royalty suspension (RS) volume. Others, which we call RS leases, will have a royalty suspension included in the lease terms. In some circumstances, the size of the royalty suspension in the lease may be inadequate to induce development. For instance, stand-alone development of a marginal prospect may require more relief than a royalty suspension designed for a tie-back development. Because may of the special risks associated with deep water development remain, we propose to offer all leases issued in sales after November 2000 (post-2000 deep water leases) the opportunity to qualify for enough royalty suspension to make a development project or an expansion project economic. Deep water leases issued after the date of enactment of the Act and prior to November 28, 2000 (eligible leases), may not apply for royalty relief beyond the eligible amount specified in the lease.

Since the minimum suspension volumes set in the Act do not apply to leases issued in sales held after November 28, 2000, we propose to offer royalty suspension volumes on a project rather than a field-basis for post-2000 deep water leases. Specifically, any future deep water lease that lies west of 87 degrees, 30 minutes west longitude in the GOM may apply for royalty suspension on a development project if it had not produced, or on an expansion project if it has produced. Hereinafter, unless otherwise specified, reference to a ''project'' includes either a development of an expansion project. (See the new applicant category we add in proposed changes to § 203.60.)

The Act established a deadline by which we must evaluate a DWRR application for a pre-Act lease. The deadline helps development planning by giving applicants certainty about how long they can expect to wait for our relief determination. When companies have other investment opportunities, that planning certainty may be an important factor for keeping a marginal project alive. We plan to retain this deadline as a commitment for applications for post-2000 deep water leases. The Act also sets a default royalty suspension in the event we fail to act in time on an application. We propose to adopt a default royalty suspension amount that reflects the length of the delay, rather than the fixed default amount set by the DWRR Act for pre-Act leases. Specifically, if we fail to render a DWRR determination within 180 days (plus authorized extensions), a project on a post-2000 deep water lease will produce royalty-free for the number of months we delay a decision, plus the entire volume which our belated decision grants. (See the proposed new category we add to the table in § 203.66.)

Adjustments to Our DWRR Program

We have considered six DWRR applications over 4 years under the existing rules in 30 CFR part 203. During those evaluations, we identified some program elements that may produce results contrary to our intentions. We will therefore adjust provisions on minimum suspension volumes, sunk costs, discount rates, performance conditions, and allowable price increases while we modify these rules to authorize applications for royalty suspension by leases issued in OCS sales after November 2000.

Adjustments to Minimum Suspension Volumes and Relief Shares

Except for an application involving a pre-Act lease on a field that did not produce before the Act, we propose to reduce the minimum suspension volumes for DWRR we grant to nonproducing leases. The field-sized minimums established in the Act will continue to apply to qualifying applications that involve pre-Act leases. Congress based those original minimums on cost and producibility estimates from the early 1990's for field development. Since then, improved knowledge of deep water resources, technical progress, and new infrastructure have significantly reduced the size necessary for an economic prospect. As early as February 1996, the ''Oil and Gas Journal'' reported that industry experts believe the economic threshold for developing deep water projects had dropped from the 150 million barrels of oil equivalent (MMBOE) range to the 30 to 35 MMBOE range because deep water fields were proving more prolific and less troublesome than fields on the near-shore shelf. The fact that the Act's minimum suspension volumes exceed the expected resource sizes (in some cases by a large margin) in all but one of the deep water field applications we have reviewed, reflects the change in economic threshold.

We propose to offer more appropriate minimum royalty suspension volumes for development projects and for expansion projects that qualify for relief. For a development project on a pre-production RS lease, the minimum will equal the royalty suspension volume with which we issued the lease, plus an increment explained in the following section on sunk cost. As explained in our companion proposed rule modifying 30 CFR part 260, published on

September 14, 2000 (65 FR 55476), we plan to update the royalty suspension volumes with which we issue RS leases over time as needed. We also propose to offer a minimum suspension volume to expansion projects and to development projects on leases issued with no royalty suspension volume in sales after November 2000. The minimum for these projects will equal the increment explained in the next section on sunk cost.

When multiple nonproducing RS leases participate, the minimum volume suspension for the project equals the sum of the royalty suspension volumes applicable to the participating leases plus the increment explained in the next section. As with an expansion project, the applicant defines the scope of the development project, and relief applies only to wells included in the application. We reserve the right, as we do under the current program, to remove nonprospective wells or leases from the evaluation. (See the proposed new paragraph and conforming changes in § 203.69.)

With one exception, all leases participating in a successful application for DWRR share the single relief volume we approve. If the application involves a pre-Act lease, the single volume must at least equal the field-sized minimum set in the Act and applies to all production from the field. In these cases, we evaluate field rather than project economics, and all lessees share the volume we grant to the field.

If the application involves only post-2000 deep water leases, the single relief volume equals the amount we judge necessary to make the project economic. In this case, the royalty suspension replaces any suspension volume in the lease instruments and only applies to the reservoirs identified in the application. Thus, should a qualifying project fail to produce the full royalty suspension volume we grant in response to an application, the leases that participated in the application may not apply the unused volume suspension to other production. To do otherwise encourages understatement of a lease's potential in the application we review. If no production has occurred from the participating leases, the royalty suspension volume is subject to the minimum applicable for the development or expansion project.

The one exception to sharing a single volume occurs when an eligible lease is part of the field, In that instance, the eligible lease may produce royalty-free up to its field-sized suspension volume, regardless of the volume we set for the project proposed by the other leases. However, production from a development project on the same field counts against the field-sized volume available to the eligible lease.

We reflect these principles by adding the new applicant category in the proposed changes to § 203.71.

Adjustments to the Evaluation Elements

Except for cases that involve fields with a pre-Act lease, we propose to change the way we count sunk costs in the determination of whether an application qualifies for royalty relief. To comply with the Act's instruction to consider historic costs for pre-Act leases, we originally included the costs of and after the discovery well when calculating whether a field appeared economic, but only on fields where no production had yet occurred. We now propose to allow the documented costs of the discovery well, both for development projects on post-2000 deep water leases and for expansion projects on pre-Act or on post-2000 deep water leases. The discovery well is the one that penetrates the first reservoir targeted by the project and that meets the well producibility requirements of 30 CFR part 250. We expect that allowing sunk costs for this broader scope of prospects will help promote exploration in deep water and greater use of the opportunity to obtain supplementary royalty suspension volumes. Allowing some sunk costs to more applicants permits more leases to quality for royalty relief and thus encourages more exploration.

Unlike the treatment of sunk costs on pre-Act leases, we do not intend to count pre-application costs subsequent to the discovery well. This more limited treatment reflects a balanced approach to competing considerations. On the one hand, overcoming the unusual risks of deep water development may depend on Government sharing some of the uncertainty burden, even on expansion projects. Also, our regulations require only a discovery well before we will consider an application. Further, the uneconomic level for development projects will be lower because determination of whether the project qualifies for a supplemental volume suspension includes the value of any volume suspension with which we issued the participating leases. On the other hand, only future costs, not historic costs, influence decisions on whether to proceed on a specific project. Further, activities and costs other than the discovery well, such as acquiring seismic data, completing engineering studies, or drilling additional wells, are conducted at the applicant's discretion before filing an application for royalty relief. Additionally, costs associated with these other activities are more likely than a discovery well to benefit other prospects for help attract other partners or successor owners to this prospect. Counting only the cost of the discovery well balances sharing the exploration risk with the responsibility to include only relevant costs. (See the new category of sunk cost treatment proposed in the table in § 203.68.)

We do not propose to change the exclusion of sunk cost from the determination of how much relief a project needs to become economic (volume test). To do otherwise risks adding relief well beyond that necessary to make development economic. Also, it directs more relief to just the wrong projects, specifically those that are more likely to continue anyway because they have relatively smaller costs left to incur and that must be covered by future production. However, we will ensure that inclusion of sunk cost in the qualification determination gives the applicant an unambiguous benefit. We propose to do that by adding an increment of royalty-free production to any royalty suspension volume with which a qualifying project starts the application process. Our qualification test does factor in the volume suspensions with which we issued leases participating in the application, but not this increment.

We propose to set this increment at 10 percent of the most likely resource size we agree is appropriate for the project. For instance, consider a development project that MMS agrees has a most likely resource size of 60 MMBOE. If it qualifies for relief and is located on RS leases that we issued with a combined royalty suspension volume of 20 MMBOE, it will get a royalty suspension of at least 26 MMBOE. An expansion project in this situation would get at least 6 MMBOE.

This form of increment improves on a universal fixed increment or one tied to water depth because it is project-specific. Further, its relatively small size ensures that it neither provides too much or too little relief to encourage individual project development and program-wide exploration. It is preferable to a time-based increment, such as an extra year of royalty-free production, because it does not risk damaging ultimate recovery by creating an incentive to accelerate production to avoid royalties. A sub-marginal project may need royalty suspension for anywhere from a small fraction of its reserves to virtually all of them to be worth developing. If something less than royalty-free production of 50 percent of reserves on average justifies development on a look-forward basis

(excluding sunk costs), a fraction of that could be safely provided to induce exploration. The 10-percent share represents a considered amount designed to encourage exploration on future projects deemed marginally or sub-marginally profitable. This policy leaves up to 90 percent of the project's production still subject to royalties.

Thus, the project-specific increment serves as a uniform replacement for sunk cost in the volume determination test. This increment assures any project that qualifies for supplemental relief because of sunk cost will have an additional volume suspension on top of what it has already. A development or an expansion project, therefore, may get a somewhat larger volume suspension than it needs to be economic on a look-forward basis. Alternatively, the project would get a larger volume than the minimum volume suspension if our evaluation indicates it needs more relief than the minimum to be economic on a look-forward basis. (See changes in § 203.69.)

To help us evaluate the effects of revising our treatment of sunk cost, we would like your comments on the following questions.

- How does a credit for sunk costs change your incentive to explore a risky prospect and to apply for royalty relief?
- What other treatments of sunk costs promote exploration without resulting in excessive volume suspension for many projects?

Also, we propose to lower the viability standard we set as a prerequisite to evaluating a field's or a project's need for relief. Our current evaluation procedure requires that the application meet two economic criteria. First, the application must show that a field or project is viable, i.e., would be economic assuming it paid no royalties and no sunk costs. Second, qualification for relief requires that the application show a nonproducing field would not be profitable assuming it paid certain sunk costs and full royalties, or that an expansion project would not be profitable paying full royalties. We have revised § 203.67 to clarify the dual criteria for qualification.

Until now, we insisted that the same discount rate be used for both the viability and the profitability estimates. While ensuring that the application does not give an overly pessimistic portrayal of the field or expansion project, this equivalence of discount rates may be too restrictive. Development without royalty or sunk costs should be less risky than if these costs have to be covered. Thus, the cost of capital under the viability circumstances should be lower than when full royalties and sunk costs must be paid. To acknowledge this potential difference, we propose to accept applications that demonstrate fields or projects have a positive value at a 10-percent real rate of discount. Applicants retain the right to set the discount rate we use for the profitability test at any value between 10 and 15 percent. (See changes to the guidelines that accompany § 203.67.) The MMS website, *www.gomr.mms.gov/homepg/offshore/royrelef.html*, provides the most current version of these guidelines, including the parameters we prescribe for discount rates and prices.

This change in our discount rate procedure offsets one effect of changing the way we treat sunk costs, for leases other than pre-Act leases, in our qualification determination. A 10-percent discount rate has the effect of raising the estimated present value of the field or project in the absence of royalties. Past applicants always chose a 15-percent discount rate. We anticipate that future applicants will continue to choose the maximum allowed discount rate for the full royalty profitability analysis. Thus, while limiting sunk costs generally reduces the difference between the viability and profitability estimate, a lower discount rate for the viability estimate than for the profitability estimate will increase this difference. The larger difference allows a wider range of circumstances to qualify as marginal fields or projects in need of royalty relief. More generally, limiting sunk costs for post-2000 deep water leases and acknowledging that development risks may be different with and without royalties makes our evaluation of economic need more realistic.

Finally, we are proposing to add language that clarifies what we seek in the administrative and design parts of an application. As with the G&G report, these changes reflect additional information we have requested from previous applicants. (See changes proposed to §§ 203.83 and 203.87.)

Adjustments to Post-Evaluation Elements

We propose adjustments in several of the conditions successful applicants must meet to realize a royalty suspension or to re-apply for relief. We propose adjustments in the deadline to start fabrication of the development system, in correcting for overestimating costs in the application, and in what constitutes an appropriate reason for us to reconsider the need for relief. These three proposed adjustments apply to all fields or projects seeking a volume suspension after the effective date of these revisions. Also, we propose to specify in the leasing documents the price thresholds (which we identify at the time of lease sale) above which we will suspend any remaining royalty relief for post-2000 deep water leases.

Current regulations require applicants to give evidence of a timely commitment to development by starting fabrication of their production facility within 1 year after we approve their application. We established this deadline to avoid premature applications. Requiring that projects or developments be ready to commence soon after approval means we make the relief decision close to the same point and with about the same quality of information as the applicant uses to make the commitment decision. While the fact that the ability to get into production quicker than expected partially accounts for the improvement in deep water economics, the 1-year-to-fabrication deadline we set needs lengthening. Shortages of drilling, design, and fabrication capacity for deep water development may make meeting the currently required schedule difficult. Also, we don't want to encourage token actions that don't really signal the start of development. Thus, we propose to lengthen the period when fabrication must start to 18 months after relief approval. Added to the 6-month period we use for evaluation, that gives a full 2 year lead-time between application and commitment to development. With our authority to extend that period for up to 6 months for events beyond the applicant's control, we feel this change should provide ample time to make the necessary arrangements to start development on projects or fields that receive royalty relief. (See change to deadlines proposed in § 203.70.)

Along with this deadline change, we propose to clarify that the meaning of ''starting fabrication'' requires continuous fabrication. Starting and then suspending fabrication of the production facility does not fulfill this performance condition. (See the addition we propose in § 203.76(b)).

Another performance condition we use to help ensure we deal with a realistic application has to do with estimated costs. We require actual expenditures to equal at least 80 percent of the costs that the applicant estimates spending. Both estimated and actual figures cover the period between the application and first production. The current correction for overestimating actual costs by too much is retention of only half of the volume suspension we originally granted. This correction has no real effect when the minimum

suspension volume prescribed by the Act more than doubles the field's expected production. Thus, we propose to adjust the correction volume to retention of the smaller of one-half of the granted suspension volume or one-half of the most likely production specified in the application. (See changes to a deadline and the relief correction amount proposed in § 203.76.)

In conjunction with this change, we also propose to broaden what constitutes a development system. For instance, we will no longer consider Spars and mini-tension-leg platforms different development systems. Both are essentially floaters with export pipelines and little if any storage capacity. With this change, we intend to maximize the flexibility applicants have to entertain bids for competing versions of the same basic development system.

We also propose to expand the situations in which fields or projects may seek a redetermination of our initial relief decision. We provide more flexibility for allowing redeterminations when relief is withdrawn or relinquished. Also, we add another condition in which we permit a redetermination if we deny your application or you seek to increase an approved volume suspension. In these instances, in addition to substantial increases in estimated costs, reductions in expected prices, or new geologic information on the field, we propose to allow a re-application for a change of development system under certain conditions. It must be clear that the original application did not consider or deem the new development system infeasible. This situation might arise because new technology becomes available or a new owner with a different perspective takes over field development after the initial application. In either case, the new application needs to demonstrate that the new approach more efficiently develops the resource than what we originally evaluated. By more efficient, we mean either clearly lower costs or clearly larger recovery, so that estimated profit would increase under the circumstances we previously evaluated. (See the new fourth condition and the removal of the restriction on the price condition in the changes we propose to § 203.74.)

More realistic performance conditions may add value to the successful applicant's explicit right to renounce relief. Several successful past applicants have lost relief because they violated a withdrawal condition. Rather than wait until we formally withdraw relief, they could have renounced relief as soon as they realized they needed to change the proposed development system or significantly revise cost estimates. By renouncing, they could accelerate the start of a redetermination, thereby converting after-tax, sunk costs on authorized fields to before-tax, post-application costs for purposes of the next application. We propose to simplify § 203.77 to avoid confusion about this right.

Further, we propose to review the level we set and to which prices must rise before the need for royalty relief, granted under an earlier expectation of lower prices, disappears. By 1999, the Act's escalation procedure meant that oil prices must exceed $30/bbl or natural gas prices must exceed $3.80/MMBtu for an entire calendar year before pre-Act leases with a remaining volume suspension owe royalty. For comparison, royalties reduce realized price by slightly less than the royalty percentage, e.g., 12.5 percent for deep water tracts in greater than 400 meters (m) of water. When market prices rise above levels that prompted development by more than that percentage for at least a year, the need for the royalty suspension incentive disappears, at least for these projects or fields. Therefore, we propose to suspend royalty relief for projects when prices rise and remain substantially above levels prevalent when we approved relief. To reflect evolving market conditions, we will set these threshold levels in the Notice of Sale and lease documents associated with each future lease. (See the proposed changes that add the new relief recipient category to § 203.78.)

Finally, we propose to make clear in the regulations that we want a Certified Public Account (CPA) not affiliated with the applicant to vouch for the historic data in the application and post-production report. Thus, we have added the word ''independent'' before CPA in changes proposed to §§ 203.81 and 203.91.

The following table summarizes the elements of the current DWRR program that we propose to modify with this rule.

PROPOSED MODIFICATIONS TO DWRR APPLICATIONS

Element	Current and continuing program Applies to pre-Act leases	Proposed changes Applies to post-2000 deep water leases
Eligibility (Central, Western, and western part of Eastern Gulf of Mexico).	Leases in 200m or more water depth issued before 1996.	Leases in 200m or more water depth issued after 2000.
Royalty-free production can come from	Any production from the field until cumulative recovery volume equals the suspension volume.	Only production from resources identified in the application until cumulative recovery equals the suspension volume
Minimum suspension volume for non-producing leases.	For fields that did not produce before the Act, matches eligible lease suspension volumes (17.5, 52.5, 87.5 MMBOE) in equivalent water depths.	For development projects, matches volumes designated in sale and lease documents for various water depths of 200m or greater plus 10 percent of reserves.
Credit for sunk costs in application	For fields with pre-Act leases that did not produce before the application, after-tax costs of and after discovery well used in qualification.	For development projects, after-tax cost of only the discovery well, except when the application involves a pre-Act lease.
Threshold oil and gas price levels for lifting relief.	Statute sets threshold price for light sweet crude oil and natural gas.	Lease terms set threshold price for light sweet crude oil and natural gas.

PROPOSED MODIFICATIONS TO DWRR APPLICATIONS

Element	Current and discontinuing program Applies to pre-Act leases	Proposed changes Applies to pre-Act and post-2000 deep water leases
Discount rate used in evaluation	Same rate used on viability and profitability tests, applicant chooses between 10% and 15%.	Use 10% on viability test, applicant chooses rate between 10% and 15% for profitability test.
Redetermination of field qualification or volume by MMS.	Available for new well or seismic data, 25% lower prices, or 20% higher cost.	Available anytime after relief relinquished or withdrawn. Otherwise, for new well or seismic data, 25% lower prices, 20% higher cost, or more efficient development system.
Deadline for starting fabrication	Within 1 year of approval, extendable for up to 1 year.	Within 18 months of approval, extendable for up to 6 months.
Correction for overestimating cost by 20% or more.	Retain only half of suspension volume granted	Retain only half or smaller of granted suspension volume or most likely resource size.
Minimum suspension volume for expansion project.	None	10 percent reserves.
Credit for sunk costs in application for expansion project.	None	After-tax cost of the discovery well.

Royalty Relief in Special Circumstances

Certain circumstances can make leases ineligible for one of our established royalty relief programs. Yet, royalty relief may benefit both the lessee and the Federal Government. For example, a recent, significant renovation of operations prevents a lessee from seeking end-of-life royalty relief, at least temporarily. Or, the operator of a marginal expansion project in less than 200m of water cannot apply for a royalty suspension, even if it is located in the central and western GOM. When combined with other circumstances, such as a sudden drop in prices or unusually high original royalty rates, this ineligibility could cause substantial resources to be left unproduced. Some form of royalty relief in these unusual situations can serve the statutory purpose of increasing production or promoting development outside our established programs. Because of the rarity of situations that meet these unusual conditions, we will not establish another formal royalty relief program. But, we leave open the opportunity for an operator to request relief in special circumstances. Before evaluating a special relief application, we require that applicants establish eligibility. An applicant does this by gaining our approval that their situation meets several of the tests listed in the new § 203.80. Once that is done, we will establish case-by-case qualification conditions and relief format appropriate to the special circumstances.

Can you suggest forms of royalty reduction that we are not now using that might encourage increased production in the special circumstances we propose in § 203.80?

Procedural Matters

Public Comment Procedure

Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the record, which we will honor to the extent allowable by law. There may be circumstances in which we would withhold from the record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. We will not consider any anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

Regulatory Planning and Review (Executive Order 12866)

The proposed rule is a significant regulatory action under Executive Order 12866, and is subject to review by the Office of Management and Budget (OMB).

a. This proposed rule will not have an annual economic effect of $100 million or adversely affect an economic sector, productivity, jobs, the environment, or other units of government. This action describes how certain new deep water leases may quality for royalty suspensions and the circumstances under which we might grant royalty relief. Historically, we have received only a limited number of applications for royalty relief. Based upon our experience, only a small number of leases will quality for royalty relief in any one year, and the annual value of the relief will be less than $100 million. The only field that has gone into production after approval may, depending on prices, avoid slightly over $7 million in royalty payments in is first year of production. The royalty suspension options in this proposal will encourage new production from a few marginal leases. Because royalty suspension volumes are an incentive to production, they likely will have a beneficial effect on the offshore oil industry, domestic oil and gas supplies, and jobs. In fact, this program should increase aggregate OCS production by making production from marginal fields more economically feasible.

b. This proposed rule does not create inconsistencies with other agencies' actions because it preserves the concepts and requirements from the existing rule.

c. This proposed rule is an administrative change that will not affect entitlements, grants, user fees, loan programs, or their recipients. This proposed rule has no effect on these programs or rights of the programs' recipients.

d. This proposed rule does not raise any novel legal issues, but does raise policy issues. The proposed rule extends and supplements the existing DWRR rule. It describes conditions under which lessees have the opportunity to apply for and acquire royalty relief on post-2000 deep water leases. Also, it modifies some conditions under which lessees of pre-Act leases obtain royalty relief. In addition, the proposed action describes special circumstances under which lessees may apply for royalty relief that were not specified in our previous regulations. All of these changes are consistent with the basic philosophy in

the current rule of granting relief only when applicants show it is economically necessary for development.

Regulatory Flexibility (RF) Act

The Department certifies that this document will not have a significant economic effect on a substantial number of small entities under the RF Act (5 U.S.C. 601 *et seq.*). The provisions of this proposed rule will not have a significant adverse economic effect on offshore lessees and operators, including those that are classified as small businesses. The proposed rule extends the benefit of discretionary royalty relief to certain OCS leases issued after November 2000 that qualify as marginally uneconomic. In any one year, we are likely to receive only a small number of royalty relief applications, which limits the number of entities the proposed rule may affect. Based on past experience, we expect to receive between one and two applications a year for DWRR. Also, because firms initiate applications, they have the ability to avoid any adverse effects they foresee. As suggested below, the new provisions proposed should actually lower the cost to those who choose to take advantage of the benefit offered by this regulation. An RF analysis is not required. A Small Entity Compliance Guide is not required.

Companies that extract oil, gas, or natural gas liquids or are otherwise in oil and gas exploration and development activities acquire the vast majority of leases offered at OCS lease sales and will be most affected by this rule. The Small Business Administration (SBA) defines a small business as having:

- Annual revenues of $5 million or less for exploration service and field service companies.
- Fewer than 500 employees for drilling companies and for companies that extract oil, gas, or natural gas liquids.

Under the Standard Industrial Classification code 1381, Drilling Oil and Gas Wells, MMS estimates that a total of 1,380 firms drill oil and gas wells onshore and offshore. Of these, approximately 130 companies are offshore lessess/operators, based on current estimates. Publicly available data indicate that 39 companies qualify as large firms according to SBA criteria, leaving up to 91 companies that may qualify as small firms with fewer than 500 employees. However, because of the extremely high cost and technical complexity involved in exploration and development in deep water, the vast majority of lessees/operators that will be affected by this rule will be large companies. Of the 211 deep water leases that have a discovery or production by mid-2000, 19 large firms are the lessee/operator of 193, while 7 small firms are lessee/operator of the other 18. While that ratio suggests a 1-in-12 chance that a small operator may apply for relief, 2 of the 16 past applications we received have been from small operators. This rule proposes continuing the same basic application system we now use. Small operators do not appear to be at a disadvantage in our application process.

Provisions of the proposed rule, in comparison with existing rules for discretionary DWRR for pre-Act leases, may reduce applicant costs in three areas:

- First, new applications for DWRR will be on the basis of a fully identified project rather than a whole, often incompletely identified field. Consequently, applicants may need to provide less extensive G&G data. For instance, we will not require them to submit data they have access to on reservoirs that may be in the field but clearly are not part of the project. There is no sound basis for estimating the size of any savings associated with this reduced data burden because only some applications would involve potential extra reservoirs. For those that do, however, this change can reduce the amount of follow-up data we typically have to request from applicants and can expedite our evaluation.
- Second, applicants may no longer have to incur the cost of additional drilling or acquisition of new seismic data to request a determination. While significant new geologic information or price or cost changes still enable a redetermination, applicants may now seek a redetermination upon identification of a more efficient development system. That new reason could save drilling a new deep water well at a cost of $20 million or more or acquiring additional seismic data at a cost of about $100,000 per tract. We have received no redetermination requests. We attribute this to the fact that the DWRR program has not been active long enough to reach the redetermination stage for most of the applications we have already processed.
- Third, under the proposed rule, we give successful applicants more time to initiate development than under existing rules. This added time gives operators more time to arrange financing and to negotiate contracts with suppliers. Again, there is no sound basis for estimating the size of any savings associated with this greater applicant flexibility. It is clear, however, that this change, like the other two, cannot be considered to impose a significant adverse economic effect on a substantial number of small business entities. If anything, all four changes ameliorate the existing applicant cost burden.

Your comments are important. The Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness boards were established to receive comments from small businesses about Federal agency enforcement actions. The Ombudsman will annually evaluate the enforcement activities and rate each agency's responsiveness to small business. If you wish to comment on the enforcement actions of MMS, call toll-free (888) 734–3247.

Small Business Regulatory Enforcement Fairness Act (SBREFA)

This proposed rule is not a major rule under 5 U.S.C. 804(2), the SBREFA. This proposed rule:

a. Does not have an annual effect on the economy of $100 million or more. This proposed rule modifies some procedures used under the current rule, specifies how certain new deep water leases may qualify for royalty suspensions in the future, and describes circumstances that may cause us to grant royalty relief that were not covered in the current regulations. In general, the effect of qualifying for a royalty suspension increases production from a few marginal fields but does not change royalty collections—since without relief, no production or royalty payments would occur or be expected, so suspending them forfeits little if any revenue. To the extent that royalty relief encourages new production, it benefits applicants, one-third of which in the past have been small business. But only one of the four fields for which we have approved relief has gone into production. We expect, however, that in any one year, this proposed rule will not have an annual effect on the economy of $100 million or more.

b. Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. Oil prices are not based on the production from any one region, but are based on worldwide production and demand at any point in time. While natural gas prices are more localized, they correlate to oil prices. The proposed rule does not change any existing leasing policies, so it should not cause prices to increase.

c. Does not have significant adverse effects on competition, employment, investment, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises.

Leasing on the United States OCS is limited to residents of the United States or companies incorporated in the United States. This proposed rule does not change that requirement, so it does not change the ability of United States firms to compete in any way.

Unfunded Mandates Reform Act (UMRA)

This proposed rule does not impose an unfunded mandate on State, local, or tribal governments or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on State, local, or tribal governments. The proposed rule modifies some procedures in the existing regulation, describes how certain new leases may qualify for royalty suspensions, and specifies special circumstances that might cause us to grant royalty relief that were not considered previously. None of these changes involve State, local, or tribal mandates. A statement containing additional UMRA (2 U.S.C. 1531 *et. seq.*) information is not required.

Takings Implications Assessment (Executive Order 12630)

According to Executive Order 12630, the proposed rule does not have significant Takings implications. A Takings Implication Assessment is not required because the proposed rule would not take away or restrict a bidder's right to acquire or develop OCS leases.

Federalism (Executive Order 13132)

According to Executive Order 13132, this rule does not have Federalism implications. This rule does not substantially and directly affect the relationship between the Federal and State Governments. This rule affects the collection of royalty revenues from lessees in the deep water GOM, all of which is outside State jurisdiction. States have no role in this activity with or without this rule. This does not impose costs on States or localities. States and local governments play no part in the administration of the DWRR program.

Civil Justice Reform (Executive Order 12988)

According to Executive Order 12988, the Office of the Solicitor has determined that this rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order.

Paperwork Reduction Act (PRA) of 1995

The information collection requirements in the proposed rulemaking remain unchanged from those currently approved by OMB, and a new 83–I submission is not required.

The PRA provides that an agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. In 1998, OMB approved the information collection requirements in the current regulations under OMB control number 1010–0071.

Based on experience to date, MMS subsequently determined that the application filing fee schedule should be revised. In addition, the need became apparent for establishing a new fee to cover applications for ''special relief for marginal producing leases.'' Consequently, we initiated the process to obtain OMB approval of these changes to the information collection burden. We published the required 60-day **Federal Register** notice on May 11, 2000 (65 FR 30431). The comment period closed on July 11, 2000; we received no comments. We then submitted a request to OMB, and OMB approved the revised information collection burden with a current expiration date of September 30, 2003. The approved information collection burden is consistent with the proposed amendments to the regulations.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite your comments on any aspect of the reporting burden in part 203. MMS will address comments on the information collection burden in the final rule preamble. Refer to the **ADDRESSES** section for mailing instructions. We specifically solicit comments on the following questions:

(a) Is the proposed collection of information necessary for MMS to properly perform its functions, and will it be useful?

(b) Are the estimates of the burden hours of the proposed collection reasonable?

(c) Do you have any suggestions that would enhance the quality, clarity, or usefulness of the information to be collected?

(d) Is there a way to minimize the information collection burden on those who are to respond, including the use of appropriate automated electronic, mechanical, or other forms of information technology?

The title of the collection of information is ''30 CFR Part 203, Relief or Reduction in Royalty Rates.'' Respondents include approximately 130 Federal OCS oil and gas lessees. The frequency of response is on occasion. Responses to this collection of information are required to obtain or retain a benefit. MMS will protect proprietary information under applicable law and 30 CFR 203.63(b) and 250.196.

The following chart provides our estimated ''hour'' burden for part 203 regulations and the application and audit fee ''non-hour'' cost burdens authorized under § 203.3

Reporting or recordkeeping requirement 30 CFR Part 203	Application/audit fees		
	Annual responses	Hours per response	Annual burden hours
OCS Lands Act Reporting			
Application—leases that generate earnings that can't sustain continued production (end-of-life lease).	2 Applications	100	200
	Application 2×$12,000=$24,000 [1] Audit 1×$10,000=$10,000		
Application—special relief for marginal producing lease (expect less than 1 per year—new category).	1 Application	250	250
	Application 1×$15,000=$15,000 [1] Audit 1×$10,000=$10,000		

Reporting or recordkeeping requirement 30 CFR Part 203	Application/audit fees		
	Annual responses	Hours per response	Annual burden hours
§ 203.55 Renounce relief arrangement (seldom, if ever will be used; minimal burden to prepare letter).	1 Letter	1	1
§ 203.81, 203.83 through 203.89 required reports	Burden included with applications.		
OCS Lands Act Reporting Subtotal	4 responses	N/A	451
	Processing Fees=$59,000		
DWRAA Reporting			
Application—leases in designated areas of GOM deep water acquired in lease sale before 11/28/95 or after 11/28/00 and are producing (deep water expansion project).	1 Application	2,000	2,000
	Application 1×$39,000=$39,000 Audit		
Application—leases in designated areas of deep water GOM, acquired in lease sale before 11/28/95 or after 11/28/00, that have not produced (pre-Act or post-2000 deep water leases).	1 Application	2,000	2,000
	Application 1×$49,000=$49,000 Audit 1×$25,000=$25,000		
Application—short form to add or assign pre-Act lease	1 Application	40	40
	Application 1×$1,000=$1,000 No Audit		
Application—preview assessment (seldom if ever will be used as applicants opt for binding determination by MMS instead).	1 Application	900	900
	Application 1×$46,600=$46,600 No Audit		
Application—special relief for marginal expansion project or marginal non-producing lease (expect less than 1 per year—new category).	1 Application	1,000	1,000
	Application 1×$49,000=$49,000 Audit 1×$20,000=$20,000		
Redetermination	1 Redetermination	500	500
	Application 1×$32,000=$32,000 [1] Audit 1×$25,000=$25,000		
§ 203.70, 203.81, 203.90, 203.91 Submit fabricator's confirmation report	2 Reports	20	40
§ 203.70, 203.81, 203.90, 203.92 Submit post-production development report.	2 Reports [1]	50	100
§ 203.77 Renounce relief arrangement (seldom, if ever will be used; minimal burden to prepare letter).	1 Letter	1	1
§ 203.79(a) Request reconsideration of MMS field designation	4 Requests	400	1,600
§ 203.79(c) Request extension of deadline to start construction	1 Request	2	2
§ 203.81, 203.83 through 230.89 Required reports.	Burden included with applications		0
DWRR Act Reporting Subtotal	16 Responses	N/A	8,183
	Processing Fees=$286,600		
RecordKeeping Burden			
§ 203.91 Retain supporting cost records for post-production development/fabrication reports (records retained as usual/customary business practice; minimal burden to make available at MMS request).	2 Record keepers	8	16
Total Annual Burden	22 Responses	N/A	8,650

Reporting or recordkeeping requirement 30 CFR Part 203	Application/audit fees		
	Annual responses	Hours per response	Annual burden hours
	Total Processing Fees=$345,600		

[1] In addition, under § 203,81, a report prepared by an independent CPA must accompany the application and post-production report (except expansion project, short form, and preview assessment applications are excluded). The OCS Lands Act applications will require this report only once; the DWRR Act applications will require this report at two stages—with the application and post-production development report for successful applicants. We estimate an average cost for a report is $45,000 and that seven CPA certifications per year will be necessary if the applications are approved. The total estimated annual ''non-hour'' cost burden for this requirement is $315,000 ($45,000 per certification × 7 CPA certifications=$315,000).

National Environmental Policy Act (NEPA) of 1969

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the NEPA is not required.

Government-to-Government Relationship with Tribes

According to the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American Tribal Governments'' (59 FR 22951) and 512 DM 2, we have determined that there are no effects from this action on federally recognized Indian tribes.

Clarity of this Regulation

Executive Order 12866 requires each agency to write regulations that are easy to understand. We invite your comments about how to make this proposed rule easier to understand, including answers to questions like the following:

(1) Are the criteria for obtaining royalty relief clearly specified?

(2) Are the procedures for obtaining royalty relief clearly described?

(3) Are the rules for determining royalty suspension volumes for the various categories of leases clearly stated?

(4) Are the conditions for obtaining royalty relief in special circumstances adequately specified?

(5) Does the proposed rule contain technical language or jargon that interferes with its clarity?

(6) Does the format of the proposed rule (grouping and ordering of sections, use of headings, etc.) increase or reduce its clarity?

(7) Would the proposed rule be easier to understand if it were divided into more, but shorter, sections?

(8) Is there anything else we can do to make the proposed rule easier to understand? Send a copy of any comments that concern how we could make this proposed rule easier to understand to: Office of Regulatory Affairs, Department of the Interior, Room 7229, 1849 C Street, N.W., Washington, D.C. 20240. You may also e-mail your comments to: Exsec@ios.doi.gov.

List of Subjects in 30 CFR Part 203

Continental shelf, Government contracts, Indians-lands, Minerals royalties, Oil and gas exploration, Public lands-mineral resources, Reporting and recordkeeping requirements, Sulphur.

Dated: October 30, 2000.

Sylvia V. Baca,

Assistant Secretary, Land and Minerals Management.

For the reasons stated in the preamble, the Minerals Management Service (MMS) proposes to amend 30 CFR part 203 as follows:

PART 203—RELIEF OR REDUCTION IN ROYALTY RATES

1. The authority citation for part 203 continues to read as follows:

Authority: 25 U.S.C. 396 *et seq.*; 25 U.S.C. 396a *et seq.*; 25 U.S.C. 2101 *et seq.*; 30 U.S.C. 181 *et seq.*; 30 U.S.C. 351 *et seq.*; 30 U.S.C. 1001 *et seq.*; 30 U.S.C. 1701 *et seq.*; 31 U.S.C. 9701 *et seq.*; 43 U.S.C. 1301 *et seq.*; 43 U.S.C. 1331 *et seq.*; and 43 U.S.C. 1801 *et seq.*;

2. Section 203.0 is amended by adding ''Development project'' and ''Royalty suspension (RS) lease'' and revising ''Authorized field,'' ''Eligible lease,'' ''Expansion project,'' ''Fabrication (or start of construction),'' ''New production,'' ''Pre-Act lease,'' ''Redetermination,'' and ''Sunk costs'' to read as follows:

§ 203.0 What definitions apply to this part?

Authorized field means a field:

(1) Located in a water depth of at least 200 meters and in the Gulf of Mexico west of 87 degrees, 30 minutes West longitude;

(2) That includes one or more pre-Act leases; and

(3) From which no current pre-Act lease produced, other than test production, before November 28, 1995;

* * * * *

Development project means a project that:

(1) You propose in a Development Operations Coordination Document (DOCD); and

(2) Is located on one or more contiguous leases that;

(i) Were issued in a sale held after November 28, 2000;

(ii) Are located in the Gulf of Mexico west of 87 degrees, 30 minutes West longitude; and

(iii) Have had no production (other than test production) before the current application for royalty relief.

* * * * *

Eligible lease means a lease that:

(1) Results from a sale held after November 28, 1995, and before November 28, 2000;

(2) Is located in the Gulf of Mexico in water depths of 200 meters or deeper;

(3) Lies wholly west of 87 degrees, 30 minutes West longitude; and

(4) Is offered subject to a royalty suspension volume.

Expansion project means a project you propose in a Development Operations Coordination Document (DOCD) or a Supplement approved by the Secretary of the Interior after November 28, 1995, that will significantly increase the ultimate recovery of resources from pre-Act lease or a lease issued in a sale held after November 28, 2000. For a pre-Act lease, it must also involve a substantial capital investment (e.g., fixed-leg platform, subsea template and manifold, tension-leg platform, multiple well project, etc.).

Fabrication (or start of construction) means evidence of irreversible commitment to a concept and scale of development, including copies of a binding contract between you (as applicant) and a fabrication yard, a letter from a fabricator certifying that continuous construction has begun, and a receipt for the customary down payment.

* * * * *

New production means any production from a current pre-Act lease from which no royalties are due on production, other than test production, before November 28, 1995. Also, it means any production resulting from lease-development activities on a

current pre-Act lease or a lease issued in a sale after November 28, 2000, under a Development Operations Coordination Document (DOCD) or a Supplement approved by the Secretary of the Interior after November, 28, 1995, that significantly expands production.

* * * * *

Pre-Act lease means a lease that:

(1) Results from a sale held before November 28, 1995;

(2) Is located in the Gulf of Mexico in water depths of 200 meters or deeper; and

(3) Lies wholly west of 87 degrees, 30 minutes West longitude. (See this part.)

* * * * *

Redetermination means your request for us to reconsider our determination on royalty relief because:

(1) We have rejected your application;

(2) We have granted relief but you want a larger suspension volume;

(3) We withdraw approval; or

(4) You renounce royalty relief.

* * * * *

Royalty suspension (RS) lease means a lease that:

(1) Results from a lease sale held after November 28, 2000;

(2) Is in a location or planning area specified in the Notice of Sale offering that lease; and

(3) Is offered subject to a royalty suspension volume.

Sunk costs on an authorized field means the after-tax costs (as specified in § 203.89(a)) of exploration, development, and production that you incur after the date of first discovery on the field and before the date we receive your complete application for royalty relief. Sunk costs on an expansion project or development project means, and on an authorized field includes, the after-tax costs of the discovery well qualified as producible under 30 CFR part 250, subpart A. In no case does sunk cost include any pre-discovery activity costs or lease acquisition and holding costs such as cash bonus and rental payments. Discovery well costs include any tangible costs directly related to the well that you incurred prior to the discovery date. We count pre-application costs on an unescalated, after-tax basis.

* * * * *

3. Section 203.2 is revised to read as follows:

§ 203.3 When can I get royalty relief?

We can reduce or suspend royalties for Outer Continental Shelf (OCS) leases or projects that meet the criteria in the following table.

If you have a lease—	And if you—	Then we may grant you—
(a) Whose earnings cannot sustain production (*End-of-life lease*).	Would abandon otherwise potentially recoverable resources but seek to increase production significantly by operating beyond the point at which the lease is economic under the existing royalty rate.	A reduced royalty rate on current monthly production and a higher royalty rate on additional monthly production. (See §§ 203.50 through 203.56.)
(b) Located in a designated Gulf of Mexico (GOM) deep water area, and acquired in a lease sale before November 38, 1995, or after November 28, 2000, and you propose in a DOCD or supplement to expand production significantly.	Are producing and seek to make a substantial investment (e.g., a platform or subsea template) to increase ultimate resource recovery from the field or lease (*Expansion project*).	A royalty suspension for additional production large enough to make the project economic. (See §§ 203.60 through 203.79.)
(c) Located in a designated GOM deep water area and acquired in a lease she held before November 28, 1995 (*Pre-Act lease*).	Are on a field from which no current pre-Act lease produced (other than test production) before November 28, 1995 (*Authorized field*).	A royalty suspension for a minimum production volume plus any additional volume needed to make the field economic. (See §§ 203.60 through 203.79.)
(d) Located in a designated GOM deep water area and acquired in a lease sale held after November 28, 2000.	Have not produced and can demonstrate that the suspension volume in your lease is not enough to make development economic (*Development project*).	A royalty suspension for a minimum production volume plus any additional volume needed to make your project economic. (See §§ 203.60 through 203.79.)
(e) Where royalty relief would increase production significantly or, in certain areas of the GOM, would enable development.	Are not eligible to apply for end-of-life or deep water royalty relief, but show us you meet certain eligibility conditions.	A royalty reduction in a size or duration that makes your lease or project economic. (See §§ 203.80.)

4. Section 203.4 is revised to read as follows:

§ 203.4 How to do the provisions in this part apply to different types of leases and projects?

The tables in this section summarize how similar provisions of this part apply in different situations.

(a) Information elements required for applications in §§ 203.51, 205.62, and 203.81 through 203.89.

Information elements	End-of-life lease	Deep water		
		Expansion project	Pre-act lease	Development project
(1) Administrative information report	X	X	X	X
(2) Net revenue and relief justification report (prescribed format)	X	.....	.....	.....
(3) Economic viability and relief justification report (Royalty Suspension Viability Program (RSVP) model inputs justified with geological and geophysical (G&G), Engineering, Production, & Cost reports)	.....	X	X	X
(4) G&G report	.....	X	X	X
(5) Engineering report	.....	X	X	X
(6) Production report	.....	X	X	X
(7) Deep water cost report	.....	X	X	X

(b) Confirmation elements required to retain royalty relief in §§ 203.70, 203.81 and 203.90 through 203.91.

Confirmation elements	End-of-life lease	Deep water		
		Expansion project	Pre-act lease	Development project
(1) Fabricator's confirmation report		X	X	X
(2) Post-production development report approved by an independent certified public accountant (CPA)		X	X	X

(c) Prerequisites for approval of relief in §§ 203.50, 203.52, 203.60 and 203.67.

Approval conditions	End-of-life lease	Deep water		
		Expansion project	Pre-act lease	Development project
(1) At least 12 of the last 15 months have the required level of production	X			
(2) Already producing	X			
(3) Well can produce		X	X	X
(4) Royalties for qualifying months exceed 75% of net revenue (NR)	X			
(5) Substantial investment on a pre-Act lease (e.g., platform, subsea template)		X		
(6) Determined to be economic only with relief		X	X	X

(d) Prerequisites for a redetermination in §§ 203.52 and 203.74 through 203.75.

Redetermination conditions	End-of-life lease	Deep water		
		Expansion project	Pre-act lease	Development project
(1) After 12 months under current rate, criteria same as for approval	X			
(2) For material change in geologic data, prices, costs, or available technology		X	X	X

(e) Characteristics of relief in §§ 203.53 and 203.69.

Relief rate and volume	End-of-life lease	Deep water		
		Expansion project	Pre-act lease	Development project
(1) One-half pre-application effective lease rate on the qualifying amount, 1.5 times pre-application effective lease rate on additional production up to twice the qualifying amount, and the preapplication effective lease rate for any larger volumes	X			
(2) Qualifying amount is the average monthly production for 12 qualifying months	X			
(3) Zero royalty rate on the suspension volume and the original lease rate or higher on additional production		X	X	X
(4) Suspension volume is at least 17.5, 52.5 or 87.5 million barrels of oil equivalent (MMBOE)			X	
(5) Suspension volume is at least the minimum set in the lease				X
(6) Amount needed to become economic		X	X	X

(f) Provisions for discontinuing relief in §§ 203.54 and 203.78.

Full royalty resumes when	End-of-life lease	Deep water		
		Expansion project	Pre-act lease	Development project
(1) Average NYMEX price for last 12 months is at least 25 percent above the average for the qualifying months.	X			
(2) Average NYMEX price for last calendar year exceeds $28/bbl or $3.50/mcf, escalated by the gross domestic product (GDP) deflator since 1994.		X	X	
(3) Average prices for designated periods exceed levels we specify in the lease document.		X		X

(g) Provisions for ending or reducing relief in §§ 203.55 and 203.76 through 203.77.

Relief Withdrawn or Reduced	End-of-life lease	Deep water		
		Expansion project	Pre-act lease	Development project
(1) If recipient requests.	X	X	X	X

Relief Withdrawn or Reduced	End-of-life lease	Deep water		
		Expansion project	Pre-act lease	Development project
(2) Royalty rate is at the effective rate for the most recent 12 of past 15 months with qualifying amounts of production.	X			
(3) Conditions that we may specify in the approval letter in individual cases that actually occur.	X			
(4) Recipient does not submit post-production report that compares expected to actual costs.		X	X	X
(5) Recipient changes development system.		X	X	X
(6) Recipient excessively delays starting fabrication		X	X	X
(7) Recipient spends less than 80 percent of proposed pre-production costs prior to start of production		X	X	X
(8) Amount of relief volume is produced		X	X	X

5. Section 203.60 is revised to read as follows:

§ 203.60 Who may apply for deep water royalty relief?

Under conditions in §§ 203.61(b) and 203.62, you may apply for royalty relief if:

(a) You are a lessee of a lease in water at least 200 meters deep in the GOM and lying wholly west of 87 degrees, 30 minutes West longitude;

(b) We have assigned your lease to a field (as defined in § 203.0); and

(c) You either:

(1) Hold a pre-act lease on an authorized field (as defined in § 203.0) or

(2) Propose an expansion project (as defined in § 203.0) or

(3) Propose a development project (as defined in § 203.0).

6. § 203.62, the introductory sentence and paragraph (c) are revised to read as follows:

§ 203.62 How do I apply for relief?

You must send a complete application and the required fee to the MMS Regional Director for the GOM.

* * * * *

(c) Sections 203.81, 203.83, and 203.85 through 203.89 describe what these reports must include. The MMS regional office for the GOM will guide you on the format for the required reports.

7. In § 203.63, the following changes are made:

A. The introductory paragraph is redesignated (a) and is revised as set forth below.

B. Paragraphs (a), (b), and (c) following the introductory paragraph are redesignated paragraphs (1), (2), and (3).

C. A new paragraph (b) is added as set forth below.

§ 203.63 Does my application have to include all leases in the field?

(a) For authorized fields, we will accept only one joint application for all leases that are part of the designated field on the date of application, except as provided in paragraph (a)(3) of this section and § 203.64. However, we will evaluate all acreage that may eventually become part of the authorized field. Therefore, if you have any other leases that you believe may eventually be part of the authorized field, you may submit data for these leases according to § 203.81.

* * * * *

(b) No, if your application seeks only project relief.

8. In § 203.64, the section heading and the first sentence in the introductory paragraph are revised to read as follows:

§ 203.64 How many applications may I file on a field or a development project?

You may file one complete application for royalty relief during the life of the field or for a specific development project. * * *

* * * * *

9. In § 203.65 paragraph (b) is revised to read as follows:

§ 203.65 How long will MMS take to evaluate my application?

* * * * *

(b) We will evaluate your first application on a field or project within 180 days and evaluate a redetermination under § 203.75 within 120 days after we determine that is is complete.

* * * * *

10. Section 203.66 is revised to read as follows:

§ 203.66 What happens if MMS does not act in the time allowed?

If we do not act within the timeframes established under § 203.65, the conditions in the following table aply.

If you apply for royalty relief for—	And we do not decide within the time specified—	As long as you—
(a) An authorized field	You get the minimum suspension volumes specified in § 203.69	Abide by §§ 203.70 and 203.76.
(b) An expansion project	You get a royalty suspension for the first year of production	Abide by §§ 203.70 and 203.76.
(c) A development project	You get a royalty suspension for production during the number of months that a decision is delayed beyond the stipulated timeframes set by § 203.65, plus all the royalty suspension volume for which you qualify.	Abide by §§ 203.70 and 203.76.

11. Section 203.67 is revised to read as follows:

§ 203.67 What economic criteria must I meet to get royalty relief on an authorized field or project?

We will not approve applications if we determine that royalty relief cannot make the field or project economically viable. Your field or proejct must be uneconomic while you are paying royalties and must become economic with royalty relief.

12. In § 203.68, paragraph (b) is revised to read as follows:

§ 203.68 What pre-application costs will MMS consider in determining economic viability?

* * * * *

(b) We will consider sunk costs (allowable expenditures on and in some cases after the discovery well as specified in § 203.89(a)) according to the following table:

We will	When determining
(1) Include sunk costs	whether a field that includes a pre-Act lease which has not produced, other than test production, before the application or redetermination submission date needs relief to become economic.
(2) Not include sunk costs	whether an authorized field or project can become economic with any relief (see § 203.67).
(3) Not include sunk costs	how much suspension volume is necessary to make the field or project economic (see § 203.69(c)).
(4) Include sunk costs for the discovery well only.	whether a development project or an expansion project needs relief to become economic.

13. In § 203.69, the introductory paragraph and paragraphs (b) through (e) are revised and paragraph (f) is added to read as follows:

§ 203.69 If my application is approved, what royalty relief will I receive?

If we approve your application, we will not collect royalties on a specified suspension volume for your field. Suspension volumes include volumes allocated to a lease under an approved unit agreement, but exclude any volumes of production that are not normally royalty-bearing under the lease or the regulations of this chapter (e.g., fuel gas).

* * * * *

(b) For development projects, any relief we grant applies only to project wells and replaces the royalty suspension volume with which we issued your lease. If your project is economic given the royalty suspension volume with which we issued your lease, we will reject the application. Otherwise, the *minimum* royalty suspension volumes:

(1) For RS leases, is the sum of the volume suspensions with which we issued the RS leases participating in the application plus 10 percent of the most likely resource size we agree is reasonable for your project; and

(2) For other deep water leases issued in sales after November 28, 2000, is 10 percent of the most likely resource size we agree is reasonable for your project.

(c) If the application for the field includes pre-Act or eligible leases in different categories of water depth, we apply the minimum royalty suspension volume for the deepest such lease then assigned to the field. We base the water depth and makeup of a field on the water-depth delineations in the ''Royalty Suspension Areas Map'' and the ''Field Names Master List'' and updates in effect at the time your application is deemed complete. These publications are available from the MMS Regional Office for the GOM.

(d) You will get a royalty suspension volume above the minimum if we determine that you need more to make the field or development project economic.

(e) For expansion projects, the minimum suspension volumes equal 10 percent of the most likely resource size we agree is reasonable for your project plus any suspension volumes required according to § 203.66. If we determine that your expansion project may be economic only with more relief, we will determine and grant you the royalty suspension volume necessary to make the project economic.

(f) The royalty suspension volume applicable to specific leases will continue through the end of the month in which cumulative production reaches that volume. The cumulative production is from all the leases in the authorized field or project that are entitled to share the royalty suspension volume.

14. Section 203.70 is revised to read as follows:

§ 203.70 What information must I provide after MMS approves relief?

You must submit reports to us as indicated in the following table. Sections 203.81, 203,90, and 203.91 describe what these reports must include. The MMS regional office for the GOM will tell you the formats.

Required report	When due to MMS	Due date extensions
(a) Fabricator's confirmation report	Within 18 months after approval of relief	MMS Director may grant you an extension under § 203.79(c) for up to 6 months.
(b) Post-production report	Within 120 days after the start of production that is subject to the approved royalty suspension volume.	With acceptable justification from you, MMS Regional Director for the GOM may extend due date up to 30 days.

15. In § 203.71, the introductory paragraph and paragraphs (a) through (c) are revised to read as follows:

§ 203.71 How does MMS allocate a field's suspension volume between my lease and other leases on my field?

The allocation depends on when production occurs, when we issued the lease, when we assigned it to the field, and whether we award the volume suspension by an approved application or establish it in the lease terms as prescribed in this section.

(a) If your authorized field has an approved royalty suspension volume under §§ 203.67 and 203.69, we will suspend payment of royalties on production from all applying leases in the field until their cumulative production equals the approved volume.

The following conditions also apply:

If—	Then—	And—
(1) We assign an eligible lease to your field after we approve relief.	We will not change your field's royalty suspension volume.	The assigned lease(s) may share in any remaining royalty relief.

If—	Then—	And—
(2) We assign a pre-Act or post-2000 deep water lease to your field after we approve your application.	We will not change your field's royalty suspension volume.	The assigned lease(s) may share in any remaining royalty relief by filing the short-form application specified in § 203.83 and authorized in § 203.82. An assigned RS lease also gets any portion of its royalty suspension volume remaining even after the field has produced the approved relief volume.
(3) We assign another lease(s) that you operate to your field while we are evaluating your application, you agree to toll the evaluation clock until you modify your application to be consistent with the new field, and we have an additional 60 days to review the new information.	We will change your field's minimum suspension volume if the assigned lease is a pre-Act or eligible lease entitled to a larger minimum or automatic suspension volume.	The assigned lease(s) may share the royalty—suspension we grant to the new field. If you do not agree to toll, we will reject your application due to inadequate information. But, an eligible lease(s) we assign to the field keeps its automatic suspension volume.
(4) We assign another operator's lease to your field while we are evaluating your application, you both agree to toll the evaluation clock until both of you modify your application to be consistent with the new field, and we have an additional 60 days to review the new information.	We will change your field's minimum suspension volume provided the assigned lease joins the application and is entitled to a larger minimum suspension volume.	The assigned lease(s) may share the royalty suspension we grant to the new field. If you do not agree to toll, the other operator's lease retains any suspension volume it has or may share in any relief that we grant by filing the short form application specified in § 203.83 and authorized in § 203.82.
(5) We assign a lease to your field before you submitted the royalty relief application.	We will not change your field's royalty suspension volume.	The assigned lease will not share in the relief if it did not participate in the application.
(6) We reassign a well on a pre-Act, eligible, or post-2000 deep water lease to another field.	The past production from the well counts toward the royalty suspension volume of the field to which we assign the well.	The past production from that well will not count toward any royalty suspension volume granted to the field from which we reassigned it.

(b) If your authorized field has a royalty suspension volume established under § 260.111 of this chapter (i.e., a field with a pre-Act lease where an eligible lease starts production first), we will suspend payment of royalties on production from all eligible leases in the field until their cumulative production equals the established volume. The following conditions also apply:

If—	Then—	And—
(1) We assign another eligible lease to your field.	Your field's royalty suspension volume does not change.	The assigned lease may share in any remaining royalty relief.
(2) We assign and RS lease to your field	Your field's royalty suspension volume does not change.	The assigned lease gets only the volume suspension with which we issued it, and its production volume counts against the field's royalty suspension volume.
(3) We assign a pre-Act lease without royalty suspension to your field.	Your field's royalty suspension volume does not change.	The assigned lease shares none of the volume suspension, and its production does not count as part of the suspension volume.
(4) A pre-Act or post-2000 deep water lease applies (along with the other leases in the field) and qualifies (subject to any suspension volume in the lease) for royalty relief under §§ 203.67 and 203.69.	Your field's royalty suspension volume may increase or stay the same, but will not diminish.	All leases in the field share the royalty suspension volume if we approve the application; or the RS leases in the field keep their respective volumes if we reject the application.

(c) This paragraph applies to a project with more than one lease. The royalty suspension volume for each lease equals that lease's actual production from the project (or production allocated under an approved until agreement) until total production for all leases in the project equals the project's approved royalty suspension volume.

* * * * *

16. In § 203.74, the introductory paragraph is revised, paragraph (b) and (c) are revised and redesignated paragraphs (c) and (d), and a new paragraph (b) is added to read as follows:

§ 203.70 When will MMS reconsider its determination?

You may request a redetermination after we withdraw approval or after you renounce royalty relief. Under certain conditions you may also request a redetermination if we deny your application or if you want your approved royalty suspension volume to change. In these instances, to be eligible for a redetermination, at least one of the following of our conditions must occur.

* * * * *

(b) You demonstrate in your new application that a technology not considered or deemed feasible in the original application most efficiently develops this field or lease.

(c) Your current reference price decreases by more than 25 percent from your base reference price as determined under this paragraph.

(1) Your current reference price is a weighted average of daily closing prices on the NYMEX for light sweet crude oil and natural gas over the most recent full 12 calendar months;

(2) Your base reference price is a weighted average of daily closing prices on the NYMEX for oil and gas for the most recent full 12 calendar months preceding the date of your most recently approved application for this royalty relief; and

(3) The weighting factors are the proportions of the total production

volume (in BOE) for oil and gas associated with the most likely scenario (identified in §§ 203.85 and 203.88) from your most recently approved application for his royalty relief.

(d) Before starting to build your development and production system, you have revised your estimated development costs, and they are more than 120 percent of the eligible development costs associated with the most likely scenario from you most recently approved application for this royalty relief.

17. In § 203.76, paragraphs (a), (b), and (c) are revised to read as follows:

§ 203.76 When might MMS withdraw or reduce the approved size of my relief?

* * * * *

(a) You change the type of development system proposed in your application (e.g., change from a fixed platform to floating production system, an independent development and production system to one with subsea wells tied back to a host production facility, etc.).

(b) You do not start building the proposed development and production system within 18 months of the date we approved your application, unless the MMS Director grants you an extension under § 203.79(c). If you start building the proposed system and then suspend its construction before completion, and you do not restart continuous building of the proposed system within 18 months of our approval, we will withdraw the relief we granted.

(c) Your actual development costs are less than 80 percent of the eligible development costs estimated in your application's most likely scenario, and you do not report that fact in your post-production development report (§ 203.70). Development costs are those expenditures defined in § 203.89(b) incurred between the application submission date and start of production. If you report this fact in the post-production development report, you may retain the lesser of 50 percent of the original royalty suspension volume or 50 percent of the most likely size of producible resources anticipated in your application.

* * * * *

18. Section 203.77 is revised to read as follows:

§ 203.77 May I voluntarily give up relief if conditions change?

Yes, by sending a letter to this effect to the MMS Regional Director for the GOM.

19. In § 203.78, the introductory paragraph and paragraph (f) are revised to read as follows:

§ 203.78 Do I keep relief if prices rise significantly?

If prices rise above a base price for light sweet crude oil or natural gas, set by statute for pre-Act leases, or in your original lease agreement for post-2000 deep water leases, you must pay full royalties as prescribed in this section.

* * * * *

(f) We change the prices referred to in paragraphs (a), (b), and (d) of this section during each calendar year after 1994. For pre-Act leases, these prices change by the percentage that the implicit price deflator for the gross domestic product changed during the preceding calendar year. For post-2000 deep water leases, these prices change as specified in the leasing instrument and in the Notice of Sale under which we issued the lease.

20. Section 203.80 is added to read as follows:

§ 203.80 When can I get royalty relief if I am not eligible for end-of-life or deep water royalty relief?

We may grant special royalty relief when it serves the statutory purposes summarized in § 203.1, and our formal relief programs provide inadequate encouragement to increase production or development. Before you may apply for special royalty relief, we must agree that your lease or project has two or more of the following characteristics.

(a) The lease has produced for a substantial period and the lessee can recover significant additional resources.

(b) Valuable facilities (e.g., a platform or pipeline that would be removed upon lease relinquishment) exist on the lease that we do not expect a successor lessee to use.

(c) A substantial risk exists that no new lessee will recover the resources.

(d) The lessee made major efforts to reduce operating costs too recently to use the formal program for royalty relief (e.g., recent significant change in operations).

(e) Circumstances beyond the lessee's control, other than water depth, preclude reliance on one of the existing royalty relief programs.

21. In § 203.81, paragraphs (a) and (c) are revised to read as follows:

§ 203.81 What supplemental reports do royalty-relief applications require?

(a) You must send us the supplemental reports listed in the following table that apply to your field. §§ 203.83 through 203.91 describe these reports in detail.

Required reports	End-of-life lease	Deep water		
		Expansion project	Pre-act lease	Development project
(1) Administrative information report	X	X	X	X
(2) Net revenue & relief justification report	X	.....	.....	.....
(3) Economic viability & relief justification report (RSVP model inputs justified by other required reports)	.....	X	X	X
(4) G&G report	.....	X	X	X
(5) Engineering report	.....	X	X	X
(6) Production report	.....	X	X	X
(7) Deep water cost report	.....	X	X	X
(8) Fabricator's confirmation report	.....	X	X	X
(9) Post-production development report	.....	X	X	X

* * * * *

(c) With your application and post-production development report, you must submit an additional report prepared by an independent CPA that:

(1) Assesses the accuracy of the historical financial information in your report and

(2) Certifies that the content and presentation of the financial data and information conform to our most recent guidelines on royalty relief, with primary regard to including only eligible costs that are incurred during the qualification months and shown in the proper format.

* * * * *

22. In § 203.83, paragraph (c) is revised to read as follows:

§ 203.83 What is in an administrative information report?

* * * * *

(c) Lessee's well designation, the API number, and the location of each well that has been drilled on the field or lease or project (not required for non-oil and gas leases);

* * * * *

23. In § 203.86, the following changes are made:

A. The word ''and'' is removed at the end of paragraph (b)(6).

B. The ''.'' is removed and ''; and'' is added at the end of paragraph (b)(7).

C. Paragraph (b)(8) is added.

D. Paragraph (c)(4) is revised.

E. The word ''and'' is removed at the end of paragraph (d)(6).

F. The ''.'' is removed and ''; and'' is added at the end of paragraph (d)(7).

G. Paragraph (d)(8) is added.

The additions and revisions in changes C, D, and G read as follows:

§ 203.86 What is in G&G report?

* * * * *

(b) * * *

(8) A table listing the wells/completions and indicating which sands and fault blocks will be targeted for completion/recompletion.

(c) * * *

(4) an explanation for excluding the reservoirs you are not planning to develop.

(d) * * *

(8) Reserve/resource distribution by reservoir.

* * * * *

24. In § 203.87, paragraphs (a)(1) and (d) are revised to read as follows, and paragraphs (d)(1) and (d)(2) are removed.

§ 203.87 What is in an engineering report?

* * * * *

(a) * * *

(1) Its size along with basic design specifications and drawings and

* * * * *

(d) A discussion of any plans for multi-phase development which includes the conceptual basis for developing in phases and goals or milestones required for starting later phases.

* * * * *

25. In § 203.89, paragraph (a) is revised to read as follows:

§ 203.89 What is in an engineering report?

* * * * *

(a) On an authorized field, sunk costs which are all your eligible post-discovery exploration, development, and production expenses (no third party costs), and include the eligible costs of the discovery well on the field. On an expansion project or a development project, sunk costs are just the eligible costs of the discovery well for the project. Report them in nominal dollars and only if you have documentation. We count sunk costs in an evaluation (specified in § 203.68) as after-tax expenses, using nominal dollar amounts.

* * * * *

26. In § 203.91, a new last sentence is added to read as follows:

§ 203.91 What is in an engineering report?

* * * Also, you must have this report certified by an independent CPA according to § 203.81(c).

[FR Doc. 00–29372 Filed 11–15–00; 8:45 am]

BILLING CODE 4310–MR–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[MA–081–7211b; A–1–FRL–6897–5]

Approval and Promulgation of Air Quality Implementation Plans; Massachusetts; Enhanced Motor Vehicle Inspection and Maintenance Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the Commonwealth of Massachusetts. This revision establishes and requires the implementation of an enhanced inspection and maintenance program. In the Final Rules Section of this **Federal Register**, EPA is approving the Commonwealth's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action, no further activity is contemplated. If EPA receives relevant adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

DATES: Written comments must be received on or before December 18, 2000.

ADDRESSES: Comments may be mailed to David Conroy, Unit Manager, Air Quality Planning, Office of Ecosystem Protection (mail code CAQ), U.S. Environmental Protection Agency, EPA-New England, One Congress Street, Suite 1100, Boston, MA 02114–2023. Copies of the State submittal and EPA's technical support document are available for public inspection during normal business hours, by appointment at the Office of Ecosystem Protection, U.S. Environmental Protection Agency, EPA-New England, One Congress Street, 11th floor, Boston, MA and Division of Air Quality Control, Department of Environmental Protection, One Winter Street, 8th Floor, Boston, MA 02108.

FOR FURTHER INFORMATION CONTACT: Peter Hagerty, (617) 918–1049.

SUPPLEMENTARY INFORMATION: For additional information, see the direct final rule which is located in the Rules Section of this **Federal Register**.

Dated: October 27, 2000.

Mindy S. Lubber,

Regional Administrator, EPA-New England.

[FR Doc. 00–29219 Filed 11–15–00; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[Docket WA–00–01; FRL–6902–6]

Clean Air Act Reclassification; Wallula, Washington Particulate Matter (PM_{10}) Nonattainment Area

AGENCY: EPA.

ACTION: Proposed rule.

SUMMARY: EPA proposes to determine that the Wallula nonattainment area has not attained the National Ambient Air Quality Standards for particulate matter with an aerodynamic diameter of less than or equal to 10 microns (PM_{10}) by the attainment date of December 31, 1997, as required by the Clean Air Act. EPA's proposed finding is based on EPA's review of monitored air quality data reported for the years 1995 through 1999. If EPA takes final action on this proposal, the Wallula PM_{10}

nonattainment area will be reclassified by operation of law as a serious PM_{10} nonattainment area.

DATES: Comments on this proposal must be received in writing by December 1, 2000.

ADDRESSES: Submit written comments to Donna Deneen, EPA, Region 10, Office of Air Quality (OAQ–107), 1200 Sixth Avenue, Seattle, Washington 98101. You may view documents supporting this action during normal business hours at the following location: EPA, Office of Air Quality (OAQ–107), 1200 Sixth Avenue, Seattle, Washington 98101.

FOR FURTHER INFORMATION CONTACT: Donna Deneen, EPA Region 10, Office of Air Quality, at (206) 553–6706.

SUPPLEMENTARY INFORMATION: The supplementary information is organized as follows:

I. What action are we taking?
II. What is the background for this action?
III. How does EPA determine whether an area has attained the standard by the attainment date?
IV. What information supports EPA's finding that the Wallula area has not attained the PM_{10} standard by the attainment date?
V. Does the Wallula area qualify for a permanent waiver of the December 31, 1997 attainment date?
VI. What are the implications of this proposed finding?
VII. Administrative Requirements
A. Executive Order 12866
B. Executive Order 13045
C. Executive Order 13084
D. Regulatory Flexibility Act
E. Unfunded Mandates Reform Act
F. Executive Order 13132
G. National Technology Transfer and Advancement Act

I. What Action Are We Taking?

In this action, we are proposing to find that the Wallula nonattainment area has not attained the National Ambient Air Quality Standards (NAAQS) for particulate matter with an aerodynamic diameter of less than or equal to 10 microns (PM_{10}) by the attainment date of December 31, 1997, as required by the Clean Air Act. [1] This proposed finding is based on EPA's review of monitored PM_{10} air quality data reported for the years 1995 through 1999, inclusive. If EPA takes final action on this proposal, the Wallula PM_{10} nonattainment area will be reclassified by operation of law as a serious PM_{10} nonattainment area.

II. What is the Background for This Action?

The Wallula area was designated nonattainment for PM_{10} and classified as moderate under sections 107(d)(4)(B) and 188(a) of the Clean Air Act upon enactment of the Clean Air Act Amendments of 1990 (Act or CAA). [2] See 40 CFR 81.348 (PM_{10} Initial Nonattainment Areas); see also 56 FR 56694 (November 6, 1991). Under subsections 188(a) and (c)(1) of the Act, all initial moderate PM_{10} nonattainment areas had the same applicable attainment date of December 31, 1994.

States containing initial moderate PM_{10} nonattainment areas were required to develop and submit to EPA by November 15, 1991, a state implementation plan (SIP) revision providing for, among other things, implementation of reasonably available control measures (RACM), including reasonably available control technology (RACT), and a demonstration of attainment of the PM_{10} NAAQS by December 31, 1994. See section 189(a) of the CAA. [3] In response to this submission requirement, the Washington Department of Ecology (Ecology) submitted a SIP revision for Wallula on November 15, 1991. Subsequently, Ecology submitted additional information indicating that nonanthropogenic sources may be significant in the Wallula nonattainment area during windblown dust events. Based on our review of the State's submissions, we deferred action on several elements in the Wallula SIP, approved the control measures in the SIP as meeting RACM/RACT, and, under section 188(f) of the CAA, granted a temporary waiver to extend the attainment date for Wallula to December 31, 1997. See 60 FR 63109 (December 6, 1995)(proposed action); 62 FR 3800 (January 27, 1997) (final action). The temporary waiver was intended to provide Ecology time to evaluate further the Wallula nonattainment area and to determine the significance of the anthropogenic and nonanthropogenic sources impacting the area. Once these activities were complete or the temporary waiver expired, EPA was to make a decision on whether the area was eligible for a permanent waiver under section 188(f) of the CAA or whether the area had attained the standard by the extended attainment date. See 62 FR 3802. Based on all the information currently available to EPA, we do not believe that nonanthropogenic sources of PM_{10} contribute significantly to violations of the PM_{10} standards in the Wallula nonattainment area. We therefore do not believe that the State has demonstrated that the area qualifies for a permanent waiver of the attainment date. Accordingly, in this action, we are proposing to find that the Wallula area has not attained the PM_{10} standards by the applicable attainment date of December 31, 1997.

III. How does EPA Determine Whether an Area has Attained the Standard by the Attainment Date?

EPA has the responsibility, pursuant to sections 179(c)(1) and 188(b)(2) of the CAA, to determine within six months of the applicable attainment date, whether PM_{10} nonattainment areas attained the PM_{10} NAAQS by the attainment date. Determinations under section 179(c)(1) of the Act are to be based upon an area's ''air quality as of the attainment date.'' Section 188(b)(2) is consistent with this requirement. Generally, EPA will determine whether an area's air quality is meeting the PM_{10} NAAQS for purposes of sections 179(c)(1) and 188(b)(2) based upon data gathered at monitoring sites in the nonattainment area and entered into the Aerometric Information Retrieval System (AIRS). Data entered into the AIRS has been determined by EPA to meet federal monitoring requirements (see 40 CFR 50.6 and appendix J, 40 CFR part 53, 40 CFR part 58, appendices A and B). The data are reviewed in accordance with 40 CFR part 50, appendix K, to determine the area's air quality status.

Pursuant to appendix K, the annual PM_{10} standard is attained when the expected annual arithmetic average of the 24-hour samples for a period of one year does not exceed 50 micrograms per cubic meter ($\mu g/m^3$). The 24-hour PM_{10} standard is attained when the expected number of days in a year with PM_{10} concentrations greater than 150 $\mu g/m^3$, averaged over a three year period, is less than or equal to one. To calculate ''the expected number of days,'' we use the number of exceedances that are observed in a year, then adjust that number to account for the sampling schedule of the monitor and any

[1] On July 18, 1997, EPA promulgated revised and new standards for PM_{10} and $PM_{2.5}$ (62 FR 38651). The U.S. Court of Appeals for the D.C. Circuit in *American Trucking Assoc., Inc., et al.* v. *USEPA,* 175 F.3d 1027 (D.C. Cir. 1999), issued an opinion that, among other things, vacated the new standards for PM_{10} that were published on July 18, 1997, and became effective September 16, 1997. However, the PM_{10} standards promulgated on July 1, 1987, were not an issue in this litigation, and the Court's decision does not affect the applicability of those standards in the Wallula area. Codification of those standards continue to be recorded at 40 CFR 50.6. Today's proposed action relates only to the CAA requirements concerning the PM_{10} standards as originally promulgated in 1987.

[2] The 1990 Amendments to the CAA made significant changes to the CAA. *See* Public Law No. 101–549, 104 Stat. 2399. References herein are to the CAA as amended in 1990. The Clean Air Act is codified, as amended, in the United States Code at 42 U.S.C. 7401, *et seq.*

[3] The moderate area SIP requirements are set forth in section 189(a) of the CAA.

missing data. A total of three consecutive years of non-violating air quality data is generally necessary to show attainment of the 24-hour and annual standard for PM_{10}. See 40 CFR 50.6 and 40 CFR part 50, appendix K.

EPA is publishing this proposal pursuant to section 188(b)(2) of the Act. Under subpart (A) of that section, a moderate PM_{10} nonattainment area is reclassified as serious by operation of law if EPA finds that the area is not in attainment by the applicable attainment date. Pursuant to section 188(b)(2)(B) of the Act, EPA must publish a **Federal Register** document within six months after the applicable attainment date identifying those areas that have failed to attain the standard and that have been reclassified to serious by operation of law. See section 188(b)(2); see also section 179(c)(1).

IV. What Information Supports EPA's Finding That the Wallula Area has not Attained the PM_{10} Standard by the Attainment Date?

As explained above, attainment determinations are based upon an area's ''air quality as of the attainment date.'' Since Wallula's attainment date was extended to December 31, 1997, we first looked at the PM_{10} air quality data for 1995, 1996, and 1997. These data show that, for this three year period, there were no violations of the annual PM_{10} standard. For the 24-hour standard, however, there were two measured exceedances: 160 μg/m^3 on June 21, 1997, and 210 μg/m^3 on July 3, 1997. After adjusting these two 24-hour exceedances to account for the sampling schedule [4] and missing data, the expected number of days with PM_{10} concentrations greater than 150 μg/m^3 was 4.1. Since this value is greater than one, these data show that Wallula was not in attainment of the 24-hour PM_{10} standard as of its December 31, 1997, attainment date.

In addition to the 1995 through 1997 data, we also looked at the most recent data for Wallula. In 1998 and 1999 there were no violations of the annual standard. However, since January 1, 1998, there have been two additional exceedances of the 24-hour standard: 215 μg/m^3 on July 10, 1998, and 297 μg/m^3 on June 23, 1999. Using these values, along with the 1997 exceedances of 160 μg/m^3 and 210 μg/m^3, we calculated the expected number of days with PM_{10} concentrations greater than 150 μg/m^3 for the 1997 through 1999 period (i.e., the most recent three-year period). Accounting for the sampling schedule and missing data, the expected number of days for this period was 8.4. Because this value is greater than one, these data show that Wallula is still not in attainment of the 24-hour PM_{10} standard.

In a May 30, 1996, Memorandum from EPA's Assistant Administrator for Air and Radiation to EPA Regional Air Directors entitled ''Areas Affected by Natural Events'' (EPA's Natural Events Policy), EPA has stated that in some circumstances it is appropriate to exclude PM_{10} air quality data that are attributable to uncontrollable natural events, such as unusually high winds, from decisions regarding an area's attainment status. Under the policy, where a State believes natural events have caused a violation of the NAAQS, the State enters the exceedance in the AIRS data base, flags the exceedance as being attributable to a natural event, documents a clear causal relationship between the measured exceedance and the natural event, and develops a natural events action plan (NEAP) to address future natural events. In the case of high-wind events where the sources of dust are anthropogenic, the State should also document that Best Available Control Measures (BACM) were required for those sources and the sources were in compliance with BACM at the time-of the high-wind event. EPA's Natural Events Policy also contains guidance for notifying the public of the occurrence of natural events and the health effects of such events, as well as minimizing public exposure to high concentrations of PM_{10} due to natural events.

Ecology has flagged certain exceedances of the PM_{10} NAAQS in the Wallula area under EPA's Natural Events Policy and has also developed a Natural Events Action Plan for High Wind Events in the Columbia Plateau (March 1998), which includes the Wallula PM_{10} nonattainment area. Since January 1, 1995, the beginning of the time period for the data considered by EPA in this action, we are aware of one exceedance of the PM_{10} standard in the Wallula area—June 21, 1997— that Ecology has flagged as attributable to high winds under EPA's Natural Events Policy.[5] EPA has no information indicating Ecology has claimed any of the other exceedances of the 24-hour PM_{10} standard in the Wallula area since January 1, 1995, as attributable to natural events.[6] Even if the June 21, 1997, exceedance is excluded from the attainment determination, the expected number of days during the 1995–1997 time period with PM_{10} concentrations greater than 150 μg/m^3 is 2.0 and still demonstrates nonattainment of the 24-hour PM_{10} standard. Similarly, for the 1997–1999 time period, the expected number of days with PM_{10} concentrations greater than 150 μg/m^3 is 6.4 and demonstrates nonattainment of the 24-hour standard even if the June 21, 1997, exceedance is excluded.

V. Does the Wallula Area Qualify for a Permanent Waiver of the December 31, 1997, Attainment Date?

Section 188(f) of the Act provides that EPA may, on a case-by-case basis, waive a specific date for attainment of the PM_{10} standards where EPA determines that nonanthropogenic sources of PM_{10} contribute significantly to the violation of the PM_{10} standards in the nonattainment area. Based on the currently available information, we do not believe the Wallula area qualifies for a permanent waiver of the moderate area extended attainment date of December 31, 1997. EPA also has not received a request from Ecology for a permanent waiver of the attainment date under section 188(f). In addition, the information available to EPA does not establish that nonanthropogenic sources of PM_{10} contribute significantly to the violations of the PM_{10} standards in the Wallula PM_{10} nonattainment area. As discussed above, only one of the exceedances of the PM_{10} standards since January 1, 1995, has been claimed by Ecology as attributable to a natural event. EPA therefore believes that the other exceedances were due to anthropogenic sources of PM_{10}. Accordingly, in light of the data showing the Wallula area was in violation of the 24-hour PM_{10} standard as of the December 31, 1997, attainment date, as well as the data showing the area continues to violate the 24-hour PM_{10} standard, we are proposing to find, in accordance with section 188(b)(2) of the Act, that the Wallula PM_{10} nonattainment area did not attain the

[4] Because the Wallula monitor is scheduled to sample once every six days, each measured exceedance is generally counted as six expected exceedances. If there is missing data, the measured exceedance may count for more than that.

[5] Ecology subsequently submitted documentation to EPA to support its claim that the June 21, 1997 exceedance was due to a ''natural event,'' although it is unclear when EPA received this documentation. In addition, because the documentation from Ecology was marked ''draft,'' it was not clear to EPA that this was intended to be treated as the State's final submission and EPA has therefore not confirmed this flag. EPA now understands from Ecology that Ecology intended the submission marked ''draft'' to serve as its final submission, and EPA will therefore proceed with reviewing the documentation submitted by the State.

[6] Indeed, the State has specifically confirmed that it does not consider the July 10, 1998, exceedance to be due to high winds.

PM_{10} NAAQS by the applicable attainment date of December 31, 1997.

VI. What are the implications of this proposed finding?

If EPA takes final action on this proposed finding, the Wallula PM_{10} nonattainment area will be reclassified by operation of law as a serious PM_{10} nonattainment area under section 188(b)(2)(A) of the Act. PM_{10} nonattainment areas reclassified as serious under section 188(b)(2) of the Act are required to submit, within 18 months of the area's reclassification, SIP provisions providing for, among other things, the adoption and implementation of best available control measures (BACM), including best available control technology (BACT), for PM_{10} no later than four years from the date of reclassification. The SIP also must contain, among other things, a demonstration that the implementation of BACM will provide for attainment of the PM_{10} NAAQS no later than December 31, 2001.[7] In addition, the terms ''major source'' or ''major stationary source'' include any stationary source or group of stationary sources located within a contiguous area and under common control that emits, or has the potential to emit, at least 70 tons per year of PM_{10}. See sections 188(c)(2) and 189(b). These requirements are in addition to the moderate PM_{10} nonattainment requirements of RACT/RACM, which, as discussed above, were approved for the Wallula nonattainment area on January 27, 1997. See 62 FR 3800.

VII. Administrative Requirements

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735 (October 4, 1993)), EPA is required to determine whether regulatory actions are significant and therefore should be subject to Office of Management and Budget (OMB) review, economic analysis, and the requirements of the Executive Order. The Executive Order defines a ''significant regulatory action'' as one that is likely to result in a rule that may meet at least one of the four criteria identified in section 3(f), including, under paragraph (1), that the rule may ''have an annual effect on the economy of $100 million or more or adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities.''

The Agency has determined that the finding of failure to attain proposed today would result in none of the effects identified in section 3(f). Under section 188(b)(2) of the CAA, findings of failure to attain are based upon air quality considerations and the resulting reclassifications must occur by operation of law in light of certain air quality conditions. They do not, in and of themselves, impose any new requirements on any sectors of the economy. In addition, because the statutory requirements are clearly defined with respect to the differently classified areas, and because those requirements are automatically triggered by classifications that, in turn, are triggered by air quality values, findings of failure to attain and reclassification cannot be said to impose a materially adverse impact on State, local or tribal governments or communities.

B. Executive Order 13045

Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) is determined to be economically significant as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency. This proposed action is not subject to Executive Order 13045 because this is not an economically significant regulatory action as defined by Executive Order 12866.

C. Executive Order 13084

Under Executive Order 13084, Consultation and Coordination with Indian Tribal Governments, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.

Today's proposed finding of failure to attain does not significantly or uniquely affect the communities of Indian tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this proposed finding of failure to attain.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions.

Findings of failure to attain and the resulting reclassification of nonattainment areas by operation of law under section 188(b)(2) of the CAA do not in and of themselves create any new requirements. Instead, this rulemaking only proposes to make a factual determination, and does not propose to directly regulate any entities. Therefore, pursuant to 5 U.S.C. 605(b), I certify that today's proposed action does not have a significant impact on a substantial number of small entities within the meaning of those terms for RFA purposes.

E. Unfunded Mandates Reform Act

Under section 202 of the Unfunded Mandates Reform Act of 1995 (''UMRA''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated annual costs to state, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be

[7] If certain conditions are met, EPA may extend this attainment deadline to no later than December 31, 2006. CAA 188(e).

significantly or uniquely impacted by the rule.

EPA believes, as discussed above, that the proposed finding of failure to attain is a factual determination based upon air quality considerations and that the resulting reclassification of the area must occur by operation of law. Thus, the finding does not constitute a Federal mandate, as defined in section 101 of the UMRA, because it does not impose an enforceable duty on any entity.

F. Executive Order 13132

Executive Order 13132, entitled Federalism (64 FR 43255, August 10, 1999) revokes and replaces Executive Orders 12612, Federalism, and 12875, Enhancing the Intergovernmental Partnership. Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' Under Executive Order 13132, EPA may not issue a regulation that has federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, or EPA consults with State and local officials early in the process of developing the proposed regulation. EPA also may not issue a regulation that has federalism implications and that preempts State law unless the Agency consults with State and local officials early in the process of developing the proposed regulation.

This finding of failure to attain and reclassification of nonattainment area will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because these actions do not, in-and-of-themselves, impose any new requirements on any sectors of the economy, and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. Thus, the requirements of section 6 of the Executive Order do not apply to these actions.

G. National Technology Transfer and Advancement Act

Section 12 of the National Technology Transfer and Advancement Act (NTTAA) of 1995 requires Federal agencies to evaluate existing technical standards when developing a new regulation. To comply with NTTAA, EPA must consider and use ''voluntary consensus standards'' (VCS) if available and applicable when developing programs and policies unless doing so would be inconsistent with applicable law or otherwise impractical.

The EPA believes that VCS are not relevant to this action because today's action does not involve the application of new technical standards.

List of Subjects in 40 CFR Part 81

Environmental protection, Air pollution control, Intergovernmental relations, Particulate matter.

Dated: November 6, 2000.

Charles E. Findley,

Acting Regional Administrator, Region 10.

[FR Doc. 00–29360 Filed 11–15–00; 8:45 am]

BILLING CODE 6560–50–u

DEPARTMENT OF TRANSPORTATION

Maritime Administration

46 CFR Part 205

[Docket No. MARAD–2000–8284]

RIN 2133–AB42

Audit Appeals; Policy and Procedure

AGENCY: Maritime Administration, Transportation.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The Maritime Administration (MARAD, we, our, or us) is proposing to update Part 205—Audit Appeals; Policy and Procedure. Part 205 establishes appeal procedures for parties who contract with the Maritime Subsidy Board or MARAD. We propose to: Update these audit procedures to reflect current MARAD practices; and rewrite the regulations in plain language. The intended effect of this rulemaking is to improve our audit appeals process by updating and clarifying part 205.

DATES: You should submit your comments early enough to ensure that Docket Management receives them not later than January 16, 2001.

ADDRESSES: Your comments should refer to docket number [MARAD 2000–8284]. You may submit your comments in writing to: Docket Clerk, U.S. DOT Dockets, Room PL–401, 400 7th St., SW, Washington, DC 20590. You may also submit them electronically via the internet at *http://dmses.dot.gov/submit/*. You may call Docket Management at (202) 366–9324 and visit the Docket Room from 10 a.m. to 5 p.m., EST., Monday through Friday, except Federal Holidays. An electronic version of this document is available on the World Wide Web at http://dms.dot.gov.

FOR FURTHER INFORMATION CONTACT: Mr. Fred A. Slaugh, Office of Financial Approvals and Rates, (202) 366–5866. You may send mail to Mr. Slaugh at Maritime Administration, Office of Financial and Rate Approvals, Room 8117, 400 Seventh Street, SW, Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

Comments

How Do I Prepare and Submit Comments?

Your comments must be written and in English. To ensure that your comments are correctly filed in the Docket, please include the docket number of this document in your comments. We encourage you to write your primary comments in a concise fashion. However, you may attach necessary additional documents to your comments. There is no limit on the length of the attachments. Please submit two copies of your comments, including the attachments, to Docket Management at the address given above under **ADDRESSES.**

How Can I be Sure That my Comments Were Received?

If you wish Docket Management to notify you upon its receipt of your comments, enclose a self-addressed, stamped postcard in the envelope containing your comments. Docket Management will return the postcard by mail.

How do I Submit Confidential Business Information?

If you wish to submit any information under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Chief Counsel, Maritime Administration, at the address given above under **FOR FURTHER INFORMATION CONTACT**. You should mark ''CONFIDENTIAL'' on each page of the original document that you would like to keep confidential. In addition, you should submit two copies, from which you have deleted the

claimed confidential business information, to Docket Management at the address given above under **ADDRESSES**. When you send comments containing information claimed to be confidential business information, you should include a cover letter setting forth with specificity the basis for any such claim.

Will the Agency Consider Late Comments?

We will consider all comments that Docket Management receives before the close of business on the comment closing date indicated above under **DATES**. To the extent possible, we will also consider comments that Docket Management receives after that date.

How Can I Read the Comments Submitted by Other People?

You may read the comments received by Docket Management at the address given above under **ADDRESSES.** The hours of the Docket Room are indicated above in the same location. You may also see the comments on the Internet. To read the comments on the Internet, take the following steps: Go to the Docket Management System (DMS) Web page of the Department of Transportation (http://dms.dot.gov/). On that page, click on ''search.'' On the next page (http://dms.dot.gov/search/), type in the four-digit docket number shown at the beginning of this document. The docket number for this document is [xxxx]. After typing the docket number, click on ''search.'' On the next page, which contains docket summary information for the docket you selected, click on the desired comments. You may download the comments. Please note that even after the comment closing date, we will continue to file relevant information in the Docket as it becomes available. Further, some people may submit late comments. Accordingly, we recommend that you periodically check the Docket for new material.

Background

Part 205—Audit Appeals; Policy and Procedure establishes the policy and procedure for parties to use when seeking redress and appeals of decisions involving contracts with the Maritime Subsidy Board or MARAD. Part 205 applies to all MARAD contracts including the Operating-Differential Subsidy, Construction-Differential Subsidy, Capital Construction Fund, Construction Reserve Fund, and Maritime Security Program.

According to the policy in part 205, any contractor who disagrees with audit findings or decisions of MARAD and who does not reach a negotiation with the appropriate Coast Director's office may appeal. Any contractor who appeals must do so in writing to the Maritime Administrator within six (6) months following the date of the document notifying the contractor of the audit findings. MARAD will then notify the appellant in writing if a hearing or additional facts are necessary. After the Maritime Administrator renders a decision, MARAD will notify the appellant in writing. When a contract contains a disputes article, the disputes article will govern the bases for dispute and any appeals.

We are proposing revisions to part 205 that reflect our current practices of making audit appeals decisions. Appellants no longer appeal to the appropriate Coast Director's office. In the past, auditors were assigned to regional offices. However, we no longer have these auditors. MARAD headquarters is responsible for overseeing audits as deemed appropriate. Such audits may be performed by the Office of Inspector General.

Plain Language

Executive Order 12866 and the President's memorandum on plain language in government writing of June 1, 1998, require each agency to write all rules in plain language. The Department of Transportation and MARAD are committed to plain language in government writing; therefore, we propose to revise part 205 using plain language to provide easier understanding. Our goal is to improve the clarity of the regulation. We invite your comments on how to make this proposed rule easier to understand.

Rulemaking Analyses and Notices

Executive Order 12866 and DOT Regulatory Policies and Procedures

We have reviewed this notice of proposed rulemaking (NPRM) under Executive Order 12866 and have determined that this is not a significant regulatory action. Additionally, this NPRM is not likely to result in an annual effect on the economy of $100 million or more. The purpose of this NPRM is to propose updates to MARAD's audit procedures to reflect current MARAD practices and to rewrite the regulations in plain language.

This NPRM is also not significant under the Regulatory Policies and Procedures of the Department of Transportation (44 FR 11034; February 26, 1979). The costs and benefits associated with this rulemaking are considered to be so minimal that no further analysis is necessary. Because the economic impact, if any, should be minimal, further regulatory evaluation is not necessary.

Regulatory Flexibility Act

This NPRM will not have a significant economic impact on a substantial number of small entities. This NPRM only updates procedures for appealing audit findings and decisions to the Maritime Administrator. Although the number of small entities who appeal audit findings may be substantial, the cost of filing an audit appeal with MARAD is minimal, if any. Therefore, I certify that this NPRM will not have a significant economic impact on a substantial number of small entities.

Federalism

We have analyzed this final rule in accordance with the principles and criteria contained in E.O. 13132 (''Federalism'') and have determined that it does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. These regulations have no substantial effects on the States, or on the current Federal-State relationship, or on the current distribution of power and responsibilities among the various local officials. Therefore, consultation with State and local officials was not necessary.

Environmental Impact Statement

We have analyzed this NPRM for purposes of compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and have concluded that under the categorical exclusions provision in section 4.05 of Maritime Administrative Order (''MAO'') 600–1, ''Procedures for Considering Environmental Impacts,'' 50 FR 11606 (March 22, 1985), the preparation of an Environmental Assessment, and an Environmental Impact Statement, or a Finding of No Significant Impact for this NPRM is not required. This NPRM involves administrative and procedural regulations that have no environmental impact.

Executive Order 13084

MARAD does not believe that this NPRM will significantly or uniquely affect the communities of Indian tribal governments when analyzed under the principles and criteria contained in Executive Order 13084 (''Consultation and Coordination with Indian Tribal Governments''). Therefore, the funding and consultation requirements of this Executive Order would not apply.

Unfunded Mandates Reform Act of 1995

This NPRM does not impose an unfunded mandate under the Unfunded Mandates Reform Act of 1995. It does not result in costs of $100 million or more, in the aggregate, to any of the following: State, local, or Native American tribal governments, or the private sector. This NPRM is the least burdensome alternative that achieves the objective of the rule.

Paperwork Reduction Act

This NPRM does not contain information collection requirements covered by 5 CFR Part 1320 (specifically 5 CFR 1320.3(c)) in that appellants choose the information to be provided in their appeal and may choose to interpret the collection of information differently.

Regulation Identifier Number (RIN)

The Department of Transportation assigns a regulation identifier number (RIN) to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number is contained in the heading of this document to cross-reference this action with the Unified Agenda.

List of Subjects in 46 CFR Part 205

Administrative practice and procedure, Government contracts.

Accordingly, 46 CFR part 205 is proposed to be revised to read as follows:

PART 205—AUDIT APPEALS; POLICY AND PROCEDURE

Sec.
205.1 Purpose.
205.2 Policy.
205.3 Procedure.
205.4 Finality of decisions.
205.5 Contracts containing disputes article.

Authority: Sec. 204, 49 Stat. 1987, 1998, 2004, 2011; 46 U.S.C. 1114, 1155, 1176, 1212.

§ 205.1 Purpose.

This part establishes the policy and procedure for parties to use when seeking redress and appeals of decisions involving contracts with the Maritime Subsidy Board or The Maritime Administration (MARAD, we, our, or us). A party to a contract (you or your) may appeal MARAD's findings, interpretations, or decisions of annual or special audits.

§ 205.2 Policy.

If you disagree with audit findings and fail to settle any differences with the appropriate Office Director, you may ask the appropriate office Associate Administrator to review the audit findings. If you disagree with the Associate Administrator, you may appeal to the Maritime Administrator (Administrator).

§ 205.3 Procedure.

(a) You must submit your appeal in writing to the Administrator within 6 months following the date of the document notifying you of the audit findings, interpretations, or decisions. However, the Administrator may, at his discretion, extend this time limitation in the case of extenuating circumstances.

(b) We will notify you, in writing, if you must submit additional facts for our consideration of the appeal. We will notify you, in writing, once the Maritime Administrator has made a decision regarding your appeal.

§ 205.4 Finality of decisions.

The Administrator's decision will be final on all questions of fact involved in the appeal, unless:

(a) Otherwise determined by the Secretary of Transportation pursuant to 49 CFR 1.43(a); or

(b) A court of competent jurisdiction determines the findings to have been fraudulent, capricious, arbitrary, so grossly erroneous as necessarily to imply bad faith, or not supported by substantial evidence.

§ 205.5 Contracts containing disputes article.

When a contract contains a disputes article, the disputes article will govern the bases for negotiating disputes regarding audit findings, interpretations, or decisions made by MARAD and any appeals.

By Order of the Maritime Administrator.
Dated: November 13, 2000.

Joel C. Richard,

Secretary, Maritime Administration.

[FR Doc. 00–29386 Filed 11–15–00; 8:45 am]

BILLING CODE 4910–81–P

Notices

Federal Register

Vol. 65, No. 222

Thursday, November 16, 2000

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.

AGENCY FOR INTERNATIONAL DEVELOPMENT

Senior Executive Service: Membership of Performance Review Board

ACTION: Notice.

SUMMARY: The Performance Review Board will initiate their labors on or about November 15, 2000. The following persons are members of the Performance Review Board for 2000. Members:

Corbett Flannery, Chair
Robert Lester, SES Member
Elmer S. Owens, SES Member
Roxann A. Van Dusen, SES Member
Lois E. Hartman, Public Member

FOR FURTHER INFORMATION CONTACT: Mary Anne Conboy, 202–712–5438.

Dated: November 7, 2000.

Henry W. Reynolds,

Executive Secretary, Executive Resources Board.

[FR Doc. 00–29390 Filed 11–15–00; 8:45 am]

BILLING CODE 6116–01–M

DEPARTMENT OF AGRICULTURE

Forest Service

Supplemental to Final Environmental Impact Statement for Uncompahgre National Forest Travel Plan; Grand Mesa, Uncompahgre and Gunnison National Forests; Montrose, Gunnison, Mesa, San Miguel, Ouray, Hinsdale, and San Juan Counties, Colorado

AGENCY: Forest Service, USDA.

ACTION: Notice of Intent to Prepare a Supplement to the Final Environmental Impact Statement (EIS) in conjunction with an amendment of the land and resource management plan for the Grand Mesa, Uncompahgre and Gunnison National Forests.

SUMMARY: Over a six-year period the Forest Service, working with the public, developed the Uncompahgre National Forest Travel Plan and decision. The process included 38 open public meetings, a Draft Environmental Impact Statement, a Final Environmental Impact Statement and a Record of Decision finally published in April of 2000 (published notices 62 FR 25162–25163, 63 FR 49911, 65 FR 26198). The Uncompahgre Travel Plan Decision of April 2000 was reversed on appeal. The issue of Forest Plan compliance with the standard for Habitat Capability was raised in the appeal. In his reversal decision, Deputy Regional Forester Tom Thompson instructed the Forest Supervisor to ''promptly begin a new decisionmaking process'' incorporating a ''procedural remedy of the NEPA/NFMA flaw'' discovered through the appeal. NEPA is the National Environmental Policy Act, which requires Environmental Analyses of proposed Federal actions; NFMA is the National Forest Management Act, which establishes Forest Plans.

The Forest Service will prepare a supplement to the Final Environmental Impact Statement (FEIS) for the Uncompahgre National Forest Travel Plan. The supplement will examine a proposed amendment to the Land and Resource Management Plan for the Grand Mesa, Uncompahgre, Gunnison National Forests (GMUG) to accommodate departure from the Forest Plan standards for Habitat Capability for an Uncompahgre Travel Plan Decision. Alternatives will be considered, including the No Action Alternative.

Public Participation: Scoping is not a required part of the preparation of a Supplement to an EIS. However limited scoping was conducted, with a comment period from mid September through October 20, 2000. There was an open public meeting at the Montrose Pavilion on September 27, to discuss this proposal.

ADDRESSES: To be included on the mailing list to receive copies of the Draft Supplement to the FEIS please send your address to: Uncompahgre Travel Plan, GMUG National Forests, 2250 Highway 50, Delta, CO 81416.

Responsible Official: Robert L. Storch, Forest Supervisor of the Grand Mesa, Uncompahgre and Gunnison National Forests, 2250 Highway 50, Delta, CO.

FOR FURTHER INFORMATION CONTACT: Jeff Burch, Project Leader, at (970) 874–6600.

SUPPLEMENTARY INFORMATION: We expect to file a draft supplement to the final environmental impact statement with the Environmental Protection Agency (EPA) and make it available for public comment on December 2000. At that time, the EPA will publish a notice of availability for the DSEIS in the **Federal Register**. The comment period on the DSEIS will be 60 days from the date the EPA publishes the notice of availability in the **Federal Register**. The agency expects to file a final SEIS in April 2001.

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of the DSEIS must participate in the environmental review of the proposal in such a way that their participation is meaning full and alerts an agency to the reviewer's position and contentions; *Vermont Yankee Nuclear Power Corp.* v. *NRDC.* 435 U.S. 519, 553 (1978). Is very important that those interested in this proposed action participate by the close of the 60 day comment period that will be provided for public review of the Draft Supplement to the EIS, so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the FSEIS.

To assist the Forest Service in identifying and considering issues and concerns relating to the proposed actions, comments on the DSEIS should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the DSEIS or the merits of the alternatives formulated and discussed in the statements. In addressing these points, reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3.

After the comment period on the DSEIS ends, comments will be analyzed, considered, and responded to by the Forest Service in preparing the Final Supplemental EIS. The FSEIS is scheduled to be completed in April 2001. The responsible official will consider the comments, responses,

environmental consequences discussed in the FSEIS, and applicable laws, regulations, and policies in making decisions regarding these revisions. The responsible official will document the decisions and reasons for the decisions in a Record of Decision. The decision will be subject to appeal in accordance with 36 CFR 215.

Dated: October 30, 2000.

Robert L. Storch,

Forest Supervisor, Grand Mesa, Uncompahgre and Gunnison National Forests, Rocky Mountain Region, USDA Forest Service.

[FR Doc. 00–29283 Filed 11–15–00; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Gold/Boulder/Sullivan, Kootenai National Forest, Lincoln County, Montana

AGENCY: Forest Service, USDA.

ACTION: Notice of revision of intent to prepare an environmental impact statement.

SUMMARY: The USDA—Forest Service is revising its notice of intent to prepare an Environmental Impact Statement for the Gold/Boulder/Sullivan Project, as described in the **Federal Register** dated March 24, 2000 (Vol. 65, No. 58, Pages 15892–15895), due to the following major changes:

1. The filing of the DEIS will be delayed more than six months, and
2. There will be changes to the Proposed Action

The delay and changes are attributable to wildfires that occurred in the Gold/Boulder/Sullivan Project Area during August 2000.

FOR FURTHER INFORMATION: Contact Ron Komac, Acting NEPA Coordinator, Rexford Ranger District, Phone (406) 296–7130.

Dated: November 7, 2000.

Bob Castaneda,

Forest Supervisor, Kootenai National Forest.

[FR Doc. 00–29387 Filed 11–15–00; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Grain Inspection, Packers and Stockyards Administration

Advisory Committee Meeting

Pursuant to the provisions of section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following committee meeting:

Name: Grain Inspection Advisory Committee.

Dates: November 28–29, 2000.

Place: Crystal City Marriott, 1999 Jefferson Davis Highway, Arlington, Virginia.

Time: 8 am–5 pm on November 28 and 8 am–11:30 am on November 29, 2000.

Purpose: To provide advice to the Administrator of the Grain Inspection, Packers and Stockyards Administration (GIPSA) with respect to the implementation of the U.S. Grain Standards Act (7 U.S.C. 71 *et seq.*).

The agenda includes a review and discussion of GIPSA's financial status, wheat dockage proposal, reauthorization, biotechnology, research initiatives, standardization and training services for the grain industry, certification of producers and grain elevators, and other related issues concerning the delivery of grain inspection and weighing services to American agriculture.

Public participation will be limited to written statements, unless permission is received from the Committee Chairman to orally address the Committee. Persons, other than members, who wish to address the Committee or submit written statements before or after the meeting, should contact the Administrator, GIPSA, U.S. Department of Agriculture, 1400 Independence Avenue, SW., STOP 3601, Washington, DC 20250–3601, telephone (202) 720–0219 or FAX (202) 205–9237.

The meeting will be open to the public. Persons with disabilities who require alternative means of communication of program information or related accommodations should contact Marianne Plaus, telephone (202) 690–3460 or FAX (202) 205–9237.

Dated: November 9, 2000.

David R. Shipman,

Acting Administrator, Grain Inspection, Packers and Stockyards Administration.

[FR Doc. 00–29474 Filed 11–15–00; 8:45 am]

BILLING CODE 3410–EN–U

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–808; A–583–810]

Revocation of Antidumping Duty Orders: Chrome-Plated Lug Nuts From the People's Republic of China and Taiwan

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

ACTION: Notice of revocation of antidumping duty orders: chrome-plated lug nuts from the People's Republic of China and Taiwan.

SUMMARY: Pursuant to section 751(c) of the Tariff Act of 1930, as amended (''the Act''), the United States International Trade Commission (''the Commission'') determined that revocation of the antidumping duty orders on chrome-plated lug nuts from the People's Republic of China (''China'') and Taiwan is not likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time. See 65 FR 66558 (November 6, 2000). Therefore, pursuant to section 751(d)(2) of the Act and 19 CFR 351.222(i)(1), the Department of Commerce (''the Department'') is revoking the antidumping duty orders on chrome-plated lug nuts from China and Taiwan. Pursuant to section 751(c)(6)(A)(iv) of the Act and 19 CFR 351.222(i)(2), the effective date of revocation is January 1, 2000.

EFFECTIVE DATE: January 1, 2000.

FOR FURTHER INFORMATION CONTACT: Martha V. Douthit or James P. Maeder, Office of Policy for Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Ave., NW., Washington, DC 20230; telephone: (202) 482–5050 or (202) 482–3330, respectively.

Background

On August 2, 1999, the Department initiated, and the Commission instituted, sunset reviews of the antidumping duty orders on chrome-plated lug nuts from China and Taiwan, pursuant to section 751(c) of the Act.[1] As a result of the reviews, the Department found that revocation of the antidumping duty orders would be likely to lead to continuation or recurrence of dumping and notified the Commission of the magnitude of the margins likely to prevail were the antidumping orders revoked.[2]

On November 6, 2000, the Commission determined, pursuant to section 751(c) of the Act, that revocation of the antidumping duty orders on chrome-plated lug nuts from China and Taiwan would not likely lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time. See Chrome-Plated Lug Nuts from China and Taiwan, 65 FR 66558 (November 6, 2000) and USITC

[1] See Initiation of Five-Year (''Sunset'') Reviews; 64 FR 41915 (August 2, 1999), and Chrome-Plated Lug Nuts from China and Taiwan, 64 FR 41949 (August 2, 1999).

[2] See Chrome-Plated Lug Nuts From the People's Republic of Chin and Taiwan; Final Results of Antidumping Duty Sunset Reviews: 65 FR 11762 (March 6, 2000).

Publication 3362, Investigations Nos. 731–TA–474 and 475 (Review) (October 2000).

Scope of the Orders

The products covered by these orders are one-piece and two-piece chrome-plated and nickel-plated lug nuts from China and Taiwan. The subject merchandise includes chrome-plated and nickel-plated lug nuts, finished or unfinished, which are more than 11/16 inches (17.45 millimeters) in height and which have a hexagonal size of at least 3/4 inches (19.05 millimeters) but not over one inch (25.4 millimeters), plus or minus 1/16 of an inch (1.59 millimeters). The term ''unfinished'' refers to unplated and/or unassembled chrome-plated lug nuts. The subject merchandise is used for securing wheels to cars, vans, trucks, utility vehicles, and trailers. Excluded from the orders are zinc-plated lug nuts, finished or unfinished, stainless steel capped lug nuts, and chrome-plated lock nuts. The merchandise covered by the orders currently classifiable under item 7318.16.00 of the Harmonized Tariff Schedule of the United States (''HTSUS''). Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the subject merchandise remains dispositive.

The Department has made several scope rulings on the subject merchandise from China and Taiwan. The following products were determined to be within the scope of the order:

Product within scope	Importer	Citation
Certain hex size nuts	Consolidated International	59 FR 54888
Certain nickel-plated lug nuts	Consolidated International Automative, Inc	62 FR 9176
Imported zinc-plated lug nuts-chrome-plated in the United States.	Wheel Plus, Inc.	63 FR 59544

Determination

As a result of the determination by the Commission that revocation of these antidumping duty orders is not likely to lead to continuation or recurrence of material injury to an industry in the United States, the Department, pursuant to section 751(d)(2) of the Act and 19 CFR 351.222(i)(1), is revoking the antidumping duty orders on chrome-plated lug nuts from China and Taiwan. Pursuant to section 751(c)(6)(A)(iv) of the Act and 19 CFR 351.222(i)(2)(ii), this revocation is effective January 1, 2000.

The Department will instruct the Customs Service to discontinue the suspension of liquidation and collection of cash deposit rates on entries of the subject merchandise entered or withdrawn from warehouse on or after January 1, 2000 (the effective date). The Department will complete any pending administrative reviews of these orders and will conduct administrative reviews of subject merchandise entered prior to the effective date of revocation in response to appropriately filed requests for review.

Dated: November 9, 2000.

Troy H. Cribb,

Assistant Secretary for Import Administration.

[FR Doc. 00–29407 Filed 11–15–00; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–843]

Notice of Final Determination of Sales at Not Less Than Fair Value: Expandable Polystyrene Resins from the Republic of Korea

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

EFFECTIVE DATE: November 16, 2000.

ACTION: Notice of final determination of sales at not less than fair value.

FOR FURTHER INFORMATION CONTACT: Valerie Ellis or David Layton, at (202) 482–2336 or (202) 482–0371, respectively; Import Administration, International Trade Administration, U.S. Department of Commerce, Washington, D.C. 20230.

The Applicable Statute and Regulations

Unless otherwise indicated, all citations to the Tariff Act of 1930, as amended (the Act), are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Act by the Uruguay Round Agreements Act (URAA). In addition, unless otherwise indicated, all citations to the Department of Commerce (the Department) regulations are to 19 CFR Part 351 (1999).

Final Determination

We determine that expandable polystyrene resin (EPS) from the Republic of Korea (Korea) is not being sold, nor is likely to be sold, in the United States at less than fair value (LTFV), as provided in section 735 of the Act. The estimated margins of sales at not LTFV are shown in the ''Termination of Liquidation'' section of this notice.

Case History

The preliminary determination in this investigation was issued on June 20, 2000. *See Notice of Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination: Certain Expandable Polystyrene Resins From the Republic of South Korea,* 65 FR 39351 (June 26, 2000). The investigation covers two manufacturers/exporters: Shinho Petrochemical Co., Ltd. (Shinho) and Cheil Industries Incorporated (Cheil). Both of these companies are located in Seoul, Korea.

The Department verified the responses of Cheil Industries Incorporated in Seoul, South Korea from August 21, 2000 to August 25, 2000; Shinho Petrochemical Co., Ltd. in Seoul, South Korea from August 28, 2000 to September 1, 2000; Samsung America Incorporated (SAI), Cheil's affiliated importer, at Ridgefield Park, New Jersey from September 27, 2000 to September 28, 2000; and Cheil's Los Angeles branch and the division of Samsung America, Incorporated located in the same building, in La Mirada City, California, on September 29, 2000.

Scope of Investigation

For purposes of this investigation, the products covered includes EPS in primary forms; namely, raw material or resin manufactured in the form of polystyrene beads, whether of regular (shape) type or modified (block) type, regardless of specification, having a weighted-average molecular weight of between 160,000 and 260,000, containing from 3 to 7 percent blowing

agents, and having bead sizes ranging from 0.4 mm to 3 mm. Specifically excluded from the scope of this investigation are off-grade, off-specification expandable polystyrene resins. The covered merchandise is found in the Harmonized Tariff Schedule of the United States (HTSUS) subheading 3903.11.00.00. Although this HTSUS subheading is provided for convenience and customs purposes, the written description of the merchandise is dispositive.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties to this investigation, as well as certain other findings by the Department which are listed in an appendix to this notice, are addressed in the ''Issues and Decision Memorandum for the Final Determination in the Antidumping Duty Investigation of Expandable Polystyrene Resins from South Korea'' (Decision Memorandum), from Holly A. Kuga, Acting Deputy Assistant Secretary, Import Administration, to Troy H. Cribb, Assistant Secretary for Import Administration, dated November 8, 2000, which is hereby adopted by this notice. A list of issues which parties have raised and to which we have responded, all of which are in the Decision Memorandum, is attached to this notice as an appendix. Parties can find a complete discussion of all issues raised in this investigation and the corresponding recommendations in this public memorandum which is on file in the Central Records Unit, Room B–099 of the main Department building and on the Web at: *www.ia.ita.doc.gov.* The paper copy and electronic version of the Decision Memorandum are identical in content.

Changes Since the Preliminary Determination

Based on our analysis of comments received, we have made changes in the margin calculations for both companies under review. These changes are discussed in the relevant sections of the Decision Memo.

Termination of Suspension of Liquidation

Pursuant to section 735(c)(2) of the Act, we are instructing Customs to terminate suspension of liquidation of all entries of EPS from South Korea that are entered, or withdrawn from warehouse, for consumption on or after June 26, 2000, the date of publication of the preliminary determination. The Customs Service shall refund any cash deposit and release any bond or other security previously posted in connection with this case.

We determine that the following *de minimis* weighted-average dumping margins exist for October 1, 1998, through September 30, 1999:

Manufacturer/Exporter	Weighted Average Margin (percent)
Cheil Industries Incorporated ...	0.82
Shinho Petrochemical Co.	0.83

ITC Notification

In accordance with section 735(d) of the Act, we have notified the International Trade Commission (ITC) of our determination. As our final determination is negative, this proceeding is terminated and all securities posted will be refunded.

Notification to Interested Parties

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This determination is issued and published in accordance with sections 735(d) and 777(i)(1) of the Act.

Dated: November 8, 2000.

Joseph A. Spetrini,

Acting Assistant Secretary for Import Administration.

Appendix

Issues Covered in Decision Memorandum

I. General Issues

1. Allegations of Mexican Transshipments
2. Using Monthly Averaging Groups in Place of Annual Averages to Calculate Normal Value

II. Issues Specific to Cheil Industries, Inc. (Cheil)

3. Constructed Export Price Offset
4. Duty Drawback
5. Credit Expense—Home Market Interest Rate
6. Reclassification of Certain Sales from Constructed Export Price to Export Price
7. General & Administrative Expense
8. Inclusion of Import Duties in the Cost of Manufacture

III. Issues Specific to Shinho Petrochemical Co., Ltd (Shinho)

9. Credit Expense
10. Gain on Foreign Currency Translation

[FR Doc. 00–29405 Filed 11–15–00; 8:45 am]
BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–560–810]

Notice of Final Determination of Sales at Less Than Fair Value: Certain Expandable Polystyrene Resins From Indonesia

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

EFFECTIVE DATE: November 16, 2000.

FOR FURTHER INFORMATION CONTACT: Charles Riggle at (202) 482–0650 or David Layton at (202) 482–0371, AD/CVD Enforcement, Office V, Group II, Import Administration, International Trade Administration, U.S. Department of Commerce, Room 1870, 14th Street and Constitution Avenue, NW., Washington, DC 20230.

The Applicable Statute and Regulations

Unless otherwise indicated, all citations to the statute are references to the provisions effective January 1, 1995, the effective date of the amendments made to the Tariff Act of 1930 (the Act) by the Uruguay Round Agreements Act (URAA). In addition, unless otherwise indicated, all citations to the Department of Commerce (the Department) regulations refer to the regulations codified at 19 CFR Part 351 (2000).

Final Determination

We determine that certain expandable polystyrene resins from Indonesia are being sold, or are likely to be sold, in the United States at less than fair value (LTFV), as provided in section 735 of the Act. The estimated margins of sales at LTFV are shown in the *Suspension of Liquidation* section of this notice.

Case History

The preliminary determination in this investigation was issued on June 20, 2000. *See Notice of Preliminary Determination of Sales at Less Than Fair Value: Certain Expandable Polystyrene Resins From Indonesia*, 65 FR 39349 (June 26, 2000) (*Preliminary Determination*). No briefs were filed in this investigation.

On August 3, 2000, the Department published a **Federal Register** notice postponing the deadline for the final determination until no later than November 8, 2000. *See Notice of Postponement of Final Antidumping*

Duty Determination: Certain Expandable Polystyrene Resins from Indonesia, 65 FR 47713 (August 3, 2000).

Scope of Investigation

The scope of this investigation includes certain expandable polystyrene resins in primary forms; namely, raw material or resin manufactured in the form of polystyrene beads, whether of regular (shape) type or modified (block) type, regardless of specification, having a weighted-average molecular weight of between 160,000 and 260,000, containing from 3 to 7 percent blowing agents, and having bead sizes ranging from 0.4 mm to 3 mm.

Specifically excluded from the scope of this investigation are off-grade, off-specification expandable polystyrene resins.

The covered merchandise is found in the Harmonized Tariff Schedule of the United States (HTSUS) subheading 3903.11.00.00. Although this HTSUS subheading is provided for convenience and customs purposes, the written description of the merchandise is dispositive.

Period of Investigation

The period of investigation is October 1, 1998, through September 30, 1999.

Facts Available

In the preliminary determination, the Department based the dumping margin for the mandatory respondent, PT Risjad Brasali Styrindo (Brasali), on facts otherwise available, pursuant to section 776(a)(2)(A) of the Act. The use of facts otherwise available was required because the record did not contain company-specific information, given the respondent's failure to respond to the Department's antidumping questionnaire. For purposes of the preliminary determination, the Department also found that Brasali failed to cooperate by not acting to the best of its ability to comply with the Department's request for information, pursuant to section 776(b), and determined to use an adverse inference in selecting from among the facts otherwise available. Specifically, the Department assigned to the mandatory respondent the highest margin alleged in the petition, which was corroborated as required by section 776(c) of the Act. *See Preliminary Determination.* Following the preliminary determination, interested parties did not file any comment and have not objected to the Department's decision to use adverse facts available for the mandatory respondent in this investigation, or to the Department's choice of facts available. Accordingly, for the reasons discussed in the *Preliminary Determination*, for this final determination the Department is continuing to use the highest margin alleged by the petitioners for the mandatory respondent in this proceeding. In addition, the Department has left unchanged from the preliminary determination the ''All Others Rate'' in this investigation, which is the average of all the rates provided in the petition.

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, we are directing the Customs Service to continue to suspend all entries of expandable polystyrene resins from Indonesia, that are entered, or withdrawn from warehouse, for consumption on or after June 26, 2000, the date of publication of our preliminary determination. The Customs Service shall require a cash deposit or bond equal to the dumping margin, as indicated in the chart below. These instructions suspending liquidation will remain in effect until further notice. The dumping margins are provided below:

Manufacturer/exporter	Margin (percent)
PT Risjad Brasali Styrindo	96.65
All Others	95.79

ITC Notification

In accordance with section 735(d) of the Act, we have notified the International Trade Commission (ITC) of our determination. As our final determination is affirmative, the ITC will, within 45 days, determine whether these imports are materially injuring, or threaten material injury to, the U.S. industry. If the ITC determines that material injury or threat of material injury does not exist, the proceeding will be terminated and all securities posted will be refunded or canceled. If the ITC determines that such injury does exist, the Department will issue an antidumping duty order directing the Customs Service to assess antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation.

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This determination is issued and published pursuant to sections 735(d) and 777(i)(1) of the Act.

Dated: November 8, 2000.

Joseph A. Spetrini,

Acting Assistant Secretary, for Import Administration.

[FR Doc. 00–29406 Filed 11–15–00; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Coastal Zone Management: Federal Consistency Appeal by Ricardo Ramirez by an Objection by the Puerto Rico Planning Board

ACTION: Dismissal of appeal.

By letter dated April 6, 1999, Ricardo Ramirez (Appellant) filed with the Secretary of Commerce a notice of appeal pursuant to section 307(c)(3)(A) of the Coastal Zone Management Act. The appeal is taken from an objection by the Puerto Rico Planning Board (PRPB) to the Appellant's consistency certification for an Army Corps of Engineers permit to reconstruct a stilt house of 47′ by 42′.

The CZMA provides that a timely objection by a state (including Puerto Rico) to a consistency certification precludes any Federal agency from issuing licenses or permits for the activity unless the Secretary finds that the activity is either ''consistent with the objectives of the CZMA (Ground I) or ''necessary in the interest of national security'' (Ground II). Section 307(c)(3)(A). To make such a determination, the Secretary must find that the project satisfies the requirements of 15 CFR 930.121 or 930.122. Generally, the Appellant has the burden of submitting evidence in support of his appeal and the burden of persuasion under both Grounds I and II.

The Federal regulations implementing the CZMA provide, in part, that the Secretary may dismiss an appeal for failure of the Appellant to base the appeal on Grounds I or II.

In light of Appellant's failure to describe the way in which the proposed activity is either (1) consistent with the objectives or purposes of the CZMA or (2) necessary in the interest of national security, the appeal has been dismissed. The Appellant is barred from filing

another appeal from the Puerto Rico Planning Board's objection to his original consistency certification. This is a final agency action for purposes of judicial review.

FOR ADDITIONAL INFORMATION CONTACT: Ms. Mary Gray Holt, Attorney-Adviser, Office of the Assistant General Counsel for Ocean Services, National Oceanic and Atmospheric Administration, U.S. Department of Commerce, 1305 East-West Highway, Room 6111, Silver Spring, MD 20910, 301–713–2967.

[Federal Domestic Assistance Catalog No. 11.419 Coastal Zone Management Program Assistance]

Dated: November 2, 2000.

Craig O'Connor,

Acting General Counsel.

[FR Doc. 00–29388 Filed 11–15–00; 8:45 am]

BILLING CODE 3510–08–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 091300A]

Small Takes of Marine Mammals Incidental to Specified Activities; Explosives Testing at Eglin Air Force Base, FL

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of withdrawal of a request for a small take exemption authorization.

SUMMARY: On October 26, 2000, NMFS was notified by the U.S. Air Force that it was withdrawing its request for an authorization under the Marine Mammal Protection Act (MMPA) to take small numbers of bottlenose and spotted dolphins, by harassment, incidental to explosive testing of obstacle and mine clearance systems at Eglin Air Force Base, FL (Eglin).

ADDRESSES: A copy of the application and/or letter of withdrawal may be obtained by writing to Donna Wieting, Chief, Marine Mammal Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Silver Spring, MD 20910, or by telephoning the contact listed here.

FOR FURTHER INFORMATION CONTACT: Kenneth Hollingshead 301-713-2055 ext. 128.

SUPPLEMENTARY INFORMATION: On August 6, 2000, NMFS received a small take application, under section 101(a)(5)(D) of the MMPA, from the U.S. Air Force at Eglin Air Force Base, FL. The Air Force, in cooperation with the Naval Surface Warfare Center-Coastal Systems Station, U.S. Navy, requested, on that date, an authorization to take, by harassment and non-serious injury, bottlenose dolphins (*Tursiops truncatus*), and spotted dolphins (*Stenella frontalis*), incidental to explosive testing of an obstacle clearance system at Eglin. Eglin is located in the Florida Panhandle approximately midway between the cities of Pensacola and Panama City, FL. The location of the proposed action is on the beach areas on Santa Rosa Island, approximately 27 kilometers (17 mi) west of Destin, FL.

A notice of receipt of the application and proposed incidental harassment authorization (IHA) under the MMPA was published on October 20, 2000 (65 FR 63059), and a 30-day public comment period was provided on the application and proposed authorization. Please refer to that document for additional information on the Air Force request.

On October 26, 2000, NMFS received a letter from the Air Force at Eglin noting that the U.S. Navy does not support the acoustic modeling that was performed for the Biological Assessment under section 7 of the Endangered Species Act or the application for an IHA; in particular, a marine mammal injury threshold criterion of 5 pounds/inch2-milliseconds. The Navy believes that the methodologies and criteria developed by acousticians, energetic scientists, and independent scientific review for the SEAWOLF ship shock trial (63 FR 66069, December 1, 1998), as updated in the shock trial of the USS WINSTON CHURCHILL (65 FR 11542, March 3, 2000), are the appropriate means to establish harassment to marine mammals. As a result, the Air Force has requested NMFS to withdraw the application. The Air Force will inform NMFS if the Navy requests to use Eglin to conduct this or other tests in the future.

Dated: November 6, 2000.

Phil Williams,

Acting Deputy Director, Office of protected Resourses, National marine Fisheries Service.

[FR Doc. 00–29413 Filed 11–15–00; 8:45 am]

BILLING CODE: 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 110800D]

Fisheries of the Exclusive Economic Zone Off Alaska; Recordkeeping and Reporting Requirements; Public Workshops

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of workshops.

SUMMARY: NMFS, Alaska Region, and the U.S. Coast Guard North Pacific Regional Fisheries Training Center will present workshops on the 2001 recordkeeping and reporting requirements for the Alaska groundfish fisheries.

DATES: See **SUPPLEMENTARY INFORMATION** under the heading, ''Meeting Dates and Addresses,'' for dates the workshops will be held.

ADDRESSES: See **SUPPLEMENTARY INFORMATION** under the heading, ''Meeting Dates and Addresses,'' for meeting addresses.

FOR FURTHER INFORMATION CONTACT: Patsy A. Bearden, 907-586-7008.

SUPPLEMENTARY INFORMATION: The workshops will include discussion of proposed 2001 changes to the recordkeeping and reporting requirements for Alaska groundfish fisheries along with instructions for completion and submittal of the required forms and logsheets. Suggestions and feedback on existing procedures are welcome.

Meeting Dates and Addresses

1. November 17, 2000, 10 a.m. to 12 noon Pacific standard time—FISH EXPO, Washington State Trade and Convention Center, Room 310, Seattle, WA.
2. December 4, 2000, 9 a.m to 11 a.m. for vessels, 12:30 p.m. to 2:30 p.m. for shoreside processors, Alaska local time—Anchorage Federal Building, Room 154, 222 West Seventh Avenue, Anchorage, AK.
3. January 4, 2001, 9 a.m. to 11 a.m. for vessels, 12:30 p.m. to 2:30 p.m. for shoreside processors, Pacific standard time—NOAA Western Regional Center, 7600 Sandpoint Way, N.E., Building 9, Room A/B, Seattle, WA.
4. January 16, 2001, 9 a.m. to 11 a.m. for vessels, 12:30 p.m. to 2:30 p.m. for shoreside processors, Alaska local time—U.S. Coast Guard Base, North Pacific Regional Fisheries Training Center, Kodiak, AK.

5. January 18, 2001, 9 a.m. to 11 a.m. for vessels, Alaska local time—Unalaska City Hall, Council Chambers, Unalaska, AK.

6. January 19, 2001, 9 a.m. to 11 a.m. for shoreside processors, Alaska local time—Unalaska City Hall, Council Chambers, Unalaska, AK.

Special Accommodations

These workshops will be physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Patsy Bearden (see **FOR FURTHER INFORMATION CONTACT**) at least 7 working days prior to the meeting date.

Dated: November 9, 2000.

Bruce C. Morehead,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 00–29414 Filed 11–15–00; 8:45 am]

BILLING CODE: 3510–22 –S

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Adjustment of Import Restraint Limits for Certain Cotton, Wool, Man-Made Fiber, Silk Blend and Other Vegetable Fiber Textiles and Textile Products Produced or Manufactured in Macau

November 9, 2000.

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

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

EFFECTIVE DATE: November 16, 2000.

FOR FURTHER INFORMATION CONTACT: Ross Arnold, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482–4212. For information on the quota status of these limits, refer to the Quota Status Reports posted on the bulletin boards of each Customs port, call (202) 927–5850, or refer to the U.S. Customs website at http://www.customs.gov. For information on embargoes and quota re-openings, call (202) 482–3715.

SUPPLEMENTARY INFORMATION:

Authority: Section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854); Executive Order 11651 of March 3, 1972, as amended.

The current limits for certain categories are being increased for carryforward.

A description of the textile and apparel categories in terms of HTS numbers is available in the CORRELATION: Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 64 FR 71982, published on December 22, 1999). Also see 64 FR 70222, published on December 16, 1999.

Richard B. Steinkamp,

Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

November 9, 2000.

Commissioner of Customs,

Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on December 10, 1999, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool, man-made fiber, silk blend and other vegetable fiber textiles and textile products, produced or manufactured in Macau and exported during the period which began on January 1, 2000 and extends through December 31, 2000.

Effective on November 16, 2000, you are directed to increase the limits for the following categories, as provided for under the Uruguay Round Agreement on Textiles and Clothing:

Category	Adjusted limit [1]
Levels in Group I	
336/836	94,038 dozen.
338	495,763 dozen.
339	2,056,211 dozen.
340	479,694 dozen.
341	308,432 dozen.
342	141,059 dozen.
345	86,254 dozen.
347/348/847	1,150,548 dozen.
350/850	98,199 dozen.
351/851	107,398 dozen.
359–C/659–C [2]	589,203 kilograms.
638/639/838	2,522,327 dozen.
642/842	186,270 dozen.
647/648	839,301 dozen.
Group II	
400–431, 433–438, 440–448, 459pt. [3], 464 and 469pt. [4], as a group.	1,717,544 square meters equivalent.
Sublevel in Group II	
445/446	94,293 dozen.

[1] The limits have not been adjusted to account for any imports exported after December 31, 1999.

[2] Category 359–C: only HTS numbers 6103.42.2025, 6103.49.8034, 6104.62.1020, 6104.69.8010, 6114.20.0048, 6114.20.0052, 6203.42.2010, 6203.42.2090, 6204.62.2010, 6211.32.0010, 6211.32.0025 and 6211.42.0010; Category 659–C: only HTS numbers 6103.23.0055, 6103.43.2020, 6103.43.2025, 6103.49.2000, 6103.49.8038, 6104.63.1020, 6104.63.1030, 6104.69.1000, 6104.69.8014, 6114.30.3044, 6114.30.3054, 6203.43.2010, 6203.43.2090, 6203.49.1010, 6203.49.1090, 6204.63.1510, 6204.69.1010, 6210.10.9010, 6211.33.0010, 6211.33.0017 and 6211.43.0010.

[3] Category 459pt.: all HTS numbers except 6405.20.6030, 6405.20.6060, 6405.20.6090, 6406.99.1505 and 6406.99.1560.

[4] Category 469pt.: all HTS numbers except 5601.29.0020, 5603.94.1010 and 6406.10.9020.

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

Sincerely,

Richard B. Steinkamp,

Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 00–29363 Filed 11–15–00; 8:45 am]

BILLING CODE 3510–DR–F

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Proposed New Information Collection; Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (hereinafter the ''Corporation''), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirement on respondents can be properly assessed. This proposed information collection is available in alternate formats. Individuals who use a telecommunications device for the deaf (TTY/TDD) may call (202) 606–5256 between the hours of 9:00 a.m. and 4:30 p.m. Eastern time, Monday through Friday.

Currently, the Corporation is soliciting comments concerning its

request for information collection from schools, higher education institutions, and community-based organizations that have received grants through the federally-funded Learn & Serve America program. The information will be used to evaluate the effectiveness of the Learn & Serve America grants in promoting the institutionalization of service-learning activities in the funded institutions.

DATES: Written comments must be submitted to the office listed in the **ADDRESSES** section by January 16, 2001.

ADDRESSES: Send comments to the Corporation for National and Community Service, Attn: Mr. Charles Helfer, Office of Evaluation, 1201 New York Avenue, NW, Washington, DC, 20525.

FOR FURTHER INFORMATION CONTACT: Charles Helfer (202) 606–5000, ext. 248, or by e-mail at chelfer@cns.gov.

SUPPLEMENTARY INFORMATION: The Corporation is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Corporation, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Background

The Learn and Serve America Program was established by the National and Community Service Trust Act of 1993 (Pub.L. 103–82) to support efforts in schools, higher education institutions and community-based organizations to involve young people in meaningful service to their communities while improving academic, civic, social and career-related skills. The Learn and Serve America program is administered by the Corporation and funded through grants to states, national organizations, and institutions of higher education, and through them to individual schools and school districts, community-based organizations, and colleges or universities. The first round of grants under the Learn and Serve America program were awarded in 1994. Approximately 3500 local schools, colleges, and community-based organizations receive Learn and Serve America funds each year.

One of the primary goals of the Learn and Serve America program is to promote the expansion of service-learning opportunities for school and college-aged youth through the establishment of programs that will persist beyond the life of the Learn and Serve America grant to the institution. To accomplish this, the Learn and Serve America program encourages the growth and expansion of service-learning within grant-recipient institutions through the awarding of time-limited (3 year) grants, use of matching fund requirements for the grants, and through technical assistance and training for local grantees.

The purpose of the proposed data collection is to evaluate the effectiveness of the Learn and Serve America grants in promoting the institutionalization of service-learning in the grantee institutions and the degree to which funded programs have been and are likely to be sustained after the completion of the grant period. The evaluation will examine the growth and current status of service-learning in a sample of grantees and subgrantees from two cohorts of grant recipients: those who were funded in 1994–95, the first year of Learn and Serve America funding, and those funded in a second major round of grant awards in 1997–98. The information will be used to determine whether changes need to be made in current Learn and Serve America grantmaking policies and procedures and will help the Corporation determine the need for additional strategies (such as provision of training and technical assistance) to support institutionalization among its grantees. Data collection will take place one time as part of the proposed evaluation.

Current Collection

The Corporation seeks approval of a single, multipart survey form that will be used in the evaluation of the impact of Learn and Serve America grants on the institutionalization and sustainability of service-learning in the grantee institutions.

The survey will be broken down into separate parts consisting of : Part I—Elementary and Secondary School-based Grantees; Part II—Higher Education Institutions, and Part III—Community-based Organizations. Each Part will include a Section A—short version, and a Section B—long version. The three major parts (A, B, and C) are similar in focus and content, with variations aimed at addressing specific characteristics and circumstances at each type of institution. Each part is designed to collect information on (a) the scope and purpose of the original Learn and Serve America grant; (b) growth and expansion of specific grant-related activities; (c) the current structure and scope of service-learning at the grantee institution; (d) current policies and practices supporting institutionalization of service-learning; and (e) factors that have supported or hindered the growth of service-learning at the institution, including (f) the specific role and contribution of the Learn and Serve America grant.

The survey will be administered to a random sample of approximately 540 grantee institutions that will include representation of all of the major funding streams and program types supported through Learn and Serve America. The survey will be administered through a telephone interview with a representative of each grantee institution. One half of the telephone interviews will use the short version of the survey instrument, aimed at collecting basic information on the growth and current status of service-learning activities and on current policies and practices supporting service-learning. The other half of the interviews will use the longer version of the survey with additional questions designed to elicit more detailed information on the factors that support or hinder growth of service-learning in the institution.

The paragraph below summarizes the characteristics of the proposed data collection:

Type of Review: New request.

Agency: Corporation for National and Community Service.

Title: Institutionalization of Learn and Serve America Programs.

OMB Number: None.

Agency Number: None.

Affected Public: Institutional recipients of Learn and Serve America grants: elementary and secondary schools, higher education institutions, and community-based organizations.

Total Respondents: Approximately 540.

Frequency: One time.

Average Time Per Response: 45 minutes.

Estimated Total Burden Hours: 405 hours.

Total Burden: (capital /startup): None.

Total Burden Cost: None.

Dated: November 13, 2000.

Lance Potter,

Director, Office of Evaluation.

[FR Doc. 00–29366 Filed 11–15–00; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Intent To Grant Exclusive Patent Licenses to BTG International, Inc.

AGENCY: Department of the Navy, DOD.

ACTION: Notice.

SUMMARY: The Department of the Navy hereby gives notice of prospective licenses to BTG International Inc. to the Government-owned inventions described in:

U.S. Patent No. 5,932,006 entitled, ''BaF_2/GaAs Electronic Components'', date issued: August 3, 1999.

U.S. Patent Application Serial No. 09/197,440 entitled, ''Gallium Arsenide Semiconductor Devices Fabricated with Insulator Layer'', filing date: November 23, 1998, Navy Case No. 79412.

U.S. Patent Application Serial No. 09/563,740 entitled, ''Electronic Devices With Diffusion Barrier and Process for Making Same'', filing date: May 3, 2000, Navy Case No. 82111.

U.S. Patent Application Serial No. 09/631,121 entitled, ''Gallium Arsenide Semiconductor Devices Fabricated With Insulator Layer'', filing date: August 2, 2000, Navy Case No. 82528.

DATES: Anyone wishing to object to the grant of this license must file written objections along with supporting evidence, if any, not later than January 16, 2001.

ADDRESSES: Written objections are to be filed with the Office of Patent Counsel, Naval Surface Warfare Center, Dahlgren Laboratory, CD222, 17320 Dahlgren Road, VA 22448–5100, telephone (540) 653–8061.

Authority: 35 U.S.C. 207, 37 CFR Part 404.

Dated: November 3, 2000.

J.L. Roth,

Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 00–29389 Filed 11–15–00; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before January 16, 2001.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: November 9, 2000.

John Tressler,

Leader, Regulatory Information Management, Office of the Chief Information Officer.

Office of Special Education and Rehabilitative Services

Type of Review: Revision.

Title: Independent Living Services for Older Individuals Who are Blind.

Frequency: Annually.

Affected Public: Individuals or household; Not-for-profit institutions.

Reporting and Recordkeeping Hour Burden:

Responses: 55.

Burden Hours: 330.

Abstract: The new form will be used to evaluate and monitor Independent Living Services for Older Individuals who are blind related to: (a) the type of services provided and the number of persons receiving each type of service, (b) the amounts and percentage of funds reported on each type of service provided.

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov,* or should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW, Room 4050, Regional Office Building 3, Washington, D.C. 20202–4651. Requests may also be electronically mailed to the internet address OCIO_IMG—Issues@ed.gov or faxed to 202–708–9346. Please specify the complete title of the information collection when making your request. Comments regarding burden and/or the collection activity requirements should be directed to Sheila Carey at (202) 708–6287 or via her internet address Sheila_Carey@ed.gov. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 00–29305 Filed 11–15–00; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

SUMMARY: The Leader, Regulatory Information Management Group, Office of the Chief Information Officer invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before December 18, 2000.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Lauren Wittenberg, Acting Desk Officer, Department of Education, Office of Management and Budget, 725 17th Street, NW., Room 10235, New Executive Office Building, Washington, DC 20503 or should be electronically mailed to the internet address Lauren__Wittenberg@omb.eop.gov.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Leader, Regulatory Information Management Group, Office of the Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment.

Dated: November 9, 2000.

John Tressler,

Leader, Regulatory Information Management, Office of the Chief Information Officer.

Office of Educational Research and Improvement

Type of Review: New.

Title: National Assessment of Educational Progress (NAEP) Technology Based Assessment Project, Pretest and Field Test.

Frequency: Pilot and field test.

Affected Public: Individuals or household; Not-for-profit institutions; State, Local, or Tribal Gov't, SEAs or LEAs.

Reporting and Recordkeeping Hour Burden:

Responses: 5,750.

Burden Hours: 1,438.

Abstract: The NAEP Technology Based Assessment Project (TBA) is meant to explore the feasibility and best methods for assessing mathematics and writing on line. It is also intended to explore students' abilities to solve problems in technology-rich environments. It is anticipated that in the future such technology-based assessments will reduce assessment burden by allowing, among other things, for online administration and scoring of assessment instruments. The pilot study uses background questions and items from suitable subject questionnaires, including questions about computer use that are currently cleared for other NAEP studies.

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov,* or should be addressed to Vivian Reese, Department of Education, 400 Maryland Avenue, SW, Room 4050, Regional Office Building 3, Washington, DC 20202–4651. Requests may also be electronically mailed to the internet address OCIO__IMG__Issues@ed.gov or faxed to 202–708–9346. Please specify the complete title of the information collection when making your request. Comments regarding burden and/or the collection activity requirements should be directed to Kathy Axt at her internet address Kathy__Axt@ed.gov. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 00–29306 Filed 11–15–00; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[CFDA NO.: 84.031H]

Strengthening Institutions (SIP), American Indian Tribally Controlled Colleges and Universities (TCCU), Alaska Native and Native Hawaiian-Serving Institutions (ANNH) and Developing Hispanic-Serving Institutions (HSI) Programs; Notice Inviting Applications for Designation as Eligible Institutions for Fiscal Year (FY) 2001

Purpose of Programs: Under the Strengthening Institutions, American Indian Tribally Controlled Colleges and Universities, and Alaska Native and Native Hawaiian-Serving Institutions Programs authorized under Part A of Title III of the Higher Education Act of 1965, as amended (HEA), institutions of higher education are eligible to apply for grants if they meet specific statutory and regulatory eligibility requirements. Similarly, HSIs are eligible to apply for grants under the HSI Program, authorized under Title V of the HEA, if they meet specific statutory and regulatory requirements.

In addition, an institution that is designated as an eligible institution under those programs may also receive a waiver of certain non-Federal share requirements under the Federal Supplemental Educational Opportunity Grant (FSEOG), Federal Work Study (FWS), and Undergraduate International Studies and Foreign Language Programs (UISFLP). These first two programs are student financial assistance programs authorized under Title IV of the HEA; the third program is authorized under Title VI of the HEA. Qualified institutions may receive these waivers even if they are not recipients of grant funds under the Title III Part A or Title V programs.

Special Note: To become eligible, your institution must satisfy a criterion related to needy student enrollment and one related to Educational and General (E&G) expenditures for a particular base year. Because we changed the collection processes for determining the thresholds for these criteria, we do not have base year data beyond 1997–98. In order to award FY 2001 grants in a timely manner, we will use threshold data from base year 1997–98 rather than a later base year. In completing your eligibility application, therefore, you are to use data from the base year 1997–98.

Eligible Applicants: To qualify as an eligible institution under any of the programs included in this notice, an accredited institution must, among other requirements, have a high enrollment of needy students, and its E&G expenditures per full-time equivalent (FTE) undergraduate student must be low in comparison with the average E&G expenditures per FTE undergraduate student of institutions that offer similar instruction. The complete eligibility requirements for the HSI Program are found in 34 CFR 606.2–606.5, which was published in the **Federal Register** of December 15, 1999 (64 FR 70146–70153). The complete eligibility requirements for the remaining programs are found in 34 CFR 607.2–607.5, a portion of which was also amended in the **Federal Register** of December 15, 1999 (64 FR 70146, 70153–70155). The regulations may also be accessed by visiting the following Department of Education web site on the World Wide Web:

http:/www.ed.gov/legislation/FedRegister/finrule/1999–4/121599a.html

Enrollment of Needy Students: Under 34 CFR 606.3(a) and 607.3(a), an institution is considered to have a high enrollment of needy students if—(1) at least 50 percent of its degree students received financial assistance under one or more of the following programs: Federal Pell Grant, FSEOG, FWS, and Federal Perkins Loan Programs; or (2) the percentage of its undergraduate degree students who were enrolled on at least a half-time basis and received Federal Pell Grants exceeded the median percentage of undergraduate degree students who were enrolled on at least a half-time basis and received

Federal Pell Grants at comparable institutions that offered similar instruction.

To qualify under this latter criterion, an institution's Federal Pell Grant percentage for base year 1997–1998 must be more than the median for its category of comparable institutions provided in the table in this notice.

Educational and General Expenditures Per Full-Time Equivalent Student: An institution should compare its 1997–1998 average E&G expenditures per FTE student to the average E&G expenditure per FTE student for its category of comparable institutions contained in the table in this notice. If the applicant institution's E&G expenditures for the 1997–1998 base year are less than the average for its category of comparable institutions, it meets this eligibility requirement.

An institution's E&G expenditures are the total amount it expended during the base year for instruction, research, public service, academic support, student services, institutional support, operation and maintenance, scholarships and fellowships, and mandatory transfers.

The following table identifies the relevant median Federal Pell Grant percentages and the relevant average E&G expenditures per FTE student for the base year, 1997–98, for the four categories of comparable institutions:

Type of institution	Median Pell Grant percentage	Average E&G FTE
2-year Public Institutions	18.0%	$7,092
2-year Non-Profit Private Institutions	29.9	20,392
4-year Public Institutions	24.8	17,715
4-year Non-Profit Private Institutions	24.5	23,162

Waiver Information: Institutions of higher education that are unable to meet the needy student enrollment requirement or the E&G expenditures requirement may apply to the Secretary for waivers of these requirements, as described in 34 CFR 606.3(b), 606.4 (c) and (d), 607.3(b), and 607.4(c) and (d). *Institutions requesting a waiver of the needy student or the E&G expenditures requirement must include the detailed information as set forth in the instructions for completing the application.*

The needy student requirement waiver authority, provided in 34 CFR 606.3(b)(2) and (3) and 607.3(b)(2) and (3), refers to ''low-income'' students and families. The regulations define ''low-income'' as an amount that does not exceed 150 percent of the amount equal to the poverty level in the 1997–1998 base year as established by the U.S. Bureau of the Census, 34 CFR 606.3(c) and 607.3(c). For the purposes of this waiver provision, the following table sets forth the low-income levels for the various sizes of families:

ANNUAL LOW-INCOME LEVELS FOR 1997–98

Size of family unit	Contiguous 48 States, the District of Columbia and Outlying	Alaska	Hawaii
1	$11,835	$14,805	$13,605
2	15,915	19,905	18,300
3	19,995	25,005	22,995
4	24,075	30,105	27,690
5	28,155	35,205	32,385
6	32,235	40,305	37,080
7	36,315	45,405	41,775
8	40,395	50,505	46,470

For family units with more than eight members, add the following amount for each additional family member: $4,080 for the contiguous 48 states, the District of Columbia and outlying jurisdictions; $5,100 for Alaska; and $4,695 for Hawaii.

The figures shown as low-income levels represent amounts equal to 150 percent of the family income levels established by the U.S. Bureau of the Census for determining poverty status. The Census levels were published by the U.S. Department of Health and Human Services in the **Federal Register** on March 10, 1997 (62 FR 10856–10859).

In reference to the waiver option specified in 606.3(b)(4) and 607.3(b)(4) of the regulations, information about ''metropolitan statistical areas'' may be obtained by requesting the *Metropolitan Statistical Areas, 1999*, order number PB99–501538, from the National Technical Information Services, Document Sales, 5285 Port Royal Road, Springfield, Virginia 22161, telephone number 1–800–553–6847. There is a charge for this publication.

Applications Available: November 30, 2000.

Deadline for Transmittal of Applications:

- February 2, 2001 for applicant institutions that wish to apply for fiscal year 2001 grants under the Strengthening Institutions, American Indian Tribally Controlled Colleges and Universities, Alaska Native and Native Hawaiian-Serving Institutions, or the HSI Programs.
- May 25, 2001 for applicant institutions that wish to apply only for cost-sharing waivers under the FSEOG, FWS, or UISFLP Programs.
- February 2, 2001 for applicant institutions that wish to apply for both a grant and a waiver of the cost-sharing requirements.

Electronic Submission of Applications: For FY 2001, we are again offering applicant institutions the option of submitting their Designation of Eligibility application in hard copy or sending it electronically to our eligibility web site:

http://webprod.cbmiweb.com/title3and5/index.html

To enter the web site, you must use your institution's unique 8-digit identifier, i.e. your OPE ID number. Your business office or student financial aid office should have the OPE ID number. If your business office or student financial aid office does not have that OPE ID number, contact a Department of Education staff member using the e-mail address located at the end of the Web page or the contact persons' telephone numbers or e-mail addresses included in this notice.

You may find more detailed instructions for completing the form electronically under the ''eligibility 2001'' link at either of the following web sites:

http://www.ed.gov/offices/OPE/HEP/idues/title3a.html
http://www.ed.gov/hsi

We encourage applicants to complete their form electronically and to complete it as soon as possible. For institutions of higher education that are unable to meet the needy student enrollment requirement or the E&G expenditure requirement and wish to request a waiver of one or both of those requirements, you may complete your designation application form on-line, print the form, and attach your narrative waiver request(s) to the printed form and mail both to the address in the next paragraph.

Mail your Designation of Eligibility application request to: U.S. Department of Education, 1990 K Street, NW, Request for Eligibility Designation, Washington, DC 20006–8513.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 74, 75, 77, 82, 85, 86, 97, 98 and 99 and (b) The regulations for the SIP in 34 CFR part 607, and the HSI Program in 34 CFR part 606.

For Applications and Further Information Contact: Thomas M. Keyes or Margaret A. Wheeler, Institutional Development and Undergraduate Education Service, U.S. Department of Education, 1990 K Street, NW., Request for Eligibility Designation, Washington, DC 20006–8513. Mr. Keyes' telephone number is (202) 502–7577. Ms. Wheeler's telephone number is (202) 502–7583. Mr. Keyes and Ms. Wheeler may be reached by e-mail at:

thomas_keyes@ed.gov
margaret_wheeler@ed.gov

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Program Authority: 20 U.S.C. 1057, 1059c, and 1065a.

Dated: November 9, 2000.

A. Lee Fritschler,

Assistant Secretary, Office of Postsecondary Education.

[FR Doc. 00–29302 Filed 11–15–00; 8:45 am]

BILLING CODE 4001–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER00–3774–000]

Adirondack Hydro Fourth Branch, LLC; Notice of Issuance of Order

November 9, 2000.

Adirondack Hydro Fourth Branch, LLC (Adirondack) submitted for filing a rate schedule under which Adirondack will engage in wholesale electric power and energy transactions at market-based rates. Adirondack also requested waiver of various Commission regulations. In particular, Adirondack requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by Adirondack.

On November 1, 2000, pursuant to delegated authority, the Director, Division of Corporate Applications, Office of Markets, Tariffs and Rates, granted requests for blanket approval under Part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Adirondack should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214).

Absent a request for hearing within this period, Adirondack is authorized to issue securities and assume obligations or liabilities as guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of Adirondack's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is December 1, 2000.

Copies of the full text of the Order are available from the Commission's Public Reference Branch, 888 First Street, NE, Washington, DC 20426. The order may also be viewed on the Internet at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 00–29339 Filed 11–15–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP01–27–000]

Columbia Gas Transmission Corporation; Notice of Application

November 9, 2000.

On November 3, 2000, Columbia Gas Transmission Corporation (Columbia), P.O. Box 1273, Charleston, West Virginia 25325–1273, filed an application in Docket No. CP01–27–000 pursuant to Section 7(b) of the Natural Gas Act (NGA) and Section 157.18 of

the Commission's Regulations for permission and approval to abandon by sale to Viking Energy, Incorporated, a West Virginia corporation, certain natural gas storage facilities (known as the Grapevine B Storage field) located in Kanawha County, West Virginia, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing may be viewed at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance).

Columbia states that the Grapevine B Storage Field consists of one storage well, approximately 0.09 mile of 4-inch well pipeline, approximately 0.8 mile of 4-inch storage pipeline, one measuring and regulating station, appurtenances, and storage field reservoir of 177 acres. Columbia states that the facilities were constructed by United Fuel Gas Company, a predecessor of Columbia, and certificated in Docket No. G–1202.[1] The field was designated as Storage Field X–53 in that order. Columbia states that its authorization to own and operate the Grapevine B Storage Field was granted by the Commission in Docket No CP71–132.[2] Columbia states that historically gas has been injected into Grapevine B utilizing high pressure gas received from Line SM–80; and, withdrawal volumes have been delivered into a low pressure transmission line without compression. Columbia states that due to changes in Columbia's customer obligations, the storage field can no longer operate without compression. Due to the ''de minimus'' nature of the facilities on Columbia's storage system (Grapevine B has historically averaged a total withdrawal of 30 MMcf during the heating season), the changes in market requirements, and the sources of supply in the area of the facilities, Columbia has determined that its current and future obligation can be met without the Grapevine B Storage field. Columbia states that therefore the capital expenditure required to install the necessary compression is not warranted.

Columbia states that it does not propose the abandonment of service to any customer as a result of the proposed sale. Columbia states that there are no mainline tap consumers on the facilities to be sold nor are there any firm or non-firm contracts currently utilizing the facilities.

Questions regarding the details of this proposed abandonment should be directed to Victoria J. Hamilton, Certificate Coordinator, Columbia Gas Transmission Corporation, P.O. Box 1273, Charleston, West Virginia 25325–1273, call (304) 357–2297.

There are two ways to become involved in the Commission's review of this abandonment. First, any person wishing to obtain legal status by becoming a party to the proceedings for this abandonment should, on or before November 30, 2000, file with the Federal Energy Regulatory Commission, 888 First Street, NE, Washington, D.C. 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this abandonment. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the abandonment provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this abandonment should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

Beginning November 1, 2000, comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.ferc.fed.us/efi/doorbell.htm.*

If the Commission decides to set the application for a formal hearing before an Administrative Law Judge, the Commission will issue another notice describing that process. At the end of the Commission's review process, a final Commission order approving or denying abandonment will be issued.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 00–29346 Filed 11–15–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP01–28–000]

Columbia Gulf Transmission Company; Notice of Request Under Blanket Authorization

October 9, 2000.

Take notice that on November 3, 2000, Columbia Gulf Transmission Company (Columbia Gulf), 2603 Augusta, Suite 125, Houston, Texas 77057–5637. filed in Docket No. CP01–28–000 a request pursuant to Sections 157.205 and 157.208(b)(2), of the Commission's Regulations (18 CFR Sections 157.205 and 157.208) under the Natural Gas Act (NGA) for authorization to construct, own and operate a lateral line and related facilities to permit the delivery of natural gas to Entergy Mississippi, Inc. (EMI) and Warren Power, LLC (Warren) at EMI's existing Baxter Wilson, and to Warren's proposed Warren Power Plant, both in Warren County, Mississippi, all as more fully set forth in the application which is on file with the Commission and open to public inspection. This filing may be viewed on the web at *http://www.ferc.fed.us/online/htm* (call 202–208–2222 for assistance).

Columbia Gulf request authorization to construct and operate a delivery lateral, referred to as the Vicksburg Lateral, consisting of approximately 37 miles of 20-inch pipeline that will extend from Columbia Gulf's mainline system in Richland Parish, Louisiana to interconnections with EMI's existing Baxter Wilson Plant and with Warren's proposed Warren Power Plant. It is

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[1] *United Fuel Gas Co.,* 8 FPC¶ 945 (1949).

[2] *Columbia Gas Transmission Corp.,* 45FPC¶ 398 (1971).

stated that the lateral will accommodate up to 285,000 dt per day, both in Warren County, Mississippi. Columbia Gulf estimates a construction cost of $20,148,000, which would be financed through internally-generated funds. It is stated that Columbia Gulf will construct and operate two new points of delivery under the automatic authorization provisions of its Part 157, Subpart F blanket certificate. Columbia Gulf indicates that it will provide the requested firm transportation services under its Rate Schedule FTS–1 under agreements with a primary term of ten years and at negotiated rates.

Any questions regarding the application may be directed to Jacquelyne M. Rocan, Senior Attorney at (713) 267–4100.

Any person or the Commission's staff may, within 45 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and, pursuant to Section 157.205 of the Commission's regulations under the NGA (18 CFR 157.205), a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the NGA. Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(iii) and the instructions on the Commission's web site at *http://www.ferc.fed.us/efi/doorbell.htm*.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 00–29347 Filed 11–15–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER00–3251–000]

Exelon Generating Company, L.L.C.; Notice of Issuance of Order

November 9, 2000.

Exelon Generating Company, L.L.C. (Exelon) filed with the Commission a rate schedule under which Exelon will engage in wholesale electric power and energy transactions at market-based rates. In its filing, Exelon also requested certain waivers and authorizations. In particular, Exelon requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liabilities by Exelon. On November 8, 2000, the Commission issued an Order Granting Market-Based Rate Authority, Accepting Tariffs, Service Agreement And Power Purchase Agreement, And Waiving Code of Conduct (Order), in the above-docketed proceeding.

The Commission's November 8, 2000 Order granted the request for blanket approval under Part 34, subject to the conditions found in Ordering Paragraphs (C), (D), and (F):

(C) Within 30 days of the date of issuance of this order, any person desiring to be heard or to protest the Commission's blanket approval of issuances of securities or assumptions of liabilities by Exelon should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.211 and 385.214.

(D) Absent a request to be heard within the period set forth in Ordering Paragraph (C) above, Exelon is hereby authorized to issue securities and assume obligations and liabilities as guarantor, indorser, surety or otherwise in respect of any security of another person; provided that such issue or assumption is for some lawful object within the corporate purposes of Exelon, compatible with the public interest, and reasonably necessary or appropriate for such purposes.

(F) The Commission reserves the right to modify this order to require a further showing that neither public nor private interests will be adversely affected by continued Commission approval of Exelon's issuances of securities or assumptions of liabilities * * *.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is December 8, 2000.

Copies of the full text of the Order are available from the Commission's Public Reference Branch, 888 First Street, NE., Washington, DC 20426. The Order may also be viewed on the Internet at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 00–29338 Filed 11–15–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP99–94–003]

Florida Gas Transmission Company; Notice of Application

November 9, 2000.

Take notice that on November 3, 2000, Florida Gas Transmission Company (FGT), 1400 Smith Street, P.O. Box 1188, Houston, Texas 77251–1188, filed in Docket No. CP99–94–003, pursuant to Section 7(c) of the Natural Gas Act (NGA) and Part 157 of the Federal Energy Regulatory Commission's (Commission) Regulations, to amend its certificate issued in Docket Nos. CP99–94–000 and –001 on February 28, 2000, to modify certain facilities located in Hillsborough County, Florida, all as more fully set forth in the application which is on file with the Commission and open to public inspection. This filing may be viewed at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance).

As part of the Phase IV Expansion FGT was authorized to construct the Tampa South Lateral Extension (5.62 miles of 4-inch line starting at the terminus of the existing Tampa South Lateral near mile post 16.5) and a measurement and regulation station, located at the end of the extension, to serve as a gas delivery point to National Gypsum Company (National Gypsum). By this amendment, FGT seeks authorization to: (1) Change the route of the Tampa South Lateral Extension by constructing approximately 6.18 miles of pipeline (starting at mile post 14.8 on the existing Tampa South Lateral); (2) change the pipe diameter by constructing the first 5.97 miles as 6-inch; and the last 0.21 miles as 8-inch pipeline; and (3) change the location of the regulation station to mile post 5.97 on the Tampa South Lateral Extension. The National Gypsum measurement station will not be relocated.

FGT explains that, as amended: (1) The new route for the Tampa South Lateral Extension will result in less of an impact to the environment; (2) the upsizing of the first 5.97 miles of pipeline to 6-inch diameter will accommodate future gas deliveries by FGT to Big Bend Transfer Company (Big Bend); and (3) relocating the construction of the regulation station to a site 0.21 miles upstream of the National Gypsum measurement station will, along with upsizing the last 0.21 miles of pipeline to 8-inch diameter, accomplish the reduction of delivery

pressures to no higher than 25 psi, as requested by National Gypsum. FGT states that there will be no incremental construction costs passed on to FGT's customers because Big Bend and National Gypsum have agreed to reimburse FGT for all additional construction costs. FGT further states that the changes proposed will have no effect on the mainline capacity, the rates, or the market data as reflected in FGT's August 31, 1999, filing in its Phase IV certificate proceeding.

Questions regarding the details of this proposed project should be directed to Mr. Stephen T. Veatch, Director of Certificates and Regulatory Reporting, Suite 3997, 1400 Smith Street, Houston, Texas 77002 or call (713) 853–6549.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before November 30, 2000, file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 14 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission may issue a preliminary determination on non-environmental issues prior to the completion of its review of the environmental aspects of the project. This preliminary determination typically considers such issues as the need for the project and its economic effect on existing customers of the applicant, on other pipelines in the area and on landowners and communities. For example, the Commission considers the extent to which the applicant may need to exercise eminent domain to obtain rights-of-way for the proposed project and balances that against the non-environmental benefits to be provided by the project. Therefore, if a person has comments on community and landowner impacts from this proposal, it is important either to file comments or to intervene as early in the process as possible.

Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.ferc.fed.us/efi/doorbell.htm.*

If the Commission decides to set the application for a formal hearing before an Administrative Law Judge, the Commission will issue another notice describing that process. At the end of the Commission's review process, a final Commission order approving or denying a certificate will be issued.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 00–29345 Filed 11–15–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01–77–000]

Midwestern Gas Transmission Company; Notice of Tariff Filing

November 9, 2000.

Take notice that on November 2, 2000, Midwestern Gas Transmission (Midwestern), tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the following revised tariff sheets, with an effective date of December 1, 2000:

Second Revised Sheet No. 60
Sixth Revised Sheet No. 61

Midwestern states that the purpose of this filing is to revise its tariff in order to incorporate GISB Standards' language and terms. Further, Midwestern states the revisions will bring Midwestern's Tariff more in-line with standard practices across the interstate pipeline grid.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at @http://www.ferc.fed.us/efi/doorbell.htm.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 00–29333 Filed 11–15–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01–80–000]

Majave Pipeline Company; Notice of Proposed Changes in FERC Gas Tariff

November 9, 2000.

Take notice that on November 2, 2000, Mojave Pipeline Company (Mojave), tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, First Revised Sheet No. 236, with an effective date of December 3, 2000. Mojave also filed a revised Statement on Standards of Conduct.

Majave states that this filing updates Mojave's Standards of Conduct and related tariff sheets.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(ii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

Linwood A. Watson, Jr.,

Acting Secretary

[FR Doc. 00–29336 Filed 11–15–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP00–399–000]

National Fuel Gas Supply Corporation; Notice Rescheduling Technical Conference

November 9, 2000.

Take notice that the conference scheduled for Tuesday, November 14, 2000, at 10 a.m. has been rescheduled.

The conference will be held on Tuesday, December 5, 2000, at 10 a.m. in a room to be designated at the offices of the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

All interested persons and Staff are permitted to attend.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 00–29332 Filed 11–15–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER00–3767–000]

Praxair, Inc.; Notice of Issuance of Order

November 9, 2000.

Praxair, Inc. (Praxair) submitted for filing a rate schedule under which Praxair will engage in wholesale electric power and energy transactions at market-based rates. Praxair also requested waiver of various Commission regulations. In particular, Praxair requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by Praixair.

On November 2, 2000, pursuant to delegated authority, the Director, Division of Corporate Applications, Office of Markets, Tariffs and Rates, granted requests for blanket approval under Part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Praxair should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214).

Absent a request for hearing within this period, is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of Praxair's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is December 4, 2000.

Copies of the full text of the Order are available from the Commission's Public Reference Branch, 888 First Street, NE., Washington, DC 20426. The Order may also be viewed on the Internet at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 00–29342 Filed 11–15–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER01–40–000]

Quinnipiac Energy, LLC; Notice of Issuance of Order

November 9, 2000.

Quinnipiac Energy, LLC (Quinnipiac) submitted for filing a rate schedule under which Quinnipiac will engage in wholesale electric power and energy transactions at market-based rates. Quinnipiac also requested waiver of various Commission regulations. In particular, Quinnipiac requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuance of securities and assumptions of liability by Quinnipiac.

On November 3, 2000, pursuant to delegated authority, the Director, Division of Corporate Applications, Office of Markets, Tariffs and Rates, granted requests for blanket approval under Part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by Quinnipiac should file a motion to intervene or protest with the Federal Energy Regulatory Commission,

888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214).

Absent a request for hearing within this period, Quinnipiac is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuance or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of Quinnipiac's issuances of securities or assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is December 4, 2000.

Copies of the full text of the Order are available from the Commission's Public Reference Branch, 888 First Street, NE., Washington, DC 20426. The Order may also be viewed on the Internet at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 00–29340 Filed 11–15–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01–83–000]

Seagull Marketing Services, Inc., Complainant, v. Columbia Gulf Transmission Company, Respondent; Notice of Complaint

November 9, 2000.

Take notice that on November 8, 2000, pursuant to Sections 5, 7, and 16 of the Natural Gas Act (NGA), 15 U.S.C. 717d, 717f, and 717o, and Rule 206 of the Commission's Rules of Practice and Procedure, 18 CFR 385.206, Seagull Marketing Services, Inc. (Seagull) tendered for filing a complaint against Columbia Gulf Transmission Company (Columbia Gulf). Seagull has requested Fast Track processing under 18 CFR 385.206(h).

Seagull alleges that Columbia Gulf has used an inappropriate cash-out price for imbalance volumes and improperly assessed imbalance penalties against Seagull that are in violation of Sections 5 and 7 of the NGA, Part 284 of the Commission's regulations, operative provisions of the currently effective Columbia Gulf Tariff (Tariff), and Commission policy and precedent.

Seagull requests Fast Track processing under 18 CFR 385.206(h) because of the threat of additional monthly imbalance penalties. To the extent that Fast Track procedures do not apply, Seagull asks the Commission to issue an immediate stay of any further assessment by Columbia Gulf of monthly imbalance penalties pending a disposition on the merits of this complaint.

Any person desiring to be heard or to protest this filing should file a motion to intervene or protest with the Federal Energy Regulation Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests must be filed on or before November 28, 2000. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may also be viewed on the Internet at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222) for assistance. Answers to the complaint shall also be due on or before November 28, 2000.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 00–29343 Filed 11–15–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01–78–000]

Tennessee Gas Pipeline Company; Notice of Tariff Filing

November 9, 2000.

Take notice that on November 2, 2000, Tennessee Gas Pipeline Company (Tennessee), tendered for filing as part of its FERC Gas Tariff, Fifth Revised Volume No. 1, the following revised tariff sheets, with an effective date of December 1, 2000:

Fifth Revised Sheet No. 310
Second Revised Sheet No. 311
Sixth Revised Sheet No. 312

Tennessee states that the purpose of this filing is to revise its tariff in order to incorporate GISB Standards' language and terms, as well as provide more conciseness and clarity to this tariff provision. Further, Tennessee states the revisions will bring Tennessee's tariff more in-line with standard practices across the interstate pipeline grid.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(ii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

Linwood A. Watson, Jr.,

Acting Secretary

[FR Doc. 00–29334 Filed 11–15–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01–81–000]

Tennessee Gas Pipeline Company; Notice of Proposed Changes in FERC Gas Tariff

November 9, 2000.

Take notice that on November 3, 2000, Tennessee Gas Pipeline Company (Tennessee), as part of its FERC Gas Tariff, Fifth Revised Volume No. 1, original and revised tariff sheets listed in Appendix A to the filing, with an effective date of December 14, 2000.

Tennessee states that the tariff sheets setting a new rate schedule Rate Schedule FT–H pursuant to which Tennessee will provide a firm hourly transportation service which would allow shippers to take delivery of their

scheduled quantity at an hourly rate that exceeds 1/24th of such scheduled quantity. FT–H service will be available on an open access, non-discriminatory basis to all shippers who meet the eligibility requirements for such service.

Tennessee states that under Rate Schedule FT–H, Tennessee will transport natural gas for a shipper up to a specified daily transportation quantity (TQ) and allow the shipper to take delivery of its scheduled quantity up to a specified maximum hourly delivery quantity (MHQ). Under Rate Schedule FT–H, the MHQ must be no less than 1/18th of the TQ and no greater than 1/4th of the TQ. Tennessee will provide the FT–H service only after it determines that it has sufficient uncommitted capacity to perform the service requested by a shipper. The FT–H service will not degrade the firm primary rights of any of Tennessee's existing firm shippers. Rate Schedule FT–H service will have the same scheduling and curtailment priority as Tennessee's other firm transportation services.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 00–29337 Filed 11–15–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP97–255–015]

TransColorado Gas Transmission Company; Notice of Compliance Filing

November 9, 2000.

Take notice that on November 2, 2000, TransColorado Gas Transmission Company (TransColorado) tendered for filing of its FERC Gas Tariff, Original Volume No. 1, Fifteenth Revised Sheet No. 21, and Eleventh Revised Sheet No. 22, with an effective date of November 1, 2000:

TransColorado states that the filing is being made in compliance with the Commission's letter order issued March 20, 1997, in Docket No. RP97–255–000.

TransColorado states that the tendered tariff sheets revised TransColorado's tariff to reflect the new negotiated-rate firm transportation service contracts with Barrett Resources Corporation and Retex, Inc.

TransColorado stated that a copy of this filing has been served upon all parties to this proceeding, TransColorado's customers, the Colorado Public Utilities Commission and the New Mexico Public Utilities Commission.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations, Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.ferc.fed.us/efi/doorbell.htm.*

Linwood a. Watson, Jr.,

Acting Secretary.

[FR Doc. 00–29331 Filed 11–15–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RP01–79–000]

Transcontinental Gas Pipe Line Corporation; Notice of Tariff Filing

November 9, 2000.

Take notice that on November 3, 2000 Transcontinental Gas Pipe Line Corporation (Transco) tendered for filing to become part of its FERC Gas Tariff, Third Revised Volume No. 1, Thirtieth Revised Sheet No. 50, with an effective date of November 1, 2000.

Transco states that the purpose of the instant filing is to track fuel changes attributable to transportation service purchased from Texas Gas Transmission Corporation (Texas Gas) under its Rate Schedule FT the costs of which are included in the rates and charges payable under Transco's Rate Schedule FT–NT. This filing is being made pursuant to tracking provisions under Section 4 of the Transco's Rate Schedule FT-NT. Transco states that included in Appendix B attached to the filing is the explanation of the fuel changes and details regarding the computation of the revised FT–NT fuel percentages.

Transco states that copies of the filing are being mailed to each of its FT–NT customers and interested State Commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Sections 385.214 or 385.211 of the Commission's Rules and Regulations. All such motions or protests must be filed in accordance with Section 154.210 of the Commission's Regulations. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See 18 CFR 385.2001(a)(1)(iii) and the instructions

on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

Linwood A. Watson, Jr.

Acting Secretary.

[FR Doc. 00–29335 Filed 11–15–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER01–36–00]

USPowerEnergy, LLC; Notice of Issuance of Order

November 9, 2000.

USPowerEnergy, LLC (USPowerEnergy) submitted for filing a rate schedule under which USPowerEnergy will engage in wholesale electric power and energy transactions at market-based rates. USPowerEnergy also requested waiver of various Commission regulations. In particular, USPowerEnergy requested that the Commission grant blanket approval under 18 CFR Part 34 of all future issuances of securities and assumptions of liability by USPowerEnergy.

On November 2, 2000, pursuant to delegated authority, the Director, Division of Corporate Applications, Office of Markets, Tariffs and Rates, granted requests for blanket approval under Part 34, subject to the following:

Within thirty days of the date of the order, any person desiring to be heard or to protest the blanket approval of issuances of securities or assumptions of liability by USPowerEnergy should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214).

Absent a request for hearing within this period, USPowerEnergy is authorized to issue securities and assume obligations or liabilities as a guarantor, indorser, surety, or otherwise in respect of any security of another person; provided that such issuances or assumption is for some lawful object within the corporate purposes of the applicant, and compatible with the public interest, and is reasonably necessary or appropriate for such purposes.

The Commission reserves the right to require a further showing that neither public nor private interests will be adversely affected by continued approval of USPowerEnergy's issuance of securities of assumptions of liability.

Notice is hereby given that the deadline for filing motions to intervene or protests, as set forth above, is December 4, 2000.

Copies of the full text of the Order are available from the Commission's Public Reference Branch, 888 First Street, NE., Washington, DC 20426. The Order many also be viewed on the Internet at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance).

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 00–29341 Filed 11–15–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER01–388–000]

WFEC GENCO, L.L.C.; Notice of Filing

November 9, 2000.

Take notice that on November 7, 2000, WFEC GENCO, L.L.C., petitioned the Commission for acceptance of its Rate Schedule FERC No. 1, the granting of certain blanket approvals, including the authority to sell electricity at market-based rates, and the waiver of certain of the Commission's Regulations.

Any person desiring to be heard or to protest such filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions and protests should be filed on November 20, 2000. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection. This filing may also be viewed on the Internet at *http://www.ferc.fed.us/online/rims.htm* (call 202–208–2222 for assistance). Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.ferc.fed.us/efi/doorbell.htm*

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 00–29344 Filed 11–15–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project Nos. 1759–036, 2074–007, 2072–008, 11830–000, 2073–008, 11831–000, 2131–020, and 1980–009—Michigan/Wisconsin]

Wisconsin Electric Power Company; Notice of Availability of Environmental Assessment

November 9, 2000.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR Part 380 (Order No. 486, 52 FR 47897), the Office of Energy Projects has reviewed the applications for new and subsequent licenses for the existing Way Dam, Hemlock Falls, Lower Paint, Peavy Falls, Michigamme Falls, Twin Falls, Kingsford, and Big Quinnesec Falls Projects, collectively referred to as the Upper Menominee River Basin Projects, located on the Menominee River and its tributaries, the Paint and Michigamme Rivers, in Dickinson and Iron Counties, Michigan, and Florence and Marinette Counties, Wisconsin, and has prepared an Environmental Assessment (EA) for the projects. In the EA, the Commission staff has analyzed the potential environmental effects of the projects and has concluded that approval of the projects, with appropriate environmental measures, would not constitute a major Federal action significantly affecting the quality of the human environment.

Copies of the EA are available for review in the Commission's Public Reference Branch, Room 2A, located at 888 First Street, NE, Washington, DC 20426. The EA may also be viewed on the Internet at *http://www.ferc.fed.us/online/rims.htm*. Please call (202) 208–2222 for assistance.

Any comments should be filed by December 1, 2000, and should be addressed to David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426. Please affix Project Nos. 1759–036, 2074–007, 2072–008, 11830–000, 2073–008, 11831–000, 2131–020, and 1980–009 to all

comments. Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.ferc.fed.us/efi/doorbell.htm*.

For further information, please contact Patti Leppert at (202) 219–2767.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 00–29348 Filed 11–15–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2471–005—Michigan]

Wisconsin Electric Power Company; Notice of Availability of Environmental Assessment

November 9, 2000.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission) regulations, 18 CFR Part 380 (Order No. 486, 52 FR 47897), the Office of Energy Projects has reviewed the application to surrender license for the Sturgeon Plant Project located on the Sturgeon River, a tributary of the Menominee River, in Dickinson County, Michigan, and has prepared an Environmental Assessment (EA) for the project. In the EA, the Commission staff has analyzed the potential environmental effects of the proposed action and has concluded that accepting surrender of the license, with appropriate environmental measures, would not constitute a major Federal action significantly affecting the quality of the human environment.

Copies of the EA are available for review in the Commission's Public Reference Branch, Room 2A, located at 888 First Street, NE, Washington, DC 20426. The EA may also be viewed on the Internet at *http://www.ferc.fed.us/online/rims.htm*. Please call (202) 208–2222 for assistance.

Any comments should be filed by December 1, 2000, and should be addressed to David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE, Washington, DC 20426. Please affix Project No. 2471–005 to all comments. Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.ferc.fed.us/efi/doorbell.htm*.

For further information, please contact Patti Leppert at (202) 219–2767.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 00–29349 Filed 11–15–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Scoping Meetings and Site Visits and Soliciting Scoping Comments

November 9, 2000.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* A New Major License.

b. *Project Nos.:* 2597–018 and 2576–023.

c. *Date filed:* August 31, 1999.

d. *Applicant:* Northeast Generation Company.

e. *Names of Projects:* Falls Village Project and Housatonic Project which are filed as a single application under the designation ''The Housatonic River Project.''

f. *Location:* On the Housatonic River, near the towns of Canaan, North Canaan, Salisbury, Bridgewater, Brookfield, Danbury, Kent, Monroe, Newtown, New Fairfield, New Milford, Oxford, Roxbury Sherman and Southbury, in Fairfield, New Haven and Litchfield counties, Connecticut. Approximately 74 acres of federal land are within project boundaries.

g. *Filed Pursuant to:* Federal Power Act, 16 USC 791(a)–825(r).

h. *Applicant Contact:* Mr. Robert A. Gates, Project Manager, Northeast Generating Services, 143 West Street, New Milford, Connecticut 06776 (860) 354–8840. Gatesr@nu.com

i. *FERC Contact:* James T. Griffin, (202) 219–2799.

j. *Deadline for filing scoping comments:* 60 days from the issuance of this Notice.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Agency Regulatory Commission, 888 First Street, NE, Washington, DC 20426. Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at *http://www.ferc.fed.us/efi/doorbell.htm*.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Status of environmental analysis:* This application is not ready for environmental analysis at this time.

l. *Description of the projects:*

The two projects represented in the Housatonic River Project Application comprise five developments: the Falls Village, Bulls Bridge, Shepaug, Rocky River and Stevenson developments are located on the Housatonic River, 76.2 miles, 52.9 miles, 44.1 miles, 30.0 and 19.3 miles respectively from its mouth.

1. *The Falls Village* development consists of the following existing facilities: (a) A 300-foot-long, 14-foot-high concrete gravity dam with two spillways having a combined overflow length of approximately 280 feet, and a crest elevation of 631.5 feet National Geodetic Vertical Distance (NGVD); (b) an impoundment 3.8 miles long containing 1,135 acre-feet when at elevation 633.2 feet NGVD; (c) a dam-integral powerhouse with a total installed capacity of 9.0 megawatts (MW) producing approximately 39,733,500 kilowatt-hours (kWh) annually; and (d) a switch yard connected to the project via a 69 kilovolt (kV) interconnected transmission line.

2. *The Bulls Bridge* development consists of: (a) A 203-foot-long, 24-foot-high stone and concrete gravity dam with a dam crest of 354 feet NGVD; (b) a two-mile-long power canal; (c) a 156-foot-long, 17-foot-high rock fill gravity weir dam; (d) a 2.25-mile-long reservoir with an 1,800 acre-feet storage capacity and a surface area of approximately 120 acres at normal elevation of 354 feet NGVD; (e) a powerhouse with a capacity of 7.2 MW, developing an average of 44,079,300 kWh annually; and (f) a 69 kV line which connects the development to the Rocky River development.

3. The *Rocky River Pumped Storage* development consists of: (a) A 952-foot-long earth-filled core wall dam, a 2,500-foot-long earthen canal dike that forms the north bank of the power canal to the intake structure, two earthen and one concrete Lanesville dike, Recreation Point and Danbury dikes, a dam crest elevation averaging 440.1 feet NGVD, and an intake canal 3,190 feet in length; (b) the seven mile-long Candlewood

Lake reservoir with a 5,610 acre impoundment at 428.1 feet NGVD; (c) a powerhouse with a rated capacity of 31,000 kW and averaging 14,238,100 kWh production per year; and (d) a development connection to the applicant's transmission system via the Rocky River-Carmel Hill 1813 line, the Rocky River-Bull Bridge 1555 line and the Rocky River-West Brookfield 1618 line.

4. The *Shepaug* development consists of: (a) A 1412-foot, bedrock-anchored, concrete gravity dam having a crest elevation of 205.3 feet NGVD; (b) an impoundment, at maximum operational elevation level of 198.3 feet NGVD, measuring 1,870 acres; (c) a powerhouse with a rated capacity of 37,200 kW, with an average annual production of 129,663,300 kWh and (d) a development connection to the applicant's transmission system via the Shepaug-Bates 1622 line and the Shepaug-Stony-Hill-West Brookfield 1887 line.

5. The *Stevenson* Development consists of: (a) A 1,250-foot, bedrock-anchored, concrete gravity dam with a crest elevation of 98.3 feet NGVD, 696 feet of spillway and an integral powerhouse; (b) an impoundment having a surface area measuring 1,063 acres at 101.3 feet NGVD, with a storage volume of 2,650 acre-feet; (c) a powerhouse with a rated capacity of 30,500 kW, with an average annual production of 92,970,270 kWh; and (d) a development connection to the applicant's transmission system via several 115-kV transmission lines.

m. *Locations of the application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE, Room 2A, Washington, D.C. 20246, or by calling (202) 208–1371. This filing may be viewed on the web at http://www.ferc.fed.us/online/rims.htm (call 202–208–2222 for assistance). A copy is also available for inspection and reproduction at the address in item h above.

n. *Scoping Process:* The Commission intends to prepare an Environmental Assessment (EA) for the proposed relicensing of the Falls Village Project (FERC No. 2597–018) and Housatonic Project (FERC No. 2576–023), in accordance with the National Environmental Policy Act. The EA will consider both site-specific and cumulative environmental impacts and reasonable alternatives to the proposed actions.

Scoping Meetings

The Commission will hold three scoping meetings, one in the daytime and two in the evening, to help us identify the scope of issues to be addressed in the EA.

The daytime scoping meeting will focus on resource agency concerns, while the evening scoping meetings are primarily for public concerns. All interested individuals, organizations, and agencies are invited to attend either or both meetings, and to assist the staff in identifying the scope of the environmental issues that should be analyzed in the EA. The times and locations of these meetings are as follows:

Evening Meetings

Monday, December 4, 2000, 7:00 to 9:00 p.m., Lee Kellogg Elementary School, Multipurpose Room, 47 Main Street, Falls Village, CT 06031

Wednesday, December 6, 2000, 7:00 to 9:00 p.m., Northville Elementary School Cafeteria, 22 Hipp Road, New Milford, CT 06776

Afternoon Meeting

Thursday, December 7, 2000, 1:00—3:00 p.m., First South Congregational Church, Stanley Room (Second Floor), 277 Main St., Hartford, CT 06106

To help focus discussions, we will distribute to parties on the Commission's mailing list a Scoping Document (SD1) outlining the subject areas to be addressed in the EA. Copies of the SD1 will also be available at the scoping meetings.

Objectives

At the scoping meetings, the staff will: (1) Summarize the environmental issues that the Commission staff tentatively has identified for analysis in the EA; (2) take statements from experts and the public on issues that should be analyzed in the EA, including viewpoints in opposition to, or in support of, those issues identified by the Commission staff; (3) identify those issues that require a detailed analysis, as well as those issues that do not require a detailed analysis; and (4) solicit all available information, especially quantifiable data, on the resources at issue;

The meetings will be recorded by a stenographer and will become part of the formal record of the Commission's proceeding on the project. Individuals presenting statements at the meeting will be asked to sign in before the meeting starts and to identify themselves clearly for the record.

Individuals, organizations, and agencies are encouraged to attend the meeting and to assist the staff in defining and clarifying the issues to be addressed in the EA.

Site Visit

The applicant and the Commission staff will conduct a project site visit in two segments on December 5th and 6th, 2000. The first day we will meet at 8:30 a.m. the Northeast Generation Services—CT Hydro Office parking lot in New Milford and travel by bus to the facilities in the upper part of the study area, returning to New Milford at about 4:00 p.m. The second day we will meet at the same location and time but will proceed (again by bus) to the southern facilities, completing the visit in New Milford at about 4:00 p.m. If you would like to attend one or both days of the site visit, please call (Robert Gates of Northeast Generation Services), no later than December 1, 2000, at (860)354–8840 or at *gatesr @nu.com.*

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 00–29350 Filed 11–15–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Extension of Time for Notice of Transfer of Licenses and Soliciting Comments, Motions To Intervene, and Protests

November 9, 2000.

In light of requests in recent filings for an extension of time to comment regarding the above-captioned proceeding, the Commission hereby extends the comment date 45 days.

Take notice that the following application has been filed with the Commission and is available for public inspection:

a. *Application Type*: Transfer of Licenses.

b. *Project Nos*: 2894–005, 9184–006, and 9185–005.

c. *Date Filed*: August 16, 2000.

d. *Applicants*: Northwestern Wisconsin Electric Company (transferor) and Flambeau Hydro, LLC (transferee).

e. *Name and Location of Projects*: The Black Brook Dam Project is on the Apple River in Polk County, Wisconsin. The Danbury Dam Project is on the Yellow River and the Clam River Dam Project is on the Clam River, both in Burnett County, Wisconsin. The projects do not occupy federal or tribal lands.

f. *Filed Pursuant to*: Federal Power Act, 16 U.S.C. 791(a)–825(r).

g. *Applicant Contacts*: Mr. Mark F. Dahlberg, Northwestern Wisconsin Electric Company, P.O. Box 9, Grantsburg, WI 54840–0009, (715) 463–

5371 and Mr. Donald H. Clarke, Wilkinson Barker Knauer, LLP, 2300 N Street NW, No. 700, Washington, DC 20037, (202) 783–4141.

h. *FERC Contact*: Any questions on this notice should be addressed to James Hunter at (202) 219–2839.

i. *Deadline for filing comments and or motions*: November 27, 2000.

All documents (original and eight copies) should be filed with: David P. Boergers, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE, Washington DC 20426. Comments and protests may be filed electronically via the internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's web site at http://www.ferc.fed.us/efi/doorbell.htm.

Please include the noted project numbers on any comments or motions filed.

j. *Description of Proposal*: The applicants state that the transfer will assure the continued operation of these hydroelectric projects and will effect the desired change of ownership of the generating facilities consistent with the restructuring plans of these members of the electric industry.

k. *Locations of the application*: A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE, Room 2A, Washington, DC 20426, or by calling (202) 208–1371. The application may be viewed on the web at www.ferc.fed.us/online/rims.htm (Call (202) 208–2222 for assistance). A copy is also available for inspection and reproduction at the addresses in item g above.

l. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS'', ''RECOMMENDATIONS FOR TERMS AND CONDITIONS'', ''PROTEST'', or ''MOTION TO INTERVENE'' as applicable, and the Project Number of the particular application to which the filing refers. Any of the above-named documents must be filed by providing the original and the number of copies provided by the Commission's regulations to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

Agency Comments—Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 00–29351 Filed 11–15–00; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Sunshine Act Meeting

November 14, 2000.

The following notice of meeting is published pursuant to section 3(A) of the Government in the Sunshine Act (Pub. L. No. 94–409), 5 U.S.C 552B:

AGENCY HOLDING MEETING: Federal Energy Regulatory Commission.

DATE AND TIME: November 21, 2000, 10 a.m.

PLACE: Room 2C, 888 First Street, NE., Washington, DC 20426.

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda

NOTE: Items listed on the agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION: David P. Boergers, Secretary, Telephone (202) 208–0400, For a recording listing items stricken from or added to the meeting, call (202) 208–1627.

This is a list of matters to be considered by the Commission. It does not include a listing of all papers relevant to the items on the agenda; however, all public documents may be examined in the reference and information center.

754th—Meeting November 21, 2000, Regular Meeting (10:00 a.m.)

Consent Agenda—Markets, Tariffs and Rates—Electric

CAE–1.
Docket# ER00–3771, 000, Firstenergy Operating Companies

CAE–2.
Docket# ER00–3740, 000, New York Independent System Operator, Inc.

CAE–3.
Docket# ER00–3785, 000, Virginia Electric & Power Company

CAE–4.
Omitted

CAE–5.
Docket# ER01–62, 000, Entergy Services, Inc.
Other#s ER00–2621, 000, Entergy Services, Inc.
ER00–3671, 000, Entergy Services, Inc.

CAE–6.
Docket# ER01–66, 000, Pacific Gas and Electric Company

CAE–7.
Docket# ER01–80, 000, California Power Exchange Corporation
Other#s ER01–81, 000, California Power Exchange Corporation

CAE–8.
Omitted

CAE–9.
Docket# ER01–180, 000, New York Independent System Operator, Inc.

CAE–10.
Docket# ER01–102, 000, Cinergy Services, Inc.

CAE–11.
Docket# ER00–3577, 000, New England Power Pool

CAE–12.
Docket# ER00–3691, 000, Sithe Edgar LLC, Sithe New Boston LLC, Sithe Framingham LLC, Sithe West Medway LLC, Sithe Wyman LLC, Sithe Mystic LLC, AE–Energy, L.P., Power City Partners, L.P., Seneca Power Partners, L.P., Sterling Power Partners, L.P., Sithe Power Marketing, L.P. and Sithe Power Marketing, Inc.

CAE–13.
Docket# ER01–53, 000, Confederated Tribes of the Warm Springs Reservation of Oregon, a Federally Recognized Indian Tribe, and Warm Springs Power Enterprises, a Chartered Enterprise of the Confederated Tribes of the Warm Springs Reservation of Oregon

CAE–14.
Docket# ER00–188, 001, PSI Energy, Inc.

CAE–15.
Docket# ER99–3531, 000, Southern Company Services, Inc.
Other#s ER99–3531, 001, Southern Company, Services, Inc.
ER99–4384, 000, Southern Company, Services, Inc.
ER99–4384, 001, Southern Company, Services, Inc.

CAE–16.
Docket# EC00–63, 000, Sierra Pacific Power Company, Nevada Power Company and Portland General Electric Company
Other#s ER00–1801, 000, Sierra Pacific Power Company, Nevada Power

Company and Portland General Electric Company
CAE–17.
Docket# EC00–136, 000, Madison Gas & Electric Company, Wisconsin Public Service Corporation and American Transmission Company, LLC
CAE–18.
Docket# EC00–80, 000 Portland General Electric Company
CAE–19.
Docket# EC00–118, 000, Arizona Public Service Company, Pinnacle West Capital Corporation and Pinnacle West Energy Corporation
Other#s EC00–118, 001, Arizona Public Service Company, Pinnacle West Capital Corporation and Pinnacle West Energy Corporation
CAE–20.
Docket# EC00–106, 000, Entergy Power Marketing Corporation and Koch Energy Trading, Inc.
CAE–21.
Docket# ER90–54, 002, People's Electric Cooperative
Other#s ER91–221, 001, Peoples Electric Cooperative
EL91–20, 003, Peoples Electric Cooperative
CAE–22.
Docket# EC99–81, 002, Dominion Resources, Inc. and Consolidated Natural Gas Company
Other#s MG00–6, 001, Consolidated Natural Gas Company
CAE–23.
Docket# EL00–118, 000, Public Service Company of New Mexico
CAE–24.
Docket# EL00–114, 000, Dynegy Power Marketing, Inc. v. Ameren Services Company
CAE–25.
Docket# EL01–4, 000, Western Farmers Electric Cooperative
CAE–26.
Docket# ER01–94, 000, New York Independent System Operator, Inc.

Consent Agenda—Markets, Tariffs and Rates—Gas

CAG–1.
Docket# RP01–63, 000, Columbia Gas Transmission Corporation
CAG–2.
Docket# RP96–383, 012, Dominion Transmission, Inc.
CAG–3.
Docket# RP96–383, 013, Dominion Transmission, Inc.
CAG–4.
Docket# RP01–4, 001, Midcoast Interstate Transmission, Inc.
CAG–5.
Docket# RP01–5, 001, Mid Louisiana Gas Company
CAG–6.
Docket# RP98–54, 032, Colorado Interstate Gas Company
CAG–7.
Docket# RP01–64, 000, Southern Natural Gas Company
CAG–8.
Docket# RP00–374, 000, Columbia Gas Transmission Corporation
CAG–9.
Docket# RP95–364, 010, Williston Basin Interstate Pipeline Company
Other#s RP95–364, 000, Williston Basin Interstate Pipeline Company
RP95–364, 005, Williston Basin Interstate Pipeline Company
RP95–364, 007, Williston Basin Interstate Pipeline Company
RP95–364, 009, Williston Basin Interstate Pipeline Company
CAG–10.
Docket# GP91–8, 010, Jack J. Grynberg, Individually and as General Partner for the Greater Green River Basin Drilling Program: 72–73 v. Rocky Mountain Natural Gas Company, a Division of K N Energy Inc.
Other#s GP91–10, 010, Rocky Mountain Natural Gas Company, a Division of K N Energy Inc. v. Jack J. Grynberg, Individually and as General Partner for the greater Green River Basin Drilling Program: 72–73
CAG–11.
Docket# GP97–1, 003, Rocky Mountain Natural Gas Company
CAG–12.
Docket# TM00–1–25, 004, Mississippi River Transmission Corporation
CAG–13.
Docket# RP00–162, 006, Panhandle Eastern Pipe Line Company
Other#s RP00–162, 005, Panhandle Eastern Pipe Line Company
CAG–14.
Docket# RP00–354, 002, Columbia Gas Transmission Corporation
Other#s RP00–354, 001, Columbia Gas Transmission Corporation
CAG–15.
Docket# RM96–1, 015, Standards for Business Practices of Interstate Natural Gas Pipelines
CAG–16.
Docket# PR00–15, 000, Overland Trail Transmission Company
Other#s PR00–15, 001, Overland Trail Transmission Company
CAG–17.
Docket# GT01–3, 000, El Paso Natural Gas Company
CAG–18.
Docket# RP96–320, 033, Koch Gateway Pipeline Company
CAG–19.
Docket# RP01–76, 000, Northern Natural Gas Company
CAG–20.
Docket# RP00–257, 004, Ozark Gas Transmission, L.L.C.
CAG–21.
Docket# RP99–518, 018 PG&E Gas Transmission, Northwest Corporation
CAG–22.
Docket# RP01–73, 000, Southwest Gas Transmission Company
CAG–23.
Docket# RP01–56, 000, Transwestern Pipeline Company
CAG–24.
Docket# RP01–72, 000, Wyoming Interstate Company, Ltd.

Consent Agenda—Miscellaneous

CAM–1.
Docket# RM98–1, 001, Regulations Governing Off-the-Record Communications

Consent Agenda—Energy Projects—Hydro

CAH–1.
Omitted
CAH–2.
Docket# DI00–1, 001, City and County of San Francisco
CAH–3.
Docket# UL96–1, 003, Blackstone Mill Depot Street Trust
CAH–4.
Docket# P–2030, 031, Portland General Electric Company
Other#s P–2030, 032, Portland General Electric Company
P–11832, 000, Confederated Tribes of the Warm Springs Reservation of Oregon, a Federally Recognized Indian Tribe, and Warm Springs Power Enterprises, a Chartered Enterprise of the Confederated Tribes of the Warm Springs Reservation of Oregon

Consent Agenda—Energy Projects—Certificates

CAC–1.
Docket# CP00–140, 000, Black Marlin Pipeline Company, WBI Offshore Pipeline, Inc. and MCNIC Black Marlin Offshore Company
CAC–2.
Docket# CP00–456, 000, Montana Power Company and 3698157 Canada Ltd.
CAC–3.
Docket# CP00–457, 000, Canadian-Montana Pipeline Corporation and 3698157 Canada Ltd.
CAC–4.
Docket# CP00–40, 000, Florida Gas Transmission Company
Other#s CP00–39, 000, Koch Gateway Pipeline Company
CP00–40, 001, Florida Gas Transmission Company
CP00–40, 002, Florida Gas Transmission Company
CAC–5.
Docket# CP97–119, 001, Dauphin Island Gathering System
Other#s CP97–300, 001, Dauphin Island Gathering Partners
CP97–301, 001, Dauphin Island Gathering Partners
CP97–302, 001, Dauphin Island Gathering Partners
RP97–371, 001, Dauphin Island Gathering Partners
CAC–6.
Docket# CP00–421, 001, Distrigas LLC

Energy Projects—Hydro Agenda

H–1.
Reserved

Energy Projects—Certificates Agenda

C–1.
Reserved

Markets, Tariffs and Rates—Electric Agenda

E–1.
Reserved

Markets, Tariffs and Rates—Gas Agenda

G–1.

Reserved

David P. Boergers,

Secretary.

[FR Doc. 00–29534 Filed 11–14–00; 4:12 pm]

BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6901–6]

Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) or Superfund, Section 104; Announcement of Proposal Deadline for the Competition for Fiscal Year 2001 Supplemental Assistance to the National Brownfields Assessment Demonstration Pilots

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposal deadline and guidelines.

SUMMARY: The United States Environmental Protection Agency (EPA) will begin to accept proposals for supplemental assistance for the National Brownfields Assessment Pilots on November 16, 2000. Assessment pilots awarded on or before September 30, 1999, may apply for up to $150,000 for continuance and expansion of their brownfields assessment efforts. This supplemental funding will be awarded on a competitive basis. Recipients of supplemental assessment pilot funding in FY2000 and Showcase Community funding in FY2001 are not eligible to apply.

In fiscal year 2001, an additional $50,000 may be awarded to an applicant to assess the contamination of a brownfields site(s) that is or will be used for greenspace purposes. Greenspace purposes may include, but are not limited to, parks, playgrounds, trails, gardens, habitat restoration, open space, and/or greenspace preservation.

EPA expects to select up to 10 National brownfields assessment pilots to receive supplemental assistance by April 2001. The deadline for proposals for the 2001 supplemental assistance is January 8, 2001. Proposals must be post-marked or sent to EPA via registered or tracked mail by the stated deadline.

The supplemental assistance for the National brownfields assessment pilots will be administered on a competitive basis. To ensure a fair selection process, evaluation panels consisting of EPA Regional and Headquarters staff will assess how well the proposals meet the selection criteria outlined in the application booklet The Brownfields Economic Redevelopment Initiative: Proposal Guidelines for Supplemental Assistance for the Brownfields Assessment Demonstration Pilots (October 2000). Applicants are encouraged to contact and, if possible, meet with EPA Regional Brownfields Coordinators.

DATES: All proposals must be post-marked or sent to EPA via registered or tracked mail by January 8, 2001.

ADDRESSES: The proposal guidelines can be obtained by calling the Superfund Hotline at the following numbers: Washington, DC Metro Area at 703–412–9810, Outside Washington, DC Metro at 1–800–424–9346, TDD for the Hearing Impaired at 1–800–553–7672.

Copies of the guidelines are also available via the Internet:

http://www.epa.gov/brownfields/

FOR FURTHER INFORMATION CONTACT: The Superfund Hotline, 800–424–9346.

SUPPLEMENTARY INFORMATION: As a part of the Environmental Protection Agency's (EPA) Brownfields Economic Redevelopment Initiative, the Brownfields Assessment Demonstration Pilots are designed to empower States, communities, tribes, and other stakeholders in economic redevelopment to work together in a timely manner to prevent, assess, and safely cleanup brownfields to promote their sustainable reuse. EPA has awarded cooperative agreements to States, cities, towns, counties and Tribes for demonstration pilots that test brownfields assessment models and facilitate coordinated public and private efforts at the Federal, State, tribal and local levels. To date, the Agency has funded 362 Brownfields Assessment Pilots.

In fiscal year 2001, EPA has determined that brownfields assessment pilots awarded on or before September 30, 1999, may apply for up to $150,000 for continuance and expansion of their brownfields assessment efforts. Recipients of supplemental assessment pilot funding in FY2000 and Showcase Community funding in FY2001 are not eligible to apply. These pilots focus on EPA's primary mission—protecting human health and the environment. They are also an essential piece of the nation's overall community revitalization efforts. EPA works closely with other federal agencies through the Interagency Working Group on Brownfields, and builds relationships with other stakeholders on the national and local levels to develop coordinated approaches for community revitalization.

Supplemental funding for the brownfields assessment pilots is authorized under Section 104(d)(1) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended, (CERCLA or Superfund), 42 U.S.C. 9604(d)(1). States (including U.S. Territories), political subdivisions (including cities, towns, counties), and federally recognized Indian Tribes which received a brownfields assessment pilot grant on or before September 30, 1999, are eligible to apply. EPA welcomes and encourages brownfields projects by coalitions of such entities, but only a single eligible entity may receive a cooperative agreement. Cooperative agreement funds will be awarded only to a state, a political subdivision of a state, or a federally recognized Indian tribe.

Through a brownfields cooperative agreement, EPA provides funds to an eligible state, political subdivision, or Indian Tribe to undertake activities authorized under CERCLA section 104. Use of these supplemental assistance pilot funds must be in accordance with CERCLA, and all CERCLA restrictions on use of funds also apply to the assessment pilots.

The evaluation panels will review the proposals carefully and assess each response based on how well it addresses the selection criteria, briefly outlined below:

Part I (Required)

1. Established Brownfields Program

2. Accomplishments under Existing Brownfields Assessment Pilot

3. Demonstrated Ability to Administer Existing Brownfields Assessment Demonstration Pilot

4. Work to be Performed

Part II (Optional)

5. Greenspace

—Authority and Context
—Community Involvement
—Site Identification, Site Assessment Plan, Flow of Ownership, and Reuse Planning

Submission to Congress and the General Accounting Office

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and

the Comptroller General of the United States prior to publication in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This action will be effective on November 16, 2000.

Dated: November 2, 2000.
Approved:

Linda Garczynski,

Director, Outreach and Special Projects Staff, Office of Solid Waste and Emergency Response.

[FR Doc. 00–29223 Filed 11–15–00; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6901–5]

Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) or Superfund, Section 104; Announcement of Proposal Deadline for the Competition for the 2001 National Brownfields Assessment Demonstration Pilots

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposal deadlines, revised guidelines.

SUMMARY: The United States Environmental Protection Agency (EPA) will begin to accept proposals for the National Brownfields Assessment Pilots on November 16, 2000. The brownfields assessment pilots (each funded up to $200,000 over two years) test assessment models, and facilitate coordinated assessment and cleanup efforts at the federal, state, and local levels.

In fiscal year 2001, an additional $50,000 may be awarded to an applicant to assess the contamination of a brownfields site(s) that is or will be used for greenspace purposes. Greenspace purposes may include, but are not limited to, parks, playgrounds, trails, gardens, habitat restoration, open space, and/or greenspace preservation.

EPA expects to select up to 35 additional National brownfields assessment pilots by April 2001. The deadline for new proposals for the 2001 assessment pilots is January 12, 2001. Proposals must be post-marked or sent to EPA via registered or tracked mail by the stated deadline. Previously unsuccessful applicants are advised that they must revise and resubmit their proposals to be considered for the 2001 National assessment pilot competition.

The National brownfields assessment pilots are administered on a competitive basis. To ensure a fair selection process, evaluation panels consisting of EPA Regional and Headquarters staff and other federal agency representatives will assess how well the proposals meet the selection criteria outlined in the newly revised application booklet The Brownfields Economic Redevelopment Initiative: Proposal Guidelines for Brownfields Assessment Demonstration Pilots (October 2000). Applicants are encouraged to contact and, if possible, meet with EPA Regional Brownfields Coordinators.

DATES: This action is effective as of November 16, 2000, and expires on January 12, 2001. All proposals must be post-marked or sent to EPA via registered or tracked mail by the expiration date cited above.

ADDRESSES: The proposal guidelines can be obtained by calling the Superfund Hotline at the following numbers: Washington, DC Metro Area at 703–412–9810, Outside Washington, DC Metro at 1–800–424–9346,TDD for the Hearing Impaired at 1–800–553–7672.

Copies of the guidelines are also available via the Internet:

http://www.epa.gov/brownfields/

FOR FURTHER INFORMATION CONTACT: The Superfund Hotline, 800–424–9346.

SUPPLEMENTARY INFORMATION: As a part of the Environmental Protection Agency's (EPA) Brownfields Economic Redevelopment Initiative, the Brownfields Assessment Demonstration Pilots are designed to empower States, communities, tribes, and other stakeholders in economic redevelopment to work together in a timely manner to prevent, assess, and safely cleanup brownfields to promote their sustainable reuse. EPA has awarded cooperative agreements to States, cities, towns, counties and Tribes for demonstration pilots that test brownfields assessment models and facilitate coordinated public and private efforts at the Federal, State, tribal and local levels. To date, the Agency has funded 362 Brownfields Assessment Pilots.

EPA's goal is to select a broad array of assessment pilots that will serve as models for other communities across the nation. EPA seeks to identify proposals that demonstrate the integration or linking of brownfields assessment pilots with other federal, state, tribal, and local sustainable development, community revitalization, and pollution prevention programs. Special consideration will be given to Federal Empowerment Zones and Enterprise Communities (EZ/ECs), communities with populations of under 100,000, and federally recognized Indian tribes. These pilots focus on EPA's primary mission—protecting human health and the environment. However, it is an essential piece of the nation's overall community revitalization efforts. EPA works closely with other federal agencies through the Interagency Working Group on Brownfields, and builds relationships with other stakeholders on the national and local levels to develop coordinated approaches for community revitalization.

Funding for the brownfields assessment pilots is authorized under Section 104(d)(1) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (CERCLA or Superfund), 42 U.S.C. 9604(d)(1). States (including U.S. Territories), political subdivisions (including cities, towns, counties), and federally recognized Indian Tribes are eligible to apply. EPA welcomes and encourages brownfields projects by coalitions of such entities, but only a single eligible entity may receive a cooperative agreement. Cooperative agreement funds will be awarded only to a state, a political subdivision of a state, or a federally recognized Indian tribe.

Through a brownfields cooperative agreement, EPA provides funds to an eligible state, political subdivision, or Indian Tribe to undertake activities authorized under CERCLA section 104. Use of these assessment pilot funds must be in accordance with CERCLA, and all CERCLA restrictions on use of funds also apply to the assessment pilots.

The evaluation panels will review the proposals carefully and assess each response based on how well it addresses the selection criteria, briefly outlined below:

Part I (Required)

1. Problem Statement and Needs Assessment

—Effect of Brownfields on your Community or Communities
—Value Added by Federal Support

2. Community-Based Planning and Involvement

—Existing Local Commitment
—Community Involvement Plan
—Environmental Justice Plan

3. Implementation Planning

—Government Support
—Site Selection and Environmental Site Assessment Plan
—Reuse Planning and Proposed Cleanup Funding Mechanisms
—Flow of Ownership Plan

4. Long-Term Benefits and Sustainability

—Long-Term Benefits
—Sustainable Reuse
—Measures of Success

Part II (Optional)

5. Greenspace

—Authority and Context
—Community Involvement
—Site Identification, Site Assessment Plan, Flow of Ownership, and Reuse Planning

Submission to Congress and the General Accounting Office

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). This action will be effective on November 16, 2000.

Dated: November 2, 2000.

Linda Garczynski,

Director, Outreach and Special Projects Staff, Office of Solid Waste and Emergency Response.

[FR Doc. 00–29224 Filed 11–15–00; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6902–5]

Second Consultation Meeting on a Longitudinal Cohort Study of Environmental Effects on Children

AGENCY: Environmental Protection Agency.

ACTION: Notice of public meeting: consultation on the plans for a longitudinal cohort study of environmental effects on children.

SUMMARY: The Environmental Protection Agency (EPA) is announcing a two-day meeting cosponsored by the Office of Behavioral and Social Science Research (OBSSR) of the National Institutes of Health (NIH), the National Institute of Child Health and Human Development (NICHD)/NIH, and the National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC). The meeting is being convened to discuss the development of a longitudinal cohort study of environmental effects on the health and well-being of children. Content of the meeting will include the status of activities to date, outline of study rationale and plan, issues of longitudinal cohort design, ethical issues, and discussion groups for input and feedback.

DATES: The meeting dates are December 12, 2000, from 8:30 a.m. until 5:00 p.m., and December 13, 2000, from 8:30 a.m. until 12:30 p.m.

ADDRESSES: The meeting site is the Marriott at Metro Center, 775 12th Street, NW., Washington, DC. The workshop is open to the public, but seating is limited to a maximum of 400. Those planning to attend must register no later than November 29, 2000.

FOR FURTHER INFORMATION CONTACT: To register as an observer, contact Ms. Kim Brickhouse, TASCON, P.O. Box 30686, Bethesda, MD 20824–0686; telephone: 301–315–9000, ext. 516; facsimile: 301–738–9786; email: kbrickhouse@tascon.com. For further information, contact Dr. Peter Scheidt, National Institute of Child Health and Human Development, National Institutes of Health, U.S. Department of Health and Human Services, Room 7B05, 6100 Executive Boulevard, Bethesda, MD 20892; telephone: 301–496–5064; facsimile: 301–402–2084; e-mail: scheidtp@mail.nih.gov.

Dated: November 8, 2000.

William H. Farland,

Director, National Center for Environmental Assessment.

[FR Doc. 00–29359 Filed 11–15–00; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6902–8]

Proposed CERCLA Administrative Cost Recovery Settlement; FMC Dublin Road Superfund Site, Towns of Shelby and Ridgeway, Orleans County, New York

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request public comment.

SUMMARY: In accordance with section 122(i) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (''CERCLA''), 42 U.S.C. 9622(i), notice is hereby given of a proposed administrative settlement for recovery of past and future response costs concerning the FMC Dublin Road Superfund Site (''Site'') located in the Towns of Shelby and Ridgeway, Orleans County, New York with the settling party, FMC Corporation. The settlement requires the settling party to pay $200,000.00 to the Hazardous Substance Superfund in reimbursement of past response costs incurred with respect to the Site. The settling party will also pay the interest on that amount calculated from March 25, 2000 through the date of payment and has agreed to reimburse the U.S. Environmental Protection Agency (''EPA'') for all future response costs not inconsistent with the National Contingency Plan, 40 CFR part 300, as amended (''NCP''), incurred by EPA in connection with the Site. The settlement includes a covenant not to sue the settling party pursuant to section 107(a) of CERCLA, 42 U.S.C. 9607(a) for past and future costs incurred at the Site by EPA.

For thirty (30) days following the date of publication of this document, EPA will receive written comments relating to the settlement. EPA will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the proposed settlement is inappropriate, improper, or inadequate. EPA's response to any comments received will be available for public inspection at the EPA's regional office, 290 Broadway, New York, New York 10007–1866.

DATES: Comments must be submitted on or before December 18, 2000.

ADDRESSES: The proposed settlement is available for public inspection at EPA, 290 Broadway, New York, New York 10007–1866. A copy of the proposed settlement may be obtained from Marla Wieder, Assistant Regional Counsel, Office of Regional Counsel, EPA, 290 Broadway, 17th Floor, New York, New York 10007–1866. Comments should reference the FMC Dublin Road Superfund Site, EPA Index No. CERCLA–02–2000–2030, and should be addressed to Marla Wieder, Assistant Regional Counsel, EPA, 290 Broadway, 17th Floor, New York, New York 10007–1866.

FOR FURTHER INFORMATION CONTACT: Marla Wieder, Assistant Regional Counsel, Office of Regional Counsel, EPA, 290 Broadway, 17th Floor, New York, New York 10007–1866. Telephone: (212) 637–3184.

Dated: October 24, 2000.

William J. Muszynski,

Acting Regional Administrator, Region 2.

[FR Doc. 00–29361 Filed 11–15–00; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6902–9]

Operating Industries, Inc. Landfill Superfund Site; Notice of Proposed CERCLA Administrative De Minimis Settlement

AGENCY: Environmental Protection Agency.

ACTION: Notice; request for public comment.

SUMMARY: In accordance with section 122(i) of the Comprehensive Environmental Response, Compensation, and Liability Act, as amended (''CERCLA''), 42 U.S.C. 9622(i), the Environmental Protection Agency (''EPA'') is hereby providing notice of a proposed administrative *de minimis* settlement concerning the Operating Industries, Inc. Landfill Superfund site in Monterey Park, California (the ''OII Site''). Section 122(g) of CERCLA, 42 U.S.C. 9622(g), provides EPA with the authority to enter into administrative de minimis settlements. This settlement is intended to resolve the liabilities of 22 settling parties, 18 of which have a limited ability to pay, for the OII Site under CERCLA and section 7003 of the Resource Conservation and Recovery Act (''RCRA''), 42 U.S.C. 6973. The settlement will also resolve OII Site-related claims by California Department of Toxic Substances Control against the settling parties. The settling parties will pay a total of $1,080,602 toward OII Site response costs.

For thirty (30) days following the date of publication of this notice, EPA will receive written comments relating to the settlement. In accordance with section 7003(d) of RCRA, 42 U.S.C. 6973(d), commenters may request an opportunity for a public meeting in the affected area. EPA will consider all comments it receives during this period, and may modify or withdraw its consent to the settlement if any comments disclose facts or considerations indicating that the settlement is inappropriate, improper, or inadequate.

DATES: Comments must be submitted on or before December 18, 2000.

ADDRESSES: Comments and requests for a public meeting should be addressed to the Regional Hearing Clerk, U.S. EPA Region IX (ORC–1), 75 Hawthorne Street, San Francisco, CA 94105, and should refer to: Operating Industries, Inc. Landfill Superfund Site, Monterey Park, CA, U.S. EPA Docket No. 00–09. The proposed settlement and additional background information relating to the settlement are available for inspection, and EPA's response to any comments received will be available for inspection, at the U.S. EPA Region IX Superfund Records Center, 95 Hawthorne Street, Suite 403 S, San Francisco, CA 94105; at the Bruggemeyer Memorial Library, 318 South Ramona Avenue, Monterey Park, CA 91754; the Montebello Regional Library, 1550 West Beverly Boulevard, Montebello, CA 90640; and the Chet Holifield Library, 1060 South Greenwood Avenue, Montebello, CA 90640. A copy of the proposed Administrative Order on Consent may be obtained from the Regional Hearing Clerk at the address provided above.

FOR FURTHER INFORMATION CONTACT: Arthur Haubenstock, Assistant Regional Counsel, U.S. EPA Region IX (ORC–3), 75 Hawthorne Street, San Francisco, CA 94105; E-Mail: haubenstock.arthur@epa.gov; Tel: (415) 744–1355.

Michael Feeley,

Acting Director, Superfund Division, Region IX.

[FR Doc. 00–29362 Filed 11–15–00; 8:45 am]

BILLING CODE 6560–50–P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Meeting of the President's Committee of Advisors on Science and Technology

ACTION: Notice of meeting.

SUMMARY: This notice sets forth the schedule and summary agenda for a meeting of the President's Committee of Advisors on Science and Technology (PCAST), and describes the functions of the Committee. Notice of this meeting is required under the Federal Advisory Committee Act.

Date and Place: Friday, December 1, 2000, Washington, DC. This meeting will take place in the Truman Room (Third Floor) of the White House Conference Center, 726 Jackson Place, NW., Washington, DC.

Type of Meeting: Open.

Proposed Schedule and Agenda: The President's Committee of Advisors on Science and Technology (PCAST) is scheduled to meet in open session on Friday, December 1, 2000, from approximately 1:00–4:00 p.m., to discuss (1) PCAST recommendations regarding the National Science and Technology Council, (2) lessons learned from the work of the President's Committee of Advisors on Science and Technology, (3) PCAST recommendations regarding science and technology capacity building abroad, (4) research misconduct, and (5) the Federal Government-University Research Partnership activities.

Public Comments: There will be a time allocated for the public to speak on any of the above agenda items. Please make your request for the opportunity to make a public comment five (5) days in advance of the meeting. Written comments are welcome any time prior to or following the meeting. Please notify Cynthia Chase, of the PCAST Executive Secretariat, at (202) 456–6100, or fax your requests/comments to (202) 456–6026.

FOR FURTHER INFORMATION CONTACT: For information regarding time, place, and agenda, please call Cynthia Chase, of the PCAST Executive Secretariat, at (202) 456–6100, prior to 3:00 p.m. on Thursday, November 30, 2000. Information may also be available at the PCAST website at: http://www.ostp.gov/PCAST/pcast.html. Please note that public seating for this meeting is limited, and is available on a first-come first served basis.

SUPPLEMENTARY INFORMATION: The President's Committee of Advisors on Science and Technology was established by Executive Order 12882, as amended, on November 23, 1993, September 29, 1995, September 29, 1997, and September 30, 1999. The purpose of PCAST is to advise the President on matters of national importance that have significant science and technology content, and to assist the President's National Science and Technology Council in securing private sector participation in its activities. The Committee members are distinguished individuals appointed by the President from non-Federal sectors. The PCAST is co-chaired by the Assistant to the President for Science and Technology and, by John Young, former President and CEO of the Hewlett-Packard Company.

Barbara Ann Ferguson,

Assistant Director, Budget and Administration, Office of Science and Technology Policy.

[FR Doc. 00–29329 Filed 11–15–00; 8:45 am]

BILLING CODE 3170–01–U

FEDERAL COMMUNICATIONS COMMISSION

Performance Review Board

As required by the Civil Service Reform Act of 1978 (Pub. L. 95–454), Chairman William E. Kennard appointed the following executives to the Performance Review Board: Richard Lee, Renee Licht, David Solomon, Thomas Tycz.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 00–29364 Filed 11–15–00; 8:45 am]

BILLING CODE 6712–01–M

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will 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 November 29, 2000.

A. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. Robert B. Mathieu, Delhi, Louisiana; to retain voting shares of Delhi Bancshares, Inc., Delhi, Louisiana, and thereby indirectly retain voting shares of Guaranty Bank and Trust Company of Delhi Louisiana, Delhi, Louisiana.

Board of Governors of the Federal Reserve System, November 9, 2000.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 00–29304 Filed 11–15–00; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 11, 2000.

A. Federal Reserve Bank of Minneapolis (JoAnne F. Lewellen, Assistant Vice President), 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Marquette Bancshares, Inc.,* Minneapolis, Minnesota; to acquire up to 64 percent of the voting shares of Commerce Bank of Santa Barbara, N.A., Santa Barbara, California (in organization).

Board of Governors of the Federal Reserve System, November 9, 2000.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 00–29303 Filed 11–15–00; 8:45 am]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION

Women's Progress Commemoration Commission

AGENCY: General Services Administration.

ACTION: Meeting notice.

SUMMARY: Notice is hereby given that the Women's Progress Commemoration Commission will hold an open meeting from 9:00 a.m. to 4:00 p.m. on Tuesday, December 5, 2000, at the Hilton of Santa Fe, 100 Sandoval Street, Santa Fe, NM 97501, (505) 988–2811.

PURPOSE: The Commission will meet to discuss their role in identifying and commemorating Women's History sites.

FOR FURTHER INFORMATION CONTACT: Martha Davis (202) 501–0705, Assistant to the Associate Administrator for Communications, General Services Administration. Also, inquiries may be sent to *martha.davis@gsa.gov.*

Dated: November 11, 2000.

Beth Newburger,

Associate Administrator for Communications.

[FR Doc. 00–29373 Filed 11–15–00; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[ATSDR–163]

Availability of Final Toxicological Profiles

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: This notice announces the availability of one new final and six updated final toxicological profiles of priority hazardous substances comprising the twelfth set prepared by ATSDR.

FOR FURTHER INFORMATION CONTACT: Ms. Franchetta Stephens, Division of Toxicology, Agency for Toxic Substances and Disease Registry, Mailstop E–29, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone 1–(888) 422–8737 or (404) 639–6345.

SUPPLEMENTARY INFORMATION: The Superfund Amendments and Reauthorization Act (SARA) (Pub. L. 99–499) amends the Comprehensive Environmental Response, Compensation, and Liability Act

(CERCLA or Superfund) (42 U.S.C. 9601 *et seq.*) by establishing certain requirements for ATSDR and the Environmental Protection Agency (EPA) with regard to hazardous substances which are most commonly found at facilities on the CERCLA National Priorities List (NPL). Among these statutory requirements is a mandate for the Administrator of ATSDR to prepare toxicological profiles for each substance included on the priority lists of hazardous substances. These lists identified 275 hazardous substances that ATSDR and EPA determined pose the most significant potential threat to human health. The availability of the revised list of the 275 most hazardous substances was announced in the **Federal Register** on October 21, 1999 (64 FR 56792). For prior versions of the list of substances see **Federal Register** notices dated November 17, 1997 (62 FR 61332); April 29, 1996 (61 FR 18744); April 17, 1987 (52 FR 12866); October 20, 1988 (53 FR 41280); October 26, 1989 (54 FR 43619); October 17, 1990 (55 FR 42067); October 17, 1991 (56 FR 52166); October 28, 1992 (57 FR 48801); and February 28, 1994 (59 FR 9486).

Notices (63 FR 56191) and (62 FR 55818) announcing the availability of the draft toxicological profiles for public review and comment were published in the **Federal Register** on October 21, 1998 or October 28, 1997 with notice of a 90-day public comment period for each profile, starting from the actual release date. Following the close of the comment period, chemical-specific comments were addressed, and where appropriate, changes were incorporated into each profile. The public comments and other data submitted in response to the **Federal Register** notices bear the docket control numbers ATSDR–137 or ATSDR–127. This material is available for public inspection at the Division of Toxicology, Agency for Toxic Substances and Disease Registry, Building 4, Suite 2400, Executive Park Drive, Atlanta, Georgia, (not a mailing address) between 8:00 a.m. and 4:30 p.m., Monday through Friday, except legal holidays.

Availability

This notice announces the availability of one new final and six updated final toxicological profiles comprising the twelfth set prepared by ATSDR. The following toxicological profiles are now available through the U.S. Department of Commerce, National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, Virginia 22161, telephone 1–800–553–6847. There is a charge for these profiles as determined by NTIS.

Toxicological profile	NTIS order No.	CAS No.
Twelfth Set:		
1. Arsenic	PB2000–108021	007440–38–2
2. Chromium	PB2000–108022	007440–47–3
3. Endosulfan	PB2000–108023	000115–29–7
Endosulfan, alpha		000959–98–8
Endosulfan, sulfate		001031–07–8
Endosulfan, beta		33213–65–9
4. Ethion	PB2000–108024	00563–12–2
5. Manganese	PB2000–108025	007439–96–5
Manganese chloride		007773–01–5
Manganese dioxide		001313–13–9
Maneb		012427–38–2
Methylcyclopentadienyl Manganese Tricarbony		012108–13–3
6. Methylene Chloride	PB2000–108026	000075–09–2
7. Toluene	PB2000–108028	000108–88–3

Dated: November 9, 2000.

Georgi Jones,

Director, Office of Policy and External Affairs, Agency for Toxic Substances and Disease Registry.

[FR Doc. 00–29311 Filed 11–15–00; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Program Announcement 01011]

Improving Contact Investigations in Foreign-Born Populations; Notice of Availability of Funds

A. Purpose

The Centers for Disease Control and Prevention (CDC) announces the availability of Fiscal Year 2001 funds for a cooperative agreement for improving contact investigations in foreign-born populations. This program addresses the ''Healthy People 2010,'' focus areas of Immunization and Infectious Diseases. For the conference copy of ''Healthy People 2010,'' visit the internet site *http://www.health.gov/healthypeople.*

The purpose of this cooperative agreement is to (1) improve contact identification for foreign-born (FB) TB cases; (2) improve completeness and timeliness of screening for identified contacts to FB TB cases; (3) improve the interpretation of screening results for contacts to FB TB cases in [a] the context of screening results for U.S.-born contacts to the same cases and [b] using serum immunologic profile (IFN-gamma and TNF-alpha) and results of skin test screening with non-tuberculous mycobacterial antigens to aid interpretation of screening results for FB contacts; and (4) improve completion of treatment for latent TB

infection for foreign-born contacts to pulmonary TB cases. These funds will be used to provide information for public health officials and policy makers to better understand methods for conducting contact investigations in FB populations and will provide improved completeness and timeliness of screening, interpretation of screening results, and treatment for latent TB infection for FB contacts to pulmonary TB cases.

This cooperative agreement will provide funds to build capacity at state and local health departments to conduct and implement protocol-driven epidemiologic and operational research. Such actions are consistent with recommendations issued by the Advisory Council for the Elimination of Tuberculosis (ACET) calling for decisive actions to: (1) Better understand the changing epidemiology of TB to rebuild the public health infrastructure; (2) identify challenges and opportunities for TB control in an era of changes in health care organizations and delivery; (3) recognize the interdependence of global TB and TB in the United States; and (4) develop and evaluate new tools for TB diagnosis, treatment and prevention.

B. Eligible Applicants

Assistance will be provided only to official public health agencies of States and territories, or their bona-fide agents that are (1) current recipients of the Tuberculosis Cooperative Awards announced in PA 00001 and (2) reported 200 or more TB cases in 1999, of which at least 100 must be among foreign-born persons. Eligible applicants are the states of Arizona, California, Florida, Georgia, Illinois, Maryland, Massachusetts, Minnesota, New Jersey, New York, North Carolina, Pennsylvania, Texas, Virginia, and Washington and the cities of Chicago, New York, Houston, Los Angeles, and San Francisco.

C. Availability of Funds

Approximately $625,000 is available in FY 2001 to fund up to 4 awards for the initial 12-month budget period within a project period of 2 years. It is expected that the average award would be $200,000 per year, ranging from $175,000 to $235,000. Funding estimates may change.

It is anticipated that awards will begin on or about February 15, 2001. Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

Direct Assistance

Applicants may request Federal personnel as direct assistance in lieu of a portion of financial assistance.

Use of Funds

Categorical funds are awarded for a specifically defined purpose and may not be used for any other purpose or program. Funds for contractual services may be requested; however, the grantee, as the direct and primary recipient of grant funds, must perform a substantive role in carrying out project activities and not merely serve as a conduit for an award to another party or provide funds to an ineligible party. Funds may be used to support personnel and to purchase equipment, supplies, and services directly related to project activities. Funds may not be used to supplant state or local health department funds or for inpatient care or construction of facilities. Funds may not be used to purchase drugs for treatment. In addition, recipients must maintain clear accounting records to demonstrate that the funding awarded under this cooperative agreement is used toward the activities under this announcement and remains separate from any funding the recipient may be awarded under other mechanisms.

Funding Preference

Funding preference will be applied to ensure a balance of sites with exclusively urban populations, exclusively rural populations, and both urban and rural populations.

D. Program Requirements

In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities listed under 1. (Recipient Activities), and CDC will be responsible for conducting activities listed under 2. (CDC Activities).

1. Recipient Activities

a. Access patients with tuberculosis, latent tuberculosis infection, or recent exposure to persons with active tuberculosis (''contacts'') in the implementation of protocols for epidemiologic and operational research.

b. Conduct site-specific epidemiologic and operational research activities in TB which rely upon the implementation of common, agreed-upon study protocols.

c. Within 3 months of award, attend an investigator meeting at CDC with the CDC Project Officer to develop a study protocol, questionnaires, and data abstraction forms.

d. Promptly obtain all necessary human subjects protections assurances from the Office for Human Research Protections (OHRP). Submit protocol to local IRB and work with CDC to finalize protocol with appropriate approvals from the local IRB and CDC IRB. Ensure that the study is conducted according to the IRB-approved protocol, including that all policies to provide data security and protect confidentiality are implemented.

e. Complete retrospective review of contact investigations done in the 12 months before this project according to protocol. This will include reviews of existing health department records of TB cases, their contacts, and the contact investigations.

f. Complete survey of recent TB cases, their contacts, and community leaders to identify social networks and major contact sites, and to refine questions for the structured interview format to be used in case and contact interviews in the prospective phase of the study.

g. Attend an investigator meeting at CDC with the CDC Project Officer to develop a prospective study protocol. Input from an ethnographer, results of the retrospective foreign-born study, results of the social networking survey, and preliminary results from the prospective US-born contact investigation study already ongoing at CDC will be considered in developing this protocol.

h. Conduct prospective study of all foreign-born culture-positive pulmonary TB cases age >15 years of age reported during a specified 12-month period and all their contacts. TB cases within each project area will be selected according to the protocol and their medical records will be reviewed. Cases will be interviewed in a structured format according to the study protocol. It is anticipated that there may be multiple interviews of the source case to obtain detailed information. Patients whose HIV status is not known will be encouraged to undergo HIV testing as per CDC recommendations. An example of the anticipated protocol activities is summarized in Attachment 1.

i. Interview contacts. Review medical records of contacts using a standard data abstraction form. It is anticipated that multiple interviews with contacts may be needed to obtain detailed information. Contacts whose HIV status is unknown will be offered HIV testing. All contacts without evidence of prior *Mycobacterium tuberculosis* infection or disease will receive a tuberculin skin test when first identified as a contact and at 12 weeks after their last contact with the case while the case was infectious. Those with positive tuberculin skin tests will be evaluated for preventive or curative therapy as indicated.

j. Test contacts with a panel of non-tuberculous mycobacterial antigens to determine whether supplementing tuberculin skin test screening with these antigens results in improved identification of persons recently infected with *M. tuberculosis.*

k. Obtain serum from close contacts and test for a number of cytokines known to be associated with the immune response to *M. tuberculosis* infection. This information will be used to determine whether cytokine profiles are a useful supplement to tuberculin skin test screening for determining whether recent *M. tuberculosis* transmission has occurred.

l. Conduct targeted tuberculin skin test screening in locations where the TB case spent time according to procedures and criteria specified in the study protocol.

m. Monitor contacts with latent TB infection to determine rates of treatment for latent TB infection recommendation, initiation, and completion. Reason for not recommending, initiating, or completing therapy will be delineated.

n. If secondary cases are identified, send *M. tuberculosis* isolates from the cases and their source case to the designated regional laboratory for DNA fingerprints.

o. Ensure that all data collected are maintained in confidential and secured files.

p. Send questionnaires and data abstraction forms for study participants to the CDC in accordance with the frequency specified in the protocol.

2. CDC Activities

a. Assist in the development of a research protocol for IRB review by all cooperating institutions participating in the research project. Assist in development of a study protocol for retrospective, social networking survey, and prospective portions of the study.

b. The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

c. Organize and host a meeting at CDC with all the principal investigators within 3 months of awards being granted.

d. Assist in development of questionnaires and data abstraction forms for collecting and reporting results.

e. Collaborate as necessary in training the persons interviewing cases and contacts and doing the data abstraction from medical records.

f. Assist as needed and review the results of data analysis done locally.

g. Prepare study report and disseminate findings.

E. Application Content

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than 15 double-spaced on 8½ by 11″ pages (excluding budget justification), printed on one side, with one inch margins, and unreduced font. Applications must be developed in accordance with CDC Form 0.1246(E). Pages must be clearly numbered, and a complete index to the application and its appendices must be included. The original and each copy of the application must be submitted unstapled and unbound. Materials which should be part of the basic plan should not be in the appendices. For the budget section, submit a Form 424A (included in the Application Package) and detailed line-item justification for this focus area project. Applicants should follow the outline below in preparing the narrative.

1. *Abstract* (not to exceed 1 page): Applicants should provide a summary of their proposal and rational plan to carry out the project activities.

2. *Understanding the Project:* Applicants should describe their knowledge of current research conducted in this area, past studies and existing literature. Applicants should state clear study objectives for the current proposed study. Applicants should describe experience with conducting thorough, timely, and comprehensive contact investigations for foreign-born TB cases and their contacts, and the related public health impact.

3. *Methodology and Approach:* Applicants should describe a rational plan to carry out the project activities, including timely methods for the identification of newly diagnosed TB cases and their contacts; methods for medical record review and source case and contact interviews; ability to integrate serologic and non-tuberculous antigen testing portions of the study into existing contact investigation procedures; and ability to conduct targeted location based screening in immigrant communities. Recognition of and plans for overcoming difficulties that may be encountered during the study should be described.

4. *Program Management and Staff experience:* Describe the personnel who will be involved in this project, including information about who will be responsible for general oversight and management of this project. Include descriptions of the experience required for each proposed staff member to conduct their assigned duties in the proposed project and the projected time commitment from each.

5. *Data Management:* Provide a brief outline of data flow for the proposed project. Provide a description how data abstraction forms will be handled and maintained. Provide a plan for updating data abstraction forms as additional information becomes available over time. Provide a plan for including quality assurance steps that will be used in managing the data.

6. *Budget:* Provide an itemized budget and supporting justification for the first 12 months of the anticipated 2-year project.

F. Submission and Deadline

Submit the original and 2 copies of the application including the CDC Form 0.1246(E). Forms are available at the following Internet address: http://www.cdc.gov/od/pgo/forminfo.htm or in the application kit. On or before January 5, 2001, submit your application to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

Deadline: Applications shall be considered as meeting the deadline if they are either:

(a) Received on or before the deadline date; or

(b) Sent on or before the deadline date and received in time for submission to the independent review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing).

Late Applications: Applications which do not meet the criteria in (a) or (b) above are considered late applications, will not be considered, and will be returned to the applicant.

G. Evaluation Criteria

Your application will be evaluated individually against the following criteria by an independent review group appointed by CDC.

1. Understanding of the Project (20 Points)

The extent to which the applicant demonstrates a clear understanding of the public health impact of conducting thorough, timely, and comprehensive contact investigations for foreign-born TB cases and their contacts as demonstrated through experience, a

knowledge of current research conducted in this area, past studies, existing literature, and the clarity of the proposed study objectives.

2. Methodology and Approach (45 Points)

a. The extent to which the applicant describes a rational plan to carry out the project activities, including timely methods for the identification of newly diagnosed TB cases and their contacts; methods for medical record review and source case and contact interviews; ability to integrate serologic and non-tuberculous antigen testing portions of the study into existing contact investigation procedures; and ability to conduct targeted location based screening in immigrant communities. Recognition of and plans for overcoming difficulties that may be encountered during the study are described.

b. The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes:

(1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

(2) The proposed justification when representation is limited or absent.

(3) A statement as to whether the design of the study is adequate to measure the differences when warranted.

(4) A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

(5) The proposed plan to address language needs during the course of the project.

(6) Delineate the countries of origin from the major foreign-born populations in the projected area.

(7) Describe the language capabilities of staff proposed for this study.

3. Program Management and Staff experience (20 Points)

The proposal clearly describes the (1) qualifications, commitment, and epidemiologic skills and experience of the project director and his/her ability to devote adequate time and effort to provide effective leadership; (2) qualifications and experience of other staff involved in the project to accomplish the proposed activity, and their commitment and time they will devote; (3) successful experience the project director and staff have in managing, coordinating and conducting similar or related projects; (4) a study coordinator with epidemiologic training and experience who is able to devote at least 50 percent of his or her time to this project; and (5) facilities, space, and equipment necessary for conducting the project.

4. Data Management (10 points)

The proposal clearly describes how data management and data validation will be done.

5. The extent to which the applicant demonstrates continued achievement of the following National TB Program Objectives (5 Points):

a. At least 90 percent of patients with newly diagnosed TB, for whom therapy for 1 year or less is indicated*, will complete therapy within 12 months (*please refer to the definitions in ''Reported Tuberculosis in the United States, 1997'' for more information). To obtain a copy of this report, you may order through the CDC Website http://www.cdc.gov/nchstp/tb/ and go to online ordering; or you may contact the Communication and Education Branch, Sherry Hussain, 404–639–8135.

b. At least 85 percent of infected contacts who are started on treatment for latent TB infection will complete therapy.

c. Completeness of RVCT reporting on HIV status for at least 75 percent of all newly reported TB cases age 25–44.

6. Other (Not Scored)

a. Budget

Extent to which the budget is reasonable, clearly justified, and consistent with the intended use of the funds.

b. Human Subjects

Does the application adequately address the requirements of 45 CFR 46 for the protection of human subjects?

H. Other Requirements

Technical Reporting Requirements

Provide CDC with an original plus two copies of:

1. Annual progress report, no more than 90 days after the end of the budget period;

2. Financial status report, no more than 90 days after the end of the budget period; and

3. Final financial and performance report, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the ''Where to Obtain Additional Information'' section of this announcement.

The following additional requirements are applicable to this announcement.

AR–1 Human Subjects Requirements

AR–2 Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

AR–4 HIV/AIDS Confidentiality Provisions

AR–5 HIV Program Review Panel Requirements

AR–7 Executive Order 12372 Review

AR–9 Paperwork Reduction

AR–10 Smoke-Free Workplace Requirements

AR–11 Healthy People 2010

AR–12 Lobbying

I. Authority and Catalog of Federal Domestic Assistance Number

This program is authorized under section 317E of the Public Health Service Act, 42 U.S.C. 247b–6, as amended. The Catalog of Federal Domestic Assistance number is 93.947.

J. Where To Obtain Additional Information

This and other CDC Announcements can be found on the CDC homepage Internet address—http://www.cdc.gov. Click on ''Funding'' then ''Grants and Cooperative Agreements.''

To obtain additional information, contact: Carrie Palumbo, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 2920 Brandywine Road, Room 3000, Atlanta, GA 30341–2783. Telephone (770) 488–2783. Email address: zri4@cdc.gov.

For program technical assistance, contact: Your program consultant at (404) 639–8125 and from Mary Reichler, Project Officer, Division of Tuberculosis Elimination, Centers for Disease Control and Prevention, National Center for HIV, STD, and TB Prevention, Division of TB Elimination, 1600 Clifton Road, Mailstop E–10, Atlanta, Georgia 30333. Telephone: (404) 639–8118. E-Mail Address: mrr3@cdc.gov.

Dated: November 9, 2000.

John L. Williams,

Director, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 00–29312 Filed 11–15–00; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1604]

Agency Information Collection Activities; Proposed Collection; Comment Request; OTC Test Sample Collection Systems for Drugs of Abuse Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for over-the-counter (OTC) test sample collection systems for drugs of abuse testing.

DATES: Submit written or electronic comments on the collection of information by January 16, 2001.

ADDRESSES: Submit electronic comments on the collection of information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All documents should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

OTC Test Sample Collection Systems for Drugs of Abuse Testing—21 CFR Part 809 (OMB Control Number 0910–0368)—Extension

FDA has reclassified OTC test sample collection systems for drugs of abuse testing from class III (premarket approval) into class I (general controls) subject to restrictions established in accordance with section 520(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j).

The labeling requirements for certain in vitro diagnostic products require that manufacturers of OTC test sample collection systems for drugs of abuse testing provide certain information to consumers for the proper use of the test sample collection system and for interpreting the results. The purpose of this regulation is to ensure that lay persons collecting samples for testing have adequate instructions for sample collection and handling and for receiving and understanding the test results reported by laboratories performing the analyses.

The most likely respondents to this information collection will be manufacturers of over-the-counter drugs of abuse test kits.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
809.10	20	1	20	100	2,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based upon submissions to the agency (premarket notifications, premarket approval applications, registration and listing), FDA estimates that there will be about 20 manufacturers of these devices.

FDA estimates, based upon discussions with manufacturers of similar devices required to comply with 21 CFR 809.10, that it will take approximately 40 hours to gather the information required by the rule, 40 hours to design and prepare the labeling, and an additional 20 hours per year to review and revise the labeling as necessary.

Dated: November 9, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–29326 Filed 11–15–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N–0393]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; MedWatch: The FDA Medical Products Reporting Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by December 18, 2000.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Mark L. Pincus, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1471.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

MedWatch—The FDA Medical Products Reporting Program (Forms FDA 3500 and FDA 3500A) (OMB Control Number 0910–02910)—Extension

Under sections 505, 512, 513, 515, and 903 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355, 360b, 360c, 360e, and 393), and section 351 of the Public Health Service Act (42 U.S.C. 262), FDA has the responsibility to ensure the safety and effectiveness of drugs, biologics, and devices. Under section 502(a) of the act (21 U.S.C. 352(a)), a drug or device is misbranded if its labeling is false or misleading. Under section 502(f)(1) of the act it is misbranded if it fails to bear adequate warnings, and under section 502(j), it is misbranded if it is dangerous to health when used as directed in its labeling.

Under section 4 of the Dietary Supplement Health and Education Act of 1994 (the DSHEA) (21 U.S.C. 301), section 402 of the act (21 U.S.C. 342) is amended so that FDA must bear the burden of proof to show a dietary supplement is unsafe. Likewise for cosmetics, the act does not give FDA the authority to require manufacturers to register their cosmetic establishments, file data on ingredients, conduct safety testing, or report cosmetic-related injuries. Only postmarket surveillance allows FDA to assess cosmetic problems in the marketplace.

To carry out its responsibilities, the agency needs to be informed whenever an adverse event or product problem occurs. Only if FDA is provided with such information will the agency be able to evaluate the risk, if any, associated with the product, and take whatever action is necessary to reduce or eliminate the public's exposure to the risk through actions ranging from labeling changes to the rare product withdrawal. To ensure the marketing of safe and effective products, certain adverse events must be reported. Requirements regarding mandatory reporting of adverse events or product problems have been codified in parts 310, 314, 600, 606, and 803 (21 CFR parts 310, 314, 600, 606, and 803), specifically §§ 310.305, 314.80, 314.98, 600.14, 600.80, 606.170, 606.171, 803.30, 803.50, 803.53, and 803.56.

To implement these provisions for reporting of adverse events and product problems with human medications, devices, and biologics, as well as any other products that are regulated by FDA, two very similar forms are used (an exception is biologic product deviation reports). Form FDA 3500 is used for voluntary (i.e., not mandated by law or regulation) reporting of adverse events and product problems by health professionals and the public. Form FDA 3500A is used for mandatory reporting (i.e., required by law or regulation). New biologic regulations §§ 600.14 and 606.171 require that biologic product deviation reports, which are similar to drug product problem reports, be submitted to FDA via a different form. Reports of fatalities as a complication of blood collection or transfusion are reported as per § 606.170.

Respondents to this collection of information are health professionals, hospitals and other user-facilities (e.g., nursing homes, etc.), consumers, manufacturers of biologics, drugs and medical devices, and importers.

I. Use of the Voluntary Version (FDA Form 3500)

Individual health professionals are not required by law or regulation to submit adverse event or product problem reports to the agency or the manufacturer. There is one exception. The National Childhood Injury Act of 1986 mandates that certain adverse events following immunization be reported by health care providers to the joint FDA/Centers for Disease Control and Prevention Vaccine Adverse Event Reporting System (VAERS). Vaccine reporting should be submitted on Form VAERS–1 (FDA).

Hospitals are not required by Federal law or regulation to submit adverse event reports on medications. However, hospitals and other medical facilities are required by Federal law to report medical device-related deaths and serious injuries, biological product deviation reports, and reports of fatalities as a complication of blood collection or transfusion.

Manufacturers of dietary supplements do not have to prove safety or efficacy of their products prior to marketing, nor do they have mandatory requirements for reporting adverse reactions to FDA. However, the DSHEA puts the onus on FDA to prove that a particular product is unsafe. Likewise for cosmetics, the act does not give FDA the authority to require manufacturers to register their cosmetic establishments, file data on ingredients, conduct safety testing, or report cosmetic-related injuries. Only postmarket surveillance allows FDA to assess cosmetic problems in the marketplace. If a problem is detected, it is up to the agency to demonstrate that the product is harmful when used according to label directions or under customary conditions of use. Consequently, the agency is totally dependent on voluntary reporting by health professionals and consumers about problems with the use of dietary supplements and cosmetics.

The voluntary version of the form is used to submit all adverse event and product problem reports not mandated by Federal law or regulation.

II. Use of the Mandatory Version (FDA Form 3500A)

A. Drug and Biologic Products

In section 505(j) and 704 of the act (21 U.S.C. 374), Congress has required that important safety information relating to all human prescription drug products be made available to FDA so that it can take appropriate action to protect the public health when necessary. Section 702 of the act (21 U.S.C. 372) authorizes investigational powers to FDA for enforcement of the act. These statutory requirements regarding mandatory reporting have been codified by FDA under parts 310 and 314 (drugs) and part 600 (biologics) of the Code of Federal Regulations. Parts 310, 314, and 600 mandate the use of the FDA Form 3500A for reporting to FDA on adverse events that occur with drugs and biologics. Blood-related fatalities are reported per § 606.170.

B. Medical Device Products

Section 519 of the act (21 U.S.C. 360i) requires manufacturers or importers of devices intended for human use to establish and maintain records, make reports, and provide information as the Secretary of Health and Human Services

may by regulation reasonably require to ensure that such devices are not adulterated or misbranded and to otherwise ensure its safety and effectiveness. Furthermore, the Safe Medical Device Act of 1990, signed into law on November 28, 1990, amends section 519 of the act. The amendment requires that user facilities such as hospitals, nursing homes, ambulatory surgical facilities, and outpatient treatment facilities report deaths related to medical devices to FDA and to the manufacturer, if known. Serious illnesses and injuries are to be reported to the manufacturer or to FDA if the manufacturer is not known. FDA has codified these statutory requirements regarding mandatory reporting under part 803. Part 803 mandates the use of FDA Form 3500A for reporting to FDA on medical devices.

C. Other Products Used in Medical Therapy

There are no mandatory requirements for the reporting of adverse events or product problems with products such as dietary supplements. However, the DSHEA puts the onus on FDA to prove that a particular product is unsafe. Consequently, the agency is totally dependent on voluntary reporting by health professionals and consumers about problems with the use of dietary supplements. (Most pharmaceutical manufacturers already use a one-page modified version of the Form FDA 3500A where section G from the back is substituted for section D on the front of the form.)

D. Medical Device Baseline Information

The Medical Device Reporting form (Form FDA 3417) relates specifically to the individual device and must be submitted with the first adverse event on that device reported via Form FDA 3500A. The information collected includes the basis for marketing (510(k), PMA, etc.), product code for the device, common name, location where manufactured, and other identifying information. The Health Industry Manufacturers Association (HIMA) first commented in 1992 on the redundancy of information required for the Baseline form stating that the information is also collected by the agency though the device listing process (Form FDA 2892) and through Form FDA 3500A. In 1998, HIMA commented again and, at the request of OMB, FDA explored revising Form FDA 3500A to include the information required by the Baseline form that is not collected through the listing process.

In discussions with OMB it was decided that FDA would not attempt to revise Form FDA 3500A at this time, but would proceed with collecting the information required by the Baseline form as a separate part of the device listing process especially because some of the information required by the current Baseline form will be collected in that listing as a change in the listing regulations. Because the collection of registration and listing information will be through electronic means, the agency envisions a menu option on the Internet to facilitate the collection of the remainder of Baseline information.

FDA has held stakeholder meetings and discussed the new device registration and listing system and using the new device and listing system electronic process as the vehicle for the Baseline information collection at those meetings.

The agency requested comments on this proposed collection of information in the **Federal Register** of July 26, 2000 (65 FR 45988).

FDA received comments from four interested parties, but some comments raised multiple concerns.

While the comments on the proposed revisions to the form(s) were mainly favorable, the agency has decided to not revise either form at this time. This decision reflects several concerns. The financial burden that would be placed on sponsors and others required to report, and FDA if the forms underwent revision, and the availability of other avenues by which use of the voluntary and mandatory forms can be optimized, namely appropriate revision of documents related to their completion.

One comment suggested more detailed instructions for completing the MedWatch form. The instructions for the voluntary form 3500 were updated and posted on the Internet in April 2000 and the instructions for 3500A were extensively revised and posted May 2000 (http://www.fda.gov/medwatch/report/instruc.htm). Regarding voluntary reporting, updated instructions for completing the 3500 form were posted on the MedWatch homepage in December 1998 and April 2000. They are available by mail/fax upon request. The revisions of both the voluntary and mandatory instructions for use were based on questions/comments about adverse event/product problem reporting received by the agency over time. One main revision on both forms was to include information about reporting on reuse of medical devices labeled for single use.

One comment suggested revising the March 1992 guidelines to incorporate MedWatch form use. FDA published a revised guidance for industry entitled ''Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report,'' in August 1997 (http://www.fda.gov/cder/guidance/1830fn1.pdf). In this guidance it states that the agency is still considering comments received in response to the proposed **Federal Register** of October 27, 1994, and recommendations recently developed by the International Conference on Harmonization and plans to propose additional amendments to its postmarketing safety reporting regulations. FDA also plans to prepare a single consolidated guidance document on this topic once the process is concluded.

One comment suggested a FDA industry-wide assessment of consistency of MedWatch field use for both devices and drugs. At this time a formal assessment of the completion of the forms is not planned. As stated above, questions/comments about use of the form and reporting have been incorporated into the revised instructions for use for both forms. This issue can also be addressed in any new proposed regulations or guidance documents.

One comment suggested expanding public education regarding postmarketing events. The MedWatch Office is in the process of developing educational materials, primarily for health professionals, to assist in the overall effort to improve the quality of MedWatch reports.

One comment was made about the estimate of the ''hours per response.'' Because the 3500A is used for mandatory reporting subject to different regulations (i.e., 21 CFR 310.305, 312.32, 314.80, 600.80, and part 803), this estimate for reporting burden is limited to completing the form. Estimates of the burden placed on user-facilities, importers and manufacturers to investigate a report and compile the necessary information would be addressed in the final rules for those regulations.

One comment suggested further clarification of the August 1997 guidance for definitions of identifiable patient and reporter. This topic is currently being discussed in the World Health Organization's Council for International Organizations of Medical Sciences, Work Group 5.

One comment suggested focusing on new or unusual events and to allow reporting of known non-serious events via line listing. This same commenter suggested minimal data collection for known and well-characterized cases. These comments are addressed in the August 1997 guidance for industry entitled ''Postmarketing Adverse

Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report.''

One comment suggested adding a box to the 3500A form to require drug manufacturers to state the date the report was forwarded to FDA. This is currently required for medical device reporting, but not for drugs and biologics. However, all manufacturers must report the date received by the manufacturer on form 3500A, section G4. Many large manufacturers have data bases that contain the date the information was received and the date the report was sent to FDA. As a surrogate, these two dates can be compared to see if the company is fulfilling its requirements under the regulations. The agency can use its regulatory discretion in deciding whether or not action is warranted in the case of delayed reports. What is of greater concern is the failure to report and that cannot be detected by adding this information to the form. Given that the goal is for both pharmaceutical and medical device industries to submit the majority of mandatory reports electronically, it would present a financial burden to revamp systems to accommodate a paper form that will be virtually obsolete in the future.

One comment suggested a ''tick box for a 30-day report,'' for form 3500A. At this time there is no requirement for a 30-day report.

As both the 3500 instructions and 3500A instructions can be updated periodically based on questions/comments from stakeholders and statutory/regulatory changes, changing the forms themselves is not seen as necessary at this point.

At such time it is decided to repropose revisions, FDA will consult all interested parties for input into the design.

FDA estimates the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA center(s) (21 CFR section)	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
CBER/CDER[2]					
Form 3500	16,198	1	16,198	0.5	8,099
Form 3500A (310.305, 314.80, 314.98, and 600.80)	600	455.2	273,109	1	273,109
CDRH[3]					
Form 3500	2,650	1	2,650	0.5	1,325
Form 3500A (part 803)	2,046	24	49,305	1	49,305
CFSAN[4]					
Form 3500	550	1	550	0.5	275
Form 3500A	0	0	0	1	0
No mandatory requirements					
Total Hours					332,113
Form 3500					9,699
Form 3500A					322,414

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Center for Biologics Evaluation and Research/Center for Drug Evaluation and Research.
[3] Center for Devices and Radiological Health.
[4] Center for Food Safety and Applied Nutrition.
FDA Form 3500 is for voluntary reporting. FDA Form 3500A is for mandatory reporting.
The figures shown in table 1 of this document are based on actual calendar year 1999 reports and respondents.

As more medical products are approved by the FDA and marketed, and as knowledge increases regarding the importance of notifying FDA when adverse events and product problems are observed, it is expected that more voluntary reports will be submitted. Conversely, with the current plans for increasing electronic submissions it is expected that the number of mandatory reports will decrease.

Dated: November 9, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–29324 Filed 11–15–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1435]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Substantial Evidence of Effectiveness of New Animal Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by December 18, 2000.

ADDRESSES: Submit written comments on the collection of information to Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Substantial Evidence of Effectiveness of New Animal Drugs—21 CFR Part 514—(OMB Control No. 0910–0356)—Extension

Description: Congress enacted the Animal Drug Availability Act of 1996 (ADAA) (Public Law 104–250) on October 9, 1996. As directed by the ADAA, FDA published a final rule July 28, 1999 (64 FR 40746), amending part 514 (21 CFR part 514) to further define substantial evidence in a manner that encourages the submission of new animal drug applications (NADA's), supplemental NADA's and encourages dose range labeling. Substantial evidence is the standard that a sponsor must meet to demonstrate the effectiveness of a new animal drug for its intended uses under the conditions of use suggested in its proposed labeling. It is defined as evidence consisting of one or more adequate and well-controlled studies, such as a study in a target species, study in laboratory animals, field study, bioequivalence study, or an in vitro study, on the basis of which it could fairly and reasonably be concluded by qualified experts that the new animal drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof. The provisions of § 514.4(a) provide the agency with greater flexibility to make case-specific scientific determinations regarding the number and types of adequate and well-controlled studies that will provide, in an efficient manner, substantial evidence that a new animal drug is effective. The agency believes this regulation over time, will reduce the number of adequate and well-controlled studies necessary to demonstrate the effectiveness of certain combination new animal drugs, will eliminate the need for an adequate and well-controlled dose titration study, and may, in limited instances, reduce or eliminate the number of adequate and well-controlled field investigations necessary to demonstrate by substantial evidence the effectiveness of a new animal drug.

Description of Respondents: Respondents to this collection of information are persons and businesses, including small businesses. In the **Federal Register** of August 16, 2000 (65 FR 49989), the FDA published a 60-day notice concerning the proposed extension of this collection of information and requested comments. No comments were received on the estimated annual reporting burden. We therefore believe the total burden estimate of 544,036 hours for the annual reporting and recordkeeping burden should remain unchanged.

FDA estimates the burden of the collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	No. of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
514.4(a)	190	4.5	860	632.6	544,036

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated annual reporting burden is based on consultation by the Center for Veterinary Medicine with several of the major research and development firms that conduct the majority of studies submitted to establish substantial evidence of effectiveness of new animal drugs and agency records.

Dated: November 9, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–29325 Filed 11–15–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Consumer Roundtable; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing the following meeting: Consumer roundtable to discuss consumer protection priorities for the agency. The roundtable will provide an opportunity for FDA to engage in an open dialogue with individual consumer stakeholders on a variety of regulatory and consumer oriented issues. The roundtable is part of the agency's ongoing consultation with stakeholders.

Date and Time: The meeting will be held on December 13, 2000, 9 a.m. to 4 p.m.

Location: The meeting will be held at the Penthouse Conference Room, Hubert H. Humphrey Bldg., 200 Independence Ave. SW., Washington, DC.

Contact: Karen R. Mahoney, Office of Consumer Affairs (HFE–88), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4393, FAX 301–827–2866, e-mail: *kmahoney@oc.fda.gov*.

Registration: Preregistration is required as space is limited. Send registration information (including name, title, organization name, address, telephone, fax number, and e-mail) to the contact person by December 6, 2000.

If you need special accommodations due to a disability, please contact Karen R. Mahoney (address above) at least 7 days in advance.

Background information on this meeting will be available on the FDA Internet site at *http://www.fda.gov/opacom/hpmeetings.html*.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: November 9, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–29424 Filed 10–15–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 13, 2000, 8:30 a.m. to 5:30 p.m. and December 14, 2000, 8 a.m. to 5:30 p.m.

Location: Holiday Inn, Versailles Ballroom, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, e-mail: SomersK@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: On December 13, 2000, the committee will discuss: (1) New drug application (NDA)20–726/S–006, Femara® (letrozole) Tablets, 2.5 mg, Novartis Pharmaceuticals Corp., indicated as first-line therapy in postmenopausal women with advanced breast cancer; and (2) NDA 21–240, histamine hydrochloride injection (1 mg/ml), Maxim Pharmaceuticals, Inc., indicated for adjunctive use with interleukin-2 (aldesleukin) in the treatment of adult patients with advanced metastatic melanoma that has metastasized to the liver. On December 14, 2000, the committee will discuss: (1) Biologics license application (BLA) 99–0786, Campath®, (alemtuzumab), Millenium and Ilex Partners, LP., and Millenium Pharmaceuticals, indicated for the treatment of patients with chronic lymphocytic leukemia who have been treated with alkylating agents and who have failed fludarabine therapy; and (2) single patient exemptions to the use of nonapproved oncology drugs and biologics.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by December 6, 2000. Oral presentations from the public will be scheduled between approximately 8:45 a.m. and 9:15 a.m., and 1:30 p.m. and 1:45 p.m. on December 13, 2000, and between approximately 8:15 a.m. and 8:45 a.m., and 1 p.m. and 1:15 p.m. on December 14, 2000. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before December 6, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation. After the scientific presentations, a 30-minute open public session may be conducted for interested persons who have submitted their request to speak by December 6, 2000, to address issues specific to the submission or topic before the committee.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: November 8, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–29285 Filed 11–15–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of December 2000.

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: December 6, 2000; 9:00 a.m.—5:00 p.m.

Place: DoubleTree Hotel, 1750 Rockville Pike, Rockville, Maryland 20852.

The meeting is open to the public.

The full Commission will meet on Wednesday, December 6, from 9:00 a.m. to 5:00 p.m. Agenda items will include, but not be limited to: a presentation of the Petitioners Attorney Perspective, a summary of the National Vaccine Program Office (NVPO) Vaccine Risk Communication Workshop, a presentation on the Parent Understanding of Immunication Survey Results, and a FDA Workshop summary on Evaluation of New Vaccines. Updates from the Department of Justice and the National Vaccine Program Office, and routine program reports.

Public comment will be permitted before lunch and at the end of the Commission meeting on December 6, 2000. Oral presentations will be limited to 5 minutes per public speaker. Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Ms. Cheryl Lee, Principal Staff Liaison, Division of Vaccine Injury Compensation, Bureau of Health Professions, Health Resources and Services Administration, Room 8A–46, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443–6593. Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. The Division of Vaccine Injury Compensation will notify each presenter by mail or telephone of their assigned presentation time.

Persons who do not file an advance request for a presentation, but desire to make an oral statement, may sign-up in the Conference Room at the DoubleTree Hotel on December 6, 2000. These persons will be allocated time as time permits.

Anyone requiring information regarding the Commission should contact Ms. Lee, Division of Vaccine Injury Compensation, Bureau of Health Professions, Health Resources and Services Administration, Room 8A–46, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443–6593.

Agenda items are subject to change as priorities dictate.

Dated: November 13, 2000.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 00–29327 Filed 11–15–00; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of December 2000.

Name: Council on Graduate Medical Education (COGME).

Date and Time: December 13, 2000; 8:30 a.m.–4:30 p.m.; December 14, 2000; 8:30 a.m.–10:30 p.m.

Place: Holiday Inn Capitol, 550 C Street, SW., Washington, DC 20024.

The meeting is open to the public.

Agenda

The agenda will include: Welcome and opening comments from the Administrator, Health Resources and Services Administration; the Associate Administrator for Health Professions; and the Acting Executive Secretary of COGME. New COGME members will be introduced. The Council will be given an update on the COGME and the National Advisory Council on Nurse

Education and Practice (NACNEP) Report. There will be presentations on the Hispanic Physician Workforce and on Regional Trends in the Physician Workforce. The Council will hear reports from its work groups on GME Financing and Physician Workforce. There will be a discussion on future directions for the Council.

Anyone requiring information regarding the meeting should contact Stanford M. Bastacky, D.M.D., M.H.S.A., Acting Executive Secretary, Council on Graduate Medical Education, Division of Medicine and Dentistry, Bureau of Health Professions, Room 9A–27, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, telephone (301) 443–6326.

Agenda items are subject to change as priorities dictate.

Dated: November 9, 2000.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 00–29328 Filed 11–15–00; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

John H. Chafee Blackstone River Valley National Heritage Corridor Commission; Notice of Meeting

Notice is hereby given in accordance with Section 552b of Title 5, United States Code, that a meeting of the John H. Chafee Blackstone River Valley National Heritage Corridor Commission will be held on Thursday, November 16, 2000.

The Commission was established pursuant to Public Law 99–647. The purpose of the Commission is to assist federal, state and local authorities in the development and implementation of an integrated resource management plan for those lands and waters within the Corridor.

The meeting will convene at 7 p.m. in the Capron Conference Room of the Quaker Inn & Conference Center the following reasons:

1. Approval of Minutes
2. Chairman's Report
3. Executive Director's Report
4. Planning Subcommitte Report
5. Public Input

It is anticipated that about twenty people will be able to attend the session in addition to the Commission members.

Interested persons may make oral or written presentations to the Commission or file written statements. Such requests should be made prior to the meeting to:

Michael Creasey, Executive Director, John H. Chafee Blackstone River Valley National Heritage Corridor Commission, One Depot Square, Woonsocket, RI 02895; Tel.: (401) 762–0250.

Further information concerning this meeting may be obtained from Michael Creasey, Executive Director of the Commission at the aforementioned address.

Michael Creasey,

Executive Director BRVNHCC.

[FR Doc. 00–29391 Filed 11–15–00; 8:45 am]

BILLING CODE 4310–RK–P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

National Invasive Species Council

AGENCY: Office of the Secretary, Interior.

ACTION: Notice of Comment Period Extension—Second Draft of the National Invasive Species Management Plan, ''Meeting the Challenge.''

SUMMARY: The National Invasive Species Council announced the availability of the draft National Management Plan on October 2, 2000, for a public review period of 45 days. Pursuant to Executive Order 13112, this Plan was due in August of this year. In response to a number of requests, the Council is extending the comment period for an additional 15 calendar days. The new deadline for submitting comments will now be 6:00 p.m. (eastern) on Friday, December 1, 2000.

Availability: Copies of the draft Plan can still be obtained via the Council's website: www.invasivespecies.gov; or by contacting the Council Staff at 202–208–6336 (phone); 202–208–1526 (Fax); or by e-mail at invasivespecies@ios.doi.gov.

Where to Send Comments: Comments can be submitted to the Council Staff via regular mail to the address below, via e-mail at invasivespecies@ios.doi.gov, or by fax to 202–208–1526.

ADDRESSES: National Invasive Species Council, 1951 Constitution Avenue, NW., Suite 320, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Kelsey Passe, National Invasive Species Council Program Analyst; E-mail: Kelsey_Passe@ios.doi.gov; Phone: (202) 208–6336; Fax: (202) 208–1526.

Dated: November 13, 2000.

Lori Williams,

Executive Director, National Invasive Species Council.

[FR Doc. 00–29416 Filed 11–15–00; 8:45 am]

BILLING CODE 4310–RK–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Information Collection To Be Submitted to the Office of Management and Budget (OMB) for Approval Under the Paperwork Reduction Act (PRA) for the Boating Infrastructure Grant Program; Correction

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice; Correction.

SUMMARY: We published a notice on October 24, 2000 (65 FR 63606) with a date for the receipt of comments on or after December 26, 2000. The corrected date should be on or before December 26, 2000.

DATES: We will accept comments on this notice on or before December 26, 2000.

ADDRESSES: The public must make comments and suggestions directly to the Office of Management and Budget, Office of Regulatory Affairs, 725 17th Street NW, Washington, DC 20503; and Rebecca Mullin, U.S. Fish and Wildlife Service Information Collection Officer, 4401 North Fairfax Drive, Room 222, Arlington, VA 22203.

FOR FURTHER INFORMATION CONTACT: Steve Farrell, (703) 358–2156, Division of Federal Aid, U.S. Fish and Wildlife Service.

SUPPLEMENTARY INFORMATION: On October 24, 2000, we published a notice requesting comments on Information Collection for approval under the Paperwork Reduction Act for the Boating Infrastructure Grant Survey Program. The **DATES** caption stated that comments should be submitted on or after December 26, 2000. The correct date for accepting comments from the public is on or before December 26, 2000.

Accordingly, in FR Doc. 00–27109 published at 65 FR 63606 on October 24, 2000, on page 63607, in column 1, correct the **DATES** caption to read as follows:

DATES: Interested parties must submit comments on or before December 26, 2000.

Dated: November 9, 2000.

Rebecca A. Mullin,

Information Collection Officer, Fish and Wildlife Service.

[FR Doc. 00–29308 Filed 11–15–00; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Notice of Receipt of Applications for Permit

Endangered Species

The following applicants have applied for a permit 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: Steven N. Mitchell, Douglas, GA, PRT–034848

The applicant requests a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus dorcas*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Academy of Natural Sciences, Philadelphia, PA, PRT–678963

The applicant requests renewal of their permit to export and re-import non-living museum specimens of endangered and threatened species of plants and animals previously accessioned into the permittee's collection for scientific research. This notification covers activities conducted by this applicant for a period of five years.

Marine Mammals

The public is invited to comment on the following application for a permit to conduct certain activities with marine mammals. The application was submitted to satisfy requirements of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*) and the regulations governing marine mammals (50 CFR 18).

Applicant: Michael Deschamps, Brooktondale, NY, PRT–035274

The applicant requests a permit to import a polar bear (*Ursus maritimus*) sport-hunted from the McClintock Channel polar bear population Canada for personal use.

Written data or comments should be submitted to the Director, U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203 and must be received by the Director within 30 days of the date of this publication.

The U.S. Fish and Wildlife has information collection approval from OMB through February 28, 2001. OMB Control Number 1018–0093. Federal Agencies may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a current valid OMB control number.

Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, Division of Management Authority, 4401 North Fairfax Drive, Room 700, Arlington, Virginia 22203. Phone: (703/358–2104); FAX: (703/358–2281).

Dated: November 9, 2000.

Lisa Lierheimer,

Acting Chief, Branch of Permits, Division of Management Authority.

[FR Doc. 00–29307 Filed 11–15–00; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Receipt of Application for Endangered Species Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of application for endangered species permit.

SUMMARY: 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.*).

If you wish to comment, you may submit comments by any one of several methods. You may mail comments to the Service's Regional Office (see **ADDRESSES**). You may also comment via the internet to ''victoria_davis@fws.gov''. Please submit comments over the internet as an ASCII file avoiding the use of special characters and any form of encryption. Please also include your name and return address in your internet message. If you do not receive a confirmation from the Service that we have received your internet message, contact us directly at either telephone number listed below (see **FURTHER INFORMATION**). Finally, you may hand deliver comments to either Service office listed below (see **ADDRESSES**). Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the administrative record. We will honor such requests to the extent allowable by law. There may also be other circumstances in which we would withhold from the administrative record a respondent's identity, as allowable by law. If you wish us to withhold your name and address, you must state this prominently at the beginning of your comments. We will not; however, consider anonymous comments. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

DATES: Written data or comments on these applications must be received, at the address given below, by December 18, 2000.

ADDRESSES: Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, 1875 Century Boulevard, Suite 200, Atlanta, Georgia 30345 (Attn: Victoria Davis, Permit Biologist). Telephone: 404/679–4176; Facsimile: 404/679–7081.

FOR FURTHER INFORMATION CONTACT: Victoria Davis, Telephone: 404/679–4176; Facsimile: 404/679–7081.

SUPPLEMENTARY INFORMATION:

Applicant: Kevin J. Roe, University of Alabama, Tuscaloosa, Alabama TE035514–0.

The applicant requests authorization to take the Kentucky Cave shrimp, *Palaemonias ganteri* and the Alabama Cave shrimp, *Palaemonias alabamae. Palaemonias ganteri* will be obtained throughout the species range at Mammoth Cave National Park, Barren, Edmonson, and Hart Counties. *Palaemonias alabamae* will be obtained throughout the species range at the Glover-Brazelton Cave system and Bobcat Cave, Madison, County, Alabama. The purpose of the take to examine morphological and molecular characters of extant population to accurately determine their taxonomic and systematic status.

Dated: November 6, 2000.

H. Dale Hall,

Acting Regional Director.

[FR Doc. 00–29313 Filed 11–15–00; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Geological Survey

Request for Public Comments on Proposed Information Collection To Be Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The proposal for the collection of information described below will be submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35). Copies of the proposed collection of information and related forms may be obtained by contacting the Bureau's clearance officer at the phone number listed below. Comments and suggestions on the proposal should be made within 60 days directly to the Bureau clearance officer, U.S. Geological Survey, 807 National Center, 12201 Sunrise Valley Drive, Reston, Virginia 20192, telephone (703) 648–7313.

Specific public comments are requested as to:

1. Whether the collection of information is necessary for the proper performance of the functions on the bureaus, including whether the information will have practical utility;
2. The accuracy of the bureau's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
3. The quality, utility, and clarity of the information to be collected; and
4. How to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other forms of information technology.

Title: Understanding Visitor Uses, Motives and Benefits at Sherburne National Wildlife Refuge.

OMB approval number: New collection.

Abstract: Respondents supply information through a mailed survey and onsite interviews on (1) their motivations for visiting Sherburne National Wildlife Refuge; (2) desired experiences and benefits they receive from Sherburne National Wildlife Refuge; (3) attitudes and perceptions of various management issues on Sherburne National Wildlife Refuge, and (4) the management actions and objectives they prefer for Sherburne National Wildlife Refuge. This information will be used to help improve the management and operation of Sherburne National Wildlife Refuge.

Bureau form number: Various.

Frequency: One time (2001).

Description of respondents: Visitors to Sherburne National Wildlife Refuge in the state of Minnesota.

Estimated completion time: 0.33 hours (20 minutes).

Annual responses: 1000.

Annual burden hours: 330.

Bureau clearance officer: John Cordyack 703–648–7313.

Dated: November 8, 2000.

Susan Haseltine,

Chief Scientist for Biology.

[FR Doc. 00–29392 Filed 11–15–00; 8:45 am]

BILLING CODE 4310–7Y–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–105–1990–HP; GP01–0029; OR 56024]

Closure of Public Lands: Douglas County, OR

AGENCY: Bureau of Land Management, Roseburg District Office, South River Field Office, Interior.

ACTION: Closure of public lands in Douglas County, Oregon.

SUMMARY: The following areas are closed to and restricted from public uses, including camping, hunting, mining, erecting structures and storing personal property, until further notice. The Oregon Department of Environmental Quality is conducting an interim removal action of acid mine drainage from the Formosa Abandoned Mine Land. This closure is to protect human health and to provide security for the facilities.

EFFECTIVE DATE: The closure will become effective immediately and will remain in effect until further notice.

FOR FURTHER INFORMATION CONTACT: Eric Heenan, Mining Engineering Technician, South River Field Office, 777 NW Garden Valley Blvd., Roseburg, Oregon 97470, (541) 440–4930.

SUPPLEMENTARY INFORMATION: Notice is hereby given that pursuant to 43 CFR 8364.1 (Closure and Restriction Orders), which provides, in part, for the authorized officer to close or restrict use of designated public lands for the protection of persons, property, and public lands and resources, the following areas are closed to and restricted from public uses, including camping, hunting, mining, erecting structures and storing personal property, until further notice. Maps showing the described area are available at the BLM's Roseburg District Office. The public lands closed under this order will be posted with signs at points of access. This closure is consistent with the Roseburg District Record of Decision and Resource Management Plan, June 1995.

The public lands affected by this closure are located around Silver Butte and along Middle Creek and South Fork Middle Creek, approximately 6 miles south of Riddle, Oregon. Use of motorized vehicle on existing improved roads is allowed. The lands involved are more specifically described as:

Willamette Principal Meridian, Douglas County, Oregon

T. 31 S., R. 6 W.,
Sec. 22, S½S½SE¼,
Sec. 23, S½SW¼.
Containing approximately 120 acres.

The following persons, operating within the scope of their official duties, are exempt from the provisions of this closure order: Bureau of Land Management employees; State of Oregon employees and subcontractors; state, local and federal law enforcement and fire protection personnel. Additional parties may be allowed, but must have advanced written approval from the Authorized Officer.

Any person who fails to comply with the provisions of this closure may be subject to, but not limited to, the penalties provided in 43 CFR 8360.0–7, which include a fine not to exceed $1,000 and/or imprisonment of not to exceed 12 months, as well as the penalties provided under Oregon State law.

Dated: November 1, 2000.

E. Dwight Fielder,

Field Manager, South River Field Office.

[FR Doc. 00–29395 Filed 11–15–00; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–930–01–1990–00; CACA–35511]

Imperial Project Proposed Open Pit Gold Mine, Southeastern Imperial County, California; Notice of Availability of Final Environmental Impact Statement/Environmental Impact Report

AGENCY: Bureau of Land Management, Department of the Interior, El Centro Field Office, California Desert District.

ACTION: Correction of **Federal Register** Notice of 11/09/00, Vol. 65, No. 218.

SUMMARY: This notice corrects the ending date of acceptance of public comments on the Imperial Project FEIS/EIR from November 27, 2000, to the close of business on December 18, 2000.

The remainder of this notice, with the exception of the December 18, 2000 date, and a minor correction of the internet web page address from ''imperial project'' to ''imperial_project'' is identical to the November 9th notice.

In compliance with the National Environmental Policy Act (NEPA) of 1969 and 40 CFR 1503.4, this is notice that the Bureau of Land Management (BLM) and the County of Imperial have jointly published the Final Environmental Impact Statement/ Environmental Impact Report (Final EIS/EIR) on the proposed Imperial Project. The Bureau of Land Management (BLM) has prepared a Final EIS/EIR for the Imperial Project, proposed by Glamis Imperial Corporation is an open-pit gold mine on about 1,500 acres of public land. The project is located on BLM-administered public lands in an unincorporated area of southeastern Imperial County, California. The Final EIS/EIR contains the BLM preferred alternative.

Interested citizens are invited to review a copy of the Final EIS. The entire document will be available on the internet at http://www.ca.blm.gov/ elcentro/imperial_project. The document also is available by request to the BLM El Centro Field Office on CD-ROM. The CD-ROM is in Adobe Acrobat Reader format, and contains a free download of Acrobat Reader so it can be opened easily.

A limited number of paper copies of the Final EIS are available, and a copy may be obtained by telephoning or writing the contact person listed below. Public reading copies are available at the following public libraries:

List of Libraries to Which Copies of the Final EIS/EIR Have Been Sent

Arizona Western College Library, 9500 South Avenue 8 East, Yuma, AZ 85365
Holtville Library, 101 East Sixth Street, Holtville, CA 92250
BLM Library SC–322A, Bldg. 50, Denver Federal Center, Denver, CO 80225
Brawley Public Library, 400 Main Street, Brawley, CA 92227
Calexico City Library, 850 Encinas Avenue, Calexico, CA 92231
El Centro Public Library, 539 State Street, El Centro, CA 92243
Imperial County Library, 1647 West Main Street, El Centro, CA 92243
Imperial County Free Library, 939 West Main Street, El Centro, CA 92243
Imperial Valley College Library, 380 East Aten Road, Imperial, CA 92251
Imperial Public Library, 200 W. Ninth Street, Imperial, CA 92251
Meyer Memorial Library, 225 West Main Street, Calipatria, CA 92233
Palo Verde District Library, 125 W. Chanslor Way, Blythe, CA 92225
San Diego City Public Library—Clairemont, 2920 Burgener Boulevard, San Diego, CA 92110–1027
San Diego City Public Library—Logan Hills, 811 South 28th Street, San Diego, CA 92113–2498
San Diego City Pub. Library—Mission Hills, 925 West Washington Street, San Diego, CA 92103–1895
San Diego City Public Library—Oak Park, 2802 54th Street, San Diego, CA 92105–4941
San Diego City Public Library—Paradise Hills, 5922 Rancho Hills Drive, San Diego, CA 92139–3137
San Diego County Public Library, 2130 Arnold Way, Alpine, CA 91901–9499
San Diego County Public Library, 652 Palm Canyon Drive, Borrego Springs, CA 92004–0297
San Diego County Public Library, 1309 Camino del Mar, Del Mar, CA 92014–2693
San Diego County Public Library, 201 E. Douglas, El Cajon, CA 92020–4519
San Diego County Public Library, 8055 University Avenue, La Mesa, CA 91941–5097
San Diego County Public Library, 1406 Monicito Road, Ramona, CA 92065–2296
San Diego County Public Library, 700 Eucalyptus Avenue, Vista, CA 92084–6245
San Diego State University Library, 720 Heber Avenue, Calexico, CA 92231
Sierra Club, San Diego Chapter Office Library, 3820 Ray Street, San Diego, CA 92104–3623
Yuma County Library District, 350 South 3rd Avenue, Yuma, AZ 85364.

DATES: Public comments on the Final EIS/EIR will be accepted at the BLM El Centro Field Office until close of business on December 18, 2000. Unless specifically requested otherwise, names of commentators will be available to the public. BLM will be rendering a decision on the proposed Project no sooner than mid-December 2000.

FOR ADDITIONAL INFORMATION CONTACT: Comments on the Final EIS/EIR should be addressed to Mr. Glen R. Miller, BLM El Centro Field Office, 1661 S. 4th St., El Centro, CA 92243. To obtain copies of the Final EIS/EIR, contact Mr. Miller at (760) 337–4473. Fax requests may be sent to the attention of Mr. Glen Miller at (760) 337–4490. Requests also may be placed through email at: gmiller@ ca.blm.gov. Please specify either CD-ROM or the specific volume(s) desired (see Supplemental Information below). Include your name, complete mailing address (no P.O. Boxes), and phone number on all requests.

SUPPLEMENTARY INFORMATION:

A Draft EIS/EIR was published in November 1997, with a comment period closing on April 13, 1998.

A Recirculated Supplement to the Draft EIS/EIR (SDEIS/EIR) was released in March 1999.

The Final EIS/EIR incorporates changes based on public comments received on the Draft EIS/EIR. The Final EIS/EIR contains the BLM Preferred Alternative, along with responses to written comments received during the 135-day public comment period for the Draft EIS/EIR. Both the Solicitor's Opinion on regulation of hardrock mining in the California desert, and a report of the task force of the Advisory Council on Historic Preservation are included as appendices to Volume I. The Final EIS/EIR has 3 volumes:

- Volume I—Main Text—(incorporates changes to DEIS/EIR, text and appendices)
- Volume II—Technical Appendices—(this is identical to the DEIS/EIR Volume II)
- Volume III—Public Comments to the Draft EIS/EIR and Responses to Comments—Written Comment Letters from Individuals/Petitions/Form Letters

Dated: November 9, 2000.

Greg Thomsen,

Field Manager.

[FR Doc. 00–29401 Filed 11–15–00; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CO–14000–01–1610–DH]

Resource Management Plan Amendment

AGENCY: Bureau of Land Management, Glenwood Springs Field Office, Interior.

ACTION: Notice of Intent to Prepare an Environmental Impact Statement (EIS) to Amend the Glenwood Springs Field Office Resource Management Plan (RMP) and the White River Field Office RMP for the Roan Plateau Area.

SUMMARY: Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969 and section 202 of the Federal Land Policy and Management Act of 1976 and Bureau of Land Management (BLM) regulations in CFR 1610.2 and 1610.5–5. BLM intends to write an Environmental Impact Statement which will amend the RMP for the Glenwood Springs Field Office (GSFO) approved in January of 1984 and

the White River Field Office RMP of 1997.

The planning area is northwest of the town of Rifle, Colorado. It generally includes all BLM managed public lands west of State Highway 13 and north of Interstate 70, east of Parachute Creek, and roughly south of the Garfield County Rio Blanco County line. The amendment will consider management changes to the on approximately 73,367 acres (68,447 surface and 4,455 sub-surface, including 4,455 surface/sub-surface acres within the White River Resource Area). Boundaries may be adjusted after the scoping phase of planning is completed.

The BLM proposes to develop a scientifically sound, community supported strategy for the management of the public lands in the Roan Plateau area. The EIS will be prepared using an inter-disciplinary approach to insure the integration of biological, social and environmental values. The disciplines of the preparers shall be appropriate to the scope and issues identified in the scoping process. The analysis for the amendment will be embodied with the analysis for the EIS.

The amendment will focus on the major needed land use allocation decisions including; oil and gas management, wilderness suitability, special area designations (Area of Critical Environmental Concern, Wilderness Study Area, etc.) and travel management. The amendment will also review and analyze the multiple of public land uses and resource issues as identified by scoping and necessary to develop a proactive integrated management strategy.

DATES: The BLM can best utilize your input if you submit written comments pertaining to management concerns; important social, economic and environmental values; resource use; resource development and resource protection before January 31, 2001. A public scoping meeting will be held from 3:30 p.m. to 7:30 p.m. on December 13, 2000 at the Rifle Fire Department, 1850 Railroad Ave in Rifle, Colorado 81650.

ADDRESSES: Comments should be sent to the Field Manager, Glenwood Springs Field Office, Bureau of Land Management, 50629 Highway 6 & 24, P.O. Box 1009, Glenwood Springs, CO 81602

FOR FURTHER INFORMATION CONTACT: Requests to be placed on a mailing list should be mailed to the address above. You can also telephone Brian Hopkins at (970) 947–2840 or e-mail him at bhopkins@co.blm.gov. Documents and maps relevant to the planning process will be available for public review at the Glenwood Springs Field Office and, as feasible, available on the Glenwood Springs Field Office website http://www.co.blm.gov/gsra/roanplateau.htm.

SUPPLEMENTARY INFORMATION: In November, 1997 Public Law 105–85 directed the transfer of jurisdiction of the area formally known as the (NOSR) from the Department of Energy (DOE) to the BLM. The transfer directed that the lands be managed in accordance with laws applicable to public lands, including Federal Land Policy and Management Act (FLPMA.).

BLM has been providing custodial surface management for some activities on the Naval Oil Shale Reserve (NOSR) for many years under a Memorandum of Understanding (MOU) with the Department of Energy. The formal transfer of the lands to the BLM has broadened BLM's overall management responsibilities and created the need to amend the RMPs for the GSFO and the WRFO. From a planning and public involvement standpoint it is efficient to include the identified adjacent lands in the planning process.

The foremost goal of the planning process is to ensure opportunities for the public to participate in the planning process. Individuals will have the opportunity to attend public meetings and field trips, write letters, telephone and meet with directly with the planning staff.

Anne Huebner,

Glenwood Springs Field Manager.

[FR Doc. 00–29402 Filed 11–15–00; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF INTERIOR

Bureau of Land Management

[CA–160–1220–00]

Meeting of the Central California Resource Advisory Council

AGENCY: Bureau of Land Management, Department of the Interior.

ACTION: Meeting of the Central California Resource Advisory Council.

SUMMARY: Pursuant to the authorities in the Federal Advisory Committee Act (Pub. L. 92–463) and the Federal Land Policy and Management Act of 1976 (sec. 309), the Bureau of Land Management Resource Advisory Council for Central California will meet in Sacramento.

DATES: Thursday and Friday, November 30–December 1, 2000.

ADDRESSES: BLM-California State Office, 2135 Butano Drive, Sacramento, CA 95825.

SUPPLEMENTARY INFORMATION: The 12 member Central California Resource Advisory Council is appointed by the Secretary of the Interior to advise the Bureau of Land Management on public land issues. On Friday morning, the Council will hold a satellite teleconference with Secretary of the Interior Bruce Babbitt, and will meet with new BLM-California State Director Mike Pool. Other agenda items for the two meetings include a discussion of the BLM land exchange program, and a review of Council's proposed standards and guidelines for the recreation program. There will be a public comment period at 11:30 a.m. Thursday and at 1 p.m. on Friday at which time the Council will hear comments on any public land issue. Written comments will also be accepted, either at the meeting or at the address below.

FOR FURTHER INFORMATION CONTACT: Larry Mercer, Public Affairs Officer, Bureau of Land Management, 3801 Pegasus Drive, Bakersfield, CA 93308, telephone 661–391–6010.

Dated: November 9, 2000.

Ron Fellows,

Field Manager.

[FR Doc. 00–29397 Filed 11–15–00; 8:45 am]

BILLING CODE 4310–40–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–670–00–1220–00, C00–0927 WHA–ADR]

Imperial Sand Dunes Vehicular Use Closure

AGENCY: Bureau of Land Management, Department of the Interior, El Centro Field Office, California Desert District.

ACTION: Temporary closure of parts of the Imperial Sand Dunes Recreation Management Area to off-highway vehicle and other vehicular use in compliance with court-approved stipulations resulting from a lawsuit involving the Endangered Species Act.

SUMMARY: On March 16, 2000 a lawsuit was filed against the Bureau of Land Management by Center for Biological Diversity, Sierra Club and Public Employees for Environmental Responsibility. The basis of the lawsuit is that BLM has not yet consulted with the U.S. Fish and Wildlife Service, as required by the Endangered Species Act, on the effects of the California Desert Conservation Area Plan on species listed by the Service as threatened or

endangered. In compliance with stipulations agreed to by the plaintiffs and the BLM and approved by the U.S. District Court for the Northern Jurisdiction regarding Case No. C00–0927 WHA–ADR, the public land areas described below within the Imperial Sand Dunes Recreation Management Area are closed to off-highway vehicle and other vehicular use effective Nov 3, 2000.

This is a temporary closure until the Bureau of Land Management consults with and receives a Biological Opinion from the U. S. Fish and Wildlife Service on the impacts of vehicular use in the Imperial Sand Dunes Recreation Area on the Peirson's milk-vetch *(Astragalus magdalenae var. peirsonii),* designated by Service in 1998 as a threatened species under the Endangered Species Act.

Affected Lands

Parcel 1, the northern closure area as stipulated in the above mentioned case, is bounded on the southeasterly side by the North Algodones Wilderness Area, on the northeasterly side by Niland-Glamis Road, on the north side by a latitudinal line, and on the southwesterly side by the New Coachella Canal Road. Said parcel contains 3,800 acres more or less, and is more particularly described as follows:

Beginning at the northwesterly corner of the North Algodones Wilderness Area; thence southwesterly on a prolongation of the northwesterly line of the above mentioned wilderness area, approximately 300 feet to a line parallel with and 15.00 feet northeast of the center line of the New Coachella Canal Road (approximate geographic position: longitude 115.26404 degrees, latitude 33.06407 degrees); thence northwesterly, parallel with and 15.00 feet northeast of the center line of the New Coachella Canal Road, to a point at latitude 33.1038 degrees (approximate geographic position: longitude 115.31038 degrees, latitude 33.1038 degrees); thence east to a line parallel with and 20.00 feet southwesterly of the center line of Niland-Glamis Road (approximate geographic position: longitude 115.23364 degrees, latitude 33.1038 degrees); thence southeasterly, parallel with and 20.00 feet southwesterly of the center line of Niland-Glamis Road, to a prolongation of the northwesterly line of the North Algodones Wilderness Area (approximate geographic position: 115.23123 degrees, latitude 33.10230 degrees); thence southwesterly along said line of prolongation 85.00 feet to point 1 of the North Algodones Wilderness Area; thence continuing southwesterly along the northwesterly line of the wilderness boundary to the point of beginning.

Parcel 2, the small central closure as stipulated in the above mentioned case, contains 2,000 acres more or less, and is more particularly described as follows:

Beginning at longitude 115.09392 degrees, latitude 32.92036 degrees; thence to longitude 115.10286 degrees, latitude 32.91969 degrees; thence to longitude 115.10916 degrees, latitude 32.92183 degrees; thence to longitude 115.11854 degrees, latitude 32.93341 degrees; thence to longitude 115.12616 degrees, latitude 32.93998 degrees; thence to longitude 115.11041 degrees, latitude 32.95332 degrees; thence to longitude 115.09628 degrees, latitude 32.95288 degrees; thence to longitude 115.09225 degrees, latitude 32.94338 degrees; thence to point of beginning.

Parcel 3, the large central closure area as stipulated in the above-mentioned case, is bounded on the northeasterly side by Wash Road, on the north side by a latitudinal line, on the southwesterly side by the Sand Highway, and on the southeasterly side by a line falling northerly of Patton Valley. Said parcel contains 43,035 acres more or less, and is more particularly described as follows:

Beginning at the point of intersection of a line parallel with and 20.00 feet northeasterly of the northeasterly edge of the Sand Highway and a line parallel with and 150.00 feet northwesterly of the center line of Patton Valley Road (approximate geographic position: longitude 114.96653 degrees, latitude 32.76586 degrees); thence northwesterly, parallel with and 20.00 feet northeasterly of the northeasterly edge of the Sand Highway, to a point at latitude 32.90653 degrees (approximate geographic position: longitude 115.11257 degrees, latitude 32.90653 degrees); thence east to a line parallel with and 20.00 feet southwesterly of the center line of Wash Road (approximate geographic position: longitude 114.95415 degrees, latitude 32.90653 degrees); thence southeasterly, parallel with and 20.00 feet southwesterly of the center line of Wash Road, to a point at latitude 32.83805 degrees (approximate geographic position: longitude 114.86802 degrees, latitude 32.83805 degrees); thence southwesterly to a line parallel with and 150.00 feet northwesterly of the center line of Patton Valley Road, at latitude 32.78236 degrees (approximate geographic position: longitude 114.95298 degrees, latitude 32.78236 degrees); thence southwesterly, parallel with and 150.00 feet northwesterly of the center line of Patton Valley Road, to the point of beginning.

Parcel 4, the south central closure as stipulated in the above mentioned case is bounded on the southwesterly side by the Sand Highway, on the northwesterly side by Patton Valley Road, with the remainder being defined by longitude and latitude. Said parcel contains 310 acres more or less, and is more particularly described as follows:

Beginning at the point of intersection of a line parallel with and 20.00 feet northeasterly of the northeasterly edge of the Sand Highway and a line parallel with and 150 feet southeasterly of the center line of Patton Valley Road; thence northeasterly, parallel with and 150.00 feet southeasterly of the center line of Patton Valley Road, to a point at latitude 32.77713 degrees (approximate geographic position: longitude 114.95341 degrees, latitude 32.77713 degrees); thence easterly, leaving said road, to longitude 114.94770 degrees, latitude 32.77746 degrees; thence to longitude 114.94433 degrees, latitude 32.77629 degrees; thence to longitude 114.94401 degrees, latitude 32.77449 degrees; thence to longitude 114.94708 degrees, latitude 32.77218 degrees; thence to longitude 114.95472 degrees, latitude 32.76916 degrees; thence southwesterly to a line parallel with and 20.00 feet northeasterly of the northeasterly edge of the Sand Highway, at latitude 32.76222 degrees (approximate geographic position: longitude 114.96253 degrees, latitude 32.76222 degrees); thence northwesterly, parallel with and 20.00 feet northeasterly of the northeasterly edge of the Sand Highway, to the point of beginning.

Parcel 5, the southern closure as stipulated in the above mentioned case, contains 160 acres more or less, and is more particularly defined as follows:

Beginning at longitude 114.91161 degrees, latitude 32.71803 degrees; thence to longitude 114.91115 degrees, latitude 32.72076 degrees; thence to longitude 114.90694 degrees, latitude 32.72732 degrees; thence to longitude 114.90049 degrees, latitude 32.72711 degrees; thence to longitude 114.90507 degrees, latitude 32.71860 degrees; thence to longitude 114.90873 degrees, 32.71786 degrees; thence to point of beginning.

In all five areas, the longitudes and latitudes are based upon the North American Datum of 1983, and were derived from the Bureau of Land Management's Base Cartographic Data as depicted in the exhibits for the above-mentioned case. Longitudinal and latitudinal coordinates are informative calls and shall yield to the physical features where cited. More accurate positions will be collected and recorded when the official survey is performed.

This legal land description will be finalized after formal Land Survey Plats are completed.

Official government vehicles conducting monitoring or other legitimate governmental activities shall be allowed inside the closed areas.

For Additional Information Contact: Roxie Trost, BLM, El Centro Field Office, 1661 S. 4th Street, El Centro , CA 92243, telephone (760) 337 4400.

Greg Thomsen,

Area Manager.

[FR Doc. 00–29314 Filed 11–15–00; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[WY–010–2822JL]

Emergency Closure to Motorized Vehicle Use on Public Lands Administered by the Bureau of Land Management (BLM), Worland Field Office, Within the Enos Complex Fire area, Hot Springs and Park Counties, Wyoming

AGENCY: Bureau of Land Management, Interior.

ACTION: Emergency closure.

SUMMARY: The Bureau of Land Management (BLM), Worland Field Office, hereby gives notice that, effective immediately, all tracks and other areas disturbed by fire-fighting equipment in the Enos Complex Fire area are closed to motorized vehicle use. The purpose for this emergency closure is to facilitate reclamation of the public lands disturbed or damaged during suppression of the 13,664-acre Enos Complex Fire.

An Emergency Fire Rehabilitation Plan has been prepared and approved for this burned area. Some of the rehabilitation actions include reseeding areas with native vegetation and constructing water bars on fire lines. Areas disturbed by fire-fighting equipment will be signed as ''Closed to Motor Vehicle Use.'' Motorized vehicle travel on these disturbed areas and other areas affected by the fire could increase soil erosion, impair wildlife habitat, damage cultural resources, and jeopardize the rehabilitation efforts.

This emergency closure includes some roads and trails which existed before the fire.

EFFECTIVE DATES: This closure to motorized vehicle use is effective immediately and will remain in effect until modified or rescinded by the authorized officer.

FOR FURTHER INFORMATION CONTACT: Darrell Barnes, Field Manager, Worland Field Office, P.O. Box 119, 101 South 23th Street, Worland, Wyoming 82401–0119. Telephone (307)347–5100.

SUPPLEMENTARY INFORMATION: The Enos Creek Complex Fire began with lightning strikes on July 27, 2000. The fires encompassed 13,664 acres of federal, state, and private lands. The purpose of this emergency closure is to eliminate unnecessary vehicle use while providing a minimum amount of access into the area for recreation. This order will help facilitate the area's rehabilitation from the fire. Vehicles traveling off-road in a burned area may damage reemerging plants, increase erosion, and spread noxious weeds.

The management of off-road vehicles is addressed in the Grass Creek Resource Management Plan (BLM, Sept. 1998).

The Enos Creek area is an important wildlife habitat and hunting area. The recent fire burned more then 90 percent of the area, leaving very little in the way of security cover for wildlife. Keeping vehicle traffic away from some areas for one or two growing seasons will help in the rehabilitation. There is also a need to allow some vehicle access so hunters can harvest big game animals. The Worland Field Office specialists will analyze the effects of this closure in the summer of 2001 and extend, modify, or rescind this order as deemed necessary by the authorized officer.

The following described BLM-administered lands are included in this Emergency Road Closure.

6th Principal Meridian

T. 46 N., R. 99 W., sec. 15, 17, and 18;
T. 45 N., R. 100 W., sec. 1, 2, 3 ,4, 5, 6, and 21;
T. 46 N., R, 100 W., sec. 13 through 29, 33, 34, and 35;
T. 47 N., R. 100 W., sec. 27, 28, 33, 24, and 35.

Authority for Off-Road Vehicle Management, closure and restriction orders is provided under 43 CFR subpart 8341.2 (a and b), and 8364.1. Violations of this management plan are punishable by a fine not to exceed $1,000 and (or) imprisonment not to exceed 12 months.

Dated: October 13, 2000.

Darrell Barnes,

Worland Field Manager.

[FR Doc. 00–29396 Filed 11–15–00; 8:45 am]

BILLING CODE 4310–22–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–180–1430–EU; CACA–42586]

Notice of Realty Action: Direct Sale of Public Sale, Mariposa County, CA

SUMMARY: The Bureau of Land Management (BLM) examined the following described federal lands and through the NEPA process determined them suitable for disposal by direct sale, including the mineral estate with no known value, pursuant to sections 203 and 209 of the Federal Land Policy and Management Act of October 21, 1976 (43 U.S.C. 1713 and 1719), at no less than fair market value.

Federal lands determined suitable for direct sale are described as:

Mount Diablo Meridian, California

T. 3 S., R. 16 E.,
Sec. 11: portion of the SESW.
Containing approximately 3.31 acres.

The lands are not required for federal purposes, and it has been determined that disposal of these parcels would be in the public's interest. The land is being offered by direct sale to Dr. Raymond Bessemer. It has been determined that the subject parcels contain no known mineral values. Acceptance of a direct sale offer will constitute an application for conveyance of those mineral interests having no known value. The applicant will be required to pay a $50.00 non-refundable filing fee for conveyance of the said mineral interests. The land will not be offered for sale until at least 60 days after publication of this notice in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Karen Montgomery, Realty Specialist, Bureau of Land Management, Folsom Field Office, 63 Natoma Street, Folsom, California 95630; (916) 985–4474.

SUPPLEMENTARY INFORMATION: The public lands being offered to Dr. Raymond Bessemer are currently encumbered by Dr. Bessemer's improvements. The above described land is hereby segregated from appropriation under the public land laws, including the mining laws, but not from sale under the above cited statutes, for 270 days from the date of publication of this notice, or until title transfer is completed or the segregation is terminated by publication in the **Federal Register**, whichever occurs first.

A patent, when issued, will contain the following reservations to the United States: 1. A right-of-way thereon for ditches or canals constructed by the authority of the United States pursuant to the Act of August 30, 1890 (26 Stat. 391; 43 U.S.C. 945).

Application Comments: For a period of 45 days from the date of publication of this notice in the **Federal Register**, interested persons may submit comments regarding the proposed conveyance of the land to the Field Manager, Bureau of Land Management, Folsom Field Office, 63 Natoma Street, Folsom, California 95630. Objections will be reviewed by the Field Manager who may sustain, vacate, or modify this realty action.

Dated: November 6, 2000.

D.K. Swickard,

Field Manager, Folsom Field Office.

[FR Doc. 00–29394 Filed 11–15–00; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR–025–01–1430–EU: G–1–0037]

Realty Action: Sale of Public Land in Harney County, Oregon

AGENCY: Bureau of Land Management (BLM), DOI.

ACTION: Notice of realty action, sale of public land.

SUMMARY: The following described public land in Harney County, Oregon, has been examined and found suitable for sale under sections 203 and 209 of the Federal Land Policy and Management Act of 1976 (90 Stat. 2750, 43 U.S.C. 1713 and 1719), at not less than the appraised market value. All parcels being offered are identified for disposal in the Three Rivers Resource Management Plan.

All of the land described is within the Willamette Meridian.

Parcel No.	Legal description	Acres	Minimum acceptable bid	Bidding procedures	Designated bidders
OR–53952	T.27S., R.33E., Sec. 1, SW¼NW¼, W½SW¼; Sec. 2, S½NE¼, SE¼	360	$36,000	Competitive	None.
OR–54925	T.21S., R.31E., Sec. 32, SW¼SW¼. T.22S., R.31E., Sec. 5, lot 4.	80.63	5,200	Competitive	None.
OR–55316	T.18S., R.33½E., Sec. 33, S½NW¼.	80	8,000	Competitive	None.
OR–55317	T.20S., R.30E., Sec. 22, NE¼SE¼.	40	3,600	Modified Competitive.	Clyde Cowing and Marcia L. Eggleston—Trustee.
OR–55318	T.20S., R.30E., Sec. 23, SE¼NE¼.	40	3,600	Modified Competitive.	Clyde Cowing, Ronald Whiting and Marcia L. Eggleston—Trustee.
OR–55319	T.20S., R.35E., Sec. 8, W½NE¼, E½NW¼, NE¼SW¼..	200	20,000	Competitive	None.
OR–55320	T.20S., R.35E., Sec. 4, S½SW¼; Sec. 9, N½NW¼, SE¼NW¼, NE¼SW¼, S½SW¼..	320	28,800	Modified Competitive.	Thomas M. and Barbara Jo Howard, Sitz Ranch Partnership, and Conly L. and Joanne Marshall.
OR–55321	T.20S., R.35E., Sec. 17, NE¼SE¼.	40	3,600	Competitive	None.
OR–55322	T.20S., R.35E., Sec. 25, S½SW¼.	80	8,000	Competitive	None.
OR–55323	T.25S., R.31E., Sec. 1, lots 1 and 2.	79.79	7,200	Modified Competitive.	Denny Land and Livestock.
OR–55324	T.25S., R.34E., Sec. 20, SW¼.	160	14,400	Modified Competitive.	Bell A Grazing Cooperative.
OR–55325	T.25S., R.34E., Sec. 28, SW¼NW¼, W½SW¼.	120	10,800	Modified Competitive.	Bell A Grazing Cooperative.
OR–55326	T.25S., R.34E., Sec. 28, NE¼NE¼.	40	3,600	Modified Competitive.	Bell A Grazing Cooperative.
OR–55327	T.27S., R.35E., Sec. 7, lots 3, 4, NE¼SW¼; Sec. 18, lots 1, 2.	161.12	16,100	Competitive	None.
OR–55328	T.27S., R.35E., Sec. 17, N½NE¼.	880	7,200	Modified Competitive.	Norma and Maurice Davies—Trustee c/o M. Martin and Andrea L. Davies.
OR–55329	T.27S., R.35E., Sec. 21, SE¼NE¼, NE¼SE¼.	80	8,000	Competitive	None.
OR–55330	T.27S., R.35E., Sec. 30, SE¼SW¼, SW¼SE¼.	80	7,200	Competitive	None.

The following rights, reservations, and conditions will be included on the patents conveying the land:

All Parcels—A reservation for a right-of-way for ditches and canals constructed thereon by the authority of United States.

OR–53952—Patent will be subject to a right-of-way for road purposes granted to Tom Davies and a right-of-way for power line purposes granted to Harney Electric Cooperative.

OR–55316—The patent will be subject to a right-of-way for power line purposes granted to Idaho Power Company; a right-of-way for a buried telephone line purposes granted to CenturyTel of Eastern Oregon; and a right-of-way for public road purposes granted to Harney County.

OR–55321—The patent will be subject to a right-of-way for power line purposes granted to Idaho Power Company.

OR–55330—A quitclaim deed will be issued for this parcel. The deed will be subject to a previous reservation to Harney County for county road rights-of-way.

Access will not be guaranteed to any of the parcels being offered for sale, nor any warranty made as to the use of the property in violation of applicable land use laws and regulations. Before submitting a bid, prospective purchasers should check with the appropriate city

or county planning department to verify approved uses.

All persons, other than the successful bidders, claiming to own unauthorized improvements on the land are allowed 60 days from the date of sale to remove the improvements.

All land described is hereby segregated from appropriation under the public land laws, including the mining laws, pending disposition of this action, or 270 days from the date of publication of this notice, whichever occurs first.

Bidding Procedures

Competitive Procedures

The Federal Land Policy and Management Act and its implementing regulations (43 CFR 2710) provide that competitive bidding will be the general method of selling land supported by factors such as competitive interest, accessibility, and usability of the parcel, regardless of adjacent ownership.

Under competitive procedures the land will be sold to any qualified bidder submitting the highest bid. Bidding will be by sealed bid followed by an oral auction to be held at 2:00 p.m. PST on Wednesday, January 31, 2001, at the Burns District Office, Bureau of Land Management, Hwy 20 West, Hines, Oregon.

To qualify for the oral auction bidders must submit a sealed bid meeting the requirements as stated below. The highest valid sealed bid will become the starting bid for the oral auction. Bidding in the oral auction will be in minimum increments of $100. The highest bidder from the oral auction will be declared the prospective purchaser.

If no valid bids are received, the parcel will be declared unsold and offered by unsold competitive procedures on a continuing basis until sold or withdrawn from sale.

Modified Competitive Procedures

Modified competitive procedures are allowed by the regulations (43 CFR 2710.0–6(c)(3)(ii)) to provide exceptions to competitive bidding to assure compatibility with existing and potential land uses.

Under modified competitive procedures the designated bidders identified in the table above will be given the opportunity to match or exceed the apparent high bid.

The apparent high bid will be established by the highest valid sealed bid received in an initial round of public bidding. If two or more valid sealed bids of the same amount are received for the same parcel, that amount shall be determined to be the apparent high bid. The designated bidders are required to submit a valid bid in the initial round of public bidding to maintain their preference consideration. The bid deposit for the apparent high bid(s) and the designated bidders will be retained and all others will be returned.

The designated bidders will be notified by certified mail of the apparent high bid. Where there are two or more designated bidders for a single parcel, they will be allowed 30 days to provide the authorized officer with an agreement as to the division of the property or, if agreement cannot be reached, sealed bids for not less than the apparent high bid. Failure to submit an agreement or a bid shall be considered a waiver of the option to divide the property equitably and forfeiture of the preference consideration. Failure to act by all of the designated bidders will result in the parcel being offered to the apparent high bidder or declared unsold, if no bids were received in the initial round of bidding.

Unsold Competitive Procedures

Unsold competitive procedures will be used after a parcel has been unsuccessfully offered for sale by competitive or modified competitive procedures.

Unsold parcels will be offered competitively on a continuous basis until sold. Under competitive procedures for unsold parcels the highest valid bid received during the preceding month will be declared the purchaser. Sealed bids will be accepted and held until the second Wednesday of each month at 2:00 p.m. PST when they will be opened. Openings will take place every month until the parcels are sold or withdrawn from sale.

All sealed bids must be submitted to the Burns District Office, no later than 2 p.m. PST on Wednesday, January 31, 2001, the time of the bid opening and oral auction. The outside of bid envelopes must be clearly marked with ''BLM Land Sale,'' the parcel number and the bid opening date. Bids must be for not less than the appraised market value (minimum bid). Separate bids must be submitted for each parcel. Each sealed bid shall be accompanied by a certified check, postal money order, bank draft, or cashier's check made payable to the Department of the Interior—BLM for not less than 20 percent of the amount bid. The bid envelope must also contain a statement showing the total amount bid and the name, mailing address, and phone number of the entity making the bid. A successful bidder for competitive parcels shall make an additional deposit at the close of the auction to bring the total bid deposit up to the required 20 percent of the high bid. Personal checks or cash will be acceptable for this additional deposit only.

Federal law requires that public land may be sold only to either: (1) Citizens of the United States 18 years of age or older; (2) corporations subject to the laws of any state or the United States; (3) other entities such as associations and partnerships capable of holding land or interests therein under the laws of the state within which the land is located; or (4) states, state instrumentalities or political subdivisions authorized to hold property. Certifications and evidence to this effect will be required of the purchaser prior to issuance of conveyance documents.

Prospective purchasers will be allowed 180 days to submit the balance of the purchase price. Failure to meet this timeframe shall cause the deposit to be forfeited to the BLM. The parcel will then be offered to the next lowest qualified bidder, or if no other bids were received, the parcel will be declared unsold.

A successful bill on a parcel constitutes an application for conveyance of those mineral interests offered under the authority of section 209(b) of the Federal Land Policy and Management Act of 1976. In addition to the full purchase price, a nonrefundable fee of $50 will be required from the prospective purchaser for purchase of the mineral interests to be conveyed simultaneously with the sale of the land.

DATES: On or before January 2, 2001, interested persons may submit comments regarding the proposed sale to the Three Rivers Resource Area Field Manager at the address described below. Comments or protests must reference a specific parcel and be identified with the appropriate serial number. In the absence of any objections, this proposal will become the determination of the Department of the Interior.

ADDRESSES: Comments, bids, and inquiries should be submitted to the Three Rivers Resource Area Field Manager, Bureau of Land Management, HC 74–12533, Hwy 20 West, Hines, Oregon 97738.

FOR FURTHER INFORMATION CONTACT: Detailed information concerning this public land sale is available on the internet at *http://www.or.blm.gov/Burns* or may be obtained from Craig M. Hansen, Field Manager; Rudy Hefter, Supervisory Natural Resource Specialist; or Holly LaChapelle, Resource Assistant, Three Rivers

Resource Area at the above address, phone (541) 573–4400.

Dated: November 7, 2000.

Rudolph J. Hefter,

Supervisory Natural Resource Specialist.

[FR Doc. 00–29117 Filed 11–15–00; 8:45 am]

BILLING CODE 4310–33–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NM–030–1310–DB]

Draft Resource Management Plan Amendment (RMPA) and Environmental Impact Statement (EIS) for Federal Fluid Minerals Leasing and Development in Sierra and Otero Counties, New Mexico

AGENCY: Bureau of Land Management (BLM), Interior.

ACTION: Notice of availability and public hearings.

SUMMARY: Pursuant to 102(2)(c) of the National Environmental Policy Act (NEPA) of 1969, Council on Environmental Quality (CEQ) regulations (40 CFR 1500–1508), and the Federal Land Policy and Management Act (FLPMA) of 1976, the BLM Las Cruces Field Office (through Dames and Moore, Inc., a qualified consultant) has prepared a Draft RMPA/EIS. The RMPA/EIS addresses Federal fluid minerals (oil, gas, and geothermal) leasing and subsequent activities (*e.g.,* exploration, development, or production) in Sierra and Otero Counties, New Mexico.

DATES: Written comments on the Draft RMPA/EIS must be postmarked on or before February 20, 2001. Public hearings will be held at the times and places listed under **SUPPLEMENTARY INFORMATION.**

ADDRESSES: Written comments should be sent to: Tom Phillips, RMPA/EIS Team Leader, BLM, Las Cruces Field Office, 1800 Marquess, Las Cruces, NM 88005.

FOR FURTHER INFORMATION CONTACT: Tom Phillips, RMPA/EIS Team Leader, (505) 525–4377.

SUPPLEMENTARY INFORMATION: Public hearings will be held at the following times and locations.

Date	Time	City	Location
January 9, 2001	7:00 p.m.	Roswell, New Mexico	Sally Port Inn, 2000 N. Main St.
January 10, 2001	7:00 p.m.	Alamogordo, New Mexico.	County Commission Chambers, 1000 New York Ave.
January 11, 2001	7:00 p.m.	Truth or Consequences, New Mexico.	County Commission Chambers, 100 N. Date St.

Both oral and written comments may be given at the hearings. Written comments may also be submitted to the BLM, Las Cruces Field Office, 1800 Marquess, Las Cruces, NM 88005 on or before February 20, 2001.

A time limit for oral testimony at the hearings will be established by the presiding hearings officer, based on the number of people wishing to make comments at each hearing. Written text of prepared comments may be filed at the hearing whether or not the speaker has been able to complete the oral delivery in the allotted time.

All oral and written comments on the adequacy of the Draft RMPA/EIS will receive consideration in the Proposed RMPA/Final EIS.

Copies of the Draft RMPA/EIS have been distributed to a mailing list of identified interested parties. Single copies of the Draft RMPA/EIS may be obtained from the BLM Las Cruces Field Office, 1800 Marquess, Las Cruces, New Mexico.

Public reading copies are available for review at public and university libraries in Las Cruces, Alamogordo, Truth or Consequences, Roswell, and Santa Fe, New Mexico and El Paso, Texas.

The RMPA amends the 1986 RMP for the White Sands Resource Area. The objective of the RMPA is to determine (1) which lands overlying Federal fluid minerals are suitable and available for leasing and subsequent development and (2) how those leased lands will be managed. The EIS identifies the potential impacts that alternative plans for fluid minerals leasing and subsequent activities could have on the environment and identifies appropriate measures to mitigate those impacts.

Dated: November 7, 2000.

Amy L. Lueders,

Field Manager, Las Cruces.

[FR Doc. 00–29315 Filed 11–15–00; 8:45 am]

BILLING CODE 4310–VC–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–942–5700–BJ–044B]

Filing of Plats of Survey; California

AGENCY: Bureau of Land Management, Interior

ACTION: Notice.

SUMMARY: The purpose of this notice is to inform the public and interested state and local government officials of the latest filing of Plats of Survey in California.

EFFECTIVE DATE: Unless otherwise noted, filing was effective at 10 a.m. on the next federal work day following the plat acceptance date.

FOR FURTHER INFORMATION CONTACT: Lance J. Bishop, Chief, Branch of Geographic Services, Bureau of Land Management (BLM), California State Office, 2800 Cottage Way, Room W–1834, Sacramento, CA 95825; (916) 978–4310.

SUPPLEMENTARY INFORMATION: The plats of Survey of lands described below have been officially filed at the California State Office of the Bureau of Land Management in Sacramento, California.

Humboldt Meridian, California

T. 5 N., R. 1 W.

Supplemental Plat of a portion of the south half of sections 31 and 32, accepted June 27, 2000, to meet certain administrative needs of the BLM, Arcata Field Office.

Ts. 4 and 5 N., R. 1 W.

Dependent resurvey, corrective resurvey, and survey Group 1313, accepted June 27, 2000, to meet certain administrative needs of the BLM, Arcata Field Office.

T. 3 S., R. 2 W.

Dependent resurvey and survey under Group 1302 accepted July 13, 2000, to meet certain administrative needs of the BLM, Arcata Field Office.

T.3 N., R.1 E.

Retracement, corrective dependent resurvey and survey, on two sheets, under Group 1300 accepted September 26, 2000, to meet certain administrative needs of the BLM, Arcata Field Office.

Mount Diablo Meridian, California

T. 27 S., R. 9 E.

Dependent resurvey, and subdivision of sections 1, 12, and 13, under Group 1220, accepted February 23, 2000, to meet certain administrative needs of the BLM, Bakersfield Field Office.

T. 26 S., R. 35 E.

Dependent resurvey and metes-and-bounds survey, on two sheets, under Group 1318, accepted March 3, 2000, to meet certain administrative needs of the BLM, Bakersfield Field Office.

T. 32 N., R. 5 W.

Supplemental plat of a portion of the northwest quarter of section 32, accepted March 21, 2000, to meet certain administrative needs of the BLM, Redding Field Office.

T 21. S., R. 5 E.

Metes-and-bounds survey of tract 38, (Group 1179) accepted March 27, 2000, to meet certain administrative needs of the USDA, Forest Service, Los Padres National Forest.

T. 22 S., R. 38 E.

Supplemental plat of the northwest quarter of section 31, accepted March 29, 2000, to meet certain administrative needs of the BLM, California Desert District, Ridgecrest Field Office.

T. 33 N., R. 9 W.

Supplemental plat of the southeast quarter of section 6, accepted April 4, 2000, to meet certain administrative needs of the BLM, Redding Field Office.

T. 16 N., R. 16 E.

Supplemental plat of the southeast quarter of the northeast quarter section 28 (Group 1314), accepted April 12, 2000, to meet certain administrative needs of the USDA, Forest Service, Tahoe National Forest.

T. 29 N., R. 3 W.

Dependent resurvey and the metes-and-bounds survey of tracts 38 and 39 (Group 1316), accepted April 13, 2000, to meet certain administrative needs of the BLM, Redding Field Office.

T. 14 S., R. 24 E.

Dependent resurvey and metes-and-bounds survey (Group 1341), accepted June 21, 2000, to meet certain administrative needs of the BLM, Bakersfield Field Office.

T 10 S., R. 23 E.,

Supplemental Plat of the northeast quarter of section 24, accepted July 19, 2000, to meet certain administrative needs of the USDA, Forest Service, Sierra National Forrest.

T. 18 S., R. 3 E.

Dependent resurvey and metes-and-bounds survey (Group 1335), accepted September 11, 2000, to meet certain administrative needs of the USDA, Forest Service, Los Padres National Forest.

T. 35 N., R. 1 W.

Dependent resurvey and subdivision of section 29 (Group 1268), accepted September 18, 2000, to meet certain administrative needs of the USDA, Forest Service, Shasta Trinity National Forest.

T. 1 S., R. 31 E.

Dependent resurvey, subdivision and metes-and-bounds survey, accepted September 18, 2000, to meet certain administrative needs of the BLM, Bishop Field Office.

T. 29 N., R. 3 W.

Supplemental Plat, accepted October 5, 2000, to meet certain administrative needs of the BLM, Redding Field Office.

San Bernardino Meridian, California

T. 9 N., R. 13 W.

Supplemental plat of the northeast of section 15, accepted February 11, 2000, to meet certain administrative needs of the BLM, California Desert District, Ridgecrest Field Office.

T. 15 S., R. 1 E.

Dependent resurvey and subdivision (Group 1291), accepted April 25, 2000, to meet certain administrative needs of the BLM, California Desert District, Palm Springs-South Coast Field Office.

Ts. 11 & 12 N., R. 15 W.

Dependent resurvey and metes-and-bounds survey, two plats (Group 1304), accepted July 13, 2000, to meet certain administrative needs of the BLM, Bakersfield Field Office.

T. 5 N., R. 24 E.

Supplemental plat of tract 38 and the protraction of unsurveyed sections, accepted September 6, 2000, to meet certain administrative needs of the BLM, Needles Field Office.

T. 1 N., R. 14 W.

Mete-and-bounds survey in fractional section 31, accepted September 6, 2000, to meet certain administrative needs of the National Park Service, Santa Monica Mountains National Recreation Area.

T., 4 N., R. 14 W.

Amended plat of the dependent resurvey and subdivision (Group 1200), accepted September 6, 2000, to meet certain administrative needs of the USDA, Forest Service, Angeles National Forest.

T. 9 S., R. 22 E.

Dependent resurvey, subdivision, meanders and metes-and-bounds survey (Group 1346), accepted September 29, 2000, to meet certain administrative needs of the BLM, El Centro Field Office.

All of the above listed survey plats are now the basic record for describing the lands for all authorized purposes. The survey plats have been placed in the open files in the BLM, California State Office, and are available to the public as a matter of information. Copies of the survey plats and related field notes will be furnished to the public upon payment of the appropriate fee.

Dated: October 24, 2000.

Lance J. Bishop,

Chief, Branch of Geographic Services.

[FR Doc. 00–29393 Filed 11–15–00; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Notice of Proposed Information Collection

AGENCY: Office of Surface Mining Reclamation and Enforcement.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSM) is announcing its intention to request approval for the collection of information for its technical training program nomination form (OSM 105) and request for payment of travel and per diem form (OSM 140). The collection described below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The information collection request describes the nature of the information collection and the expected burden and cost.

DATES: OMB has up to 60 days to approve or disapprove the information collection but may respond after 30 days. Therefore, public comments should be submitted to OMB by December 18, 2000, in order to be assured of consideration.

FOR FURTHER INFORMATION CONTACT: To request a copy of the information collection request, explanatory information and related form, contact John A. Trelease at (202) 208–2783, or electronically to *jtreleas@osmre.gov.*

SUPPLEMENTARY INFORMATION: The Office of Management and Budget (OMB) regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). OSM has submitted a request to OMB to approve the collection of information for its technical training program nomination form (OSM 105) and request for payment of travel and per diem form

(OSM 140). OSM is requesting a 3-year term of approval for this information collection activity.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this collection of information will be placed on the As required under 5 CFR 1320.8(d), a **Federal Register** notice soliciting comments on these collections of information was published on August 22, 2000 (65 FR 51021). No comments were received. This notice provides the public with an additional 30 days in which to comment on the following information collection activity:

Title: Technical Training Program Non-Federal Nomination Form (OSM 105) and Request for Payment of Travel and Per Diem Form (OSM 140).

OMB Control Number: 1029–XXXX.

Summary: The information is used to identify and evaluate the training courses requested by students to enhance their job performance, to calculate the number of classes and instructors needed to complete OSM's technical training mission, and to estimate costs to the training program.

Bureau Form Numbers: OSM 105, OSM 140.

Frequency of Collection: Once.

Description of Respondents: State and Tribal regulatory and reclamation employees and industry personnel.

Total Annual Responses: 1,600.

Total Annual Burden Hours: 134 hours.

Send comments on the need for the collection of information for the performance of the functions of the agency; the accuracy of Send comments on the need for the collection of information for the performance of the functions of the agency; the accuracy of the agency's burden estimates; ways to enhance the quality, utility and clarity of the information collection; and ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information, to the following addresses. Please refer to the appropriate OMB control number in all correspondence.

ADDRESSES: Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Department of Interior Desk Officer, 725 17th Street, NW, Washington, DC 20503. Also, please send a copy of your comments to John A. Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave, NW, Room 210–SIB, Washington, DC 20240, or electronically to *jtreleas@osmre.gov.*

Dated: November 8, 2000.

Richard G. Bryson,

Chief, Division of Regulatory Support.

[FR Doc. 00–29298 Filed 11–15–00; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Abandoned Mine Land Reclamation Program Guidelines

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of intent.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) proposes to amend the Abandoned Mine Land (AML) Reclamation Program Guidelines published on December 30, 1996 (61 FR 68777). The proposed changes will make the guidelines easier to read and understand. The changes also incorporate new procedures found in the AML Enhancement Rule published February 12, 1999 (64 FR 7482). Comments are requested.

DATES: *Written comments:* We will accept written comments on the proposed changes until 5 p.m., Eastern time, January 16, 2001.

ADDRESSES: *Written comments:* You may submit your comments by mail, or hand-deliver comments to the Office of Surface Mining Reclamation and Enforcement, Administrative Record, Room 101, 1951 Constitution Avenue NW, Washington, DC 20240. You may also submit comments to OSM via the Internet at: *osmrules@osmre.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. Gene Krueger, Chief, Division of Reclamation Support, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Avenue NW, Washington, DC 20240; Telephone (202) 208–2937. E-mail: *gkrueger@osmre.gov.*

SUPPLEMENTARY INFORMATION: The AML Reclamation Program Guidelines give general guidance to States, Indian tribes, the U.S. Department of Agriculture, and OSM in the administration of reclamation activities. This includes activities carried out under programs authorized by Title IV of the Surface Mining Control and Reclamation Act of 1977 (SMCRA). These guidelines are considered to be statements of policy and do not set new legal requirements or obligations and could change at our discretion. Section B.5a–d of the guidelines has been revised to reflect the new procedures in the AML Enhancement Rule and the complete document is set forth below:

AML Reclamation Program Guidelines for Reclamation Programs and Projects

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A. Definitions

1. Abandoned Property

Real and personal property, associated with past mining activities, forsaken or deserted by an owner. This includes real estate, structures, and equipment.

a. *Abandoned Structures*—Abandoned permanent improvements or fixtures firmly attached to the land and considered as part of real property. Abandoned structures include but are not limited to coal tipples, coal washers, storage and grading facilities, loading docks, rail spurs, concrete foundations, dams, reservoirs, and bridges. Other items such as crushers, elevators, bins, loaders, conveyors and similar equipment are within this definition if firmly attached to the land.

b. *Abandoned Equipment*—Abandoned movable items not attached to the land. Such items are considered as personal property and include equipment and dismantled machinery not attached to the land and which could be moved. These items include but are not limited to shovels, scrapers, tires, machinery parts, trailers, trucks, electrical substations on skids, feeders, and loaders.

c. *Disposal*—The sale, federal use, demolition, removal, and the burning and burial of scrap or other debris resulting from abandoned structures and equipment.

2. Act

The Surface Mining Control and Reclamation Act of 1977 enacted as Public Law 95–87 (30 U.S.C. 1201 *et seq.*), as amended.

3. Administering Agency

The agency responsible for carrying out a reclamation program or project. This includes OSM for federal reclamation projects; United States Department of Agriculture (USDA), Natural Resources Conservation Service (NRCS) for the Rural Abandoned Mine Program; designated State reclamation agencies for projects carried out under an approved State Reclamation Plan; and Indian tribes for projects carried out under an approved Indian Reclamation Plan.

4. Eligible Lands

Land and water which were mined for coal or which were affected by such mining, wastebanks, coal processing, or other coal mining processes and left or abandoned in either an unreclaimed or inadequately reclaimed condition prior to August 3, 1997, and for which there is no continuing reclamation responsibility. Provided, however, that lands and water damaged by coal mining operations after that date and on or before November 5, 1990, may also be eligible for reclamation if they meet the requirements specified in 30 CFR 874.12(d) and (e). Eligible lands and water for noncoal reclamation purposes are those sites that meet the eligibility requirements specified in Section 409 of the Act or, following certification of the completion of all know coal problems, those in Section 411 of the Act of 30 CFR 875.14. For additional eligibility requirements for water projects, see 30 CFR 874.14, and for lands affected by remining operations, see Section 404 of the Act.

5. Emergency

A sudden dangerous condition or impairment that constitutes a situation with a high probability of substantial physical harm to the health, safety, or general welfare of people before the danger can be abated under normal program procedures.

6. Hydrologic Balance

The relationship between the quality and quantity of water inflow to water outflow from an abandoned mine land site. The relations hip includes water storage and transfer within hydrologic units as they now exist or may have existed.

7. Toxic Materials

Earth materials or wastes resulting from mining operations which, if acted upon by air, water, or micro-biological processes are likely to produce chemical or physical conditions in soils or water that are harmful to the animal and plant lift or water use.

B. Program Considerations

1. Land, Water, or Mineral Rights Required for Reclamation

a. *Consent Requirements and Responsibility.* In addition to the rights of entry required by 30 CFR part 877, other consents required by the specific type of reclamation program should be secured. In water limited areas reclamation programs that propose to restore or alter water quality or quantity should not be undertaken until the appropriate water right authorizations are secured. If the mineral estate is severed from the surface estate, consents should be secured from both parties. All necessary consents should be secured for a time period sufficient to complete the reclamation activities. The administering agency has the responsibility to make certain that no reclamation work is carried out without such authorizations.

b. *Written Consent Versus Police Power.* Written consent from the owner of record and the tenant holding a lease or his authorized agent should be the preferred means for securing agreements to enter lands in order to carry out reclamation work. Entry by use of police power is restricted to those reclamation projects that will protect public health, safety, and general welfare as authorized under Sections 407(a), 409(c), and 410 of the Act. They should be undertaken only after all possibilities of securing written consents have been exhausted.

c. *Monitoring and Maintenance.* Written consent by the landowner should include considerations for monitoring and maintenance, including rights of entry as necessary.

d. *Property Acquisition.* Acquisition of property may be undertaken only under the conditions specified in Sections 407 and 409 of the Act.

2. Jurisdictional Responsibilities

a. *Reclamation Program Legal Requirements.* The administering agency should make certain of compliance with all applicable Federal, State, Tribal, and local laws and coordination with the appropriate agencies as necessary.

b. *Environmental Evaluation Requirements.* Compliance with the National Environmental Policy Act of 1969 (NEPA) is mandatory for every proposed AML reclamation project. Authorization by the Council on Environmental Quality (CEQ), at 40 CFR 1506.11, to abate emergency conditions without preparing an environmental

document does not relieve us or the States/Tribes of this responsibility.

(1) OSM and the States are authorized to act where emergency circumstances at the site require immediate abatement action if the environmental document cannot be completed prior to the initiation of action. The action taken must be limited to that necessary to control the immediate impacts of the emergency.

(2) Actions which remain to be taken at the site of an emergency after the abatement of the immediate impacts require the preparation of an environmental document.

c. *Interstate Coordination Requirements.* Where reclamation is proposed that may affect bordering States or other jurisdictional authorities, the administering agency should coordinate planning and implementation of these projects with those entities.

3. Selection Criteria (Non-Emergency)

a. *Reclamation Site Ranking.* Procedures for selecting non-emergency sites for reclamation should use weighing factors to rank the proposed sites in accordance with priorities set in Section 403 of the Act. Non-coal sites must comply with Section 409 or 411 as appropriate. Negative weights should be considered for negative impacts resulting from the proposed project. Generally, reclamation of lower priority projects should not begin until all known higher priority projects have been completed, are in the process of being reclaimed, or have been approved for funding by the Secretary. Lower priority projects, or contiguous work, may be undertaken in conjunction with high priority projects in accordance with these guidelines.

(1) The administering agency may give priority consideration to reclamation projects where:

(a) The landowner(s) consent to participate in post reclamation maintenance activities of the area;

(b) Reclamation provides many benefits to the landowner(s) and where those benefits have a greater cumulative value than other projects;

(c) Reclamation provides offsite public benefits; and/or,

(d) Acid Mine Drainage (AMD) is a major problem and/or the Appalachian Clean Streams Initiative (ACSI) can be used in restoration of streams polluted with AMD.

b. *Reclamation Considerations.* The following items should be considered in determining whether a non-emergency site should be reclaimed.

(1) The lands proposed for reclamation are eligible as defined by Section 404, 409, or 411 of the Act.

(2) Problems associated with the site can be abated by using current available technology or horizon technology with a high probability of success to prevent or minimize present or future negative effects. When necessary to determine which technology is best suited to a particular problem area, test plots and/or field trials are allowed. Such activities are appropriate and do not constitute ''research'' as prohibited by the Act.

(3) Reclamation can be carried out in a manner that minimizes maintenance to achieve a self-sustaining reclamation solution. Self-sustaining implies reclamation which is permanent and stable under the prevailing environmental and land-use conditions using current technology. Projects which require continuous maintenance and/or operating costs should be undertaken only if a commitment exists to bear these indefinite costs.

(4) Reclamation activities can be planned in a manner that is cost effective and agreeable with the proposed post reclamation land use as intended by the landowner(s).

(5) Reclamation activities and post reclamation land use is cost effective and agreeable with surrounding land uses, complies with local, State, Tribal, and Federal requirements, and is acceptable to the community involved.

(6) If the project area is to be remined or developed in the foreseeable future and these activities will eliminate the adverse effects of past mining, reclamation should only be undertaken where the offsite adverse impacts from the affected area are so severe as to cause significant danger to public health and safety or to the environment if not abated before the proposed remining or development takes place.

c. *Reclamation Extent.* The amount of reclamation performed on a site depends upon the priority, funding available, and technology available for reclaiming the site. When it is cost effective to do so, consideration should be given to lower priority problems in the reclamation plan when contracting for the elimination of a high priority problem. The original purpose of the reclamation should be to address the higher priority problems. Factors that should be considered in determining the amount of reclamation to be done at a site include the following:

(1) The total area of affected land and water;

(2) Uniformity/diversity of the problem(s) over the entire site;

(3) Minimum reclamation needed to restore the site and additional low priority work needed, if any;

(4) Availability of funds;

(5) Cost effectiveness of the proposed work;

(6) Proposed post reclamation land use;

(7) Onsite, offsite and multiple use benefits;

(8) Post reclamation maintenance required and landowner participation in that maintenance;

(9) Accommodating landowner(s) land use and treatment requests, if possible without incurring additional costs above that required for the minimum reclamation needed; and,

(10) The possibility of remining.

d. *Cooperative Efforts.* In addition to the landowner consent requirements described in Section B. Part 1 of these guidelines, a maintenance agreement between the administering agency and the landowner(s) may be included as part of the reclamation plan to make certain the continued success of the reclamation project. Estimated costs as well as financial and administrative responsibilities should be recognized in any agreement.

e. *Joint Projects.* Joint undertakings between the administering agency and the landowner(s) or other local, State, Tribal, or Federal agencies are supported and encouraged.

4. Emergency Projects

a. *Authority for Emergency Reclamation.* Authorities and requirements for rights of entry to carry out emergency reclamation projects are contained in Section 410 of the Act.

b. *Emergency Project Considerations.*

(1) Emergencies are unlike Priority 1 projects by interpretation of the phrases ''sudden danger'' and ''high probability of substantial physical harm'' in the definition of ''emergency'' contained in these guidelines.

(2) Justification for emergency action must be based on whether immediate action is crucial to remove the danger of harm to persons. The time element is referenced by the phrase ''before the danger can be abated under normal program operation procedures.'' This means the danger is imminent and time is not available for normal project contractual procedures.

(3) A limited amount of non-emergency work may be conducted in conjunction with emergency abatement if such work is cost effective in reclaiming the entire project site.

c. *Emergency Project Examples.* The following list shows examples of sudden situations with a high probability of causing substantial

physical harm to the health, safety, and general welfare of people.

(1) Subsidence suddenly occurring in or near populated areas or roadways.

(2) Mine water ''blow-outs'' in or near highly used public areas.

(3) Landslides caused by movement of spoil material or mass movement due to drainage or seepage from abandoned coal mines threatening to destroy homes and businesses or block roads and stream channels.

(4) Actual or potential failure of unstable coal refuse impoundments, processing waste banks, or abandoned sediment control structures caused by unusual precipitation events significantly risking downstream populated areas.

(5) Mine or coal refuse fires that harm the health or safety of residents in populated areas.

d. *Abatement Procedures.*

(1) Reclamation procedures are site specific and often cannot be determined until after onsite inspection and evaluation of the nature of the emergency, number of people affected, resources available, and existing time restrictions.

(2) Emergency reclamation need not resemble final restoration. The goal of emergency reclamation is to stabilize the problem and remove the danger to the public. Additional reclamation, to fully reclaim the area, may be carried out under regular reclamation programs at a later date. Limited reclamation may also be performed in connection with emergency work if cost effective as noted above at part 4.b.(3).

5. Incidental Recovery of Coal in Connection With Reclamation Activities

a. *Active Mining Permit Requirements.* Coal removed and sold must be ''incidental'' to the reclamation project, *i.e.*, physically necessary to remove in order to address the identified health, safety, or environmental problem of the approved AML construction project. This concept conforms to existing regulations at 30 CFR 707.5. Coal extracted beyond that which is determined to be incidental will be subject to Title V permitting provisions.

b. *Resource recovery potential.* AML construction is considered government financed construction in accordance with 30 CFR 707.5. Therefore, whenever coal is to be recovered incidental to reclamation, and the government contribution is less than 50 percent of the cost of reclamation, it may be sold and the proceeds kept by the contractor.

c. *Substantial deposits of incidental coal.* For sites with substantial deposits of incidental coal, we expect that AML contractors will reflect the anticipated sale of such coal through a lowered project bid price. The lowered project bid price would, in turn, reduce the government's share of the total cost of the project. As a result, less public funding will be required for these sites to accomplish the same level of AML reclamation. By reducing the government's share of the cost of reclamation, AML money becomes available for other AML reclamation projects that would otherwise not be funded. The contractor makes a profit, the government saves money—and most important of all—additional abandoned sites that we could not afford to reclaim in the past are reclaimed.

d. *Less than 50 percent financing.* Undertaking AML projects that use less than 50 percent government-financing will not be mandatory for States or Indian Tribes; they may choose not to participate in this aspect of AML reclamation. However, State and Tribal programs that do participate will be responsible to ensure that the provisions of this rule are applied appropriately and not abused.

6. Abandoned Structures and Equipment

a. *Investigation and Report.*

(1) The administering agency should perform an onsite investigation of abandoned structures or equipment and encourage the landowner(s) to recover any salvage value by disposal before the start of any reclamation project.

(2) Upon completion of the onsite investigation, a report must be prepared by the administering agency which addresses the following:

(a) The type, quantity, age, and apparent condition of all abandoned structures or equipment;

(b) The structural soundness, visual quality, historical significance, effect on proposed reclamation activities, and land uses in the area. The structural soundness of the structure should be evaluated in relation to public health, safety, general welfare, and the post reclamation;

(c) The disposal or retention of the structures or equipment in accordance with local, State, Tribal and Federal laws; and,

(d) The recommended methods to remove the safety hazards associated with structures or equipment that are retained on the reclaimed site.

b. *Ownership Rights.* Based on the investigation and report, the administering agency is responsible for determining the disposal of the abandoned structures or equipment and securing consent to dispose of or change such structures.

c. *Disposal Revenues or Benefits.* Any revenues or benefits received from the sale or use of abandoned structures or equipment should be used to offset the cost of reclamation or deposited to the Fund pursuant to Section 401(b)(4) of the Act.

7. Borrow and Disposal Areas

a. *Site Selection.* The borrow and disposal areas created by reclamation activities should be subject to and conducted in accordance with applicable local, State, Tribal, or Federal reclamation requirements. Borrow and disposal areas should be located on the site of the reclamation project, if possible. Offsite borrow and disposal areas should be used only when no onsite area is available and it is necessary to protect the health and safety of the public. In addition, offsite areas may be used if they provide an area more suitable for reclamation and less prone to constitute a hazard in itself, produce an improved land use, or protect the environment.

b. *Adverse Impacts.* Adverse impacts of the selected areas should be minimized by disturbing the smallest possible area; providing adequate drainage, dust, and erosion control measures; protecting historic and cultural values; protecting visual esthetics; protecting fish and wildlife values; protecting the health and the safety of the community and the public; and reclaiming the borrow and disposal area after termination of the project.

8. Program and Project Evaluation

a. *General Evaluation Considerations.* Reclamation activities are to be evaluated on a regular basis to determine the effectiveness of the program/project in reclaiming abandoned lands. The objective is to identify those abatement control methodologies that have been effective over time and those with demonstrated deficiencies that need to be improved or changed. Project evaluation measures the success or failure of the applied techniques while program evaluation determines the effectiveness of the overall program, including regulations and policies. Evaluation efforts include, but are not limited to, recording accomplishments, making onsite reviews before, during, and after reclamation, and analyzing fund management.

b. *Evaluation Report.* The administering agency will prepare a report on its findings and recommendations. Recommendations should be used to change program operations on future reclamation activities so that deficiencies will not

recur. If requested, the report should be made available to other agencies in order to share information and improve the AML program nationwide.

9. Maintenance of Reclamation Work

a. Reclamation should be done in a manner to minimize or eliminate continued maintenance and maintenance requirements. Long term maintenance requirements should be identified during the planning and design stages. These requirements must be technically and economically possible and should be developed in cooperation with the landowner(s) and/or appropriate agencies through formal agreement. Maintenance plans should include maintenance requirements, inspection schedules, technical assistance needed, and funding requirements.

10. Non-Coal Projects

a. *Guideline Applicability.* States and Indian tribes with approved reclamation plans may undertake non-coal reclamation projects under the specific provisions in Section 409 of the Act or after certification that all coal related problems have been reclaimed, as authorized in Section 411 of the Act.

b. *Priorities Under Section 409.* Non-coal projects to be reclaimed under Section 409 of the Act must be at the request of the Governor of the State or the governing body of an Indian tribe. They must comply with the priorities stated in Section 403(a)(1), except the term ''coal'' does not apply. The reclamation must be for the protection of public health, safety, general welfare, and property from extreme danger of negative mining practices.

c. *Priorities Under Section 411.* Noncoal projects to be reclaimed under Section 411 of the Act may not proceed until the State/Tribe has certified that all coal problems have been resolved. Planning and design work for reclamation of noncoal projects may commence prior to completion of all coal projects.

C. Site Considerations

1. Mine Drainage

a. *General Considerations.* The reclamation plan should attempt to minimize or control mine drainage and include procedures to treat impounded waters containing toxic materials before release. At-source control measures are preferred over long-term treatment methods to eliminate or minimize maintenance.

b. *At-Source Control Measures.* Controlling or minimizing mine drainage at its source can be accomplished by any or all of the following techniques:

(1) Mine-sealing techniques, including grout curtains and slurry trenching. Factors to be considered when planning to seal mines are the potential to develop hydrostatic heads, the accessibility of the area, and the integrity of the surrounding geologic formations;

(2) Infiltration control and water diversion. Factors to be considered include topography, control of surface water, effects on ground water, the control of water passage through openings, and the storm event design; and/or,

(3) Daylighting, the surface mining procedures and excavation processes used to expose underground mine works for partial or complete removal of the remaining mineral underlying the surface. Factors to be considered include the depth of overburden, marketability of the mineral, and safety measures.

c. *Treatment Measures.* Secondary treatment of mine drainage can be carried out by the addition of neutralizing agents. Permanent treatment facilities should be designed to minimize operation and maintenance costs and should only be considered if no other means exists to abate the problem. Written assurance, from the landowner or any other interested party, should be obtained to assure that the treatment facilities will be maintained after appropriations for the Abandoned Mine Land Program cease.

d. *Coal Refuse Piles and Coal Waste Embankments.* Methods of reclaiming land containing coal refuse, coal wastes, or abandoned workings include, but are not limited to:

(1) Removing the coal refuse or coal waste to an environmentally acceptable site, subject to all appropriate approvals;

(2) Burying the refuse or waste, diverting water away from or around the reclaimed area, whenever possible, or layering the refuse material with clay or other unpierceable material, when practical, to prevent water infiltration and contamination; and,

(3) Treating the refuse pile in place by:

(a) Diverting water around the coal refuse and/or waste;

(b) Collecting and conveying drainage from the refuse pile for safe disposition (an approved water pollution control facility should be used if needed to meet quality standards);

(c) Grading and contouring waste structures to drain water off the disposal site;

(d) Covering the refuse with a suitable thickness of nontoxic or nonacid-forming material or treating the refuse with lime or other material to prevent acid or other toxic drainage; or

(e) Any combination of the above treatments.

2. Active Slides and Slide-Prone Areas

a. *Site Evaluation Factors.* Factors that should be considered on a case-by-case basis in the evaluation of slides or slide-prone areas include the following:

(1) The topography of the ground surface as an indication of past landslide activity and potential instability. Topographic data collected should include contour maps at 2 to 5 foot intervals, surface drainage characteristics, locations of ponded surface water, and slope profiles;

(2) The geology of the subsurface. Rock formations and geologic structures including folds, faults, joints, and shear zones, should be identified whenever possible. This information may be useful in comparing the landslide potential of various areas;

(3) The soil or spoil material. Description of the slide-prone material should include its texture, permeability, and engineering properties as well as the related soil-rock ratios;

(4) Ground water sources. Springs and seeps, dump areas, adits, auger holes, drill holes, and coal seams should be identified;

(5) Vegetative cover. Vegetation will affect the stability of the slide or slide-prone area. Deep masses of roots may provide sufficient reinforcement to distort the geometry of the slide and trees with deep tap roots may curtail severe movement. Vegetative cover within a landslide area should be compared to that within the surrounding area and with that present at known landslide areas;

(6) Other physical factors. These include timber coverage or lack of it on slopes, parent material and volume of spoil, proximity to other slides, or other data specific to the slide area which may be helpful in designing the best structural specifications for stabilizing the area; and,

(7) U.S. Geological Survey slide-prone maps, U.S. Department of Agriculture soil maps, and other related data.

b. *Remedial Measures.* Reclamation and stabilization of slide areas may be achieved by one or more of the following methods:

(1) Removing unstable material or by terracing;

(2) Installing surface and/or subsurface drainage such as rip-rap channels, french drains, pumping wells, etc.;

(3) Installing support and reinforcement systems such as retaining walls, gabions, vertical pilings, etc.; and,

(4) Revegetation.

3. Erosion and Sedimentation

a. *Erosion and Sediment Control Considerations.* Erosion and sediment control measures should be designed in accordance with Federal, State and local laws and should do the following:

(1) Minimize erosion from the reclamation site and adjacent lands, minimize water pollution from sediment, acid drainage, and other toxic materials, and provide conditions suitable for the planned land use;

(2) Maintain the soil resource within acceptable soil loss limits. Allowable sheet and rill erosion rates should be equal with the soil resulting from reclamation. Information relative to allowable soil loss limits may be obtained from the local Natural Resource Conservation Service Office;

(3) Expose the least amount of land at any one time, with the more hazardous areas exposed for the shortest time and during the season when extreme rainfall is least likely to occur;

(4) Complete reclamation activities so revegetation can take place at the most advantageous time of year; and,

(5) Control foot and vehicular traffic and grazing until vegetation is established.

b. *Erosion Control Practices.* Well established vegetation is generally the most cost-effective means of erosion control. Other methods may include one or more of the following, in conjunction with vegetation, to achieve temporary and/or permanent erosion control.

(1) Mulches may be used for temporary erosion control and in some cases stabilizing agents such as gravel, stone, and concrete blocks may be used for permanent protection.

(2) Permanent structural measures may be used to turn runoff, reduce slope length, and provide for an effective runoff disposal system.

(3) Temporary vegetation and/or structural measures may be needed for erosion control during reclamation. Provisions should be made to remove the temporary control measures and stabilize the area when they are no longer needed.

c. *Sediment Trapping Practices.* When erosion controls are incapable of preventing excessive sediment buildup, either during reclamation or permanently, the excess sediment should be controlled to prevent offsite contamination.

(1) Temporary sediment control measures such as filter strips, sediment traps, and sediment basins, should be stabilized and maintained during their planned life.

(2) Permanent sediment basins should be maintained and the sediment removed when it accumulates to the design level. The use of permanent sediment basins should be minimized because of the continuing maintenance responsibility.

4. Vegetation

a. *Existing Vegetation Inventory and Evaluation.* The administering agency should complete an inventory and evaluation of existing vegetation and site conditions prior to developing the design and specifications for a project. The permanent vegetation selected to cover the reclaimed mine land should be compatible with the site characteristics and the intended land use of the reclaimed and surrounding land and provide adequate erosion control.

b. *Vegetative Requirements.* The vegetation portion of the project design and specifications should be developed considering the requirements itemized for each of the following cases.

(1) In areas where the present plant species are inadequate or undesirable and only a change in vegetation is needed.

(a) Necessary erosion an sediment control structures should be installed to protect the area from excessive erosion and sedimentation during the vegetation establishment period. Temporary vegetation may be used alone or in combination with a mulch or other stabilizing agent in accordance with the needs of the site.

(b) The newly planted area should be protected from excessive use, especially livestock grazing, during the establishment period.

(2) In areas where changes in topography and vegetation are needed.

(a) Changes in topography should be made to improve esthetic aspects of the site, permit establishment of desirable vegetative cover, and insure compatibility with the planned land use.

(b) Temporary vegetation should be used to protect stockpiles of soil materials for a short time or to provide temporary cover until the permanent vegetation is established.

(3) In areas where the present spoil material is unsuited for vegetation the spoil material should be covered or replaced with material that will support the desired vegetation. If covering or replacement costs are prohibitive, attempts should be made to create a suitable plant growth medium upon which vegetation may be established.

(4) In areas where alteration of the site to support vegetation is impractical, sediment should be confined to the immediate area, if feasible. Surface runoff should be treated to an acceptable level of quality before discharging offsite, if necessary.

5. Toxic Materials

a. *Sampling and Analysis Consideration.* The administering agency should sample sites suspected of containing toxic materials. Chemical and/or physical analyses may include, but are not limited to:

(1) pH (paste);

(2) SMP Buffer (tests pH of solution prior to weathering);

(3) Net acidity or alkalinity, or potential acidity;

(4) Total sulfur (sulfate and sulfide);

(5) Electrical conductivity (mmhos/cm);

(6) NKP and USDA texture class when material is to be used as post-reclamation plant growth medium;

(7) Organic matter (quantity and type); and,

(8) Visual and/or microscopic identification of potential toxic or acid forming minerals.

b. *Planning Considerations.* The administering agency should consider the following items in their planning efforts on projects containing toxic materials:

(1) Critical toxic limits;

(2) Containment or segregation of toxic materials using sealed pits or embankments and/or covering the toxic materials with compacted clay or some other suitable material;

(3) Site preparation, including grading, backfilling, scarification, and application of appropriate growing medium, chemical fertilizers, lime gypsum, mulches, or sludge;

(4) Water management control, including surface and subsurface drainage, sediment control, and soluble toxic elements; and,

(5) Necessary monitoring and required maintenance, if any.

c. *Sites Eligible Under CERCLA.* Abandoned mine land sites containing acid mine drainage or other toxic material may be eligible for clean-up under CERCLA, if included on the national priority list (NPL). Sites listed on the NPL are ineligible for AML funding.

6. Hydrologic Balance

a. *Planning Considerations.* After identification of areas needing restoration of the hydrologic balance, the administering agency should consider the following items in their planning.

(1) Evaluation of procedures needed to reduce or eliminate pollution to receiving surface and subsurface waters, including technical and economic constraints.

(2) Potential beneficial and/or negative effects of proposed restoration activities on offsite hydrologic systems.

(3) Post reclamation land use of the site and surrounding area.

b. *Surface-Water Considerations.* Restoration of surface drainage should minimize erosion and maximize ecological stability. Factors to be considered include, but are not limited to:

(1) Type of reconstruction materials to be used, stream gradient, fish and wildlife habitat, and compatibility with adjoining undisturbed surface drainage;

(2) Use of the reclaimed area as a source of ground-water recharge and the potential for downstream flooding;

(3) Feasibility of long-term, self-maintaining erosion control measures to enhance stream and flood plain stability; and,

(4) Construction of water impoundments which do not adversely affect the restoration of the hydrologic balance and are in accordance with applicable local, State, Tribal, or Federal requirements.

c. *Ground-Water Considerations.* Restoration of ground-water should be done in a manner that will not diminish or degrade water leaving the site. Factors to be considered include, but are not limited to:

(1) Evaluation of the re-established water table, relative to the reclaimed land surface;

(2) Evaluation of the ground-water recharge capacity, considering the underlying aquifers and backfill materials; and,

(3) Identification of toxic and/or acid forming materials and procedures to eliminate or minimize contamination of the water table.

7. Public Health and Safety

a. *Dump Sites.* Abandoned mine sites used as dumps are usually excellent breeding places for insect and vermin and could pose a hazard to public health. The presence of a dump in an abandoned mine site should not be considered the primary reason for reclamation, but may be considered in raising the site priority in the same objective category. Prior to any reclamation work on dumps, the local, State and/or Tribal agency should be encouraged to abate the problem under other existing authorities and consulted regarding proper disposal methods.

b. *Highwall Danger.* Highwalls may create a significant danger to public health or safety when there is public use of the area above or below the highwall and/or there is evidence of sloughing that may damage structures or block roads and stream channels. Reclamation techniques include, but are not limited to:

(1) Reducing the highwall height;

(2) Backfilling and grading the highwall to a stable slope; or

(3) Providing a physical barrier to limit accessibility and material movement.

c. *Mine Openings and Subsidence.*

(1) The administering agency should consider the following items when planning for subsidence control projects:

(a) Exploratory drilling to determine the locations, size, and condition of abandoned underground mine openings with the potential to subside (except in emergencies);

(b) Proximity to populated areas with high public use;

(c) Notification to all local, State, and Tribal land use planning agencies of potential subsidence areas; and,

(d) Restricting entry to mine openings by constructing physical barriers and/or fencing for emergency situations until the opening can be properly reclaimed.

d. *Radiation Emission.* Where radiation constitutes a potential public health or safety problem, the administering agency should coordinate with other pertinent agencies prior to reclamation activity. Normally, this coordination is done during the development of the State reclamation standards for radiation.

e. *Domestic Water Supplies.* Control measures designed to protect or restore domestic water supplies should consider the number of people affected, the type and concentration of pollutant(s), and the type and cost of control technology. Clean-up or restoration of domestic water supplies should be restricted to source control where possible.

f. *Surface and Underground Mine Fires.* Only fires associated with abandoned mines or in virgin seams associated with other abandoned mine reclamation problems are eligible for Title IV funding.

(1) Prior to initiating control or extinguishment efforts, geologic investigations should be carried out to determine the extent of the fire and the amount of remaining combustible material.

(2) Reclamation design and procedures should include methods to control or eliminate hazardous gases, fumes, and other types of air pollution associated with the fire.

g. *Hazardous/Explosive Gases.* Toxic gases, other than those associated with mine fires, may require site specific control or treatment procedures. For example, methane seeping into a residence must be vented and should be monitored for a reasonable amount of time to ensure the area is safe. Whenever possible gases should be vented or sealed off at their source.

8. Esthetics and Visual Values

Reclaimed lands should, to the extent that it is feasible, conform to the visual aspects of the surrounding landscape. The reclamation design and procedures should take into consideration the proximity to public high use areas and the visual impact within the context of the viewing distance.

a. *Visual Degraders.*

The administering agency determines what conditions are visually degrading and should be considered for visual improvement. Visual degraders may include, but are not limited to, highwalls, erosion, discolored water, haul roads, refuse piles, slurry ponds, spoil piles, abandoned mining equipment and structures, garbage and refuse dumps, open pits, and deforestation.

b. *Esthetics Problem Solutions.*

Solutions for esthetic problems may involve removal of offensive material or condition, strategic placement of screening materials, and/or the use of appropriate plant species. Guidelines and standards to evaluate visual resources developed by the U.S. Forest Service, Natural Resource Conservation Service, U.S. Bureau of Land Management, National Park Service, and other agencies should be adapted for use in evaluating and planning visual solutions.

9. Fish and Wildlife Values

a. *Project Identification Requirements.* The administering agency should periodically provide a list of proposed and on-going abandoned mine land activities to the conservation or land management agencies with responsibilities for fish and wildlife or their habitats and should request pertinent information and suggestions from these agencies.

b. *Determining Fish and Wildlife Values and Goals.* The administering agency should review information provided by the conservation and land management agencies with responsibilities for fish and wildlife or their habitats to determine the pre-reclamation fish and wildlife values of abandoned mine land sites. The administering agency should then determine the fish and wildlife goals for

each project, in relation to that project's determined fish and wildlife values and the program priority objectives.

c. *Planning Considerations.* The administering agency should encourage the consideration of fish and wildlife values in all reclamation activities, including those whose primary purposes for reclamation are related to public health, safety, or general welfare. If fish and wildlife values are determined to be among the goals of the reclamation efforts, the administering agency should incorporate them into the reclamation plan.

d. *Installing and Maintaining Established Fish and Wildlife Habitat Values.* The administering agency should insure that all fish and wildlife measures contained in the selected plan are implemented and should encourage the landowner(s) to maintain them at or above the planned level.

10. Air Quality

a. *Air Quality Standards.* All reclamation activities should be conducted in accordance with applicable local, State, Tribal, or Federal air quality standards.

b. *Coordination Requirements.* Local, State, Tribal, or Federal air quality officials should be contacted prior to reclamation planning activities for requirements concerning air quality permit procedures, applicable standards, and possible control measures.

c. *Air Quality Degradation and Improvement.* Long-term air quality improvements which will result from reclamation should have priority over possible short-term air quality degradation caused by reclamation construction.

Dated: November 7, 2000.

Mary Josie Blanchard,

Assistant Director, Program Support.

[FR Doc. 00–29299 Filed 11–15–00; 8:45 am]

BILLING CODE 4310–05–M

INTERNATIONAL TRADE COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: November 27, 2000 at 2 p.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Agenda for future meeting: none
2. Minutes
3. Ratification List
4. Inv. No. 731–TA–894 (Preliminary) (Ammonium Nitrate from Ukraine)—briefing and vote. (The Commission is currently scheduled to transmit its determination to the Secretary of Commerce on November 27, 2000; Commissioners' opinions are currently scheduled to be transmitted to the Secretary of Commerce on December 4, 2000.)
5. Outstanding action jackets: none

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

Issued: November 14 , 2000.

By order of the Commission:

Donna R. Koehnke,

Secretary.

[FR Doc. 00–29475 Filed 11–14–00; 1:50 pm]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant To the Comprehensive Environmental Response, Compensation, and Liability Act

Under Section 122(d) of the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9622(d), and 28 CFR 50.7, notice is hereby given that on October 10, 2000, a proposed Partial Consent Decree (''Decree'') in two consolidated cases, *United States* v. *Allied Battery Co.*, Civil No. CV–98–N–0446–S, and *United States* v. *CSX Transportation, Inc.*, Civil No. CV–98–N–2561, was lodged with the United States District Court for the Northern District of Alabama. In this action, the United States seeks recovery of its response costs incurred by EPA in cleaning up contaminated soil at the Carlie Lee Superfund Site, a former battery cracking operation located in Tarrant City, Alabama, near Birmingham. Under this Decree, four settling defendants—Allied Battery Co., Econo Battery Services, Fairfield Iron & Metals, Inc. and Joseph J. McCleney, Jr.—have agreed to pay separate amounts, collectively totaling $36,000, in partial reimbursement of the United States' response costs.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments concerning the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, U.S. Department of Justice, P.O. Box 7611, Washington, DC, 20044–7611, and should refer to *United States* v. *Allied Battery Co.* D.J. Ref. 90–11–3–1758, and *United States* v. *CSX Transportation, Inc.*, D.J. Ref. 90–11–3–1758/1.

The proposed Consent Decree may be examined at the Office of the United States Attorney for the Northern District of Alabama, 200 Robert Vance Federal Bldg., 1800 5th Ave. N., Birmingham, Alabama; and (2) the U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia. A copy of the Decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611. In requesting a copy, please enclose a check in the amount of $6.25 (25 cents per page reproduction cost) payable to the Consent Decree Library.

Walker B. Smith,

Deputy Chief, Environmental Enforcement Section, Environment & Natural Resources Division.

[FR Doc. 00–29294 Filed 11–15–00; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Morton International, Inc.; Consent Judgment

In accordance with Departmental policy, 28 CFR 50.7, notice is hereby given that on October 26, 2000 a proposed Consent Decree in *United States and State of Mississippi* v. *Morton International, Inc.,* Civil Action No. 1:00CV501 (BrR) was lodged with the United States District Court for the Southern District of Mississippi, Biloxi Division.

In this action the United States and State of Mississippi allege that the Morton International, Inc. (hereafter Morton or defendant) is liable under the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act (RCRA), the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA), the Clean Air Act (CAA), the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), the Emergency Planning and Community Right-to-Know Act (EPCRA), and the Mississippi Solid Waste Disposal Law of 1974, the Mississippi Air and Water Pollution Control Law, and the organic act of the Commission and of the Mississippi Department of Environmental Quality (MDEQ) for penalties and injunctive relief in connection with the defendant's manufacturing facility

located in Moss Point, Jackson County, Mississippi.

This consent decree represents a settlement between the United States, State of Mississippi and Morton. The consent decree requires Morton to: (1) Pay a penalty of $20 million, with $10 million being paid to the United States and $10 million being paid to the State of Mississippi, (2) perform Supplemental Environmental Projects (SEPs) valued at $16 million, (3) conduct a comprehensive analysis of conditions at the Facility, and (4) perform, if necessary, corrective measures at the Facility. In addition, the consent decree provides for audits to be conducted by a third party or parties at Morton chemical plants acquired by Rohm & Haas in 1999.

The SEPs include a Plant SEP which requires Morton to reduce or eliminate pollutants and to strive to terminate injection into deep wells as a method of disposal, a community SEP which provides for the rehabilitation or replacement of lateral sewer lines in the City of Moss Point, Mississippi, and the funding of a ''Green Chemistry'' project at the University of Southern Mississippi's School of Polymer Science. The Green Chemistry project is intended to develop architectural coatings which contain plant oils rather than volatile organic compounds. The community lateral line project will address inflow and infiltration which contributes to sewage overflows that plague Moss Point.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the proposed Second Consent Decree. Comments should be addressed to the Assistant Attorney General for the Environment and natural resources Division, U.S. Department of Justice, P.O. box 7611, Washington, D.C. 20044, and should refer to *United States and State of Mississippi* v. *Morton International, Inc.,* D.J. Ref. 90–7–1–06413. Commenters may request an opportunity for a public meeting in the affected area, in accordance with Section 7003(d) of the Resource Conservation and Recovery Act (''RCRA''), 42 U.S.C. 6973(d).

The proposed Consent Decree may be examined at the Office of the United States Attorney, Southern District of Mississippi, 808 Vieux Marche, 2nd Floor, Biloxi, Mississippi 39501; and at Region 4, Office of the Environmental Protection Agency, Atlanta Federal Center, 61 Forsyth Street, S.W., Atlanta, Georgia 30303. A copy of the proposed Consent Decree may be obtained by mail from the Department of Justice Consent Decree Library, P.O. box 7611, Washington, D.C. 20044. In requesting a copy, please enclose a check in the amount of $26.25 (without exhibits), $77.75 (with exhibits) (25 cents per page reproduction cost) payable to the Treasurer of the United States.

Walker Smith,

Deputy Chief, Environment and Natural Resources Division.

[FR Doc. 00–29291 Filed 11–15–00; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to the Clean Air Act

In accordance with 28 CFR 50.7, 38 FR 19029, notice is hereby given that on October 30, 2000, a proposed consent decree in *United States* v. *Puerto Rico Aqueduct and Sewer Authority,* Civil Action No. 00–1942 (PG), was lodged with the United States District Court for the District of Puerto Rico. The United States' complaint sought injunctive relief and civil penalties under the Clean Air Act (''CAA'') against the Puerto Rico Aqueduct and Sewer Authority (''PRASA''), in regard to violations of the New Source Performance Standards for sewage treatment plants and the Puerto Rico State Implementation Plan, resulting from PRASA's operation of the multiple hearth furnace (''MHF'') sludge incineration facility at its Puerto Nuevo wastewater treatment plant located in Puerto Nuevo, Puerto Rico.

The consent decree provides that PRASA shall pay a civil penalty of $80,000 and implement a supplemental environmental project, consisting of the installation of belt filter presses at its Bayamon wastewater treatment plant, estimated to cost about $692,000. The consent decree also requires PRASA to render its MHF units inoperable and enjoins PRASA from any future operation of those units.

The Department of Justice will receive comments relating to the proposed consent decree for a period of thirty (30) days from the date of this publication. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, Department of Justice, P.O. Box 7611, Washington, D.C. 20044, and should refer to *United States* v. *Puerto Rico Aqueduct and Sewer Authority,* D.J. Ref. 90–5–2–1–1874A.

The proposed consent decree may be examined at the office of the United States Attorney, Federal Office Building, Rm. 101, Carlos E. Chardon Avenue, Hato Rey, Puerto Rico 00918 and at the Region II office of the Environmental Protection Agency, 290 Broadway, New York, New York 10007. A copy of the proposed consent decree may also be obtained by mail from the Department of Justice Consent Decree Library, P.O. Box 7611, Washington, D.C. 20044. In requesting a copy, please enclose a check (there is a 25 cent per page reproduction cost) in the amount of $7.75 payable to the ''Consent Decree Library.''

Bruce S. Gelber,

Chief, Environmental Enforcement Section, Environment & Natural Resources Division.

[FR Doc. 00–29295 Filed 11–15–00; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree

Notice is hereby given that a proposed Consent Decree in the matter *The Surfrider Foundation* v. *John M. Bernal,* Case No. 99–CV–2441–BTM(JFS) (S.D. Cal.), was lodged with the United States District Court for the Southern District of California on October 16, 2000. The proposed Consent Decree concerns alleged violations of Section 402 of the Clean Water Act, 33 U.S.C. § 1342, at the South Bay International Wastewater Treatment Plant, located at 2415 Dairy Mart Road, San Diego County, San Diego, California.

The proposed Consent Decree would require (1) the performance of certain environmental studies and evaluations relating to discharge of wastewater from the Plant, and (2) the United States Section of the International Boundary and Water Commission to complete a secondary sewage treatment project for the Plant.

The United States Department of Justice will receive written comments relating to the proposed Consent Decree for a period of thirty (30) days from the date of publication of this notice. Comments should be addressed to S. Randall Humm, Trial Attorney, United States Department of Justice, Environmental Defense Section, P.O. Box 23986, Washington, D.C. 20026–3986, with copies provided to William A. Wilcox, Jr., International Boundary and Water Commission, Office of the Staff Counsel, 4171 No. Mesa Street; Suite C–310, El Paso, TX 79902, and Robert Moyer, Assistant Regional Counsel, United States Environmental Protection Agency—Region IX, U.S. EPA Border Office, 610 West Ash Street, Suite 703, San Diego, California, and should reference *The Surfrider Foundation* v. *John M. Bernal,* Case No. 99–CV–2441–BTM(JFS) (S.D. Cal.).

The proposed Consent Decree may be examined at the Clerk's Office, United States District Court for the Southern District of California, 4290 Edward J. Schwartz Federal Building, 880 Front Street, San Diego, California.

Letitia J. Grishaw,

Chief, Environmental Defense Section, Environment and Natural Resources Division, Department of Justice.

[FR Doc. 00–29293 Filed 11–15–00; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under the Safe Drinking Water Act

Notice is hereby given that on October 30, 2000, a proposed consent decree in *United States and the Commonwealth of Pennsylvania* v. *Tafton Water Company, et al.,* Civil Action No. 33: CV 99–263, was lodged with the United States District Court for the Middle District of Pennsylvania.

In this action, the United States and Pennsylvania Department of Environmental Protection sought civil penalties, injunctive relief, and preliminary injunctive relief for violations of the Safe Drinking Water Act and Pennsylvania's Safe Drinking Water Act at the Tafton water system which serves the Wilson Hill development in Hawley, Pennsylvania. The proposed consent decree would resolve certain claims against Winton Consolidated Companies, Inc., Public Service Water Company, Tafton Water Company, (''Corporate Defendants'') and Richard M.S. Freeman, (collectively, ''the Defendants'') by requiring the Corporate Defendants to pay $200,000 in civil penalties and the Defendants to pay $4,417.72 to the Wilson Hill Property Owners Association Water Company for reimbursement of expenses it incurred at the Tafton water system and the transfer of ownership of the Tafton water system to an unrelated entity. Additionally, Richard Freeman is required to pay $1,000 in stipulated penalties to the United States for his violation of a 1999 Consent Decree.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the consent decree. Comments should be addressed to the Assistant Attorney General of the Environment and Natural Resources Division, Department of Justice, P.O. Box 7611, Washington, DC 20044–7611, and should refer to *United States* v. *Tafton Water Company, et al.,* DOJ #90–5–1–1–06424.

The proposed consent decree may be examined at the offices of the United States Attorney, Middle District of Pennsylvania, Federal Building, 228 Walnut Street, Second Floor, P.O. Box 11754, Harrisburg, PA 17108. A copy of the proposed consent decree may also be obtained by mail from the Department of Justice Consent Decree Library, P.O. Box 7611, Washington, DC 20044–7611. In requesting a copy, please enclose a check in the amount of $5.25 (25 cents per page reproduction cost) payable to the Consent Decree Library.

Bruce Gelber,

Deputy Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 00–29290 Filed 11–15–00; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9601 to 9675

Notice is hereby given that two proposed consent decrees in *United States* v. *Weil-McLain Inc., et al.*, Civil Action No. 3:00CV0593RM, were lodged on September 25, 2000 with the United States District Court for the Northern District of Indiana, South Bend Division. Both consent decrees concern claims under the Comprehensive Environmental Compensation and Liability Act (''CERCLA'') in connection with the Waste, Inc. Superfund Site located in Michigan City, Indiana (the ''Site''). One proposed decree (the ''Conversion Consent Decree'') resolves the United States' claims for costs, civil penalties, and injunctive relief against nine settling defendants who failed to comply with a unilateral administrative order issued by the U.S. Environmental Protection Agency in December 1995. This decree also resolves claims for past costs incurred in connection with the Site against forty-three (43) other settling defendants and ensures the continued implementation of the remedial action at the Site that was begun under EPA's 1995 unilateral administrative order.

The second proposed consent decree (the ''MWS Consent Decree'') resolves the United States' claims against 18 other defendants for past costs incurred in responding to the disposal of municipal solid waste (MWS) at the Site. The settling defendants under consent decree sent only MSW to the Site, and they will pay $227,000 into a special account for use in remediation of the Site.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, P.O. Box 7611, N.W., Washington, D.C. 20044–7611, and should refer to *United States* v. *Weil-McLain, Inc., et al.*, No. 3:00CV0593RM, D.J. Ref. 90–11–3–1376B.

The consent decrees may be examined at the Office of the United States Attorney, 204 South Main Street, South Bend, Indiana 46601–2191; and at the Region 5 Office of the Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. A copy of the consent decrees may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, D.C. 20044–7611. In requesting a copy of the Conversion Consent Decree with attachments, including the draft final MSW Consent Decree, please enclose a check in the amount of $36.00 ($.25 per page reproduction cost) payable to the Consent Decree Library. In requesting a copy of just the Conversion Consent Decree without attachments, please enclose a check for $21.00 payable to the Consent Decree Library. In requesting a copy of just the MSW Consent Decree, please enclose a check in the amount of $4.00 payable to the Consent Decree Library.

Bruce S. Gelber,

Deputy Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 00–29292 Filed 11–16–00; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review; Comment Request

November 8, 2000.

The Department of Labor (DOL) has submitted the following public information collection requests (ICRs) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). A copy of each individual ICR, with applicable supporting documentation, may be obtained by calling the Department of Labor. To obtain documentation for BLS, ETA, PWBA, and OASAM contact

Karin Kurz ((202) 693–4127 or by E-mail to *Kurz-Karin@dol.gov*). To obtain documentation for ESA, MSHA, OSHA, and VETS contact Darrin King ((202) 693–4129 or by E-Mail to *King-Darrin@dol.gov*).

Comments should be sent to Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for BLS, DM, ESA, ETA, MSHA, OSHA, PWBA, or VETS, Office of Management and Budget, Room 10235, Washington, DC 20503 ((202) 395–7316), within 30 days from the date of this publication in the **Federal Register**.

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Type of Review: Extension of a currently approved collection.

Agency: Occupational Safety and Health Administration (OSHA).

Title: Recording and Reporting Occupational Injuries and Illnesses.

OMB Number: 1218–0176.

Affected Public: Business or other for-profit; Not-for-profit institutions; farms; State, Local, or Tribal Government.

Frequency: On occasion.

Number of Respondents: 1,395,516.

Number of Annual Responses: 5,067,726.

Estimated Time Per Response: 26 minutes.

Total Burden Hours: 2,229,349.

Total Annualized Capital/Startup Costs: $0.

Total Annual Costs (operating/maintaining systems or purchasing services): $0.

Description: The OSHA No. 200, Log and Summary; the OSHA 101, Supplementary Record; and the recordkeeping guidelines provide employers with the means and specific instructions needed to maintain records of work-related injuries and illnesses. The data are needed by OSHA to carry out intervention and enforcement activities in order to guarantee workers safe and healthful workplaces. The data are also needed by the Bureau of Labor Statistics (BLS) to produce national statistics on occupational injuries and illnesses. Response to this collection of information is mandatory as specified in 29 CFR Part 1904.

Type of Review: Extension of a currently approved collection.

Agency: Occupational Safety and Health Administration (OSHA).

Title: OSHA Data Collection System.

OMB Number: 1218–0209.

Affected Public: Business or other for-profit; farms; State, Local, or Tribal Government.

Frequency: Annually.

Number of Respondents: 81,425.

Number of Annual Responses: 81,425.

Estimated Time Per Response: 30 minutes.

Total Burden Hours: 39,113.

Total Annualized Capital/Startup Costs: $0.

Total Annual Cost (operating/maintaining systems or purchasing services): $0.

Description: The year 2001 OSHA Data Collection will request CY 2000 injury and illness data from 81,425 establishments throughout the Nation. The data are needed by OSHA to carry out intervention and enforcement activities in order to guarantee workers a safe and healthful workplace. The data will also be used for measurement purposes in compliance with the Government Performance and Results Act of 1995 and multiple research purposes. The data collected are already maintained by employers as required by 29 CFR Part 1904.

Type of Review: Reinstatement of a previously approved collection.

Agency: Occupational Safety and Health Administration (OSHA).

Title: Modification of Aerial Lifts in Construction.

OMB Number: 1218–0216.

Affected Public: Business or other for-profit; Federal Government; State, Local, or Tribal Government.

Frequency: On occasion.

Number of Respondents: 60.

Number of Annual Responses: 60.

Estimated Time Per Response: 3 minutes.

Total Burden Hours: 3.

Total Annualized Capital/Startup Costs: $0.

Total Annual Cost (operating/maintaining systems or purchasing services): $0.

Description: 29 CFR 1926.453 requires employers to obtain written certification of any field modifications made to aerial lifts. Such certification must be prepared in writing by either the manufacturer of the aerial lift or a nationally recognized testing laboratory. The certification is to attest to the safety of the lift after modification.

Ira L. Mills,

Departmental Clearance Officer.

[FR Doc. 00–29370 Filed 11–15–00; 8:45 am]

BILLING CODE 4510–26–M

DEPARTMENT OF LABOR

Office of the Secretary

Senior Executive Service; Appointment of a Member to the Performance Review Board

Title 5 U.S.C. 4314(c)(4) provides that Notice of the appointment of an individual to serve as a member of the Performance Review Board of the Senior Executive Service shall be published in the **Federal Register**.

The following individuals are hereby appointed to a three-year term on the Department's Performance Review Board: Leah Daughtry, Joseph Juarez, Carl Lowe, David Zeigler.

FOR FURTHER INFORMATION CONTACT: Ms. Tali R. Stepp, Director of Human Resources, Room C5526, U.S. Department of Labor, Frances Perkins Building, 200 Constitution Avenue, NW, Washington, DC 20210, telephone: (202) 219–9191.

Signed at Washington, D.C., this 9th day of November, 2000.

Alexis M. Herman,

Secretary of Labor.

[FR Doc. 00–29371 Filed 11–15–00; 8:45 am]

BILLING CODE 4510–23–M

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance and NAFTA Transitional Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, as amended, the Department of Labor herein presents summaries of determinations regarding eligibility to apply for trade adjustment assistance for workers (TA–W) issued during the period of November 2000.

In order for an affirmative determination to be made and a certification of eligibility to apply for worker adjustment assistance to be issued, each of the group eligibility

requirements of Section 222 of the Act must be met.

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision, thereof, have become totally or partially separated;

(2) That sales or production, or both, of the firm or subdivision have decreased absolutely; and

(3) That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Negative Determinations for Worker Adjustment Assistance

In each of the following cases the investigation revealed that criterion (3) has not been met. A survey of customers indicated that increased imports did not contribute importantly to worker separations at the firm.

TA–W–37,987; Hobman Corp., Jim Thorpe, PA
TA–W–37,835; Whitehall Leather Co., A Div. of Genesco, Inc., Whitehall, MI
TA–W–38,077; Paris Accessories, Inc., Belt Div., Allentown, PA

In the following cases, the investigation revealed that the criteria for eligibility have not been met for the reasons specified.

TA–W–37,990; Telxon Corp., National Service Center, Houston, TX
TA–W–38,188; Supply One, Klamath Falls, OR
TA–W–38,196; Gadsden Machine and Roll Co., Gadsden, AL

The workers firm does not produce an article as required for certification under Section 222 of the Trade Act of 1974.

TA–W–38,218; Swift Denim, Erwin, NC
TA–W–37,985; Lear Corp., Foam Line 1 and 2 of Dept 612, Detroit, MI
TA–W–38,219; C & M Corp., Wauregan, CT
TA–W–38,214; Fleetwood Homes of Georgia, Inc., Manufacturing Center #05, Douglas, GA
TA–W–38,001 & A; Warner's Distribution Center, Murfreesboro, TN & Warner's Cutting Center, Murfreesboro, TN

Increased imports did not contribute importantly to worker separations at the firm.

TA–W–38,121; Duke Energy Field Service, Ada, OK

The investigation revealed that criteria (2) and criteria (3) have not been met. Sales or production did not decline during the relevant period as required for certification. Increases of imports of articles like or directly competitive with articles produced by the firm or an appropriate subdivision have not contributed importantly to the separations of threat thereof, and the absolute decline in sales or production.

Affirmative Determinations for Worker Adjustment Assistance

The following certifications have been issued; the date following the company name and location of each determination references the impact date for all workers of such determination.

TA–W–38,078; Roanoke Electric Steel Corp., Melt Shop, Roanoke, VA: August 28, 1999.
TA–W–38,120; Bausch and Lomb, Contact Lens Div., Rochester, NY: September 6, 1999.
TA–W–38,171; Lear Corp., Lear Electronics and Electrical Div., Traverse City, MI: September 20, 1999.
TA–W–37,800; Mar-Kel Lighting, Inc., Paris, TN: June 9, 1999.
TA–W–38,154; Leather's Best, Johnstown, NY: September 19, 1999.
TA–W–38,118; Livingston Apparel, Inc., Livingston, AL: September 12, 1999.
TA–W–38,140; Esquire Novelty, Amsterdam, NY: September 15, 1999.
TA–W–38,063; International Lace and Emblem, Guttenberg, NJ: August 17, 1999.
TA–W–38,081; Bru-Mar Manufacturing Co., Inc., Allentown, PA: August 29, 1999.
TA–W–38,045; Corpus Tuscaloosa, Formerly Known as Tuscaloosa Steel, Tuscaloosa, AL: August 18, 1999.
TA–W–37,979; Newell Window Furnishing, Kirsch, Inc., Sturgis, MI: August 3, 1999.
TA–W–38,139; Ametek, U.S. Gauge Div., Sellersville, PA: September 22, 1999.
TA–W–38,148; Telex Communication, Newport, TN: September 15, 1999.
TA–W–37,986; Sumitok Magnetics Co., Bardstown, KY: August 8, 1999.
TA–W–38,095; Ungo Security, Hayward, CA: August 18, 1999.
TA–W–38,097; Toastmaster, Inc., Macon, MO: September 9, 1999.
TA–W–38,156; Matsushita Microwave Oven Co., Matsushita Home Applicance Co., Danville, KY: September 11, 1999.
TA–W–38,103; Lebanite Corp., Lebanon, OR: August 31, 1999.
TA–W–37,950; Sauer Danfoss, Inc., Formerly Danfoss Fluid Power, Inc., Racine, WI: August 7, 1999.
TA–W–38,012; Dunbrook Sportswear, Greenfield, MO: August 14, 1999.
TA–W–38,170; Advance Transformer Co., Monroe, WI: September 19, 1999.
TA–W–38,164; Nafta Textile Mills LLC, Manville, RI: September 20, 1999.

Also, pursuant to Title V of the North American Free Trade Agreement Implementation Act (Pub. L. 103–182) concerning transitional adjustment assistance hereinafter called (NAFTA–TAA) and in accordance with Section 250(a), Subchapter D, Chapter 2, Title II, of the Trade Act as amended, the Department of Labor presents summaries of determinations regarding eligibility to apply for NAFTA–TAA issued during the month of November 2000.

In order for an affirmative determination to be made and a certification of eligibility to apply for NAFTA–TAA the following group eligibility requirements of section 250 of the Trade Act must be met:

(1) That a significant number or proportion of the workers in the workers' firm, or an appropriate subdivision thereof, (including workers in any agricultural firm or appropriate subdivision thereof) have become totally or partially separated from employment and either—

(2) That sales or production, or both, of such firm or subdivision have decreased absolutely;

(3) That imports from Mexico or Canada of articles like or directly competitive with articles produced by such firm or subdivision have increased, and that the increases imports contributed importantly to such workers' separations or threat of separation and to the decline in sales or production of such firm or subdivision; or

(4) That there has been a shift in production by such workers' firm or subdivision to Mexico or Canada of articles like or directly competitive with articles which are produced by the firm or subdivision.

Negative Determinations NAFTA–TAA

In each of the following cases the investigation revealed that criteria (3) and (4) were not met. Imports from Canada or Mexico did not contribute importantly to workers; separations. There was no shift in production from the subject firm to Canada or Mexico during the relevant period.

NAFTA–TAA–04139; Lear Corp., Foam Line 1 and 2 of Dept 612, Detroit, MI
NAFTA–TAA–04181; Ametek, US Gauge Div., Sellersvile, PA
NAFTA–TAA–03993, Whitehall Leather Co., A Div. of Genesco, Inc., Whitehall, MI

NAFTA–TAA–04121; Terex Corp., Unit Rig Div., Tulsa, OK
NAFTA–TAA–04182; Fleetwood Homes of Georgia, Inc., Manufacturing Center #05, Douglas, GA
NAFTA–TAA–04075; Hobman Corp., Jim Thorpe, PA
NAFTA–TAA–04190; Chilton Toys, Div. of Strombecker Corp., Seymour, WI
NAFTA–TAA–04046; Cross Huller North America, Div. of Thyssenkrupp, Fraser, MI
NAFTA–TAA–04222; Norton Co., Coated Abrasives Div., Watervliet, NY
NAFTA–TAA–04206; Williamette Industries, Customer Products Div., Albany, OR
NAFTA–TAA–04220; Royal Oak Enterprises, Inc., Paris, TN
NAFTA–TAA–04051; Boise Cascade Corp., Timber and Wood Products Div., Independence, OR
NAFTA–TAA–04043; Scott Logging, Inc., Bend, OR
NAFTA–TAA–04096; Roseburg Forest Products Co., Big Log Sawmill, Dillard, OR
NAFTA–TAA–04102; Corlair Corp., Piedmont, MO
NAFTA–TAA–04224 & A; Northside Manufacturing, Philipsburg, PA and Streamline Fashions Manufacturing Co., Philipsburg, PA

The investigation revealed that the criteria for eligibility have not been met for the reasons specified.

NAFTA–TAA–04027; Guess?, Inc., San Diego, CA
NAFTA–TAA–04204; Supply One, Klamath Falls, OR
NAFTA–TAA–04085; GRT, Inc., Sun Valley, CA
NAFTA–TAA–04214; Gadsden Machine and Tool Co., Gadsden, AL
NAFTA–TAA–04071; Telxon Corp., National Service Center, Houston, TX

The investigation revealed that workers of the subject firm did not produce an article within the meaning of section 250(a) of the Trade Act, as amended.

Affirmative Determinations NAFTA–TAA

NAFTA–TAA–04124; Newell Window Furnishings, Kirsch, Inc., Sturgis, MI: August 3, 1999.
NAFTA–TAA–04196; Swift Denim, Erwin, NC: October 5, 1999.
NAFTA–TAA–04163; Lear Corp., Lear Electronics and Electrical Div., Traverse City, MI: September 26, 1999.
NAFTA–TAA–04183; Paper, Calmenson & Company, Blade Div., Bucyrus, OH: September 22, 1999.
NAFTA–TAA–04133; Marino Technologies, Opa-Locka, FL: August 21, 1999.
NAFTA–TAA–04141; Bru-Mar Manufacturing Co., Inc., Allentown, PA: August 29, 1999.
NAFTA–TAA–04207; United States Leather, Lackawanna Leather, Omaha, NE; September 7, 1999.
NAFTA–TAA–04208; Progress Lighting, Cowpens, SC: October 6, 1999.
NAFTA–TAA–04217; Leapwood Apparel, Adamsville, TN: October 11, 1999.
NAFTA–TAA–04236; John Crane, Inc., Morton Grove, IL: October 19, 1999.
NAFTA–TAA–04154; McDowell Manufacturing, DuBois, PA: September 11, 1999.
NAFTA–TAA–04098; Savane International Corp., El Paso, TX: July 5, 1999.
NAFTA–TAA–04171; Fruit of the Loom, Texas, Inc. Gitano Dept., Harlingen, TX: September 11, 1999.
NAFTA–TAA–04195; Avery Dennison, Writing Instruments Div., Crossville, TN: September 29, 1999.
NAFTA–TAA–04093; Central Point Lumber, a/k/a Tree Source, Central Point, OR: August 10, 1999.
NAFTA–TAA–04165; Sharp Manufacturing Co. of America, Memphis, TN: Septmeber 12, 1999.
NAFTA–TAA–04126; Acer America Corp., Manufacturing Div., San Jose, CA: August 28, 1999.
NAFTA–TAA–04134; Lebanite Corp., Lebanon, OR: August 31, 1999.
NAFTA–TAA–04225; Advance Transformer Co., Monroe, WI: September 19, 1999.

I hereby certify that the aforementioned determinations were issued during the month of November, 2000. Copies of these determinations are available for inspection in Room C–5311, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 during normal business hours or will be mailed to persons who write to the above address.

Dated: November 9, 2000.

Edward A. Tomchick,

Director, Division of Trade Adjustment Assistance.

[FR Doc. 00–29367 Filed 11–15–00; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–37,823A]

Carleton Woolen Mills, Inc., New York, NY; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974 (19 U.S.C. 2273), the Department of Labor issued an Amended Certification of Eligibility to Apply for Worker Adjustment Assistance on October 31, 2000, applicable to workers of Carleton Woolen Mills, Inc., New York, New York. The notice will be published soon in the **Federal Register.**

At the request of the State agency, the Department reviewed the certification for workers of the subject firm. The workers provided administration, sales, styling, design and support function services for the subject firm's production facility in Winthrop, Maine. Findings show that the Department incorrectly set the worker certification impact date at July 23, 2000. The impact date should be June 14, 1999, one year prior to the date of the petition. Accordingly, the Department is amending the certification to reflect this matter.

The amended notice applicable to TA–W–37,823A is hereby issued as follows:

''All workers of Carleton Woolen Mills, Inc., New York, New York who became totally or partially separated from employment on or after June 14, 1999 through August 18, 2002 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.''

Signed at Washington, DC this 8th day of November, 2000.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 00–29369 Filed 10–15–00; 8:45 am]

BILLING CODE 4510–30–M

DEPARTMENT OF LABOR

Employment and Training Administration

[TA–W–36,453]

Diamond Offshore Drilling, Inc., Houston, Texas and Operating at Various Offshore Drilling Sites Located in American Waters; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on July 13, 1999, applicable to workers of Diamond Offshore Drilling, Inc., Houston, Texas. The notice was published in the **Federal Register** on August 11, 1999 (64 FR 43724).

At the request of the company, the Department reviewed the certification for workers of the subject firm. The company reports that worker separations have occurred at Diamond Offshore Drilling operating at various offshore drilling sites located in American waters. The workers are engaged in activities related to the exploration and drilling of crude oil and natural gas.

Accordingly, the Department is amending the certification to include workers operating at various offshore drilling sites located in American waters.

The intent of the Department's certification is to include all workers of Diamond Offshore Drilling, Inc. who were adversely affected by increased imports.

The amended notice applicable to TA–W–36,453 is hereby issued as follows:

All workers of Diamond Offshore Drilling, Inc., Houston, Texas and operating at various offshore drilling sites located in American waters who became totally or partially separated from employment on or after June 6, 1998 through July 13, 2001 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

Signed at Washington, DC this 3rd day of November 2000.

Linda G. Poole,

Certifying Officer, Division of Trade Adjustment Assistance.

[FR Doc. 00–29368 Filed 11–15–00; 8:45 am]

BILLING CODE 4510–30–M

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

Government Performance and Results Act of 1993

AGENCY: Federal Mine Safety and Health Review Commission.

ACTION: Notice of Request for Comments.

SUMMARY: The Federal Mine Safety and Health Review Commission is notifying interested parties that its draft strategic plan for the fiscal years 2000–2005, is available for public comment. The draft plan, prepared in accordance with the Government Performance and Results Act of 1993 (''GPRA''), defines the Commission's goals, specific objectives, time frames and methods for achieving goals at both the trial and appellate level.

In developing its goals and objectives under GPRA, the Commission solicits the views of those who practice before it and those who are affected by its case dispositions.

DATES: Comments should be received by December 18, 2000.

ADDRESSES: Comments should be sent to Richard L. Baker, Executive Director, Federal Mine Safety and Health Review Commission, 1730 K Street, N.W., Suite 6000, Washington, D.C. 20006, fax: (202) 653–5030; E-mail: Info@FMSHRC.gov., phone: (202) 653–5625, or (202) 708–9300 for TDD Relay.

The draft plan is posted on the Commission's website, http://www.fmshrc.gov/ under ''What's New.'' Printed copies can also be obtained from the above listed address.

SUPPLEMENTARY INFORMATION: GPRA charges federal agencies with formulating strategic plans, preparing annual plans setting performance goals, and reporting annually the actual agency performance compared to those goals. In considering how best to formulate its goals and objectives, the Commission has sought to develop measures that allow it to better evaluate its performance and ultimately accomplish is statutory mission under the Federal Mine Safety and Health Act of 1977.

The Commission requests that responses to this solicitation for comments be submitted by December 18, 2000.

Dated: October 31, 2000.

Mary Lu Jordan,

Chairman.

[FR Doc. 00–29289 Filed 11–15–00; 8:45 am]

BILLING CODE 6735–01–M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (00–138)]

NASA Advisory Council (NAC), Earth Systems Science and Applications Advisory Committee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration announces a meeting of the NASA Advisory Council, Earth Systems Science and Applications Advisory Committee.

DATES: Tuesday, December 5, 2000, 8:30 am to 5:30 pm; and Wednesday, December 6, 2000, 8:30 am to 5:30 pm.

ADDRESSES: NASA Headquarters, 300 E Street SW., Room 9H40, Program Review Center, Washington, DC, 20546.

FOR FURTHER INFORMATION CONTACT: Dr. Robert Schiffer, Code YS, National Aeronautics and Space Administration, Washington, DC 20546, 202/358–1876.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the room. The agenda for the meeting is as follows:

- Assessment of the State-of-the-Enterprise
- Status Reports re: ESSAAC Subcommittees and ad hoc Panels
- Technology
- Data & Information Systems
- GPRA Performance Metrics
- ESE Budget Status
- Status of the ESE Science Implementation Plan
- Summary of First Day
- Applications Strategic and Implementation Planning
- Technology Strategy and Roadmap
- Strategic Planning Status Overview—ESE Vision
- Discussion Period
- Debriefing/Closing Remarks
- ESSAAC Deliberation Session
- Summary of Actions, Future Schedule

It is imperative that the meeting be held on these dates to accommodate the scheduling priorities of the key participants. Visitors will be requested to sign a visitor's register.

Dated: November 13, 2000.

Beth M. McCormick,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 00–29438 Filed 11–15–00; 8:45 am]

BILLING CODE 7510–01–U

NEIGHBORHOOD REINVESTMENT CORPORATION

Sunshine Act Meeting; Regular Meeting of the Board of Directors

TIME AND DATE: 2 p.m., Monday, November 20, 2000.

PLACE: Neighborhood Reinvestment Corporation, 1325 G Street, NW., Suite 800, Board Room, Washington, DC 20005.

STATUS: Open/Closed.

CONTACT PERSON FOR MORE INFORMATION: Jeffrey T. Bryson, General Counsel/Secretary (202) 220–2372.

AGENDA:

I. Call to Order
II. Approval of Minutes: August 23, Regular Meeting
III. Treasurer's Report:
IV. Executive Director's Quarterly Management Report
V. Personnel Committee Report (CLOSED) November 7, 2000 Meeting
VI. Adjourn

Jeffrey T. Bryson,

General Counsel/Secretary.

[FR Doc. 00–29465 Filed 11–14–00; 11:21 am]

BILLING CODE 7570–01–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–400–LA; ASLBP No. 99–762–02–LA; November 9, 2000]

Atomic Safety and Licensing Board; Notice (Schedule for Oral Argument)

Before Administrative Judges:
G. Paul Bollwerk, III, Chairman
Dr. Peter S. Lam
Thomas D. Murphy

In the Matter of Carolina Power & Light Company (Shearon Harris Nuclear Power Plant)

In accordance with the Licensing Board's memorandum and order of August 28, 2000, the Board will hold the 10 CFR 2.1113 argument regarding the parties' written summaries on intervenor Board of Commissioners of Orange County's (BCOC) contention EC–6, Environmental Impact Statement Required, on *Thursday, December 7, 2000, beginning at 9:30 a.m. EST, in the Jane S. McKimmon Conference Center, North Carolina State University, corner of Gorman Street and Western Avenue, Raleigh, North Carolina.* The procedures applicable to this oral argument will be the same as those used for the January 2000 oral argument. *See* Licensing Board Memorandum and Order (Subpart K Oral Argument Procedures) (Jan. 13, 2000) at 1–3 (unpublished).

At this juncture, it is the Board's intent that this oral argument will be open to the public. If, in submitting written summaries, any of the parties utilize proprietary or other nonpublic information, the parties should be prepared to advise the Board whether that information will be discussed during, or otherwise be a part of, the oral argument. *See id.* at 5.

Rockville, Maryland, November 9, 2000.

For the Atomic Safety and Licensing Board *

G. Paul Bollwerk, III,

Administrative Judge.

[FR Doc. 00–29381 Filed 11–15–00; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 72–3]

Notice of Issuance of Amendment to Materials License No. SNM–2502, Carolina Power & Light Company; Independent Spent Fuel Storage Installation

The U.S. Nuclear Regulatory Commission (NRC or the Commission) has issued Amendment No. 12 to Materials License SNM–2502 held by Carolina Power & Light Company (CP&L) for the receipt, possession, transfer, and storage of spent fuel at the H. B. Robinson Independent Spent Fuel Storage Installation (ISFSI), located on the H. B. Robinson Steam Electric Plant Unit 2 site, Darlington County, South Carolina. The amendment is effective as of the date of issuance.

By application dated August 28, 2000, CP&L requested an amendment to Materials License SNM–2502 for the H.B. Robinson ISFSI. CP&L is seeking Commission approval to amend the materials license safeguards license condition and the Technical Specifications to reflect that the Industrial Security Plan and Safeguards Contingency Plan are combined into the Physical Security and Safeguards Contingency Plan. The revision would also clarify the text to indicate that the Training and Qualification Plan no longer contains safeguards information. Such an action would only change the reference to and the location of the Industrial Security Plan and the Safeguards Contingency Plan. The requested change does not affect the design, operation, maintenance, or surveillance of the ISFSI.

This amendment complies with the requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

In accordance with 10 CFR 72.46(b)(2), a determination has been made that the amendment does not present a genuine issue as to whether public health and safety will be significantly affected. Therefore, the publication of a notice of proposed action and an opportunity for hearing or a notice of hearing is not warranted. Notice is hereby given of the right of interested persons to request a hearing on whether the action should be rescinded or modified.

The Commission has determined that the issuance of the amendment meets the criteria for a categorical exclusion set forth in 10 CFR 51.22(c)(10) of the regulations. Therefore, an environmental assessment need not be prepared in connection with issuance of the amendment.

Documents related to this action are available for public inspection at the Commission's Public Document Room located at the One White Flint Building, 11555 Rockville Pike, Rockville, Maryland, or from the publicly available records component of NRC's document system (ADAMS). ADAMS is accessible from the NRC Web site at *http://www.nrc.gov/NRC/ADAMS/index.html* (the Public Electronic Reading Room).

Dated at Rockville, Maryland, this 6th day of November 2000.

For the Nuclear Regulatory Commission.

E. William Brach,

Director, Spent Fuel Project Office, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 00–29382 Filed 11–15–00; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Application for a License to Export Highly-Enriched Uranium

Pursuant to 10 CFR 110.70(b)(2) ''Public notice of receipt of an application,'' please take notice that the Nuclear Regulatory Commission has received the following application for an export license. Copies of the application are available electronically through ADAMS and can be accessed through the Public Electronic Reading Room (PERR) link <*http://www.nrc.gov/*

* Copies of this notice were sent this date by Internet e-mail transmission to counsel for (1) applicant Carolina Power and Light Company; (2) intervenor BCOC; and (3) the NRC staff.

NRC/ADAMS/index.html> at the NRC Homepage.

A request for a hearing or petition for leave to intervene may be filed within 30 days after publication of this notice in the **Federal Register**. Any request for hearing or petition for leave to intervene shall be served by the requestor or petitioner upon the applicant, the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington D.C. 20555; the Secretary, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555; and the Executive Secretary, U.S. Department of State, Washington, D.C. 20520.

In its review of the application for a license to export special nuclear material noticed herein, the Commission does not evaluate the health, safety or environmental effects in the recipient nation of the material to be exported. The information concerning this application follows.

NRC EXPORT LICENSE APPLICATION

Name of applicant Date of application Date received Application number	Description of Material			Country of destination
	Material type	Total qty.	End use	
Transnuclear, Inc. October 23, 2000 October 24, 2000 XSNM03171	Highly-Enriched Uranium (93.30%).	10.05 kg Uranium/9.377 kg Uranium-235.	Fabrication of target material for the production of medical isotopes at the Chalk River Laboratories.	Canada.

For the Nuclear Regulatory Commission.

Dated this 8th day of November 2000 at Rockville, Maryland.

Ronald D. Hauber,

Deputy Director, Office of International Programs.

[FR Doc. 00–29380 Filed 11–15–00; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–213]

Connecticut Yankee Atomic Power Company, et al., Haddam Neck Plant; Receipt of Petition for Director's Decision Under 10 CFR 2.206

Notice is hereby given that by petition dated September 26, 2000, the Citizens Awareness Network (petitioner) has requested that NRC take action with regard to Connecticut Yankee Atomic Power Company (CYAPCO). The petitioner requests that the United States Nuclear Regulatory Commission (NRC): (1) Conduct a full investigation of CYAPCO's garment laundering practices and specifically of the September 20, 2000, incident at a public laundry facility; (2) revoke CYAPCO's license, or suspend it until such time that an investigation is completed and any contamination found as a result of that investigation is remediated; (3) report any violations of regulations to the Department of Justice, and; (4) conduct an informal public hearing.

As the basis for this request the petitioner states that on September 20, 2000, CYAPCO laundered bright yellow coveralls at a public laundromat in East Hampton, CT. In addition, the petitioner states that rubber boots and gloves from the Haddam Neck Plant are also washed at the laundromat on occasion. The petitioner contends that although it is not clear whether or not the garments were radioactively contaminated that the ''laundering of Haddam Neck's protective garments at a public facility constitutes a serious loss of radiological control, and blatant disregard for public and worker health and safety, the environment, and NRC rules and regulations.'' In support of the claim the petition cites a number of events that the petitioner believes collectively demonstrate an ''inability on the licensee's part to follow NRC rules and regulations * * *.''

Based on the findings of an inspection performed by the NRC staff as a result of the petition, the staff is confident that there is not an immediate safety issue associated with this petition. Therefore, the NRC does not intend to act immediately on the petitioners' second request (suspension or revocation of the Haddam Neck Plant operating license).

This request is being treated pursuant to 10 CFR 2.206 of the Commission's regulations. The request has been referred to the Director of the Office of Nuclear Reactor Regulation. As provided by Section 2.206, appropriate action will be taken on this petition within a reasonable time.

The petition (ADAMS Accession Number ML003755400) may be examined, and/or copied for a fee, at the NRC's Public Document Room, located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland, and is accessible electronically from the ADAMS Public Library component of the NRC Web site, *http://www.nrc.gov* (the Public Electronic Reading Room).

Dated at Rockville, Maryland, this 9th day of November 2000.

For the Nuclear Regulatory Commission.

Roy P. Zimmerman,

Acting Director, Office of Nuclear Reactor Regulation.

[FR Doc. 00–29383 Filed 11–15–00; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF MANAGEMENT AND BUDGET

OMB Circular A–133 Information Collection Under OMB Review

AGENCY: Office of Management and Budget, Executive Office of the President.

ACTION: Notice of Submission for OMB Review, Comment Request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1980, as amended (44 U.S.C. 3501 *et seq.*), this notice announces that an information collection request was submitted to the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs for processing under 5 CFR 1320.10. The first notice of this information collection request, as required by the Paperwork Reduction Act, was published in the **Federal Register** on July 11, 2000 (65 FR 42735). The information collection request involves two proposed information collections from two types of entities: (1) Reports from auditors to auditees concerning audit results, audit findings, and questioned costs; and, (2) reports from auditees to the Federal Government providing information about the auditees, the awards they administer, and the audit results. These

collection efforts are required by the Single Audit Act Amendments of 1996 (31 U.S.C. 7501 *et seq.*) and OMB Circular A–133, ''Audits of States, Local Governments, and Non-Profit Organizations.'' Circular A–133's information collection requirements apply to approximately 30,000 States, local governments, and non-profit organizations on an annual basis.

DATES: Submit comments on or before December 18, 2000. Late comments will be considered to the extent practicable.

ADDRESSES: Written comments should be sent to: Edward Springer, Office of Information and Regulatory Affairs, OMB, 725 17th Street NW., Room 10236, Washington, DC 20503. Electronic mail comments may be submitted via the Internet to espringer@omb.eop.gov. Please include the full body of the comments in the text of the message and not as an attachment. Please include the name, title, organization, postal address, and E-mail address in the text of the message as well as the name and phone number of a contact person.

FOR FURTHER INFORMATION CONTACT: For further information, contact Terrill W. Ramsey, Office of Federal Financial Management, OMB, 725 17th Street NW., Room 6025, Washington, DC 20503 (202–395–3993). The proposed data collection form and its instructions can be obtained by contacting the Office of Federal Financial Management, as indicated above or by download from the OMB Grants Management home page on the Internet at http://www.whitehouse.gov/OMB/grants.

SUPPLEMENTARY INFORMATION:

A. Background

Control No.: 0348–0057.

Title: Data Collection Form.

Form No: SF–SAC.

Type of Review: Revision of a currently approved collection.

Respondents: States, local governments, and non-profit organizations (Non-Federal entities).

Estimated Number of Respondents: 60,000.

Estimated Time per Respondent: 59 hours for each of 400 large respondents and 17 hours for each of 59,600 small respondents for estimated annual burden hours of 1,036,800.

Estimated Number of Responses per Respondent: 1.

Frequency of Response: Annually.

Needs and Uses: Reports from auditors to auditees and reports from auditees to the Federal government are used by non-Federal entities, pass-through entities, and Federal agencies to ensure that Federal awards are expended in accordance with applicable laws and regulations. The Federal Audit Clearinghouse (FAC) (maintained by the U.S. Bureau of the Census) uses the information on the SF–SAC to ensure proper distribution of audit reports to Federal agencies and identify non-Federal entities who have not filed the required reports. The FAC also uses the information on the SF–FAC to create a governmentwide database which contains information on audit results. This database is publicly accessible on the Internet at http://harvester.census.gov/sac/. It is used by Federal agencies, pass-through entities, non-Federal entities, auditors, the General Accounting Office, OMB, and the general public for management and information about Federal awards and the results of audits.

B. Public Comments and Responses

Pursuant to the July 11, 2000, **Federal Register** notice, OMB received 27 comment letters relating to the proposed revision to the information collection. Six of the letters had no suggested changes. General comments included that the changes seemed reasonable, would provide additional information at little additional costs, and the clarity of the instructions was improved. Letters came from Federal agencies (including Offices of Inspectors General), State governments (including State auditors), certified public accountants (CPAs), non-profit organizations (including colleges and universities), professional organizations, and others. The comments received relating to the information collection and OMB's responses are summarized below.

Reporting Burden

Comments: Two comments were received relating to the reporting burden. One State auditor commented that although more work will be required by non-Federal entities for the first year the amendments are in effect, they believed that in the long run the changes have the potential to lessen burdens on non-Federal entities. Another State auditor commented that the estimate to prepare the Data Collection Form seemed to be about right, maybe a little high.

Response: The Office of Management and Budget (OMB) in conjunction with the Federal awarding agencies, the National State Auditors Association (NSAA), the American Institute of Certified Public Accountants (AICPA), the General Accounting Office (GAO), and the Federal Audit Clearinghouse (FAC) assembled a task force to redesign the Data Collection Form. The primary goal of the task force was to make improvements to the form that would increase the Federal awarding agencies ability to monitor their grants, while minimizing the potential for increased reporting burden. Based on the comments received, it appears this goal was achieved.

Research and Development

Comment: The NSAA and a state auditor suggested only requiring entities to check the ''Yes'' box in Part III, Item 11b for Research and Development (R&D) programs rather than a positive answer of either ''Yes'' or ''No.''

Response: The requirement to check the ''No'' box in Part III, Item 11b for non-R&D programs was not changed. Respondents are required to provide an positive answer for every question on the Data Collection Form (with the exception of fax numbers and email addresses) for the purpose of maintaining database integrity. If Part III, Item 11b is left blank to mean ''No,'' it would be unclear whether the form preparer may have overlooked the item or meant ''No.''

Multiple Employer Identification Numbers (EINs)

Comment: Three State auditors commented on the new requirement to capture the multiple Employer Identification Numbers (EINs) covered by the single report. All three comments recognized the additional effort the States will have to put forward the first year to capture this information, but none felt the new requirement placed an undue burden. The commenters also recognized the Federal agencies need this information to help ensure that all single audit reports were filed.

Response: No change was made. The multiple EINs covered by the single audit report will improve the ability to identify entities who did not file the audits required by Circular A–133.

Cognizant Agency Determination

Comment: Three State auditors, a Federal awarding agency representative, and two CPAs submitted comments questioning the instructions relating to the cognizant agency determination. The current Data Collection Form requires entities to identify if they have a cognizant or oversight agency for audit, and the name of Federal cognizant or oversight agency. Research has shown that responses to these questions have not been completely accurate, and the FAC believes that much of the misreporting has resulted from a lack of understanding by the non-Federal entity. To simplify reporting and improve the accuracy of responses, two actions were taken in the

proposed revision. First the identification of Oversight agency will be performed by the FAC. This determination will be made after the Data Collection Form is entered into the FAC database and will be available on the FAC website. Second, the questions related to Cognizant agency have been reworded for clarity.

Response: Further clarification has been made to the instructions for determining the cognizant agency.

Comment: A Federal awarding agency representative asked whether the FAC could computer generate the cognizant agency for audit assignments the same as the oversight.

Response: § __.400(a) of the Circular provides the criteria used to make the cognizant agency determination. It explains that to provide for continuity of cognizance, the determination of the predominant amount of direct funding shall be based upon direct Federal awards expended in the recipient's fiscal years ending in 1995, 2000, 2005, and every fifth year thereafter. Since the revised Data Collection Form will apply to entities with fiscal end dates on or after January 1, 2001, and since the current Data Collection Form does not distinguish between direct and indirect awards, it is not possible to use fiscal year 2000 data to computer generate the cognizant agency assignments.

Questioned Costs Detail

Comment: Two Federal awarding agency responses stated their objections to the elimination of questioned costs detail by program.

Response: Questioned costs detail by program will not be collected because of inconsistencies in the amounts identified by the auditor as questioned costs and Federal agencies need to consider questioned costs in the context of the complete audit finding. Normally auditors only report as questioned costs the exceptions specifically identified during testing (e.g., Circular A–133 does not require the auditor to provide a statistical projection of all questioned costs). Auditors application of judgment in determining the amounts to question varies significantly. The amounts sustained by Federal agencies as part of audit resolution varies significantly with the amounts questioned by the auditor and the amount of questioned costs is only meaningful when considered in the context of the complete audit finding. As proposed in the July 11 **Federal Register** Notice, the revised Data Collection Form will identify if the audit disclosed any questioned costs related to Federal awards. Federal awarding agencies receive a copy of the reporting package, including audit findings, which provides the more complete information needed in resolving audit findings with questioned costs.

Internal Control Detail

Comment: The NSAA and two State auditors questioned the proposed removal of collecting internal control detail by program.

Response: The current Data Collection Form captures internal control detail by program. FAC research has shown that reporting in this area is inconsistent. As proposed in the July 11 **Federal Register** Notice, the revised Data Collection Form will identify if the audit disclosed any reportable conditions and material weaknesses related to the Federal awards. Federal awarding agencies receive a copy of the reporting package, including audit findings, which provides the more complete information needed in resolving the audit finding concerning internal control.

Electronic Submission of the Data Collection Form

Comment: Two State auditors, the NSAA, the AGA, and two CPAs commented on the online Internet submission process for filing the Data Collection Form and the use of electronic signatures.

Response: The online Internet submission process does not capture electronic signatures. Currently, the Data Collection Form can be entered, edited, and submitted via the Internet. The respondents are required to print a copy of the edited form for signature by the auditor and auditee. The signed copy is then attached to the reporting package and mailed to the Federal Audit Clearinghouse. Since only the Data Collection Form can be filed electronically, and non-Federal entities are required to mail the reporting package, the capability to capture electronic signatures has not been built into the online Internet submission process. During the next year, the FAC, in conjunction with the Federal awarding agencies and other single audit stakeholders, will explore the possibility of electronic submission of the reporting package.

Type of Entity

Comment: One State government suggested capturing the type of entity (nonprofit, government, hospital, school, etc.) on the Data Collection Form.

Response: The revised Data Collection Form will not capture the type of entity. The FAC will review the Data Collection Form and identify the type of entity. This information will be accessible on the FAC website. The FAC was chosen to make this determination based on their experience classifying governmental entities. Also, the FAC will use a predetermined list which should provide for consistency within the classifications. The FAC website will clearly note that this determination was made by the FAC.

Joshua Gotbaum,

Executive Associate Director and Controller.

[FR Doc. 00–29296 Filed 11–15–00; 8:45 am]

BILLING CODE 3110–01–P

SECURITIES AND EXCHANGE COMMISSION

Issuer Delisting; Notice of Application to Withdraw From Listing and Registration; (Ampal-American Israel Corporation, Class A Stock, $1.00 Par Value) File No. 1–08466

November 8, 2000.

Ampal-American Israel Corporation (''Company'') has filed an application with the Securities and Exchange Commission (''Commission''), pursuant to Section 12(d) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 12d2–2(d) thereunder,[2] to withdraw its Class A Stock, $1,00 par value (''Security''), from listing and registration on the American Stock Exchange (''Amex'').

On May 1, 2000, the Security became designated for quotation on the National Market of the Nasdaq Stock Market, Inc. (''Nasdaq National Market''), and trading was simultaneously suspended on the Amex. The Company hopes that quotation on the Nasdaq National Market will enhance the marketability of its Security by providing greater liquidity and visibility than it had found through its listing on the Amex.

The Company has stated that it has complied with the Rules of the Amex governing the withdrawal of its Security and that the Amex has indicated that it has no objection to such withdrawal.

The Company's application relates solely to the withdrawal of the Security from listing and registration on the Amex and shall have no effect upon its continuing to be designated for quotation on the Nasdaq National Market and registered under Section 12(g) of the Act.[3]

Any interested person may, on or before December 1, 2000, submit by letter to the Secretary of the Securities and Exchange Commission, 450 Fifth

[1] 15 U.S.C. 78*l*(d).

[2] 17 CFR 240.12d2–2(d).

[3] 15 U.S.C. 78*l*(g).

Street, N.W., Washington, D.C. 20549–0609, facts bearing upon whether the application has been made in accordance with the rules of the Amex and what terms, if any, should be imposed by the Commission for the protection of investors. The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[4]

Jonathan G. Katz,

Secretary.

[FR Doc. 00–29288 Filed 11–15–00; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

[Rel. No. IC–24734; File No. 812–12228]

Summit Mutual Funds, Inc., et al., Notice of Application

November 9, 2000.

AGENCY: Securities and Exchange Commission (the ''Commission'').

ACTION: Notice of application for an order pursuant to Section 6(c) of the Investment Company Act of 1940, as amended (the ''1940 Act'') providing exemptions from the provisions of Sections 9(a), 13(a), 15(a), and 15(b) of the 1940 Act, and Rules 6e–2(b)(15) and 6e–3(T)(b)(15) thereunder.

Applicants: Summit Mutual Funds, Inc. (the ''Fund'') and Summit Investment Partners, Inc. (the ''Adviser'').

Summary of Application: The Fund and the Adviser seek an order exempting them and certain life insurance companies (''Participating Insurance Companies'') and their separate accounts from the provisions of Sections 9(a), 13(a), 15(a) and 15(b) of the Act and Rules 6e–2(b)(15) and 6e–3(T)(b)(15) thereunder (including any comparable provisions of a permanent rule that replaces Ruled 6e–3(T) or Rule 6e–2, as subsequently amended) to the extent necessary to permit series of shares of any current or future investment portfolio of the Fund to be sold to and held by (a) variable annuity and variable life insurance separate accounts of both affiliated and unaffiliated life insurance companies, and (b) qualified pension and retirement plans, including, without limitation, those trusts, plans accounts, contracts or annuities described in sections 401(a), 403(a), 403(b), 408(a), 408(b), 414(d), 457(b), 408(k), or 501(c)(18) of the Internal Revenue Code of 1986, as amended (the ''Code'') and any other trust, plan, account, contract or annuity that is determined to be within the scope of Treasury Regulation 1.817.5(f)(3)(iii) outside of the separate account context (''Qualified Plans'').

Filing Date: The application was filed on August 21, 2000; an amendment substantially conforming to this Notice will be filed during the pendency of the Notice period.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Secretary of the Commission and serving Applicants with a copy of the request, personally or by mail. Hearing requests must be received by the Commission by 5:30 p.m. on December 1, 2000, and should be accompanied by proof of service on Applicants in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the requester's interest, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Secretary of the Commission.

ADDRESSES: Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609; the Fund, P.O. Box 40409, Cincinnati, Ohio 45240–0409; and the Adviser, 312 Elm Street, Suite 2525, Cincinnati, Ohio 45202.

FOR FURTHER INFORMATION CONTACT: Rebecca A. Marquigny, Senior Counsel, or Keith Carpenter, Branch Chief, Office of Insurance Products, Division of Investment Management, at (202) 942–0670.

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application is available for a fee from the Public Reference Branch of the Commission, 450 Fifth Street, NW., Washington, DC 20549–0102 (telephone (202) 942–8090).

Applicant's Representations

1. The Fund, formerly known as Carillon Fund, Inc., is a management investment company with 22 separate investment portfolios (''Portfolios''), each with its own investment objective. Nine of the Portfolios (the ''Insurance Portfolio'') currently serve as funding vehicles for registered variable annuity contracts and registered variable life insurance contracts issued by The Union Central Life Insurance Company (''Union Central''). The other 13 Portfolios (the ''Public Portfolios'') are offered directly to the public and also serve as funding vehicles for unregistered variable annuity contracts and variable life insurance policies of Union Central. The Public Portfolios are not used to fund registered variable annuity contracts. None of the relief requested here would apply to any current or future Public Portfolios. The Fund is registered under the Act (File No. 811–04000), and the offering of its shares is registered under the Securities Act of 1933 (File No. 2–90309). The Fund's shares are issuable into separate series, each series representing interests in a separate Portfolio. In addition to the nine current Insurance Portfolios, the Fund may create additional Insurance Portfolios in the future and Applicants seek relief that would encompass both existing Insurance Portfolios and new Insurance Portfolios created in the future. References herein to ''Insurance Portfolios'' encompasses both existing Insurance Portfolios and ones that may be created in the future.

2. The Adviser, formerly known as Carillon Advisers, Inc., was incorporated under the laws of Ohio on August 18, 1986, as successor to the advisory business of Carillon Investments, Inc., the investment adviser for the Fund since 1984. The Adviser is a wholly-owned subsidiary of Union Central, a mutual life insurance company organized in 1867 under the laws of Ohio. The Adviser is registered under the Investment Advisers Act of 1940 and serves as investment adviser to each of the Portfolios.

3. Participating Insurance Companies are the life insurance companies to which shares of the Insurance Portfolios will be offered. The Participating Insurance Companies will establish their own separate accounts and design their own variable annuity and variable life insurance contracts (''Contracts''). Each such Contract will undoubtedly have certain unique features and will probably differ from other Contracts supported by the Insurance Portfolios with respect to insurance guarantees, premium structure, charges, options, distribution method, marketing techniques, sales literature, etc.

4. Each Participating Insurance Company will be the legal obligation of satisfying all applicable requirements under state and federal law. It is anticipated that Participating Insurance Companies will rely on Rule 6e–2 or 6e–3(T) under the Act, although some may rely on individual exemptive orders as well, in connection with variable life insurance contracts. The role of the

[4] 17 CFR 200.30–3(a)(1).

Fund, so far as the federal securities laws are applicable, will be limited to that of offering shares of the Insurance Portfolios to separate accounts of various insurance companies and to Qualified Plans and fulfilling any conditions the Commission may impose upon granting the order requested herein.

Applicants' Legal Analysis

5. Under current tax laws, the Insurance Portfolios are afforded an opportunity to increase their asset base through the sale of shares of the Insurance Portfolios to Qualified Plans. Section 817(h) of the Code, imposes certain diversification standards on the underlying assets of variable annuity contracts and variable life policies held in the Insurance Portfolios.

6. Qualified Plans may choose any of the Insurance Portfolios as the sole investment under the Plan or as one of several investments. Plan participants may or may not be given an investment choice depending on the Plan itself. Shares of any of the Insurance Portfolios sold to certain Qualified Plans would be held by the trustee(s) of those Plans as mandated by Section 403(a) of the Employee Retirement Income Security Act (''ERISA''). As described elsewhere herein, there will be no pass-through voting to the participants in such Qualified Plans. The Adviser will not act as investment adviser to any of the Qualified Plans that will purchase shares of any of the Insurance Portfolios.

7. The promulgation of Rules 6e–2(b)(15) and 6e–3(T)(b)(15) preceded the issuance of the Treasury Regulations, which made it possible for shares of an investment company to be held by the trustee of a Qualified Plan without adversely affecting the ability of shares in the same investment company to also be held by the separate accounts of insurance companies in connection with their variable contracts. Thus, the sale of shares of the same investment company to Separate Accounts and Qualified Plans could not have been envisioned at the time of the adoption of Rules 6e–2(b)(15) and 6e–3(T)(b)(15), given the then-current tax law.

8. In connection with scheduled premium variable life insurance contracts issued through a separate account registered under the Act as a unit investment trust, Rule 6e–2(b)(15) provides partial exemptions from Sections 9(a), 13(a), 15(a) and 15(b) of the Act to the extent that those sections have been deemed by the Commission to require ''pass-through'' voting with respect to an underlying investment company's shares. The exemptions granted to a separate account by Rule 6e–2(b)(15) are available only where all of the assets of the separate account consist of the shares of one or more registered management investment companies that offer their shares ''*exclusively* to variable life insurance separate accounts of the life insurer, or of any affiliated life insurance company'' (emphasis added). Therefore, the relief granted by Rule 6e–2(b)(15) is not available with respect to a scheduled premium variable life insurance separate account that owns shares of an investment company that also offers its shares to a variable annuity separate account of the same or of any affiliated or unaffiliated insurance company. The use of a common management investment company as the underlying investment medium for both variable annuity and variable life insurance separate accounts is commonly referred to, and is referred to herein, as ''mixed funding.''

9. In addition, the relief granted by Rule 6e–2(b)(15) is not available if shares of the underlying investment company are offered to variable annuity or variable life insurance separate accounts of unaffiliated insurance companies. The use of a common investment company as the underlying investment medium for separate accounts of unaffiliated insurance companies is commonly referred to, and is referred to herein, as ''shared funding.''

10. The relief granted by Rule 6e–2(b)(15) is in no way affected by the purchase of shares of the Insurance Portfolios by Qualified Plans. However, because the relief under Rule 6e–2(b)(15) is available only where shares are offered *exclusively* to separate accounts, additional exemptive relief is necessary if the shares of the Insurance Portfolios are also to be sold to Plans.

11. Applicants request an order of the Commission exempting scheduled premium variable life insurance separate accounts (and, to the extent necessary, any investment adviser, principal underwriter and depositor of such a separate account) from Sections 9(a), 13(a), 15(a) and 15(b) of the Act, and Rule 6e–2(b)(15) thereunder, to the extent necessary to permit shares of the Insurance Portfolios, which will also be sold directly to Qualified Plans, to be offered and sold in connection with both mixed funding and shared funding.

12. In connection with flexible premium variable life insurance contracts issued through a separate account registered under the Act as a unit investment trust, Rule 6e–3(T)(b)(15) provides partial exemptions from Sections 9(a), 13(a), 15(a) and 15(b) of the Act to the extent that those sections have been deemed by the Commission to require ''pass-through'' voting with respect to an underlying investment company's shares. The exemptions granted to a separate account by Rule 6e–3(T)(b)(15) are available only where all of the assets of the separate account consist of the shares of one or more registered management investment companies that offer their shares ''*exclusively* to separate accounts of the life insurer, or of any affiliated life insurance company, offering either scheduled premium variable life insurance contracts or flexible premium variable life insurance contracts, or both; or which also offer their shares to variable annuity separate accounts of the life insurer or of an affiliated life insurance company.'' (emphasis added). Therefore, Rule 6e–3(T) permits mixed funding for flexible premium variable life insurance. However, Rule 6e–3(T) does not permit shared funding. The relief granted by Rule 6e–3(T)(b)(15) is not available with respect to a flexible premium variable life insurance separate account that owns shares of an investment company that also offers its shares to separate accounts (including flexible premium variable life insurance separate accounts) of unaffiliated life insurance companies.

13. The relief granted by Rule 6e–3(T) also is in no way affected by the purchase of shares of the Insurance Portfolios by Qualified Plans. However, because the relief under Rule 6e–3(T) is available only where shares are offered exclusively to separate accounts, additional exemptive relief is necessary if the shares of the Insurance Portfolios are also to be sold to Plans.

14. Applicants request an order exempting flexible premium variable life insurance separate accounts (and, to the extent necessary, any investment adviser, principal underwriter and depositor of such a separate account) from Sections 9(a), 13(a), 15(a) and 15(b) of the Act, and Rule 6e–3(T)(b)(15) (and any comparable permanent rule) thereunder, to the extent necessary to permit shares of the Insurance Portfolios, which will also be sold directly to Qualified Plans, to be offered and sold to separate accounts in connection with shared funding.

15. The Commission has granted numerous exemptions similar to those requested herein with respect to the mixed and shared funding component of this Application, including ones where the fund's shares also would be sold directly to Qualified Plans.

16. Section 6(c) authorizes the Commission to exempt any person, security or transaction or any class or

classes of persons, securities or transactions from the provisions of the Act and the rules promulgated thereunder if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Applicants are not aware of any stated rationale for the exclusion of separate accounts and investment companies engaged in shared funding from the exemptive relief provided under Rules 6e–2(b)(15) and 6e–3(T)(b)(15) or for the exclusion of separate accounts and investment companies engaged in mixed funding from the exemptive relief provided under Rule 6e–2(b)(15). Indeed, the Commission's proposed amendments to Rule 6e–2 would eliminate the exclusion of mixed funding from the relief provided under Rule 6e–2(b)(15) and, as noted above (*see supra* note 5), numerous exemptions permitting both mixed and shared funding have been granted since the adoption of Rules 6e–2 and 6e–3(T).

17. Similarly, Applicants are not aware of any stated rationale for excluding Participating Insurance Companies from the exemptive relief requested because the Insurance Portfolios may also sell their respective shares to Qualified Plans. If the Fund were to sell shares of the Insurance Portfolios only to Qualified Plans, no exemptive relief would be necessary. The relief provided under Rules 6e–2(b)(15) and 6e–2(T)(b)(15) does not relate to qualified pension and retirement plans or to a registered investment company's ability to sell its shares to such plans. Exemptive relief is requested in the Application only because the separate accounts investing in the Insurance Portfolios are themselves investment companies that rely upon the relief under Rules 6e–2 and 6e–3(T) and do not wish to be denied such relief if the Insurance Portfolios sell shares to Qualified Plans.

18. Applicants believe that the same policies and considerations that led the Commission to grant such exemptions to other applicants are present here. Moreover, for the reasons stated below, Applicants believe that the requested exemptions are appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

19. Section 9(a) of the Act provides that it is unlawful for any company to serve as investment adviser or principal underwriter of any registered open-end investment company if an affiliated person of that company is subject to a disqualification enumerated in Section 9(a)(1) or (2). However, Rules 6e–2(b)(15)(i) and (ii) and 6e–3(T)(b)(15)(i) and (ii) provide partial exemptions from Section 9(a) under certain circumstances, subject to the limitations discussed above on mixed and shared funding. These exemptions limit the disqualification to affiliated individuals or companies that directly participate in the management or administration of the underlying investment company.

20. The exemptions contained in Rules 6e–2(b)(15) and 6e–3(T)(b)(15) recognize that it is unnecessary to apply Section 9(a) to the thousands of individuals who may be involved in a large insurance company but would have no connection with the investment company funding the separate accounts. Applicants believe that it is unnecessary to limit the applicability of the rules merely because shares of the Insurance Portfolios may be sold in connection with mixed and shared funding. The Participating Insurance Companies are not expected to play any role in the management of the Insurance Portfolios and would play only an indirect role in the administration of the Fund (*e.g.,* by performing certain shareholder servicing and recordkeeping functions for which they may be reimbursed by the Adviser). Therefore, applying the restrictions of Section 9(a) serves no regulatory purpose. Indeed, applying such restrictions would increase the monitoring costs incurred by the Participating Insurance Companies and, therefore, would reduce the net rates of return realized by Contract owners.

21. Moreover, the relief requested herein will in no way be affected by the proposed sale of shares of Insurance Portfolios to Qualified Plans. The insulation of the Fund from those individuals who are disqualified under the Act will remain intact even if shares of the Insurance Portfolios are sold to Qualified Plans. Since the Qualified Plans are not investment companies and will not be deemed to be affiliated persons of the Participating Insurance Companies solely by virtue of their shareholdings in the Insurance Portfolios, no additional relief is necessary.

22. Rules 6e–2(b)(15)(iii) and 6e–3(T)(b)(15)(iii) assume that Contract owners are entitled to pass-through voting privileges with respect to investment company shares held by a related separate account. However, if the limitations on mixed and shared funding are satisfied, Rules 6e–2(b)(15(iii) and 6e–3(T)(b)(15)(iii) provide exemptions from the pass-through voting requirements in limited situations.

23. Rules 6e–2(b)(15)(iii)(A) and 6e–3(T)(b)(15)(iii)(A) provide that an insurance company may disregard the voting instructions of its contract owners with respect to the investments of an underlying investment company or any contract between an investment company and its investment adviser, when an insurance regulatory authority so requires. Rules 6e–2(b)(15)(iii)(B) and 6e–3(T)(b)(15)(iii)(B) provide that the insurance company may disregard contract owners' voting instructions with regard to changes initiated by the contract owners in the investment company's investment policies, principal underwriter or investment adviser.

24. Under the rules, voting instructions with respect to a change in investment policies may be disregarded only if the insurance company makes a good faith determination that the change would: (a) Violate state law; (b) result in investments that were not consistent with the investment objectives of the separate account; or (c) result in investments that would vary from the general quality and nature of investments and investment techniques used by other separate accounts of the company or of an affiliated life insurance company with similar investment objectives. Voting instructions with respect to a change in an investment adviser may be disregarded only if the insurance company makes a good faith determination that: (a) The adviser's fee would exceed the maximum rate that may be charged against the separate account's assets; (b) the proposed adviser may be expected to employ investment techniques that vary from the general techniques used by the current adviser; or (c) the proposed adviser may be expected to manage the investment company's investments in a manner that would be inconsistent with its investment objectives or in a manner that would result in investments that vary from certain standards.

25. Rule 6e–2 recognizes that variable life insurance contracts have important elements unique to insurance contracts and are subject to extensive state regulation of insurance. Thus, in adopting Rule 6e–2, the Commission expressly recognized that exemptions from pass-through voting requirements were necessary ''to assure the solvency of the life insurer and the performance of its contractual obligations by enabling an insurance regulatory authority or the life insurer to act when certain proposals reasonably could be expected to increase the risks undertaken by the life insurer.'' Flexible premium variable life insurance contracts and variable

annuity contracts are subject to substantially the same state insurance regulatory authority, and therefore, the corresponding provisions of Rule 6e–3(T) (which apply to flexible premium insurance contracts and which permit mixed funding) presumably were adopted in recognition of the same considerations as the Commission applied in adopting Rule 6e–2.

26. These considerations are no less important or necessary when an insurance company funds its separate accounts in connection with mixed and shared funding. Such funding does not compromise the goals of the insurance regulatory authorities or of the Commission. While the Commission may have wished to reserve wide latitude wither respect to the once unfamiliar variable annuity product, that product is now familiar and there appears to be no reason for the maintenance of prohibitions against mixed and shared funding arrangements. Indeed, by permitting such arrangements, the Commission eliminates needless duplication of start-up and administrative expenses and potentially increases an investment company's assets, thereby making effective portfolio management strategies easier to implement and promoting other economies of scale.

27. In addition, the Insurance Portfolio's sale of shares to Qualified Plans will not have any impact on the relief requested in this regard. Shares of the Insurance Portfolios sold to certain Plans would be held by the Plans trustees, as mandated by Section 403(a) of ERISA. Section 403(a) also provides that the trustee(s) must have exclusive authority and discretion to manage and control the plan with two exceptions: (a) When the plan expressly provides that the trustee(s) are subject to the direction of a named fiduciary who is not a trustee, in which case the trustees are subject to proper direction made in accordance with the terms of the plan and not contrary to ERISA, and (b) when the authority to manage, acquire or dispose of assets of the plan is delegated to one or more investment managers pursuant to Section 402(c)(3) of ERISA. Unless one of the two exceptions stated in Section 403(a) applies, trustees have the exclusive authority and responsibility for voting proxies. Where a named fiduciary appoints an investment manager, the investment manager has the responsibility to vote the shares held unless the right to vote such shares is reversed to the trustees or the named fiduciary. In any event, there is no pass-through voting to the participants in such plans. Accordingly, unlike the case with insurance company separate accounts, the issue of the resolution of material irreconcilable conflicts with respect to voting is not present with Qualified Plans.

28. Shared funding does not present any issues that do not already exist where a single insurance company is licensed to do business in several states. For example, when different Participating Insurance Companies are domiciled in different states, it is possible that the state insurance regulatory body in a state in which one Participating Insurance Company is domiciled could require action that is inconsistent with the requirements of insurance regulators in one or more other states in which other Participating Insurance Companies are domiciled. That possibility, however, is no different and no greater than exists when a single insurer and its affiliates offer their insurance products in several states, as currently is permitted.

29. Affiliations do not reduce the potential, if any exists, for differences in state regulatory requirements. In any event, the conditions discussed below (which are adapted from the conditions included in Rule 6e-3(T)(b)(15) are designed to safeguard against any adverse effects that differences among state regulatory requirements may produce. If a particular state insurance regulator's decision conflicts with the majority of other state regulators, the affected insurer may be required to withdraw its separate account's investment in the relevant Insurance Portfolios.

30. Similarly, affiliation does not eliminate the potential, if any exists, for divergent judgments as to when a Participating Insurance Company could disregard Contract owner voting instructions. The potential for disagreement is limited by the requirement that disregarding voting instructions be reasonable and based on specified good faith determinations. However, if a Participating Insurance Company's decision to disregard Contract owner voting instructions represents a minority position or would preclude a majority vote approving a particular change, that Participating Insurance Company may be required, at the election of the relevant Insurance Portfolio, to withdraw its separate account's investment in that fund and no charge or penalty will be imposed as a result of that withdrawal.

31. There is no reason why the investment policies of an Insurance Portfolio are mixed funding would or should be materially different from what they would or should be if that Portfolio funded only variable annuity contracts or only variable life insurance contracts. Hence, there is no reason to believe that conflicts of interest would result from mixed funding. Moreover, the Insurance Portfolios will not be managed to favor or disfavor any particular insurer or type of Contract.

32. No one investment strategy can be identified as appropriate to a particular insurance product. Each pool of Contract owners is composed of individuals of diverse financial status, age, insurance and investment goals. Those diversities are of greater significance than any differences in insurance products. An investment company supporting even one type of insurance product must accommodate those diverse factors.

33. Section 817(h) of the Code is the only section in the Code where separate accounts are discussed. Section 817(h) imposes certain diversification standards on the underlying assets of variable annuity contracts and variable life contracts held in the portfolios of investment companies. Treasury Regulation 1.817–5(f)(3)(iii), which established diversification requirements for such portfolios, specifically permits, among other things, qualified pension or retirement plans and separate accounts to share the same underlying investment company. Therefore, neither the Code, the Treasury Regulations nor Revenue Rulings thereunder present any inherent conflicts of interest if Qualified Plans, variable annuity separate accounts and variable life separate accounts all invest in the same management investment company.

34. While there are differences in the manner in which distributions are taxed for variable annuity contracts, variable life insurance contracts and Qualified Plans, the tax consequences do not raise any conflicts of interest. When distributions are to be made, and the separate account or the Qualified Plan cannot net purchase payments to make the distributions, the separate account or the Plan will redeem shares of the Fund at their net asset value. The Qualified Plan will than make distributions in accordance with the terms of the Plan and the life insurance company will make distributions in accordance with the terms of the variable contract.

35. With respect to voting rights, it is possible to provide an equitable means of giving such voting rights to separate account Contract owners and to the trustees of Qualified Plans. The transfer agent for the Fund will inform each Participating Insurance Company of its share ownership in each separate account, as well as inform the trustees of Qualified Plans of their holdings. Each Participating Insurance Company

will then solicit voting instructions in accordance with Rules 6e–2 and 6e–3(T).

36. The ability of the Fund to sell shares of the Insurance Portfolios directly to Qualified Plans does not create a ''senior security,'' as such term is defined under Section 18(g) of the Act, with respect to any Contract owner as opposed to a participant under a Qualified Plan. As noted above, regardless of the rights and benefits of participants under the Qualified Plans, or Contract owners under Contracts, the Qualified Plans and the separate accounts have rights only with respect to their respective shares of the Fund. They can only redeem such shares at their net asset value. No shareholder of any of the Insurance Portfolios has any preference over any other shareholder with respect to distribution of assets or payment of dividends.

37. There are no conflicts between the Contract owners of the separate accounts and the participants under the Qualified Plans with respect to the state insurance commissioners' veto powers (direct with respect to variable life and indirect with respect to variable annuities) over investment objectives. The basic premise of shareholder voting is that not all shareholders may agree that there are any inherent conflicts of interest among shareholders. The state insurance commissioners have been given the veto power to recognition of the fact that insurance companies cannot simply redeem their separate accounts out of one fund and invest in another. Time-consuming, complex transactions must be undertaken to accomplish such redemptions and transfers. On the other hand, trustees of Qualified Plans can made the decision quickly and implement the redemption of their shares from an Insurance Portfolio and reinvest in another funding vehicle without the same regulatory impediments or, as is the case with most Plans, even hold cash pending suitable investment. Based on the foregoing, even if there should arise issues where the interests of Contract owners and the interests of Qualified Plans are in conflict, the issues can be almost immediately resolved because the trustees of the Qualified Plans can, on their own, redeem the shares out of the Fund.

38. Various factors have kept more insurance companies from offering variable annuity and variable life insurance contracts than currently do so. These factors include the costs of organizing and operating a funding medium, the lack of expertise with respect to investment management (principally with respect to stock and money market investments) and the lack of public name recognition as investment experts. In particular, some smaller life insurance companies may not find it economically feasible, or within their investment or administrative expertise, to enter the variable life insurance or variable annuity business on their own.

39. Use of the Insurance Portfolios as common investment media for Contracts would ameliorate these concerns. Participating Insurance Companies would benefit not only from the investment advisory and administrative expertise of the Adviser, but also from the cost efficiencies and investment flexibility afforded by a large pool of funds. Therefore, making the Insurance Portfolios available for mixed and shared funding will encourage more insurance companies to offer Contracts. This should result in increased competition with respect to both Contract design and pricing, which can be expected to result in more product variation and lower charges. Contract owners would benefit because mixed and shared funding should eliminate a significant portion of the costs of establishing and administering separate funds.

40. Moreover, sale of the shares of Insurance Portfolios to Qualified Plans should result in an increased amount of assets available for investment by those Portfolios. This, in turn, should inure to the benefit of Contract owners by promoting economies of scale, by permitting greater safety through greater diversification, and by making the addition of new Insurance Portfolios to the Fund more feasible.

41. Applicants see no significant legal impediment to permitting mixed and shared funding. Indeed, as noted above, the Commission has issued several orders permitting mixed and shared funding with respect to both scheduled and flexible premium contracts. In addition, the Commission has broadened its grant of exemptive relief by issuing an order permitting mixed and shared funding while Fund shares are also sold directly to Qualified Plans. Therefore, as the Commission has tacitly acknowledged, granting the exemptions requested herein is in the public interest and, as discussed above, will not compromise the regulatory purposes of Section 9(a), 13(a), 15(a), or 15(b) of the Act or Rule 6e–2 or 6e–3(T) thereunder.

Applicants' Conditions

Applicants consent to the following conditions:

1. A majority of the Fund's board of directors (the ''Board'') will consist of persons who are not ''interested persons'' thereof, as defined by Section 2(a)(19) of the Act and the rules thereunder and as modified by any applicable orders of the Commission, except that if this condition is not met by reason of the death, disqualification of bona fide resignation of any director, then the operation of this condition shall be suspended: (a) For a period of 45 days if the vacancy or vacancies may be filled by the Board; (b) for a period of 60 days if a vote of shareholders is required to fill the vacancy or vacancies; or (c) for such longer period as the Commission may prescribe by order upon application.

2. The Board will monitor the Insurance Portfolios for the existence of any material irreconcilable conflict between and among the interests of the Contract owners of all separate accounts and participants of all Qualified Plans investing in the Insurance Portfolios. An irreconcilable material conflict may arise for a variety of reasons, including: (a) An action by any state insurance regulatory authority; (b) a change in applicable federal or state insurance, tax, or securities laws or regulations, or a public ruling, private letter ruling, no-action or interpretive letter, or any similar action by insurance, tax, or securities regulatory authorities; (c) an administrative or judicial decision in any relevant proceeding; (d) the manner in which the investments of the Insurance Portfolios are being managed; (e) a difference in voting instructions given by variable annuity contract owners, variable life insurance contract owners and trustees of the Qualified Plans; (f) a decision by a Participating Insurance Company to disregard the voting instructions of Contract owners; or (g) if applicable, a decision by a Qualified Plan to disregard the voting instructions of Qualified Plan participants.

3. Participating Insurance Companies, the Adviser and any Qualified Plan that executes a fund participation agreement upon becoming an owner of 10% or more of the assets of an Insurance Portfolio (collectively, ''Participating Parties'') will report any potential or existing conflicts of which they become aware to the Board. Participating Parties will be responsible for assisting the Board in carrying out its responsibilities under these conditions by providing the Board with all information reasonably necessary for the Board to consider any issues raised. This responsibility includes, but is not limited to, an obligation by a Participating Insurance Company to inform the Board whenever it has determined to disregard Contract owner voting instructions, and, if pass-through voting is applicable, an

obligation of each Qualified Plan to inform the Board whenever it has determined to disregard Qualified Plan participant voting instructions. The responsibility to report such information and conflicts and to assist the Board will be contractual obligations of all Participating Parties under their agreements governing participation in the Insurance Portfolios, and their participation agreements with the Fund shall provide that these responsibilities will be carried out with a view only to the interests of Contract owners and, if applicable, Qualified Plan participants.

4. If it is determined by a majority of the Board, or by a majority of its disinterested directors, that a material irreconcilable conflict exists, the relevant Participating Parties will, at their expense and to the extent reasonably practicable (as determined by a majority of the disinterested directors), take whatever steps are necessary to remedy or eliminate the irreconcilable material conflict, which steps could include: (a) Withdrawing the assets allocable to some or all of the separate accounts from the Insurance Portfolio(s) and reinvesting such assets in a different investment medium, which may include another Insurance Portfolio; (b) submitting the question of whether such segregation should be implemented to a vote of all affected Contract owners and, as appropriate, segregating the assets of any appropriate group (*i.e.,* variable annuity contract owners or variable life insurance contract owners of one or more Participating Insurance Companies) that votes in favor of such segregation, or offering to the affected Contract owners the option of making such a change; (c) in the case of Qualified Plans, withdrawing the assets allocable to some or all of the Qualified Plans from the affected Insurance Portfolio and reinvesting those assets in a different investment medium, including another Insurance Portfolio; and (d) establishing a new registered management investment company or managed separate account. If a material irreconcilable conflict arises because of a Participating Insurance Company's decision to disregard Contract owner voting instructions and that decision represents a minority position or would preclude a majority vote, the Participating Insurance Company may be required, at the election of the Fund, to withdraw its separate account's investment in one or more Insurance Portfolios, and no charge or penalty will be imposed as a result of that withdrawal. If a material irreconcilable conflict arises because of a Qualified Plan's decision to disregard Plan participant voting instructions, if applicable, and that decision represents a minority position or would preclude a majority vote, the Plan may be required, at the election of the Fund, to withdraw its investment in an Insurance Portfolio and no charge or penalty will be imposed as a result of such withdrawal. The responsibility of taking remedial action in the event of a Board determination of an irreconcilable material conflict and bearing the cost of such remedial action will be a contractual obligation of all Participating Parties under their respective participation agreements and these responsibilities will be carried out with a view only to the interests of Contract owners and participants in Qualified Plans.

5. For purposes of condition 4, a majority of the disinterested directors of the Board will determine whether or not any proposed action adequately remedies any irreconcilable material conflict, but in no event will the Fund or the Adviser be required to establish a new funding medium for any Contract. No Participating Insurance company shall be required by this condition 4 to establish a new funding medium for any Contract if an offer to do so has been declined by vote of a majority of Contract owners materially and adversely affected by the irreconcilable material conflict. Further, no Qualified Plan will be required by this condition 4 to establish a new funding medium for the Plan if: (a) A majority of Plan participants materially and adversely affected by the irreconcilable material conflict vote to decline that offer; or (b) pursuant to documents governing the Qualified Plan, the Plan makes that decision without a Plan participant vote.

6. The Board's determination of the existence of an irreconcilable material conflict and its implications will be made known promptly in writing to all Participating Parties.

7. Participating Insurance Companies will provide pass-through voting privileges to all Contract owners so long as the Commission interprets the Act to require pass-through voting privileges for Contract owners. Accordingly, the Participating Insurance Companies will vote shares of an Insurance Portfolio held in their separate accounts in a manner consistent with voting instructions timely received from Contract owners. Participating Insurance Companies will be responsible for assuring that each of their registered separate accounts calculates voting privileges in a manner consistent with other Participating Insurance Companies. The obligation to calculate voting privileges in a manner consistent with all other registered separate accounts investing in the Insurance Portfolios will be a contractual obligation of all Participating Insurance Companies under the agreements governing participation in the Insurance Portfolios. Each Participating Insurance Company will vote shares for which it has not received voting instructions, as well as shares attributable to it, in the same proportion as it votes shares for which it has received instructions. Each Qualified Plan will vote as required by applicable law and governing Plan documents.

8. The Fund will notify all Participating Insurance Companies that separate account prospectus disclosure, or Qualified Plan prospectus disclosure or other Qualified Plan document disclosure, regarding potential risks of mixed and shared funding may be appropriate. The Fund will disclose in its prospectus that: (a) Its shares are offered to Qualified Plans and to separate accounts that fund both annuity and life insurance contracts of affiliated and unaffiliated Participating Insurance Companies; (b) due to differences in tax treatment and other considerations, the interests of various contract owners participating in an Insurance Portfolio and the interests of Qualified Plans investing in such Insurance Portfolio, if applicable, may conflict as a result of the mixed and shared funding arrangement; and (c) the Fund's Board will monitor for the existence of any material conflicts and determine what action, if any, should be taken.

9. All reports of potential or existing conflicts received by a Board, and all Board action with regard to determining the existence of a conflict, notifying Participating Insurance Companies and Qualified Plans of a conflict, and determining whether any proposed action adequately remedies a conflict, will be properly recorded in the minutes of the Board or other appropriate records, and such minutes or other records shall be made available to the Commission upon request.

10. If and to the extent that Rules 6e–2 and 6e–3(T) are emended (or if Rule 6e–3 under the Act is adopted) to provide exemptive relief from any provision of the Act or the rules thereunder with respect to mixed and shared funding on terms and conditions materially different from any exemptions granted in the order requested by Applicants, then the Fund and/or the Participating Insurance Companies, as appropriate, shall take

such steps as may be necessary to comply with Rules 6e–2 and 6e–3(T), as amended, and Rule 6e–3, as adopted, to the extent applicable.

11. The Fund will comply with all provisions of the Act requiring voting by shareholders (which, for these purposes, shall be the persons having a voting interest in shares of the Insurance Portfolios), and, in particular, the Fund will either provide for annual meetings (except to the extent that the Commission may interpret Section 16 of the Act not to require such meetings) or comply with Section 16(c) of the Act (although the Fund is not an investment company of the type described in Section 16(c) of the Act), as well as with Section 16(a), and, if applicable, Section 16(b) of the Act. Further, the Fund will act in accordance with the Commission's interpretation of the requirements of Section 16(a) with respect to periodic elections of directors and with whatever rules the Commission may promulgate with respect thereto.

12. No less than annually, the Participating Insurance Companies and/or the Adviser shall submit to the Board such reports, materials, or data as the Board may reasonably request so that the Board may carry out fully the obligations imposed upon it by the conditions contained in these express conditions. Such reports, materials, and data shall be submitted more frequently if deemed appropriate by the Board. The obligations of the Participating Parties to provide these reports, materials, and date to the Board shall be a contractual obligation of all Participating Parties under the agreements governing their participation in the Insurance Portfolios.

13. In the event that a Qualified Plan shareholder should ever become an owner of 10% or more of the assets of an Insurance Portfolio, that Qualified Plan shareholder will execute a fund participation agreement with the Fund including the conditions set forth herein to the extent applicable. A Qualified Plan shareholder will execute an application containing an acknowledgment of this condition at the time of its initial purchase of shares of the Insurance Portfolio.

Conclusion

For the reasons and upon the facts stated above, Applicants assert that the requested exemptions are appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

For the Commission by the Division of Investment Management pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 00–29352 Filed 11–15–00; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43530; File No. SR–CHX–00–28]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the Chicago Stock Exchange, Inc., to Amend its Rule Relating to Automatic Execution of Agency Limit Orders for Dual Trading System Issues

November 7, 2000.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on September 14, 2000, the Chicago Stock Exchange, Inc. (''CHX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its rule relating to automatic execution of agency limit orders for Dual Trading System issues in the event of a trade-through. Specifically, the Exchange proposes to amend Article XX, Rule 37(b)(6). The text of the proposed rule change is below. Proposed additions are in italics. Proposed deletions are in brackets.

Guaranteed Execution System And Midwest Automated Execution System

Rule 37.

* * * * *

(b) Automated Executions. The Exchange's Midwest Automated Execution System (the MAX System) may be used to provide an automated delivery and execution facility for orders that are eligible for execution under the Exchange's BEST Rule (Article XX, Rule 37(a)) and certain other orders. In the event that an order that is subject to the BEST Rule is sent through MAX, it shall be executed in accordance with the parameters of the BEST Rule and the following. In the event that an order that is not subject to the BEST Rule is sent through MAX, it shall be executed in accordance with the parameters of the following:

* * * * *

(6) Execution of Dual Trading System Issues. In Dual Trading Systems issues there shall be a fifteen (15) second delay between the time a market order is entered into MAX and the time it is automatically executed. In the event that the spread between the ITS BEST Bid and ITS Best Offer in a stock eligible for automatic execution in MAX, is equal to the minimum variation at the time an order is entered into MAX, that order shall be executed immediately (*i.e.,* in 0 seconds without the 15 second delay). All agency market orders and all limit orders that are marketable when entered into the MAX System, that are of a size less than or equal to the auto-execution threshold and are eligible for execution under the BEST Rule will automatically be filled at the ITS Best Bid (for a sell order) or ITS Best Offer (for a buy order) or better. All other agency limit orders will be [automatically] filled at the limit price when there is a price penetration of *the* limit price in the primary market. *A specialist may elect automatic execution of such agency limit orders on an issue-by-issue basis.* [However, if the price differential between the trade-through price and the last sale is more than ¼ point or 1% of the value of the trade-through price, whichever is less, a second print at a trade-through price which is less than ¼ point (or 1%) away from the previous trade-through price is necessary before the MAX system will automatically execute the agency limit order.] For purposes of this Rule, ''agency order'' shall mean an order for the account for a customer but shall not include professional orders as defined in Article XXX, Rule 2, interpretation and policy .04.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change, and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Article XX, Rule 37(b)(6) to allow a specialist to elect, on an issue by issue basis, to either manually or automatically execute limit orders when a trade-through occurs in the primary market. The current rule provides that agency limit orders (that are not marketable when entered into the Exchange's MAX automatic execution system) will automatically be filled at the limit price when there is a price penetration of the limit price in the primary market for the subject security. Under the proposed amended rule, automatic execution of such limit orders will no longer be mandated. A CHX specialist may elect to provide for automatic execution of agency limit orders at the limit price when there is a price penetration of the limit price in the primary market for the subject securit(ies). The obligation to fill the order at the limit price remains the same under either election. The Exchange believes that this proposed amendment reasonably anticipates the impact that the decimal pricing environment will have on the national market system, where the number of small orders executed at multiple price levels may increase the number of inadvertent trade throughs that could otherwise lead to unwarranted automated executions of large orders in a CHX specialist's limit order book, exposing the specialist to substantially increased liability in the decimal pricing environment.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange. In particular, the Exchange believes the proposed rule is consistent with Section 6(b)(5) of the Act [3] in that it is designed to promote just and equitable principles of trade, to remove impediments and to perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

[3] 15 U.S.C. 78f(b)(5).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the CHX consents, the Commission will:

A. By order approve such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the CHX. All submissions should refer to File No. SR–CHX–00–28 and should be submitted by December 7, 2000.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[4]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 00–29353 Filed 11–15–00; 8:45 am]

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[4] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43505; File No. SR–MBSCC–00–01]

Self-Regulatory Organizations; MBS Clearing Corporation; Order Approving a Proposed Rule Change Relating to Letters of Credit

November 1, 2000.

On April 11, 2000, the MBS Clearing Corporation (''MBSCC'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change (File No. SR–MBSCC–00–01) pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'').[1] On June 13, 2000, MBSCC amended the proposed rule change. Notice of the proposal was published in the **Federal Register** on June 26, 2000.[2] No comment letters were received. For the reasons discussed below, the Commission is approving the proposed rule change.

I. Discussion

The rule change adds subsection (b) to Article IV, Rule 2, Section 9 of MBSCC's rules to prohibit MBSCC from accepting a letter of credit from a participant that is issued by that participant or by an affiliate of that participant.[3] This rule change codifies MBSCC's historical practice of requiring that a letter of credit deposited by a participant to the

[1] 15 U.S.C. 78s(b)(1).

[2] Securities Exchange Act Release No. 42961 (June 20, 2000), 65 FR 39456.

[3] Article IV, Rule 2, Section 9 of MBSCC's rules, which governs deposits of letters of credit by MBSCC's participants to the participants fund for margin purposes, provides, among other things, that MBSCC may approve as the issuer of a letter of credit any domestic or foreign bank or trust company meeting the requirements set forth in procedures adopted by MBSCC.

The rule change also amends Article I, Rule 1 of MBSCC's Rules to add a definition of ''affiliate.'' Affiliate is defined as follows: ''The term an 'Affiliate' of, or a person 'Affiliated' with, a specified person, means a person that directly, or indirectly, through one or more intermediaries, controls, or is controlled by, or is under common control with, the person specified. For purposes of this definition, the term 'control' (including the terms 'controls,' 'controlled by,' and 'under common control with') means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract, or otherwise.''

participants fund be issued by an approved letter of credit other than the participant or an affiliate of the participant.[4]

II. Discussion

Section 17A(b)(3)(F)[5] of the Act requires that the rules of a clearing agency be designed to assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible. As set forth below, the Commission believes that MBSCC's rule change is consistent with this obligation.

Letters of credit are used at MBSCC and at other clearing agencies as collateral to meet clearing fund obligations. MBSCC's clearing fund is intended to provide liquidity and protection to MBSCC and its members in the event a MBSCC member defaults on its obligation. If a member were allowed to issue a letter of credit to itself (or an affiliate of the member to the member), the letter of credit would probably not be honored in a default situation.

Because the rule change will prohibit a participant from providing a letter of credit for itself or from an affiliated entity, the rule change helps ensure that MBSCC can draw upon a letter of credit used as clearing fund collateral if MBSCC ever had the need to do so. This should assist MBSCC in safeguarding securities and funds in its possession or control or for which it is responsible.

III. Conclusion

On the basis of the foregoing, the Commission finds that the proposal is consistent with the requirements of the Act and in particular with the requirements of Section 17A of the Act and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act, that the proposed rule change (File No. SR–MBSCC–00–01) be, and hereby is, approved.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.[6]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 00–29286 Filed 11–15–00; 8:45 am]

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[4] The proposed rule change also makes a technical modification to Article III, Rule 5 of MBSCC's Rules to correct the reference contained within such rule from ''Rule 4'' to ''Rule 5.''

[5] 15 U.S.C. 78q–1(b)(3)(F).

[6] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–43533; File No. SR–NASD–00–63]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the National Association of Securities Dealers, Inc. Amending NASD Rule 4611 Relating to Registration As a Nasdaq Market Maker in a Security

November 8, 2000.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 20, 2000, the National Association of Securities Dealers, Inc. (''NASD''), through its wholly-owned subsidiary The Nasdaq Stock Market, Inc., (''Nasdaq'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by Nasdaq. Nasdaq filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act,[3] and Rule 19b–4(f)(6) thereunder,[4] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Nasdaq is proposing to amend NASD Rule 4611 to allow an application for registration as a market maker in a security to become effective on the same day the application is filed. Nasdaq is also proposing a corresponding technical change to Rule 4720 regarding SOES Participation Registration. Below is the text of the proposed rule change; proposed deletions are in brackets and proposed additions are underlined.

4611. Registration as a Nasdaq Market Maker

* * * * *

[(c) A Nasdaq market maker may become registered in a newly authorized issued by contacting Nasdaq Market Operations. If registration is requested within five (5) business days after the issue is authorized, registration shall become effective at the time the registration request is entered.]

[(d)] *(c)* A Nasdaq market maker may become registered in an issue [already included in Nasdaq] by entering a registration request via a Nasdaq terminal *or other Nasdaq approved electronic interface with Nasdaq's system or by contacting Nasdaq Market Operations.* If [registration is requested in an issue that has been included in Nasdaq for more than five (5) days, and] the requirements of paragraph (b) above are satisfied, registration shall become effective on the day [after] the registration request is entered. [Provided, however, that same day registration is permissible for:

(1) a Nasdaq market maker, registered in a security that is the subject of a publicly announced merger or acquisition offer with another Nasdaq issue, who seeks registration in the other merger or acquisition issue; and

(2) a manager or co-manger of an underwriting syndicate for a secondary offering of a security on the day of the secondary offering of that security.]

[(e)] *(d)* A Nasdaq market maker's registration in an issue shall be terminated by the Association if the market maker fails to enter quotations in the issue within five (5) business days after the market maker's registration in the issue becomes effective.

[(f)]*(e)* Unless otherwise specified by the Association, each Nasdaq market maker that is registered as a market maker in a Nasdaq National Market security shall also at all times be registered as a market maker in the Small Order Execution System (SOES) with respect to that security and be subject to the SOES Rules as set forth in the Rule 4700 Series.

[(g)]*(f)* In cases where a market making member has more than one trading location, a fifth character geographic indicator shall be appended to the market marker's identifier for that security to identify the branch location where the security is traded. The fifth-character branch indicators are established by the Association and published from time to time in the Nasdaq/CQS symbol directory.

4720. SOES Participant Registration

* * * * *

(b) Pursuant to Rule 4611[(f)], participation as a SOES Market Maker is required for any Nasdaq market maker registered to make a market in an NNM security.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, Nasdaq included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4

[3] 15 U.S.C. 78s(b)(3)(A).

[4] 17 CFR 240.19b–4(f)(6).

rule change. The text of these statements may be examined at the places specified in Item IV below. Nasdaq has prepared summaries, set forth in Sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

Presently, NASD Rule 4611 states that a request to become registered as a market maker in a security that has been trading on Nasdaq for more than five (5) days is effective on the day following the request. If a security has been trading on Nasdaq for five days or less, the market maker's request becomes effective immediately. In contrast, market makers utilizing Electronic Communication Networks/Alternative Trading Systems (''ECNs/ATSs'') may immediately upon request begin displaying quotes/orders for any security trading on Nasdaq, regardless of how long the security has been trading. To eliminate the disparate treatment of market makers, Nasdaq is proposing to allow market makers to begin trading in an issue on the same day they apply for registration.

Nasdaq believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act[5] in that it is designed to promote just and equitable principles of trade; to remove impediments to and perfect the mechanism of a free and open market and a national market system; and, in general, to protect investors and the public interest. In addition, the proposal is not designed to permit unfair discrimination between brokers and dealers, but instead is designed to eliminate the disparate treatment of market makers.

Nasdaq also believes the proposed rule change is consistent with Section 11A of the Act.[6] Section 11A set forth Congress's findings that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure, among other things, fair competition among brokers and dealers. The proposal is consistent with this goal because it will allow market makers to begin quoting in a security in the same timeframe as that which is applicable to ECNs/ATSs.

(B) Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective upon filing pursuant to Section 19(b)(3)(A) of the Act,[7] and Rule 19b–4(f)(6)[8] thereunder because the proposed rule change does not significantly affect the protection of investors or the public interest; does not impose any significant burden on competition; and does not become operative for 30 days from the date on which the proposed rule change was filed, or such shorter time as the Commission may designate. The proposal is designed to eliminate the disparate treatment of market makers in that the proposal is designed to eliminate the disparate treatment of market makers and will permit both market makers and those utilizing ECNs/ATSs to begin trading in an issue on the same day they apply for registration.

In addition, Nasdaq provided the Commission with written notice of its intent to file this proposed rule change, and the written notice included a description of the proposal and the text of the proposed rule change. Nasdaq also requested that the Commission accelerate the operative date.[9] The Commission believes that the proposal is consistent with the protection of investors and the public interest and finds good cause to designate the proposal immediately operative upon filing. At any time within 60 days of the filing of a rule change pursuant to Section 19(b)(3)(A) of the Act,[10] the Commission may summarily abrogate the rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Room. Copies of such filing will also be available for inspection and copying at the principal office of the NASD. All submissions should refer to the file number in the caption above and should be submitted by December 7, 2000.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority, 17 CFR 200.30–3(a)(12).

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 00–29287 Filed 11–15–00; 8:45 am]

BILLING CODE 8010–01–M

[5] 15 U.S.C. 780–3(b)(6).

[6] 15 U.S.C. 78k–1.

[7] 5 U.S.C. 78s(b)(3)(A).

[8] 17 CFR 204.19b–4(f)(6).

[9] For purposes only of accelerating the operative date of this proposal, the Commission has considered its impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[10] 15 U.S.C. 78s(b)(3)(A).

SOCIAL SECURITY ADMINISTRATION

Privacy Act of 1974 as Amended; Computer Matching Program (SSA) Internal Revenue Service (IRS) Match Number 1016

AGENCY: Social Security Administration (SSA).

ACTION: Notice of Computer Matching Program.

SUMMARY: In accordance with the provisions of the Privacy Act, as amended, this notice announces a computer matching program that SSA plans to conduct with IRS.

DATES: SSA will file a report of the subject matching program with the Committee on Governmental Affairs of the Senate, the Committee on Government Reform and Oversight of the House of Representatives, and the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). The matching program will be effective as indicated below.

ADDRESSES: Interested parties may comment on this notice by either telefax to (410) 966–2935 or writing to the Associate Commissioner, Office of

Program Support, 2–Q–16 Operations Building, 6401 Security Boulevard, Baltimore, MD 21235–6401. All comments received will be available for public inspection at this address.

FOR FURTHER INFORMATION CONTACT: The Associate Commissioner for Program Support as shown above.

SUPPLEMENTARY INFORMATION:

A. General

The Computer Matching and Privacy Protection Act of 1988 (Public Law (Pub. L.) 100–503), amended the Privacy Act (5 U.S.C. 552a) by describing the manner in which computer matching involving Federal agencies could be performed and adding certain protections for individuals applying for and receiving Federal benefits. Section 7201 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508) further amended the Privacy Act regarding protections for such individuals. The Privacy Act, as amended, regulates the use of computer matching by Federal agencies when records in a system of records are matched with other Federal, State, or local government records.

It requires Federal agencies involved in computer matching programs to:

(1) Negotiate written agreements with the other agency or agencies participating in the matching programs;

(2) Obtain the Data Integrity Boards' approval of the match agreements;

(3) Furnish detailed reports about matching programs to Congress and OMB;

(4) Notify applicants and beneficiaries that their records are subject to matching; and

(5) Verify match findings before reducing, suspending, terminating, or denying an individual's benefits or payments.

B. SSA Computer Matches Subject to the Privacy Act

We have taken action to ensure that all of SSA's computer matching programs comply with the requirements of the Privacy Act, as amended.

Dated: May 17, 2000.

Susan M. Daniels,

Deputy Commissioner for Disability and Income Security Programs.

Notice of Computer Matching Program, Internal Revenue Service (IRS) with the Social Security Administration (SSA).

A. Participating Agencies

SSA and IRS.

B. Purpose of the Matching Program

The purpose of this matching program is to establish conditions under which IRS agrees to disclose to SSA certain return information for use in verifying eligibility for, and/or the correct amount of, benefits provided under Title XVI of the Social Security Act to qualified aged, blind and disabled individuals, and federally administered supplementary payments of the type described in section 1616(a) of such Act (including payments pursuant to an agreement entered into under section 212(a) of Pub. L. 93–96, 87 Stat. 152).

C. Categories of Records and Individuals Covered by the Matching Program

Section 1631(e)(1)(B) of the Social Security Act (42 U.S.C. 1383(e)(1)(B)) and section 6103(1)(7) of the Internal Revenue Code (26 U.S.C. 6103(1)(7)).

D. Inclusive Dates of the Match

The matching program shall become effective no sooner than 40 days after notice for the program is sent to Congress and OMB, or 30 days after publication of this notice in the **Federal Register**, whichever date is later. The matching program will continue for 18 months from the effective date and may be extended for an additional 12 months thereafter, if certain conditions are met.

[FR Doc. 00–29281 Filed 11–15–00; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice 3474]

Privacy Act of 1974; Altered System of Records

Notice is hereby given that the Department of State proposes to alter an existing system of records, STATE–31, pursuant to the provisions of the Privacy Act of 1974, as amended (5 U.S.C. 522a (r)), and the Office of Management and Budget Circular No. A–130, Appendix I. The Department's report was filed with the Office of Management and Budget on November 3, 2000.

It is proposed that the current system STATE–31 will be renamed ''Human Resources Records,'' and due to the expanded scope of the current system, the altered system description will include revisions and/or additions to all other sections. Changes to the existing system description are proposed in order to reflect more accurately the Bureau of Human Resources' record-keeping systems and a reorganization of activities and operations. Also, certain relevant records will be removed from ''Biographic Register Records, STATE–01,'' ''Board of Foreign Service Records, STATE–03,'' and ''Personnel Travel Records, STATE–32'' and will become part of STATE–31. STATE–01, STATE–03 and STATE–32 will be deleted in the near future.

Any persons interested in commenting on the altered system of records may do so by submitting comments in writing to Margaret Peppe, Chief; Programs and Policies Division; Office of IRM Programs and Services; A/RPS/IPS/PP; U.S. Department of State, SA–2; Washington, DC 20522–6001. This system of records will be effective 40 days from the date of publication, unless we receive comments that will result in a contrary determination.

The altered system description, ''Human Resources Records, STATE–31'' will read as set forth below.

Dated: November 3, 2000.

Patrick F. Kennedy,

Assistant Secretary for the Bureau of Administration, Department of State.

STATE–31

SYSTEM NAME:

Human Resources Records.

SECURITY CLASSIFICATION:

Classified and unclassified.

SYSTEM LOCATION:

Department of State, 2201 C Street, NW, Washington, DC 20520; State Annex 01, 2401 E Street, NW, Washington, DC 29937; overseas at U.S. embassies, U.S. consulates general, and U.S. consulates; U.S. missions; and the National Personnel Records Center, 111 Winnebago Street, St. Louis, MO 63118.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All applicants for employment with the Department of State (including unsuccessful applicants); all current and former Civil Service (CS) and Foreign Service (FS) employees of the Department of State including members of the Senior Executive Service, Presidential appointees, employees under full-time, part-time, intermittent, temporary, and limited appointments; anyone serving in an advisory capacity (compensated and uncompensated); other agency employees on detail to the Department; former Foreign Service Reserve Officers; student applicants for internships, Presidential Management Interns, Foreign Affairs Fellowship Program Fellows, student interns and other student summer hires, Stay-in-School student employees, and Cooperative Education Program participants; employees who report intent to marry or cohabitate with a foreign national; prospective alien spouses of Department employees;

employees who apply for their spouses or children to be expeditiously naturalized; employees detailed or seconded to international organizations; Foreign Service personnel separated for cause; current and former Foreign Service Generalists who were/are members of class action lawsuits; annuitants under the Foreign Service Retirement and Disability System and the Foreign Service Pension System as well as civil service annuitants.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

22 U.S.C. 2581 (General Authority of Secretary of State); 22 U.S.C. 2651a (Organization of the Department of State); 22 U.S.C. 3901 *et seq.* (Foreign Service Act of 1980); 22 U.S.C. 3921 (Management of the Foreign Service); 22 U.S.C. 4041 (Administration of the Foreign Service Retirement and Disability System); 5 U.S.C. 301–302 (Management of the Department of State); Executive Order 9397 (Numbering System for Federal Accounts Relating to Individual Persons); Executive Order 9830 (Amending the Civil Service Rules and Providing for Federal Personnel Administration); and Executive Order 12107 (Relating to the Civil Service Commission and Labor-Management in the Federal Service) and successor authorities.

PURPOSES:

The Official Personnel File and other general personnel records files are the official repository of the records, reports of personnel actions, and the documents and papers required in connection with personnel actions effected during an employee's Federal service. The information and documents collected and maintained in this system are in keeping with the Bureau of Human Resources' mission to determine the size and configuration of the Department workforce in order to meet its goals of defending national security and promoting national interests; to document all processes associated with individual employment histories and career progression; to ensure that all employees and potential employees have equal opportunities and to make personnel management determinations about employees throughout their Federal careers.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records are kept in different offices within the Department according to the status of the employee and/or the action being taken. Most records are retained in the Bureau of Human Resources, however, some records are held by Bureaus with partial or fully delegated personnel authority for certain personnel functions. Eventually, the records may be merged, retired or disposed of. All categories of records may include identifying information, such as, but not limited to, name, date of birth, home address, mailing and e-mail address, social security number and home telephone number. The primary record files are the official personnel files; merit promotion files; recruitment and employment files; employee relations files; technician files; career development and counseling files; performance files; conduct, suitability, and discipline files; Foreign Service promotion files; and retirement and annuitant files; which may contain any of the following documents and various related documents not otherwise stated: applications for Federal employment; resumes; biographic information; college transcripts; crediting plans; panel rating and summary sheets; rank order list of candidates and Merit Promotion certificates of those eligible; fingerprint charts; security clearance forms and related correspondence; requests for personnel action and other related forms required for entry on duty such as health and life insurance and other benefits; questionnaires for National Security positions; correspondence documenting eligibility for priority consideration and/or placement and related documents; pre-appointment certification statements for Selective Service registration; appointment affidavits; Declarations of Appointee; Declarations of Federal Employment; Employment Eligibility Verifications; letters of appointment offer; employment confirmation letters; Statements of Understanding (employee-signed agreement to conditions of employment); official personnel actions, *e.g.,* assignment, pay, promotion, leave and/or travel; Foreign Service written and oral examination results; language proficiency ratings; reports of other processes that impact the status of an employee, *e.g.,* investigations of the Office of the Inspector General; documents related to issues raised in lawsuits; counseling messages; correspondence with parties to litigation including class actions, or their attorneys; documents regarding awarding of monetary, promotion, award or assignment relief under consent decrees, settlements, agreements, or court orders; Department letters regarding separation for cause and responses by individuals; transcripts of hearings; recommendations of hearing officers; documents related to potential and/or formal disciplinary actions such as reports of investigation from the Office of the Inspector General and/or the Bureau of Diplomatic Security, warning letters, reprimands, proposal letters, employee's written responses, summary of the employee's oral response, and decision letters imposing disciplinary action; performance evaluations and related correspondence; career development and counseling records including training and assignment records; bid lists; requests for and notifications of changes in tours of duty and home leave eligibility; grievance files; requests for medical clearance; medical clearance waivers and medical clearances; processing records and card files; promotion, upward mobility, and conversion files (Mustang and lateral entry programs); retirement applications; forms and documents related to benefits under the Federal Employees Compensation Act; documents pertaining to disabled employees; designated beneficiary information and estimated annuity calculations; records of health and life insurance enrollments for annuitants and current and former spouses; annuitant and external placement files; title and rank documents; Presidential Commission records; Foreign Service Residence and Dependency Reports; separate maintenance allowance forms; applications for marriage to foreign nationals and notices of intent of Foreign Service employees; service record cards; Personal Audit Reports and abstracts; and forms and correspondence relating to Foreign Service allowances.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The information in the Human Resources Records may be used:

- By Department personnel in the performance of their official duties including, but not limited to, recruitment, position classification, appointments, assignments, performance management/appraisal and compensation, evaluations and promotions, awards, training, staffing, counseling, disciplinary or adverse actions, grievances, litigation, travel orders and operations of the automated personnel/payroll and Foreign Service annuitant systems;
- To provide the names of those Foreign Service employees who are proposed for tenure, promotion or assignment requiring special action to the Bureau of Diplomatic Security, the Office of the Inspector General, and the Office of Employee Relations in the Bureau of Human Resources for review

and eventual submission to the Director General of the Foreign Service;

• To track security clearances for applicants;

• To provide personnel trends and demographics for resource management and analysis;

• To administer the Department's disciplinary program for both Civil Service and Foreign Service employees as well as the programs for expeditious naturalization and marriage to and cohabitation with foreign nationals;

• To examine employee complaints regarding the validity of specific documents in their files;

• By consulting services who provide information about available aids, devices and methods of accommodating employees with disabilities;

• To exchange information with the Office of Personnel Management for its government-wide personnel management functions such as pay, benefits, and retirement deductions;

• To provide information to other Federal agencies, state governments, foreign governments and international organizations where employees are being considered for detail, assignment or secondment;

• To provide information to academic institutions to which Department employees may be assigned for long-term training;

• To disclose information to any member of an agency's Performance Review Board or other panel when the member is not an official of the employing agency; information would then be used for approving or recommending selection of candidates for executive development or SES candidate programs, issuing a performance rating of record, issuing performance awards, nominating for meritorious and distinguished executive ranks, and removal, reduction-in-grade, and other personnel actions based on performance;

• By attorneys, union representatives or other persons designated by employees in writing to represent them in complaints, grievance, appeal, or litigation cases;

• To respond to requests in determining a former spouse's entitlement to benefits and other inquiries related to retirement benefits;

• By the President of the United States, the Executive Office of the President and legislative and appropriations committees of the U.S. Congress charged with consideration of legislation and appropriations for the Foreign Service, or representatives duly authorized by such committees;

• By labor organization officials when such information is relevant to personnel policies affecting employment conditions and necessary for exclusive representation by the labor organization;

• To disclose information to officials of foreign governments and other U.S. government agencies for clearance before a Federal employee is assigned to that country as well as for the procurement of necessary services for American personnel assigned overseas, such as permits of free entry and identity cards;

• To disclose information to the Department of Labor, Department of Veterans Affairs, Social Security Administration, Department of Defense, or any other Federal agencies that have special civilian employee retirement and disability programs; or to a national, state, county, municipal, or other publicly recognized charitable or income security, administration agency (e.g., State unemployment compensation agencies), when necessary to adjudicate a claim under the retirement, insurance, unemployment or health benefits programs of the Department or an agency cited above, or to an agency to conduct an analytical study or audit of benefits being paid under such programs;

• To disclose to the Office of Federal Employees Group Life Insurance, information necessary to verify election, declination, or waiver of regular and/or optional life insurance coverage, or eligibility for payment of a claim for life insurance;

• To disclose, to health insurance carriers contracting with the Federal government to provide a health benefits plan under the Federal Employees Health Benefits Program, information necessary to identify enrollment in a plan, to verify eligibility for payment of a claim for health benefits, or to carry out the coordination or audit of benefit provisions of such contracts;

• When an individual to whom a record pertains is mentally incompetent or under other legal disability, information in the individual's record may be disclosed to any person who is responsible for the care of the individual, to the extent necessary to assure payment of benefits to which the individual is entitled;

• To consider and select employees for incentive awards and other honors and to publicize those granted—this may include disclosure to other public and private organizations, including news media, which grant or publicize employee recognition;

• To disclose information to the Inspector General in conducting an official investigation of the Department or any of its personnel;

• By the subject of the record to review his/her career status and progress;

• To disclose information to the Department of Justice or in connection with proceedings before a court, adjudicative body, or other administrative body when:

(1) The agency, or any component thereof; or

(2) Any employee of the agency in his or her official capacity; or

(3) Any employee of the agency in his or her individual capacity where the Department of Justice or the agency has agreed to represent the employee; or

(4) The United States, when the agency determines that litigation is likely to affect the agency or any of its components; is a party to litigation or has an interest in such litigation, and the Department of State determines that the use of such records is arguably relevant and necessary to the litigation;

• To implement court decisions and/or terms of settlement agreements reached by the parties;

• To prepare reports to the courts in compliance with monitoring requirements;

• In response to an order from a court or an administrative body (including, but not limited to the Equal Employment Opportunity Commission, the Foreign Service Grievance Board and the Merit Systems Protection Board) directing the production of personnel records;

• By other government agencies and private organizations, institutions or individuals to verify employment, to process security clearances and to request record or credit checks;

• To provide an official of another Federal agency information needed in the performance of official duties in support of the functions for which the records were collected and maintained;

• To disclose information to Equal Employment Opportunity (EEO) counselors and EEO investigators in connection with EEO complaints and to the Equal Employment Opportunity Commission when requested in connection with investigations of alleged or possible discrimination practices in the Federal sector, examination of Federal affirmative employment programs, compliance by Federal agencies with the Uniform Guidelines on Employee Selection Procedures, or other functions vested in the Commission;

• By the Department of Labor's Office of Workers' Compensation programs relating to benefits under the Federal Employees Compensation Act; and

• To disclose information to the news media and the public when (1) a matter involving the Department of State has become public knowledge, (2) the Under Secretary for Management determines that in response to the matter in the public domain, disclosure is necessary to provide an accurate factual record on the matter, and (3) the Under Secretary determines that there exists a legitimate public interest in the information disclosed.

Also see the ''Routine Uses'' paragraph of the Prefatory Statement published in the **Federal Register**.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Electronic media and hard copy.

RETRIEVABILITY:

By individual name, social security number.

SAFEGUARDS:

All employees of the Department of State have undergone background investigations. Access to the Department and its annexes is controlled by security guards and admission is limited to those individuals possessing a valid identification card or individuals under proper escort. All records containing personal information are maintained in secured file cabinets or in restricted areas, access to which is limited to authorized personnel. Access to computerized files is password-protected and under the direct supervision of the system manager. The system manager has the capability of printing audit trails of access from the computer media, thereby permitting regular and ad hoc monitoring of computer usage.

RETENTION AND DISPOSAL:

These records will be maintained until they become inactive at which time they will be retired or destroyed in accordance with published records schedules of the Department of State and as approved by the National Archives and Records Administration. More specified information may be obtained by writing to the Director, Office of IRM Programs and Services; A/RPS/IPS; U.S. Department of State, SA–2; Washington, DC 20522–6001.

SYSTEM MANAGER(S) AND ADDRESS:

The Director General of the Foreign Service and Director of Human Resources; Department of State; 2201 C Street, NW; Washington, DC 20520.

NOTIFICATION PROCEDURES:

Individuals who have reason to believe that the Bureau of Human Resources might have records pertaining to themselves should write to the Director, Office of IRM Programs and Services (address above). The individual must specify that he/she wishes the Human Resources Records to be checked. At a minimum, the individuals must include: name; date and place of birth; approximate dates of employment with the Department of State or when in process for a potential appointment; current mailing address and zip code; signature and preferably, his/her social security number.

RECORD ACCESS AND AMENDMENT PROCEDURES:

Individuals who wish to gain access to or amend records pertaining to themselves should write to the Director, Office of IRM Programs and Services (address above).

RECORD SOURCE CATEGORIES:

These records contain information obtained directly from the individual who is the subject of these records, previous employers, supervisors, Foreign Service inspectors, any/all offices within the Bureau of Human Resources (counselors, placement officers, and personnel technicians), other bureaus (administrative/executive officers, personnel and payroll offices, security, medical, and legal), reports of the Board of Examiners of the Foreign Service, Foreign Service Employee Evaluation Reports and Selection Board findings, the Foreign Service Institute, colleges, universities, Armed Forces academic institutions, contractors responsible for administration of the Foreign Service written examination, and other authorized agencies administering pre-employment tests, Office of Personnel Management and other federal agencies, prospective alien spouses of Foreign Service employees; grievance staff and appeals boards, affidavits and testimony of witnesses.

System exempted from certain provisions of the Privacy Act:

Pursuant to 5 U.S.C. 552a(k)(4), records contained within this system that are maintained solely for statistical purposes are exempted from 5 U.S.C. 552a (c)(3), (d), (e)(1), (e)(4)(G), (H) and (I), and (f). Pursuant to 5 U.S.C. 552a (k)(5) and (k)(7), certain records contained within this system contain confidential source information and are exempted from 5 U.S.C. 552a (c)(3), (d), (e)(1), (e)(4)(G), (H) and (I), and (f). Pursuant to 5 U.S.C. 552a (k)(6), records that contain testing or examination material the release of which may compromise testing or examination procedures are also exempted from 5 U.S.C. 552a (c)(3), (d), (e)(1), (e)(4)(G), (H) and (I), and (f). See Department of State Rules published in the **Federal Register**.

[FR Doc. 00–29246 Filed 11–15–00; 8:45 am]

BILLING CODE 4710–24–U

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

[Docket No. 301–120]

Initiation of Section 302 Investigation and Request for Public Comment: Wheat Trading Practices of the Canadian Wheat Board

AGENCY: Office of the United States Trade Representative.

ACTION: Notice of initiation of investigation and request for comments.

SUMMARY: The United States Trade Representative (USTR) has initiated an investigation under Chapter 1 of Title III of the Trade Act of 1974 with respect to the wheat trading practices of the Canadian Wheat Board. The USTR invites written comments from the public on the matters being investigated, the methods to be used to conduct the investigation, and the determinations to be made pursuant to the investigation.

DATES: This investigation was initiated on October 23, 2000. Written comments from the public are due on or before noon on Wednesday, December 20, 2000.

ADDRESSES: Office of the United States Trade Representative, 600 17th Street NW., Washington, DC 20508.

FOR FURTHER INFORMATION CONTACT: Sharon Bomer Lauritsen, Director of Agricultural Affairs, (202) 395–6127, or William Busis, Associate General Counsel, (202) 395–3150. For information concerning procedures for submitting public comments, please contact Sybia Harrison, Staff Assistant to the Section 301 Committee, (202) 395–3419.

SUPPLEMENTARY INFORMATION:

The Allegations in the Petition

On September 8, 2000, the North Dakota Wheat Commission filed a petition pursuant to section 302(a) of the Trade Act of 1974, as amended (the Trade Act) (19 U.S.C. 2412(a)), alleging that certain wheat trading practices of the Government of Canada and the Canadian Wheat Board (CWB) are unreasonable, and that such practices burden or restrict U.S. commerce. The

petitioner filed additional explanatory materials on September 21, 2000, September 27, 2000, October 5, 2000, and October 10, 2000.

The petition alleges that the CWB is a state-trading enterprise with sole control over the purchase and export of western Canadian wheat for human consumption. Certain elements of the wheat trading system established by the Government of Canada allegedly provide the CWB with pricing flexibility not available to private wheat traders. According to the petition, those elements include: (1) CWB monopoly authority under Canadian federal law to purchase western Canadian wheat and to control the international marketing of western Canadian wheat; (ii) a purchasing system under which Canadian farmers are required to accept initial CWB payments based on only a portion of the price that the CWB anticipates it can obtain for the grain, with any subsequent payments to be received later in the marketing year; (iii) the provision by the Government of Canada of a full financial guarantee of the CWB's initial payments to Canadian farmers; (iv) special, preferential rail transportation arrangements which are made available to the CWB; and (v) a varietal control system which limits any foreign competition in the domestic Canadian wheat market. The petition claims that although the CWB operates in secrecy and information on the CWB's trading practices is difficult to obtain, available information indicates that the CWB exploits its pricing flexibility by engaging in certain allegedly unreasonable wheat trading practices. According to the petition, such practices include standing offers by the CWB to undersell U.S. wheat in certain third-country markets, and the targeting by the CWB of particular markets by consistently offering to sell wheat at less than the market value. The petition asserts that such practices have harmed U.S. wheat farmers by causing lost U.S. market share in the United States and particular third-country markets, by reducing the sales prices obtained by U.S. wheat farmers, and by causing a rise in unsold wheat stocks in the United States.

The petitioner does not allege that acts, policies, and practices of the Government of Canada or the Canadian Wheat Board are in violation of, or inconsistent with, the international legal rights of the United States.

Section 301

Section 302(a) of the Trade Act authorizes the USTR to initiate an investigation under chapter 1 of Title III of the Trade Act (commonly referred to as ''section 301'') in response to the filing of a petition pursuant to section 302(a)(1). Matters actionable under section 301 include, inter alia, acts, policies, and practices of a foreign country that are unjustifiable, unreasonable, or discriminatory and burden or restrict U.S. commerce. An act, policy or practice is unjustifiable if it is in violation of, or inconsistent with the international legal rights of the United States. An act, policy or practice is unreasonable if the act, policy or practice, while not necessarily in violation of, or inconsistent with, the international legal rights of the United States, is otherwise unfair or inequitable.

Initiation of Investigation and Consultations

On October 23, 2000, the USTR determined to initiate an investigation to determine whether certain acts, policies or practices of the Government of Canada and the Canadian Wheat Board with respect to wheat trading are unreasonable and burden or restrict U.S. commerce and are, therefore, actionable under section 301.

Pursuant to section 303(a) of the Trade Act, on October 23, 2000 USTR requested consultations with the Government of Canada concerning the issues under investigation. USTR will seek information and advice from the petitioner and appropriate representatives provided for under section 135 of the Trade Act in preparing the U.S. presentations for such consultations.

Public Comment: Requirements for Submissions

Interested persons are invited to submit written comments concerning the issues raised in the petition and any other submissions to USTR in this investigation. In particular, comments are invited regarding (i) the acts, policies and practices of the Government of Canada and the Canadian Wheat Board that are the subject of this investigation; (ii) the amount of burden or restriction on U.S. commerce caused by these acts, policies and practices; (iii) the methods to be used to conduct the investigation; (iv) the determinations required under section 304 of the Trade Act; and (v) appropriate action under section 301 which could be taken in response.

Comments must be filed in accordance with the requirements set forth in 15 CFR 2006.8(b) and must be filed on or before noon on Wednesday, December 20, 2000. Comments must be in English and provided in twenty copies to: Sybia Harrison, Staff Assistant to the Section 301 Committee, Room 223, Office of the U.S. Trade Representative, 600 17th Street, NW., Washington, DC 20508.

Comments will be placed in a file (Docket 301–120) open to public inspection pursuant to 15 CFR 2006.13, except confidential business information exempt from public inspection in accordance with 15 CFR 2006.15. Confidential business information submitted in accordance with 15 CFR 2006.15 must be clearly marked ''BUSINESS CONFIDENTIAL'' in a contrasting color ink at the top of each page on each of 20 copies, and must be accompanied by a nonconfidential summary of the confidential information. The nonconfidential summary shall be placed in the file that is open to public inspection. Copies of the public version of the petition and other relevant documents are available for public inspection in the USTR Reading Room. An appointment to review the docket (Docket No. 301–120) may be made by calling Brenda Webb (202) 395–6186. The USTR Reading Room is open to the public from 9:30 a.m. to 12 noon and 1:00 p.m. to 4:00 p.m., Monday through Friday, and is located in Room 101.

William L. Busis,

Chairman, Section 301 Committee.

[FR Doc. 00–29399 Filed 11–15–00; 8:45 am]

BILLING CODE 3190–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Availability of Draft Environmental Impact Statement and Notice of Public Hearing for the Chicago Terminal Airspace Project

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of availability of Draft Environmental Impact Statement and conduct of a public hearing.

SUMMARY: The Federal Aviation Administration (FAA), Great Lakes Region, is issuing this notice to advise the public that it has prepared a Draft Environmental Impact Statement (DEIS) for the Chicago Terminal Airspace Project (CTAP) and that copies of the DEIS are available for public review.

A Public Hearing and informational workshop will be held Monday, December 18, 2000, from 5 p.m. to 8 p.m. in the Illinois, Minnesota and Michigan conference rooms at the Federal Aviation Administration, Great Lakes Region, 2300 East Devon Avenue, Des Plaines, IL, 60018. The entrance is

on the northeast side of the building. All persons planning to attend should bring picture identification to allow issuance of a building security pass.

The purpose of this hearing is to consider the environmental effects of the proposed CTAP project and afford the public the opportunity to present oral and/or written comments. A transcript of the hearing will be made. Written comments will be accepted through close of business on January 12, 2001. The first half-hour of each hour of the Public Hearing will be allocated to pre-reserved testimony. Individuals may call Ms. Annette Davis at telephone (847) 294–8091 to receive a reserved time slot to testify at the Public Hearing. All individuals, organizations, agencies, and representatives will have 5 minutes to testify. Individuals, organizations, agencies, and representatives wishing to submit written comments may send them to: Ms. Annette Davis, AGL–520.E, Federal Aviation Administration, Great Lakes Region. 2300 East Devon Avenue, Des Plaines, IL, 60018.

FOR FURTHER INFORMATION CONTACT: Ms. Annette Davis Federal Aviation Administration, Great Lakes Region, Air Traffic Division, 2300 East Devon Avenue, Des Planes, Illinois, 60018, (847)–294–8091.

SUPPLEMENTARY INFORMATION: The proposed CTAP changes could affect flights to and from airports within the Chicago region, including Chicago O'Hare International Airport, Chicago Midway Airport, Milwaukee Mitchell International Airport, and general aviation reliever airports. Components of the proposal include:

- Establish a new high altitude O'Hare arrival route from the southwest, separated laterally and vertically from the existing route
- Modification of the existing high altitude routes at the southeast and northwest arrival cornerposts, separated laterally and vertically from the existing route
- Establishment of a new high altitude route to the northeast, separated vertically from the existing route
- Implementation of more efficient use of existing routes for O'Hare and Midway departures to the north, south, east, and west
- Establishment of a new high altitude route to Midway for aircraft from the northwest and northeast
- Establishment of a new high altitude arrival route for aircraft destined to Milwaukee from the south
- Transfer of portions of airspace from Chicago Center to Chicago Terminal Radar Approach Control (TRACON) and from Chicago TRACON to Rockford TRACON

The project is not associated with any airport development projects or construction of any physical facilities. The changes proposed by CTAP are designed to improve traffic flows and reduce airborne and ground delays. They would enhance safety and efficiency by maximizing controller flexibility and simplifying operations for pilots. CTAP has the potential to enhance air quality by reducing en route mileage. As disclosed in the DEIS, CTAP would not result in significant adverse impacts to any resource category.

Copies of the CTAP DEIS are available at the following locations:

State of Illinois

Bensenville Public Library, 200 S. Church Rd., Bensenville, IL 60106
Des Plaines Public Library, 841 Graceland Ave., Des Plaines, IL 60016
Eisenhower Public Library, 4652 N. Olcott Ave., Harwood Heights, IL 60656
Elk Grove Village Public Library, 1001 Wellington Ave., Elk Grove Village, IL 60007
Elmhurst Public Library, 211 Prospect Ave., Elmhurst, IL 60126
Franklin Park Public Library, 10311 Grand Ave., Franklin Park, IL 60131
Garfield Ridge Branch Library, 6348 South Archer Ave., Chicago, IL 60638
Harold Washington Library, 400 South State St., 5th Floor, Chicago, IL 60605
Mount Prospect Public Library, 10 S. Emerson St., Mount Prospect, IL 60056
Northlake Public Library, 231 N. Wolf Rd., Northlake, IL 60164
Oriole Park Branch Library, 5201 N. Oketo Ave., Chicago, IL 60656
Park Ridge Public Library, 20 S. Prospect Ave., Park Ridge, IL 60068
Schiller Park Public Library, 4200 Old River Rd., Schiller Park, IL 60176

State of Indiana

Lake County Public Library, 1919 W. 81st Ave., Merrillville, IN 46410–5382

State of Wisconsin

Milwaukee Central Public Library, 814 W. Wisconsin Ave., Milwaukee, WI 53233
Oak Creek Public Library, 8620 S. Howell Ave., Oak Creek, WI 53154

Information is also available on the Internet at the web site address http://www.faa.gov/ctap.html.

* * * * *

Issued in Des Plaines, Illinois, on November 7, 2000.

Bridgitt S. Galias,

Acting Manager, Airspace Branch, Air Traffic Division, Great Lakes Region.

[FR Doc. 00–29412 Filed 11–15–00; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2000–64]

Petitions for Exemption; Summary of Petitions Received; Dispositions of Petitions Issued

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for exemption received and of dispositions of prior petitions.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitions for exemption Part 11 of Title 14, Code of Federal Regulations (14 CFR), this notice contains a summary of certain petitions seeking relief from specified requirements of 14 CFR, dispositions of certain petitions previously received, and corrections. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and must be received on or before December 5, 2000.

ADDRESSES: Send comments on any petition to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590–0001. You must identify the docket number FAA–2000–XXXX at the beginning of your comments. If you wish to receive confirmation that FAA received your comments, include a self-addressed, stamped postcard.

You may also submit comments through the Internet to http://dms.dot.gov. You may review the public docket containing the petition, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. The Dockets Office (telephone 1–800–647–5527) is on the plaza level of the NASSIF Building at the

Department of Transportation at the above address. Also, you may review public dockets on the Internet at http://dms.dot.gov.

FOR FURTHER INFORMATION CONTACT: Forest Rawls (202) 267–8033, or Vanessa Wilkins (202) 267–8029, Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR §§ 11.85 and 11.91 of Part 11.

Issued in Washington, D.C., on November 9, 2000.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

Dispositions of Petitions

Docket No.: FAA–2000–7996.
Petitioner: Gortner Pilots Association.
Section of 14 CFR Affected: 14 CFR 135.251, 135.255, 135.353 and appendixes I and J to part 121
Description of Relief Sought/Disposition:

To permit GPA to conduct local sightseeing flights at Greater Gortner Airport, Garrett County, Maryland, for the one-day Greater Gortner Airport Fly-In/Open House in October 2000, for compensation or hire, without complying with certain anti-drug and alcohol misuse prevention requirements of part 135. *Grant, 10/13/2000, Exemption No. 7369*

Docket No.: FAA–2000–8085.
Petitioner: Carolinas Historic Aviation Commission.
Section of 14 CFR Affected: 14 CFR 135.251, 135.255, 135.353 and appendixes I and J to part 121
Description of Relief Sought/Disposition:

To permit CHAC to conduct local sightseeing flights at Charlotte/Douglas International Airport, Charlotte, North Carolina, for a two-day charitable event in October 2000, for compensation or hire, without complying with certain anti-drug and alcohol misuse prevention requirements of part 135. *Grant, 10/13/2000, Exemption No. 7368*

[FR Doc. 00–29322 Filed 11–15–00; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Petition for Waiver of Compliance

In accordance with Part 211 of Title 49 Code of Federal Regulations (CFR), notice is hereby given that the Federal Railroad Administration (FRA) received a request for a waiver of compliance with certain requirements of its safety standards. The individual petition is described below, including the party seeking relief, the regulatory provisions involved, the nature of the relief being requested, and the petitioner's arguments in favor of relief.

Canadian National Illinois Central Railroad

[Docket Number FRA–2000–8089]

Canadian National Illinois Central Railroad (CN/IC) seeks a permanent waiver of compliance from certain provisions of the Railroad Safety Appliance Standards, 49 CFR Part 231, and the Railroad Power Brakes and Drawbars regulations, 49 CFR Part 232, concerning RoadRailer®'' train operations over their system. Specifically, CN/IC requests relief from those sections of 49 CFR Part 231 which stipulates the number, location and dimensions for handholds, ladders, sill steps, uncoupling levers and handbrakes. CN/IC also seeks relief from 49 CFR Part 232.2 which sets the standard height for drawbars.

CN/IC states that this waiver is necessary to permit them to begin operation of RoadRailer equipment between Chicago, Illinois, and Port Huron, Michigan. CN/IC requests that this petition, if approved, be modeled on conditions contained in waiver FRA–1999–5895 which was granted to the Burlington Northern Santa Fe Railway in May 2000.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number (*e.g.,* Waiver Petition Docket Number 2000–8089) and must be submitted to the Docket Clerk, DOT Docket Management Facility, Room PL–401 (Plaza Level), 400 7th Street, SW., Washington, DC 20590. Communications received within 45 days of the date of this notice will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.–5 p.m.) at the above facility. All documents in the public docket are also available for inspection and copying on the Internet at the docket facility's web site at http://dms.dot.gov.

Issued in Washington, D.C. on November 9, 2000.

Grady C. Cothen, Jr.,

Deputy Associate Administrator for Safety Standards and Program Development.

[FR Doc. 00–29317 Filed 11–15–00; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Research and Special Programs Administration

[Docket No. RSPA–00–8026 (PDA–26(R))]

Application by Boston & Maine Corporation for a Preemption Determination as to Massachusetts' Definitions of Hazardous Materials

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Public notice and invitation to comment.

SUMMARY: Interested parties are invited to submit comments on an application by Boston & Maine Corporation for an administrative determination whether Federal hazardous materials transportation law preempts the Commonwealth of Massachusetts' definitions of ''hazardous materials'' as applied to hazardous materials transportation.

DATES: Comments received on or before January 2, 2001, and rebuttal comments received on or before February 14, 2001, will be considered before an administrative ruling is issued by RSPA's Associate Administrator for Hazardous Materials Safety. Rebuttal comments may discuss only those issues raised by comments received during the initial comment period and may not discuss new issues.

ADDRESSES: The application and all comments received may be reviewed in the Dockets Office, U.S. Department of Transportation, Room PL–401, 400 Seventh Street, SW, Washington, DC 20590–0001. The application and all comments are also available on-line through the home page of DOT's Docket Management System, at ''http://dms.dot.gov.''

Comments must refer to Docket No. RSPA–00–8026 and may be submitted to the docket either in writing or electronically. Send three copies of each written comment to the Dockets Office at the above address. If you wish to receive confirmation of receipt of your written comments, include a self-addressed, stamped postcard. To submit

comments electronically, log onto the Docket Management System website at http://dms.dot.gov, and click on ''Help & Information'' to obtain instructions.

A copy of each comment must also be sent to: (1) Robert B. Culliford, Esq., Corporate Counsel, Boston & Maine Corporation, Iron Horse Park, North Billerica, MA 01862, and (2) Ginny Sinkel, Esq., Assistant Attorney General, Commonwealth of Massachusetts, Office of the Attorney General, One Ashburton Place, Boston, Massachusetts 02108–1698. A certification that a copy has been sent to these persons must also be included with the comment. (The following format is suggested: ''I certify that copies of this comment have been sent to Mr. Culliford and Ms. Sinkel at the addresses specified in the **Federal Register**.'')

A list and subject matter index of hazardous materials preemption cases, including all inconsistency rulings and preemption determinations issued, are available through the home page of RSPA's Office of the Chief Counsel, at ''http://rspa-atty.dot.gov.'' A paper copy of this list and index will be provided at no cost upon request to Ms. Christian, at the address and telephone number set forth in **FOR FURTHER INFORMATION CONTACT** below.

FOR FURTHER INFORMATION CONTACT: Karin V. Christian, Office of the Chief Counsel, Research and Special Programs Administration (Tel. No. 202–366–4400), Room 8407, U.S. Department of Transportation, Washington, DC 20590–0001.

SUPPLEMENTARY INFORMATION:

I. Application for a Preemption Determination:

The Boston & Maine Corporation (Boston & Maine) has applied for a determination that Federal hazardous material transportation law, 49 U.S.C. 5101 *et seq.*, preempts the Massachusetts General Laws chapter 21K, section 1 and chapter 21E, section 2 definitions of hazardous materials. Boston & Maine asserts that the Massachusetts definition of hazardous materials is not ''substantively the same'' as the definitions of hazardous materials in the hazardous materials regulations (49 CFR Parts 171–180) issued under the Federal hazardous materials transportation law, 49 U.S.C. 5101 *et seq.*

In addition, Boston & Maine requests a determination that the regulation of hazardous materials in transportation in commerce based on a definition of hazardous materials that is not substantively the same as the designation by the Secretary of Transportation is an obstacle to accomplishing and carrying out the Federal hazardous materials transportation law.

In an August 25, 2000 letter to RSPA's Office of the Chief Counsel, the Massachusetts Office of the Attorney General responded to Boston & Maine's application on behalf of the Massachusetts Department of Fire Services. The Office of the Attorney General informed RSPA that Boston & Maine had filed a complaint against the Massachusetts Department of Fire Services in the Massachusetts Superior Court raising the same issue as in its preemption determination application, *i.e.,* whether Massachusetts General Law chapters 21K and 21E are preempted by Federal law. Massachusetts requested that RSPA not act on Boston & Maine's application until the state judicial proceedings are resolved.

RSPA reviewed Massachusetts' request and Boston & Maine's response. On September 13, 2000, RSPA sent a letter to both parties stating that RSPA has decided to proceed with docketing and taking action on the application for preemption.

Boston & Maine Application

The text of Boston & Maine's application and a list of the attachments to the application are set forth in Appendix A to this notice. A paper copy of the attachments to Boston & Maine's application (which have been placed in the public docket) will be provided at no cost upon request to Ms. Christian, at the address and telephone number set forth in **FOR FURTHER INFORMATION CONTACT** above.

In its application, Boston & Maine challenges the following:

(1) Massachusetts General Laws chapter 21K, § 1 that defines hazardous material as follows:

> ''Hazardous material'', material including, but not limited to, material, in whatever form which, because of its quantity, concentration, chemical, corrosive, flammable, reactive, toxic, infectious or radioactive characteristics, either separately or in combination with a substance, constitutes a present or potential threat to human health, safety or welfare or to the environment when improperly stored, treated, transported, disposed of, used or otherwise managed. Hazardous materials shall include, but not be limited to, oil and all substances which are included under 42 USC 9601(14).

(2) Massachusetts General Laws chapter 21E, § 2 that defines hazardous material as follows:

> ''Hazardous material'', material including but not limited to, any material, in whatever form, which because of its quantity, concentration, chemical, corrosive, flammable, reactive, toxic, infectious or radioactive characteristics, either separately or in combination with any substance or substances, constitutes a present or potential threat to human health, safety, welfare, or to the environment, when improperly stored, treated, transported, disposed of, used, or otherwise managed. The term shall not include oil. The term shall also include all those substances which are included under 42 USC 9601(14), but it is not limited to those substances.

In its application, Boston & Maine asserts that the Massachusetts regulations greatly expand the Federal designation of hazardous materials to include substances that have not been designated as ''hazardous'' materials by the Secretary of Transportation. Boston & Maine states that Massachusetts' definitions do not conform in every significant respect to the Federal definition because the State law definitions would include materials not determined by the Secretary to be capable of posing an unreasonable risk to health, safety, and property when transported in commerce.

Boston & Maine also asserts that Massachusetts' definitions of hazardous materials create an obstacle to the efficient and uniform application of the Federal hazardous materials transportation law. Boston & Maine states that when State regulations designate materials as ''hazardous'' that are not included as hazardous materials by the Secretary of Transportation, the discrepancy subjects interstate carriers to undue burdens and creates obstacles to uniform regulation of transportation of hazardous materials in interstate commerce. Boston & Maine argues that an overly broad State designation of ''hazardous'' materials potentially subjects common carriers to a multitude of different regulations because each State could have different standards requiring additional packaging requirements, labeling, storage, and documentation for substances based upon the designation of ''hazardous'' material adopted by each individual State.

With its August 25, 2000 letter to RSPA, Massachusetts attached a copy of Boston & Maine's January 20, 2000 First Amended Complaint (the Complaint) filed in Massachusetts Superior Court. In the Complaint, Boston & Maine described the action as one to correct errors of law in an administrative proceeding by the Department of Fire Services.

In the Complaint's factual background, Boston & Maine described a June 27, 1999 freight train derailment on Boston & Maine property. Boston & Maine stated that as a result of the

derailment, approximately five cars leaked materials, including latex, terephthalic acid, polyethylene, polypropene, and ''distillers'' grain onto the ground and into the river adjacent to the railroad tracks. Boston & Maine stated that immediately after the derailment, it implemented an emergency response plan, including notification of a private contractor and licensed site professional to contain the release of materials from the five leaking rail cars. Boston & Maine stated that the private contractor was licensed to respond to all releases of material, whether the materials were considered ''hazardous'' or not.

The Complaint stated that shortly after the derailment, the Fire Department of the town of Charlemont, Massachusetts, responded to the scene and contacted the regional Massachusetts Hazardous Materials Response Team (Response Team) under the belief that hazardous materials were being released or threatened to be released.

Boston & Maine stated that the Response Team arrived at the scene and prevented Boston & Maine from properly containing the materials being released from the rail cars. Boston & Maine stated that the Response Team insisted that Boston & Maine produce documentation proving that the materials being released were not ''hazardous materials.'' Boston & Maine stated that the demand for information regarding the leaking materials was made despite the fact that none of the leaking cars were placarded or were required to be accompanied by ''shipping papers'' because none of the materials were considered ''hazardous.'' Boston & Maine stated that when it produced additional documentation to prove that no release or threat of release of ''hazardous materials'' existed, the Response Team released control of the scene to Boston & Maine.

The Complaint stated that Boston & Maine received an invoice from Massachusetts seeking to recover the costs incurred by the Response Team on June 27, 1999. On September 7, 1999, Boston & Maine filed a Petition for Review of the Statement of Costs. On November 19, 1999, Massachusetts denied Boston & Maine's Petition for Review.

In the Complaint, Boston & Maine asserts that the Massachusetts Department of Fire Services had no legal authority to respond to the June 27, 1999 derailment because the State law designations of ''hazardous'' materials are preempted by Federal law and therefore has no legal authority to recover its costs for the response to the derailment on June 27, 1999 pursuant to Massachusetts General Laws Chapter 21K, Section 5(b). Boston & Maine states there was no release or threat of release of a federally designated, described, or classified ''hazardous material'' pursuant to the regulations promulgated by the Secretary of Transportation. Boston & Maine argued that the fact that the train crew did have immediate possession of the proper ''shipping papers'' and placards for other materials in the train, but no ''shipping papers'' or placards for the materials in the cars that were leaking, was proof that the leaking materials did not meet the Federal definition of ''hazardous materials.''

The following materials have been placed in the public docket of this proceeding:

Boston & Maine's August 16, 2000 application for preemption determination and attachments.

Massachusetts August 25, 2000 letter with attachment, requesting that RSPA decline to take action on Boston & Maine's application until state judicial proceedings are resolved. The First Amended Complaint filed by Boston & Maine in Massachusetts' Superior Court is attached to this letter.

Boston & Maine's September 5, 2000 response to Massachusetts' request that RSPA decline to take action on its application.

RSPA's September 13, 2000 letter informing both parties that the Associate Administrator had decided to proceed to take action on Boston & Maine's application.

These documents may be reviewed in the Dockets Office, U.S. Department of Transportation, Room PL–401, 400 Seventh Street, SW Washington, DC 20590–0001. These documents are also available on-line through the home page of DOT's Docket Management System, at ''http://dms.dot.gov.''

II. Federal Preemption

Section 5125 of Title 49 U.S.C. contains several preemption provisions that are possibly relevant to Boston & Maine's application. Subsection (a) provides that—in the absence of a waiver of preemption by DOT under section 5125(e) or specific authority in another Federal law—a requirement of a State, political subdivision of a State, or Indian tribe is preempted if—

(1) complying with a requirement of the State, political subdivision or tribe and a requirement of this chapter or a regulation issued under this chapter is not possible; or

(2) the requirement of the State, political subdivision, or Indian tribe, as applied or enforced, is an obstacle to accomplishing and carrying out this chapter or a regulation prescribed under this chapter.

These two paragraphs set forth the ''dual compliance'' and ''obstacle'' criteria that RSPA had applied in issuing inconsistency rulings prior to 1990, under the original preemption provision in the Hazardous Materials Transportation Act (HMTA). Public Law 93–633 section 112(a), 88 Stat. 2161 (1975). The dual compliance and obstacle criteria are based on U.S. Supreme Court decisions on preemption. *Hines* v. *Davidowitz,* 312 U.S. 52 (1941); *Florida Lime & Avocado Growers, Inc.* v. *Paul,* 373 U.S. 132 (1963); *Ray* v. *Atlantic Richfield, Inc.,* 435 U.S. 151 (1978).

Subsection (b)(1) of 49 U.S.C. 5125 provides that a non-Federal requirement concerning any of the following subjects, that is not ''substantively the same as'' a provision of Federal hazardous material transportation law or a regulation prescribed under that law, is preempted unless it is authorized by another Federal law or DOT grants a waiver of preemption:

(A) the designation, description, and classification of hazardous material.

(B) the packing, repacking, handling, labeling, marking, and placarding of hazardous material.

(C) the preparation, execution, and use of shipping documents related to hazardous material and requirements related to the number, contents, and placement of those documents.

(D) the written notification, recording, and reporting of the unintentional release in transportation of hazardous material.

(E) the design, manufacturing, fabricating, marking, maintenance, reconditioning, repairing, or testing of a packaging or a container represented, marked, certified, or sold as qualified for use in transporting hazardous material.

To be ''substantively the same,'' the non-Federal requirement must ''conform[] in every significant respect to the Federal requirement. Editorial and other similar de minimis changes are permitted.'' 49 CFR 107.202(d).

These preemption provisions in 49 U.S.C. 5125 carry out Congress's view that a single body of uniform Federal regulations promotes safety in the transportation of hazardous materials. In considering the HMTA, the Senate Commerce Committee ''endorse[d] the principle of preemption in order to preclude a multiplicity of State and local regulations and the potential for varying as well as conflicting regulations in the area of hazardous materials transportation.'' S. Rep. No. 1102, 93rd Cong. 2nd Sess. 37 (1974). When it amended the HMTA in 1990, Congress specifically found that:

(3) many States and localities have enacted laws and regulations which vary from Federal laws and regulations pertaining to the transportation of hazardous materials, thereby creating the potential for unreasonable hazards in other jurisdictions and confounding shippers and carriers which attempt to comply with multiple and conflicting registration, permitting, routing, notification, and other regulatory requirements,

(4) because of the potential risks to life, property, and the environment posed by unintentional releases of hazardous materials, consistency in laws and regulations governing the transportation of hazardous materials is necessary and desirable,

(5) in order to achieve greater uniformity and to promote the public health, welfare, and safety at all levels, Federal standards for regulating the transportation of hazardous materials in intrastate, interstate, and foreign commerce are necessary and desirable.

Pub. L. 101–615 section 2, 104 Stat. 3244. A Federal Court of Appeals has found that uniformity was the ''linchpin'' in the design of the HMTA, including the 1990 amendments that expanded the original preemption provisions. *Colorado Pub. Util. Comm'n* v. *Harmon,* 951 F.2d 1571, 1575 (10th Cir. 1991). (In 1994, Congress revised, codified and enacted the HMTA ''without substantive change,'' at 49 U.S.C. Chapter 51. Public Law 103–272, 108 Stat. 745.)

III. Preemption Determinations

Under 49 U.S.C. 5125(d)(1), any directly affected person may apply to the Secretary of Transportation for a determination whether a State, political subdivision or Indian tribe requirement is preempted. The Secretary of Transportation has delegated authority to make determinations of preemption that concern highway routing to FMCSA and those concerning all other hazardous materials transportation issues to RSPA. 49 CFR 1.53(b) and 1.73(d)(2) (as added October 9, 1999, 64 FR 56720, 56721 [Oct. 19, 1999], and revised January 1, 2000, 65 FR 220, 221 [Jan. 4, 2000]).

Section 5125(d)(1) requires that notice of an application for a preemption determination must be published in the **Federal Register**. Following the receipt and consideration of written comments, RSPA will publish its determination in the **Federal Register**. *See* 49 C.F.R. 107.209(d), 397.211(d). A short period of time is allowed for filing of petitions for reconsideration. 49 C.F.R. 107.211, 397.223. Any party to the proceeding may seek judicial review in a Federal district court. 49 U.S.C. 5125(f).

Preemption determinations do not address issues of preemption arising under the Commerce Clause, the Fifth Amendment or other provisions of the Constitution or under statutes other than the Federal hazardous material transportation law unless it is necessary to do so in order to determine whether a requirement is authorized by another Federal law. A State, local or Indian tribe requirement is not authorized by another Federal law merely because it is not preempted by another Federal statute. *Colorado Pub. Util. Comm'n* v. *Harmon,* above, 951 F.2d at 1581 n.10.

In making preemption determinations under 49 U.S.C. 5125(d), RSPA is guided by the principles and policies set forth in Executive Order No. 13132, entitled ''Federalism'' (64 FR 43255 (August 4, 1999)). Section 4(a) of that Executive Order authorizes preemption of State laws only when a statute contains an express preemption provision, there is other clear evidence that Congress intended to preempt State law, or the exercise of State authority directly conflicts with the exercise of Federal authority. Section 5125 contains express preemption provisions, which RSPA has implemented through its regulations.

IV. Public Comments

All comments should be limited to the issue of whether 49 U.S.C. 5125 preempts the Commonwealth of Massachusetts' definitions of hazardous materials challenged by Boston & Maine. Comments should specifically address the preemption criteria detailed in Part II, above, and should include the following:

(1) whether the term ''hazardous material'' in Massachusetts General Laws chapter 21K includes materials that are not defined as ''hazardous materials'' in the HMR, 49 CFR 171.8 (examples?);

(2) whether the term ''hazardous material'' in Massachusetts General Laws chapter 21K excludes materials that are defined as ''hazardous materials'' in the HMR, 49 CFR 171.8 (examples?);

(3) whether the term ''hazardous material'' in Massachusetts General Laws chapter 21E includes materials that are not defined as ''hazardous materials'' under the HMR, 49 CFR 171.8 (examples?);

(4) whether the term ''hazardous material'' in Massachusetts General Laws chapter 21E excludes materials that are defined as ''hazardous materials'' in the HMR, 49 CFR 171.8 (examples?); and

(5) whether and how the two cited Massachusetts definitions of ''hazardous material'' are applied and enforced by Massachusetts with respect to transportation.

Persons intending to comment should review the standards and procedures governing consideration of applications for preemption determinations set forth at 49 CFR 107.201–107.211, and 397.201–397.211.

Issued in Washington, DC on November 13, 2000.

Robert A. McGuire,

Associate Administrator for Hazardous Materials Safety.

Boston & Maine Corporation

August 16, 2000.

Associate Administrator for Hazardous Materials Safety

Research and Special Programs Administration, U.S. Department of Transportation, Washington, DC 20590–0001; Attention: Hazardous Materials Preemption Docket.

Re: APPLICATION FOR PREEMPTION DETERMINATION

Dear Sir/Madam: Please consider the attached Boston and Maine Railroad's Application for a Preemption Determination filed pursuant to 49 C.F.R. 107.203 for final determination by the Research and Special Programs Administration.

Boston and Maine Railroad (hereinafter ''B&M'') disputes the enforcement of ''hazardous'' materials designations by the Commonwealth of Massachusetts under M.G.L. c.21K, and c.21E. B&M contends the Commonwealth is preempted from enforcing the statute by the Hazardous Materials Transportation Act (hereinafter ''HMTA'') laws because the ''hazardous'' materials designation is not substantively the same as HMTA regulations.

The attached petition contains the following:

49 C.F.R. 107.203(b)(2): Text of the State Requirement;

49 C.F.R. 107.203(b)(3): Comparable Federal Hazardous Material Transportation Laws;

49 C.F.R. 107.203(b)(4): Explanation of Why the State Law Should Be Preempted;

49 C.F.R. 107.203(b)(5): Statement of How the State Regulations Affected Boston and Maine Railroad; and

49 C.F.R. 107.205(a): Certification of Notice Compliance.

A copy of this application will be forwarded to each party subject to this ruling. Should you have any questions, please contact me at (978) 663–1029. Thank you for your attention to this matter.

Sincerely,

Robert B. Culliford,

Corporate Counsel.

cc: Ginny Sinkel, Asst. Attorney General, Thomas Reilly, Attorney General.

49 C.F.R. 107.203(b)(2): Text of State Requirements

(Please see corresponding attached copies.)

1. MGL C. 21K, section 1, definition
2. MGL C. 21E, section 2, definition

49 C.F.R. 107.203(b)(3): Comparable Federal Hazardous Materials Transportation Laws

(Please see corresponding attached copies.)

Hazardous Materials Transportation Act (HMTA)

1. 49 C.F.R. 107.202(b)(2)
2. 49 C.F.R. 107.202(a)(1)
3. 49 C.F.R. 107.202(d)
4. 49 U.S.C. 5103(a)

5. 49 C.F.R. 171.8

6. 49 C.F.R. 172.101, App. A, List of Hazardous Substances and Reportable Quantities.

49 CFR 107.203(b)(4): Explanation of Why RSPA Should Issue Preemption Determination

Pursuant to 49 C.F.R. 107.203, the applicant respectfully submits this application for a determination by the Research and Special Programs Administration (hereinafter ''RSPA'') that Massachusetts General Laws c. 21K, section 1, section 21E, and section 2 [1] (see attached hereto), as these State laws apply to transportation in interstate commerce, are preempted by the Hazardous Materials Transportation Act, 49 U.S.C. 5101, *et. seq.* (hereinafter ''HMTA''). The basis for this request is that these statutes designate ''hazardous'' materials in a manner that is not substantively the same as the designation of ''hazardous'' materials in a manner that is not substantively the same as the designation of ''hazardous'' materials promulgated by the Secretary of Transportation pursuant to his authority under the HMTA.[2] (see attached hereto). In addition, the B&M also requests a determination that the regulation of transportation in interstate commerce by means of a designation of ''hazardous'' materials that is not substantively the same as the designation promulgated by the Secretary is an obstacle to accomplishing and carrying out the Hazardous materials transportation law.

1. A Preemption Determination Should Be Issued in This Instance Because the Plain Language of the HMTA Expressly Preempts Any State Designation, Description and Classification of ''Hazardous'' Material That Is Not Substantively the Same as the Federal Designation Under the HMTA

The Associate Administrator should issue a determination that M.G.L.A. c. 21K, section 1 and 21E, section 2 are preempted because the plain language of the HMTA expressly preempts any State designation of ''hazardous'' material when the non-Federal designation is not substantively the same as the Federal designation, unless the non-Federal designation is authorized by Federal law. 49 C.F.R. 107.202(a)(1).[3] (see attached hereto). In this instance, 49 C.F.R. 107.202(d) defines ''substantively the same'' to mean ''that the non-Federal requirement conforms in every significant respect to the Federal requirement. Editorial and other similar de minimis changes are permitted.''

The Massachusetts designations of ''hazardous'' material in M.G.L. c. 21K, section 1 and c.21E, section 2, include, ''material, in whatever form which, . . . constitutes a present or potential threat to human health, safety, or welfare, or to the environment, when improperly stored, treated, transported, disposed of, used, or otherwise managed. Hazardous materials shall include, *but not be limited to,* all substances which are included under 42 U.S.C. 9601(14).'' Mass. Gen. Laws c. 21K section 1, Mass. Gen. Laws c. 21E, section 2 (emphasis added). The Massachusetts regulations greatly expand the Federal designation of ''hazardous'' materials to include substances that have not been designated as ''hazardous'' materials by the Secretary pursuant to 49 U.S.C. 5103(a) and 49 C.F.R. 171.8. As a result, the State law designation of ''hazardous'' materials does not conform in every significant respect to the Federal designation because these State law designations include materials not determined by the Secretary to be capable of posing an unreasonable risk to health, safety, and property when transported in commerce, and which have been so designated as ''hazardous'' materials by the Secretary. 49 C.F.R. 171.8. Accordingly, the Massachusetts designations are not substantively the same as the Federal designation of ''hazardous'' materials. 49 C.F.R. 107.202(d). Therefore, in light of the fact that the application of these State law designations to transportation in interstate commerce is not authorized by Federal law, it is clear that these State statutes, as they apply to transportation in interstate commerce, are preempted.

2. A Preemption Determination Should Be Issued in This Instance Pursuant to 49 C.F.R. 107.202(b)(2) Because the State Law Designations of ''Hazardous'' Materials as Applied and Enforced Creates an Obstacle to Carrying Out the HMTA

The Associate Administrator should also issue a determination that these State law designations are preempted pursuant to 49 C.F.R 107.202(b)(2) [4] (see attached hereto) because the designations contained therein create obstacles to the efficient and uniform application of the HMTA. The obstacle test as determined by the Supreme Court, examines whether the State law ''stands as an obstacle to the accomplishment and execution of the full purpose and objectives of Congress.'' *Colorado Public Utilities Commission* v. *Harmon*, 951 F.2d 1571, 1580 (10th Cir. 1991) (quoting *Hillsborough County* v. *Automated Medic. Labs*, 471 U.S. 707, 713, 105 S.Ct. 2371, 2375, 85 L.Ed. 2d 714(1985)). The original intent of Congress in enacting the HMTA stressed the importance of uniform safety requirements in interstate transport of hazardous materials and authorized the Department of Transportation to preclude State and local regulations from creating conflicts and variances from Federal regulations. *Colorado Public Utilities Comm.* v. *Harmon*, 951 F.2d at 1580 (analyzing Congressional intent through H.R. Rep No. 444 (Part 1), 101st Cong., 2d Ses., at 22 (1990), and S.Rep. No. 449, 101st Cong., 2d Sess., at 2 (1990)).

The regulations promulgated by the Secretary designating ''hazardous'' materials include extensive lists of substances and quantities that fall under HMTA regulation. See 49 C.F.R. 107.101, Appendix A (attached hereto). Likewise, Massachusetts has also promulgated statewide regulation of ''hazardous'' materials under the designations found in M.G.L.A. c. section 21K, section 1 and c. 21E, section 2.

The Secretary is authorized to designate certain materials as ''hazardous'' by 49 U.S.C. 5103(a). Pursuant to this authority, the Secretary has determined which materials are capable of posing an unreasonable risk to health, safety, and property when transported in commerce, and has promulgated regulations designating those materials as ''hazardous''. 49 C.F.R. 171.8.

Where State regulations designate materials as ''hazardous'' that are not

[1] MGL c. 21K, section 1, defines ''Hazardous'' Materials as follows: ''Hazardous material'', material including, but not limited to, material, in whatever form which, because of its quantity, concentration, chemical, corrosive, flammable, reactive, toxic, infectious or radioactive characteristics, either separately or in combination with a substance, constitutes a present or potential threat to human health, safety or welfare or to the environment when improperly stored, treated, transported, disposed of, used or otherwise managed. Hazardous materials shall include, but not be limited to, oil and all substances which are included under 42 U.S.C. Sec. 9601(14)

MGL c. 21E, section 2, defines ''Hazardous'' Materials as follows: ''Hazardous material'', material including but not limited to, any material, in whatever form, which, because of its quantity, concentration, chemical, corrosive, flammable, reactive, toxic, infectious or radioactive characteristics, either separately or in combination with any substance or substances, constitutes a present or potential threat to human health, safety, welfare, or to the environment, when improperly stored, treated, transported, disposed of, used, or otherwise managed. The term shall not include oil. The term shall not include oil. The term shall also include all those substances which are included under 42 U.S.C. Sec. 9601(14), but it is not limited to those substances.

[2] 49 U.S.C. 5103(a) states: Designating material as hazardous—The Secretary of Transportation shall designate material (including an explosive, radioactive material, etiologic agent, flammable or combustible liquid or solid, poison, oxidizing or corrosive material, and compressed gas) or a group or a class of material as hazardous when the Secretary decides that transporting the material in commerce in a particular amount and form may pose an unreasonable risk to health and safety of property.

49 C.F.R. 171.8 defines ''Hazardous'' Materials as follows: Hazardous material means a substance or material, which has been determined by the Secretary of Transportation to be capable of posing an unreasonable risk to health, safety, and property when transported in commerce, and which has been so designated. The term includes hazardous substances, hazardous wastes, marine pollutants, and elevated temperature materials as defined in this section, materials designated as hazardous under the provisions of § 172.101 of this subchapter, and materials that meet the defining criteria for hazard classes and divisions in part 173 of this subchapter.

[3] 49 C.F.R. 107.202(a)(1): Standards for determining preemption:

(a): Except as provided in § 107.221 and unless authorized by Federal law, any requirement of a State, political subdivision thereof or Indian tribe, that concerns one of the following subjects and that is not substantively the same as any provision of the Hazardous materials transportation law, this subchapter or subchapter C that concerns that subject, is preempted:

(1) The designation, description, and classification of hazardous material.

[4] 49 C.F.R. 107.202(b)(2) states the following:

(b) Except as provided in § 107.221 and unless otherwise authorized by Federal law, any requirement of a State or political subdivision or Indian tribe is preempted if—

(2) The requirement of the State, political subdivision, or Indian tribe, as applied or enforced, is an obstacle to accomplishing and carrying out the Federal hazardous materials transportation law or regulations issued thereunder.

included as materials designated ''hazardous'' by the Secretary, this discrepancy subjects interstate carriers to undue burdens and creates myriad obstacles to uniform regulation of transportation of those materials in interstate commerce. Here, the overly broad State designation of ''hazardous'' materials potentially subjects common carriers to a multitude of different regulations because each State could have different standards requiring additional packaging requirements, labeling, storage, and documentation for a host of substances based upon the designation of ''hazardous'' material adopted by each individual State.

Subjecting the railroad and other interstate carriers to different designations in each State disrupts the congressional purpose of promoting uniform regulation of the safe transportation of hazardous materials under HMTA. RSPA should therefore issue a determination preempting the enforcement of M.G.L.A. c. 21K, section 1, and c. section 21E, section 2, as they apply to transportation in interstate commerce, because the designations contained in these statutes are not authorized by Federal law, and create multiple obstacles to the uniform enforcement of HMTA and unduly burdens interstate transportation of hazardous materials.

49 CFR 107.203(b)(5): Statement of How the State Regulations Affect the Applicant

The designation of ''hazardous'' contained State laws such as Mass. Gen. Laws Ann. c. 21K, section 1 and c. 21E, section 2, subjects the applicant to overly broad and disjointed regulation of transportation in interstate commerce by potentially requiring the applicant to adhere to markedly different regulations in each State in which it operates. Accordingly, subjecting the applicant to the different ''hazardous materials'' regulations and requirements of each State in which it operates would unduly burden interstate transport of materials by railroad in interstate commerce.

Respectfully submitted,

Robert B. Culliford,
James J. Steinkrauss,
Boston and Maine Corporation, Iron Horse Park, North Billerica, MA 01862, (978) 663–1029.

[FR Doc. 00–29400 Filed 11–15–00; 8:45 am]
BILLING CODE 4910–60–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for the Survey for the 2001 Electronic Tax Administration Attitudinal Tracking Study

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning the Survey for the 2001 Electronic Tax Administration Attitudinal Tracking Study.

DATES: Written comments should be received on or before January 16, 2001 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the survey should be directed to Carol Savage, (202) 622–3945, Internal Revenue Service, room 5242, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Survey for the 2001 Electronic Tax Administration Attitudinal Tracking Study.

OMB Number: 1545–1587.

Abstract: This is a survey for quantitative research to establish changes to baseline measures of public knowledge and acceptance of Electronic Tax Administration (ETA) programs. The data developed in this research will be used as a guide when making decisions on the development of future ETA products and effective marketing techniques. The survey will provide the level of detail needed to focus product development efforts and enhance current products. This information will be used to make quality improvements to products and services.

Current Actions: There are no changes being made to the survey at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals.

Estimated Number of Respondents: 1,100.

Estimated Time Per Respondent: 15 minutes.

Estimated Total Annual Burden Hours: 275. The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: October 31, 2000.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 00–29272 Filed 11–15–00; 8:45 am]
BILLING CODE 4830–01–U

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[INTL–112–88]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, INTL–112–88 (TD 8337), Allocation and Apportionment of Deduction for State Income Taxes (Section 1.861–8(e)(6)).

DATES: Written comments should be received on or before January 16, 2001 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be directed to Martha R. Brinson, (202) 622–3869, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Allocation and Apportionment of Deduction for State Income Taxes.

OMB Number: 1545–1224

Regulation Project Number: INTL–112–88

Abstract: This regulation provides guidance on when and how the deduction for state income taxes is to be allocated and apportioned between gross income from sources within and without the United States in order to determine the amount of taxable income from those sources. The reporting requirements in the regulation affect those taxpayers claiming foreign tax credits who elect to use an alternative method from that described in the regulation to allocate and apportion deductions for state income taxes.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 1,000.

Estimated Time Per Respondent: 1 hr.

Estimated Total Annual Burden Hours: 1,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 1, 2000.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 00–29273 Filed 11–15–00; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[REG–251698–96]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, REG–251698–96 (TD 8869), Subchapter S Subsidiaries (§§ 1.1361–3, 1.1361–5, and 1.1362–8).

DATES: Written comments should be received on or before January 16, 2001 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be directed to Carol Savage, (202) 622–3945, Internal Revenue Service, room 5242, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Subchapter S Subsidiaries.

OMB Number: 1545–1590.

Regulation Project Number: REG–251698–96.

Abstract: This regulation relates to the treatment of corporate subsidiaries of S corporations and interprets the rules added to the Internal Revenue Code by section 1308 of the Small Business Job Protection Act of 1996. The collection of information required in the regulation is necessary for a taxpayer to obtain, retain, or terminate S corporation treatment.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, individuals, and farms.

Estimated Number of Respondents/Recordkeepers: 10,660.

Estimated Time per Respondent/Recordkeeper: 57 minutes.

Estimated Total Annual Reporting/Recordkeeping Burden Hours: 10,110.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 7, 2000.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 00–29274 Filed 11–15–00; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[LR–236–81]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, LR–236–81 (TD 8251), Credit for Increasing Research Activity (Section 1.41–8(d)).

DATES: Written comments should be received on or before January 16, 2001 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be directed to Martha R. Brinson, (202) 622-3869, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Credit for Increasing Research Activity.

OMB Number: 1545–0732.

Regulation Project Number: LR–236–81.

Abstract: This regulation provides rules for the credit for increasing research activities. Internal Revenue Code section 41(f) provides that commonly controlled groups of taxpayers shall compute the credit as if they are a single taxpayer. The credit allowed to a member of the group is a portion of the group's credit. Section 1.41–8(d) of the regulation permits a corporation that is a member of more than one group to designate which controlled group they will be aggregated with for purposes of Code section 41(f).

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 250.

Estimated Time Per Respondent: 15 hr.

Estimated Total Annual Burden Hours: 63.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

REQUEST FOR COMMENTS: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 1, 2000.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 00–29275 Filed 11–15–00; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[REG–209835–86]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, REG–209835–86 (TD 8708), Computation of Foreign Taxes Deemed Paid Under Section 902 Pursuant to a Pooling Mechanism for Undistributed Earnings and Foreign Taxes (§ 1.902–1).

DATES: Written comments should be received on or before January 16, 2001 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be directed to Larnice Mack, (202) 622–3179, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Computation of Foreign Taxes Deemed Paid Under Section 902 Pursuant to a Pooling Mechanism for Undistributed Earnings and Foreign Taxes.

OMB Number: 1545–1458.

Regulation Project Number: Reg–209835–86 (formerly INTL–933–86).

Abstract: This regulation provides rules for computing foreign taxes deemed paid under Internal Revenue Code section 902. The regulation affects foreign corporations and their United States corporate shareholders that own directly at least 10% of the voting stock of the foreign corporation.

Current Actions: There are no changes being made to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

The burden for the collection of information is reflected in the burden for Form 1118, Foreign Tax Credit-Corporations.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

REQUEST FOR COMMENTS: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 2, 2000.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 00–29276 Filed 11–15–00; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 3520

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 3520, Annual Return To Report Transactions With Foreign Trusts and Receipt of Certain Foreign Gifts.

DATES: Written comments should be received on or before January 16, 2001 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Carol Savage, (202) 622–3945, Internal Revenue Service, room 5242, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Annual Return To Report Transactions With Foreign Trusts and Receipt of Certain Foreign Gifts.

OMB Number: 1545–0159.

Form Number: 3520.

Abstract: Form 3520 is filed by U.S. persons who create a foreign trust, transfer property to a foreign trust, receive a distribution from a foreign trust, or receive large gifts from a foreign source. IRS uses the form to identify U.S. persons who have transactions that may trigger a taxable event in the future.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 2,000.

Estimated Time Per Respondent: 53 hours, 56 minutes.

Estimated Total Annual Burden Hours: 107,880.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

REQUEST FOR COMMENTS: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 3, 2000.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 00–29277 Filed 11–15–00; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 4506

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 4506 Request for Copy or Transcript of Tax Form.

DATES: Written comments should be received on or before January 16, 2001 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Larnice Mack, (202) 622–3179, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Request for Copy or Transcript of Tax Form.

OMB Number: 1545–0429.

Form Number: Form 4506.

Abstract: Internal Revenue Code section 7513 allows taxpayers to request a copy of a tax return or related documents. Form 4506 is used for this purpose. The information provided will be used for research to locate the tax form and to ensure that the requestor is the taxpayer or someone authorized by the taxpayer to obtain the documents requested.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 914,540.

Estimated Time Per Respondent: 1 hr., 2 min.

Estimated Total Annual Burden Hours: 941,977.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

REQUEST FOR COMMENTS: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 1, 2000.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 00–29278 Filed 11–15–00; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 1310

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 1310, Statement of Person Claiming Refund Due a Deceased Taxpayer.

DATES: Written comments should be received on or before January 16, 2001 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Larnice Mack, (202) 622–3179, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Statement of Person Claiming Refund Due a Deceased Taxpayer.

OMB Number: 1545–0073.

Form Number: Form 1310.

Abstract: Form 1310 is used by a claimant to secure payment of a refund on behalf of a deceased taxpayer. The information requested on the form enables the IRS to send the refund to the correct person.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 7,500.

Estimated Time Per Respondent: 41 min.

Estimated Total Annual Burden Hours: 5,100.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

REQUEST FOR COMMENTS: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 1, 2000.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 00–29279 Filed 11–15–00; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Forms 8275 and 8275–R

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8275, Disclosure Statement, and Form 8275–R, Regulation Disclosure Statement.

DATES: Written comments should be received on or before January 16, 2001 to be assured of consideration.

ADDRESSES: Direct all written comments to Garrick R. Shear, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the forms and instructions should be directed to Faye Bruce, (202) 622–6665, Internal Revenue Service, room 5244, 1111 Constitution Avenue NW., Washington, DC 20224.

SUPPLEMENTARY INFORMATION:

Title: Disclosure Statement (Form 8275) and Regulation Disclosure Statement (Form 8275–R).

OMB Number: 1545–0889.

Form Number: Forms 8275 and 8275–R.

Abstract: Internal Revenue Code section 6662 imposes accuracy-related penalties on taxpayers for substantial understatement of tax liability or negligence or disregard of rules and regulations. Code section 6694 imposes similar penalties on return preparers. Regulations sections 1.662–4(e) and (f) provide for reduction of these penalties if adequate disclosure of the tax treatment is made on Form 8275 or, if the position is contrary to a regulation, on Form 8275–R.

Current Actions: There are no changes being made to the forms at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profit organizations, individuals, not-for-profit institutions, and farms.

Estimated Number of Responses: 1,000,000.

Estimated Time Per Response: 5 hr., 35 min.

Estimated Total Annual Burden Hours: 5,575,000.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

REQUEST FOR COMMENTS: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: October 31, 2000.

Garrick R. Shear,

IRS Reports Clearance Officer.

[FR Doc. 00–29280 Filed 11–15–00; 8:45 am]

BILLING CODE 4830–01–U

Corrections

Federal Register

Vol. 65, No. 222

Thursday, November 16, 2000

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 600 and 660

[Docket No. 991223347-9347; I.D. 102600C]

Fisheries off West Coast States and in the Western Pacific; Pacific Coast Groundfish Fishery; Recreational Fishery Closure

Correction

In rule document 00–28534 beginning on page 66655 in the issue of Tuesday, November 7, 2000, make the following correction:

On page 66656, in the second column, in paragraph (1) (b), ''[insert date of filing for public inspection with the Office of the Federal Register]'' should read ''November 2, 2000''.

[FR Doc. C0–28534 Filed 11–15–00; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF DEFENSE

48 CFR Part 252, and Appendices E and F to Chapter 2

Defense Federal Acquisition Regulation Supplement; Technical Amendments

Correction

In rule document 00–27243 beginning on page 63804 in the issue of Wednesday, October 25, 2000 make the following correction:

252.247–7015 [Corrected]

On page 63805 in Table 2, under the heading ''Address'', in the fourth line, ''CAO address otherwise specified in the contract'' should read ''CAO address unless otherwise specified in the contract''.

[FR Doc. C0–27243 Filed 11–15–00; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF DEFENSE

48 CFR Appendix F to Chapter 2

[DFARS Case 2000–D008]

Defense Federal Acquisition Regulation Supplement; Material Inspection and Receiving Report

Correction

In rule document 00–27246 beginning on page 63802 in the issue of Wednesday, October 25, 2000 make the following correction:

Chapter 2 to Appendix F–[Corrected]

On page 63803 in the third column, in paragraph (b)(1)(iii), in the fourth line ''SP'' should read ''SF''.

[FR Doc. C0–27246 Filed 11–15–00; 8:45 am]

BILLING CODE 1505–01–D

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 24645; 812-12242]

First American Investment Funds, Inc. and U.S. Bank National Association; Notice of Application

Correction

In notice document 00–24546 beginning on page 57631 in the issue of Monday, September 25, 2000, the docket number is corrected to read as set forth above.

[FR Doc. C0–24546 Filed 11–15–00; 8:45 am]

BILLING CODE 1505–01–D

SECURITIES AND EXCHANGE COMMISSION

[Release No. IC-24642; 812-11962]

Bill Gross' Idealab!; Notice of Application

Correction

In notice document 00–24270 beginning on page 57211 in the issue of Thursday, September 21, 2000, the docket number is corrected to read as set forth above.

[FR Doc. C0–24270 Filed 11–15–00; 8:45 am]

BILLING CODE 1505–01–D

Federal Register

Thursday,
November 16, 2000

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 606 and 610

Current Good Manufacturing Practice for Blood and Blood Components; Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV Infection ("Lookback"); Proposed Rule

Health Care Financing Administration

42 CFR Part 482

Medicare and Medicaid Programs; Hospital Conditions of Participation: Laboratory Services; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 606 and 610

[Docket No. 99N–2337]

RIN 0910–AB76

Current Good Manufacturing Practice for Blood and Blood Components; Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV Infection (''Lookback'')

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the biologics regulations to require that blood establishments (including plasma establishments) prepare and follow written procedures for appropriate action when it is determined that blood and blood components at increased risk of transmitting hepatitis C virus (HCV) infection have been collected from a donor who tested repeatedly reactive for evidence of HCV infection at a later date. This proposed rule would require blood establishments to quarantine prior collections from such a donor, perform further testing on the donor, and notify transfusion recipients, as appropriate, when such a donor is identified at the time of a repeat donation or after performing a review of historical testing records to identify donations at increased risk of transmitting HCV. In addition, FDA is proposing to extend the record retention period to 10 years to create opportunities for disease prevention many years after recipient exposure to such a donor. This action is taken as part of FDA's ''Blood Initiative'' to comprehensively review and, as necessary, revise its regulations, policies, guidances, and procedures related to the licensing and regulation of blood products. This proposed rule is intended to help ensure the continued safety of the blood supply and to help ensure that information is provided to consignees and to prior recipients of blood and blood components from a donor whose subsequent donation tests positive for antibody to HCV or otherwise is determined to have been at increased risk of transmitting HCV.

DATES: Submit written comments on the proposed rule by February 14, 2001. Submit written comments on the information collection provisions by December 18, 2000. See section VII of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Sharon A. Carayiannis, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

A. Blood Initiative

For a variety of reasons FDA has decided to comprehensively review and, as necessary, revise its regulations, policies, guidance, and procedures related to the licensing and regulation of blood products. In the **Federal Register** of June 3, 1994 (59 FR 28821 and 59 FR 28822, respectively), FDA issued two documents entitled ''Review of General Biologics and Licensing Regulations'' (Docket No. 94N–0066) and ''Review of Regulations for Blood Establishments and Blood Products'' (Docket No. 94N–0080). These two documents announced the agency's intent to review biologics regulations in 21 CFR parts 600, 601, 606, 607, 610, 640, and 660 (21 CFR 600, 601, 606, 607, 610, 640, and 660) and requested written comments from the public. Interested persons were given until August 17, 1994, to respond to the documents. In response to requests for additional time, FDA twice extended the comment period, as announced in the **Federal Register** of August 17, 1994 (59 FR 42193), and November 14, 1995 (59 FR 56448). In addition, FDA responded to requests for a public meeting to allow for the presentation of comments regarding the agency's intent to review the biologics regulations. On January 26, 1995, FDA held a public meeting to provide an opportunity for all interested individuals to present their comments and to assist the agency in determining whether the regulations should be revised, rescinded, or continued without change. Since the time of the regulation review, FDA has implemented a number of changes to its regulations and policies applicable to the general biologics and licensing regulations, some of which applied to blood products as well as other biological products. (See, *e.g.,* the final rules issued on May 14, 1996 (61 FR 24313); August 1, 1996 (61 FR 40153); November 6, 1996 (61 FR 57328); July 24, 1997 (62 FR 39890); and October 15, 1997 (62 FR 53536)).

Because of the importance of a safe national blood supply, the U.S. House of Representatives Committee on Government Reform and Oversight, Subcommittee on Human Resources and Intergovernmental Relations (the Subcommittee) and other groups such as the General Accounting Office (GAO), and the Institute of Medicine (IOM) have reviewed the agency's policies, practices, and regulations. Reports issued following the respective reviews made a number of recommendations as to how FDA might improve the biologics regulations, particularly as they apply to the continued safety of blood products. The relevant reports are: (1) ''Protecting the Nation's Blood Supply From Infectious Agents: The Need for New Standards to Meet New Threats,'' by the Subcommittee (August 2, 1996); (2) ''Blood Supply: FDA Oversight and Remaining Issues of Safety,'' by GAO (February 25, 1997); (3) ''Blood Supply: Transfusion-Associated Risks,'' by GAO (February 25, 1997); and (4) ''HIV and the Blood Supply: An Analysis of Crisis Decisionmaking,'' by IOM (July 13, 1995). These reports are on file with the Dockets Management Branch (address above) under the docket number given in the heading of this document.

FDA has reviewed these reports and agrees with the majority of the recommendations contained within them. However, rather than only responding specifically to the recommendations from the Subcommittee, GAO, IOM, and the public, FDA convened a number of internal task forces to review a variety of issues related to the regulation of blood and blood products, including how to most appropriately update the existing regulations applicable to blood and blood products. In the future, FDA intends to issue a number of blood-related rulemakings that various FDA task groups are currently preparing. FDA is not describing the specific recommendations it has received and the numerous objectives of the Blood Initiative in this document. Future rulemaking and other notices will describe and discuss specific recommendations and regulatory objectives.

B. Existing Donor Screening and Testing Requirements

FDA has developed five ''layers of safety'' to help ensure a safe blood supply: Donor screening, donor deferral registries, testing blood, blood quarantining, and monitoring and investigating problems. The five layers of safety are designed to overlap so that they will prevent the distribution of blood and blood products that are at increased risk of transmitting communicable disease agents such as human immunodeficiency virus (HIV) and hepatitis B virus (HBV). With regard to screening donors and testing blood, FDA has defined an extensive system of donor screening and testing procedures, two of the five layers of safety, performed by blood establishments. These procedures include the initial screening of individuals that volunteer to donate blood using a questionnaire, interview, and physical examination. This initial screening process is designed to protect the donor and to establish whether the donor is in good health, to rule out possible exposure to disease, such as through travel to an area endemic for malaria, or through close contact with an infected individual, and to identify whether the donor has engaged in behavior that would indicate increased risk of a communicable disease. Individuals who satisfactorily answer the questionnaire, pass the physical examination, and then donate blood are further screened by laboratory testing for evidence of infection due to communicable disease agents such as HIV and HBV. In the **Federal Register** of August 19, 1999 (64 FR 45340), FDA issued a proposed rule entitled ''Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents'' (hereinafter referred to as the testing proposed rule), to update, revise, and redesignate the testing requirements of § 610.45. The relevance of the testing proposed rule to this proposed rule is discussed in section III of this document.

As a result of the extensive screening and testing procedures and the other layers of safety, the risk of transmitting infection through blood transfusion is very low. Despite the best practices of blood establishments, however, a person may donate blood early in infection, during the period when the testable marker is not detectable by a screening test, but the infectious agent is present in the donor's blood (a ''window'' period). For example, if a donor donates blood on a number of occasions and each donation tests negative for antibody to HIV, but the donor returns and tests repeatedly reactive for antibody to HIV at a later date, prior collections from such a donor would be at increased risk of transmitting HIV. In addition, a recipient of a transfusion of blood or blood components collected during the ''window'' period would not know that he or she may have become infected with HIV through the transfusion unless notified.

Under such circumstances, FDA requires clarification of the donor's status and procedures to ''lookback'' at prior collections, as specified in §§ 610.46 and 610.47 (the HIV ''lookback'' regulations). (See the final rule issued in the **Federal Register** of September 9, 1996 (61 FR 47413).) The HIV ''lookback'' regulations require facilities involved in the collection, processing, and administration of blood to quarantine blood and blood components which were collected from a donor who tested negative at the time of previous donations but subsequently tests repeatedly reactive for antibody to HIV. The regulations require blood establishments to inform consignees (e.g., hospital transfusion services and manufacturers of plasma derivatives) of the collection and distribution of such previously donated blood and blood components, to perform further testing on the donor, and to notify transfusion recipients, as appropriate.

C. History of HCV Testing

HCV frequently causes a clinically inapparent, but chronic infection of the liver. Approximately 4 million individuals in the United States are believed to be chronically infected with HCV. Despite progression of disease, HCV infection is usually asymptomatic for about 20 years, but in many cases causes serious liver injury that is thought to be the leading cause of late stage cirrhosis and liver failure in the United States and to play a significant role in the development of liver cancer. Therapy with licensed interferon produces long-term benefit in only about 15 percent of cases, but a newly available therapeutic modality, combination therapy using interferon plus ribavirin, may improve this outcome.

The greatest risk for transmission of HCV is through direct percutaneous exposure to infectious blood, such as through transfusion of infectious blood or blood products, sharing of contaminated equipment among injection drug users, or transplantation of organs or tissues from infectious donors. Hemodialysis patients and health-care workers exposed to needle sticks in the occupational setting are also at risk for exposure to infectious blood. Direct percutaneous exposures to infectious blood, particularly in the setting of drug abuse, account for the majority of HCV infections acquired in the United States (Ref. 1). The incidence of transfusion transmitted HCV infection has decreased markedly since the implementation of donor screening for HCV and viral inactivation of clotting factors and intravenous immune globulins. However, approximately 7 percent of the 3.9 million Americans believed to be chronically infected with HCV were infected as a result of transfusion of blood components prior to the availability of donor screening tests or due to past use of nonviral-inactivated plasma derivative products (Ref. 2).

HCV was established as a causative agent of transfusion associated hepatitis only since its discovery in the late 1980's. In October 1989, FDA's Blood Products Advisory Committee (BPAC) first discussed ''lookback'' for HCV, prior to the availability of donor screening tests for HCV. BPAC advised that there was insufficient information available concerning HCV infection to propose either product quarantine or notification of recipients transfused with products prepared from prior collections from donors later determined to be at increased risk for transmitting HCV. Blood establishments implemented donor screening tests after a single antigen, enzyme linked immunosorbent assay (EIA) for antibody to HCV (HCV EIA 1.0 screening test) was licensed in May 1990. FDA issued a memorandum to all registered blood establishments in November 1990, entitled ''Testing for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV),'' recommending use of approved donor screening tests for antibody to HCV. A ''lookback'' program was not recommended because: (1) Screening tests available at the time could not distinguish between ongoing infection and recovery, and thus, the meaning of a reactive test result for any one individual was not clear; (2) donor screening for antibody to HCV did not include confirmatory testing and most notifications would have been based on false-positive donor test results; (3) there was limited knowledge of routes of transmission for HCV other than parenteral; and (4) no potential long-term benefits of therapy were known.

A significantly more sensitive multiantigen screening test (HCV EIA 2.0 screening test) was licensed in March 1992. In June 1993, FDA licensed an HCV 2.0 strip immunoblot assay (HCV RIBA 2.0), a supplemental (additional, more specific) test for antibody to HCV. Supplemental tests for

antibody to HCV are used to distinguish false positive from true positive repeatedly reactive screening test results. Except for tests available for investigational use, supplemental tests for antibody to HCV have only been available since the HCV RIBA 2.0 supplemental test was licensed in June 1993.

In an August 1993 memorandum to all registered blood establishments entitled ''Revised Recommendations for Testing Whole Blood, Blood Components, Source Plasma and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV),'' FDA did not recommend a ''lookback'' program pending the outcome of discussions on the issue at the December 1993 BPAC meeting. Following the discussions on HCV at the meeting in December 1993, BPAC unanimously recommended product quarantine of prior collections from a donor who later tests repeatedly reactive for antibody to HCV and tests positive or indeterminate on a supplemental test, but only marginally endorsed consignee notification for the purpose of transfusion recipient notification, and reiterated many of the reservations regarding the lack of an established public health benefit in performing this activity. FDA issued a memorandum to all registered blood establishments in July 1996 entitled ''Recommendations for the Quarantine and Disposition of Units from Prior Collections from Donors with Repeatedly Reactive Screening Tests for Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and Human T-Lymphotropic Virus Type I (HTLV–I).'' The July 1996 memorandum recommended testing, consignee notification, and quarantine of affected products but did not provide recommendations for the notification of recipients of such donations because the public health benefit of such notification was not clear.

The Public Health Service Advisory Committee on Blood Safety and Availability (the PHS Advisory Committee) discussed improvements in the treatment and management of HCV infection and improvements in testing for antibody to HCV at public meetings held on April 24 and 25, 1997, and August 11 and 12, 1997. The PHS Advisory Committee also discussed the public health benefits of notification of transfusion recipients receiving prior collections from a donor who subsequently tests repeatedly reactive for evidence of HCV infection. Following acceptance by the Department of Health and Human Services (DHHS) of recommendations for HCV ''lookback'' made in August of 1997 by the PHS Advisory Committee, FDA issued a notice in the **Federal Register** of March 20, 1998 (63 FR 13675), announcing the availability of a document entitled ''Guidance for Industry: Supplemental Testing and the Notification of Consignees of Donor Test Results for Antibody to Hepatitis C Virus (Anti-HCV)'' (the March 1998 guidance) in which FDA recommended that blood establishments implement HCV ''lookback'' procedures. In the March 1998 guidance, FDA recommended that donors currently testing repeatedly reactive for antibody to HCV in a licensed test be further tested for antibody to HCV using a licensed, multiantigen supplemental test. Additionally, FDA recommended that consignees of certain blood and blood components collected since January 1, 1988, which were anti-HCV negative or untested, be notified when donors subsequently test repeatedly reactive for anti-HCV in a licensed multiantigen screening test and reactive in a licensed or investigational supplemental test. This notification would enable recipients to be informed that they had been transfused with units that may have contained HCV so that they may obtain further medical counseling. The March 1998 guidance provided FDA's recommendations for donor screening, a review of past testing records, further testing for antibody to HCV, notification of consignees, and transfusion recipient notification and counseling by physicians regarding transfusion with blood or blood components at increased risk of transmitting HCV. The March 1998 guidance was intended to supplement the July 1996 memorandum.

In response to comments received, the March 1998 guidance was withdrawn on September 8, 1998, and FDA issued a revised guidance on October 21, 1998 (63 FR 56198, October 23, 1998) entitled ''Guidance For Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units from Prior Collections from Donors with Repeatedly Reactive Screening Tests for Hepatitis C Virus (HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Antibody to HCV (Anti-HCV),'' (the September 1998 guidance). The September 1998 guidance replaced the March 1998 guidance, and provided recommendations to enable quarantine and disposition of blood and blood components from prior collections from donors with repeatedly reactive screening test results. The September 1998 guidance was provided on the CBER Home Page for comment and implementation on September 23, 1999. Additionally, the guidance document was mailed to all blood establishments on November 20, 1998.

The September guidance addressed several significant comments and requests from industry: (1) FDA revised several time periods for ''lookback'' actions in response to concerns about impact on industry, the need for additional time for testing due to availability problems with certain test kits, and to allow time for the physician education to be completed (ensuring that counseling messages would be available for use in notification of recipients); (2) FDA clarified options for further testing with an HCV enzyme linked immunosorbent assay 3.0 (HCV EIA 3.0 screening test); (3) FDA made revisions to clarify recommendations on labeling of products released from quarantine and for consistency with existing regulations on product labeling; (4) FDA provided flow chart diagrams to assist industry in implementing procedures contained in the guidance; and (5) To permit easier, more rapid notification of the recipient, FDA recommended the option of transfusion services notifying the transfusion recipient directly as an alternative to notifying the transfusion recipient's physician of record.

At public meetings on November 24, 1998, and January 28, 1999, the PHS Advisory Committee reconsidered the issue of recipient notification related to repeatedly reactive results on the single antigen screening test. The PHS Advisory Committee recommended that targeted ''lookback'' should be initiated based on a repeatedly reactive HCV EIA 1.0 screening test result on a repeat donor unless a supplemental test was performed and the result did not indicate increased risk of HCV infection, or, in the absence of a supplemental test result, the signal to cut off (S/CO) value of the repeatedly reactive HCV EIA 1.0 screening test was less than 2.5, or follow-up testing of the donor was negative. FDA published a notice in the **Federal Register** of June 22, 1999 (64 FR 33309), announcing the availability of a draft guidance entitled, ''Guidance For Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Prior Collections from Donors with Repeatedly Reactive Screening Tests for Hepatitis C Virus (HCV); (2) Supplemental Testing, and the Notification of Consignees and Transfusion Recipients of Donor Test Results for Antibody to HCV (Anti-HCV).'' Consistent with the

recommendations of the PHS Advisory Committee, this revised draft guidance addressed ''lookback'' actions related to donor screening by HCV EIA 1.0 and also recommended that the search of historical testing records of prior donations from donors with repeatedly reactive EIA 1.0, EIA 2.0, or EIA 3.0 screening tests for HCV should extend back indefinitely to the extent that electronic or other readily retrievable records exist. In addition, FDA revised the flow chart diagrams to reflect the changes to the guidance. FDA added specific recommendations for prior collections from a repeatedly reactive autologous donor and clarified recommendations on implementing ''lookback'' for repeatedly reactive plasma donations.

Based on comments submitted to the docket, FDA will revise the June 1999 draft guidance and issue a final guidance document for implementation. These comments and comments submitted on any additional guidance issued by the agency in the future will be considered in the preparation of the final rule for HVC ''lookback.''

In addition to these recommendations, FDA is proposing in § 610.40(c) of the testing proposed rule to require ''Each donation found to be repeatedly reactive by a screening test shall be further tested whenever a supplemental (additional, more specific) test has been approved for such use by FDA.''

II. Legal Authority

FDA is proposing to issue this new rule under the authority of sections 351 and 361 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262 and 264 *et seq.*) and the provisions of the Federal Food, Drug, and Cosmetic Act (the act) which apply to drugs (21 U.S.C. 201 *et seq.*). Under section 361 of the PHS Act, FDA may make and enforce regulations necessary to prevent the introduction, transmission, and spread of communicable disease between the States or from foreign countries into the States. (See Sec. I, 1966 Reorg. Plan No. 3 at 42 U.S.C. 202 for delegation of section 361 authority from the Surgeon General to the Secretary, Health and Human Services; see 21 CFR 510(a)(4) for delegation from the Secretary to the Food and Drug Administration.) Intrastate transactions may also be regulated under section 361. (See *Louisiana* v. *Mathew*, 427 F.Supp. 174, 176 (E.D.La. 1977).) A major purpose of the HCV ''lookback'' proposed rule is to prevent the introduction, transmission, and spread of HCV.

All blood and blood components introduced or delivered for introduction into interstate commerce also are subject to section 351 of the PHS Act (42 U.S.C. 262). Section 351(a) requires that manufacturers must have a license which has been issued upon a showing that the manufacturing establishment meets all applicable standards, prescribed in the biologics regulations, designed to insure the continued safety, purity, and potency of the blood and that the product is safe, pure, and potent.

FDA's license revocation regulations provide for the initiation of revocation proceedings, among other reasons, if the establishment or the product fails to conform to the standards in the license application or in the regulations designed to ensure the continued safety, purity, or potency of the product (§ 601.5). Section 351 of the PHS Act also provides for criminal penalties for violation of the laws governing biologics. Violations can be punishable by fines or imprisonment, or both.

The act also applies to biological products (42 U.S.C. 262(d), as amended). Blood and blood components are considered drugs, as that term is defined in section 201(g)(1) of the act (21 U.S.C. 321(g)(1)). (See *United States* v. *Calise*, 217 F.Supp. 705 (S.D.N.Y. 1962)). Because blood and blood components are drugs under the act, blood and plasma establishments must comply with the substantive provisions and related regulatory scheme of the act. Under section 501 of the act (21 U.S.C. 351), drugs are deemed ''adulterated'' if the methods used in their manufacturing, processing, packing or holding do not conform with current good manufacturing practices (CGMP's). Under the proposed HCV ''lookback'' rule, blood and plasma establishments would be required to develop standard operating procedures (SOP's) for HCV ''lookback'' quarantine of affected blood and blood components and consignee and transfusion recipient notification. A blood or plasma establishment that failed to comply with HCV ''lookback'' procedures would violate CGMP's and, therefore, would be subject to the act's enforcement provisions.

III. Highlights of the Proposed Rule

FDA and the Health Care Financing Administration (HCFA) are proposing steps designed to further protect the blood supply and to notify recipients of the possibility that they may have received blood or blood components contaminated with HCV. FDA's proposed rule, along with HCFA's companion proposed rule published elsewhere in this Federal Register, would require facilities involved in the collection, processing, and administration of blood to quarantine certain blood and blood components and to inform the consignee. The consignee, as appropriate, would inform the recipient's attending physician or the recipient, of the possibility that blood previously used for transfusion was obtained from a donor who subsequently tested repeatedly reactive for antibody to HCV. FDA believes that this proposed rule, in conjunction with HCFA's companion proposed rule will provide a more efficient means of notification.

As previously discussed in section I.C of this document, chronic hepatitis due to HCV is a major health problem in the United States because the infection is usually clinically silent, and infected people usually are unaware of their disease until serious damage has been caused to the liver. Although transfusion transmitted HCV infection accounts for only a small proportion of those infected with HCV, it is possible to identify and quarantine affected blood and blood components, perform further testing, and notify some transfusion recipients who have received blood from a donor later determined to be at increased risk of transmission of HCV. This process is commonly referred to as ''lookback.''

FDA is issuing this proposed rule for HCV ''lookback'' as a consequence of numerous public discussions, and extensive discussion within DHHS, of the benefits of notifying recipients of blood at increased risk of transmitting HCV. In parallel to this proposed rule, there will be a major PHS educational campaign on HCV aimed at both the medical community and the public. This proposed rule would establish requirements, similar to those now in effect for HIV ''lookback,'' to identify and quarantine prior collections later suspected as possible window period donations because they were collected from a donor who returned to donate and tested repeatedly reactive for evidence of HCV infection, and to notify transfusion recipients based on further testing of such a donor, as appropriate. In addition to HCV ''lookback'' requirements based on current testing that are similar to those for HIV and that are triggered when a donor returns to donate and tests repeatedly reactive on a screening test, this proposed rule would require a review of historical testing records to identify prior collections from donors at increased risk of transmitting HCV.

The review of historical testing records would extend back indefinitely for computerized electronic records, and to January 1, 1998, for other readily retrievable records.

The requirements for ''lookback'' activity based on multiantigen screening test results are handled in separate sections from those based on single antigen screening test results because the proposed requirements differ. For the purpose of this proposed rule, any reference to ''blood or blood components'' will include Source Leukocytes and Source Plasma unless specifically addressed. The proposal would not require quarantine of products that have already been pooled for further processing because the process of fractionation inactivates or removes the HCV. For the purpose of this proposed rule, any reference to blood establishments will include plasma establishments.

FDA is also proposing conforming amendments to certain provisions of §§ 610.46 and 610.47, the HIV ''lookback'' regulations. The proposed revisions to §§ 610.46 and 610.47 are discussed under the corresponding sections of this proposal and are intended to clarify and provide consistency between the HIV and HCV ''lookback'' requirements.

The proposed HCV ''lookback'' regulations are particular to the testing methodologies currently used. As testing technology continues to develop, the ''window'' period might vary with the testing methodology and FDA may determine that it is necessary to amend the final rule that results from this proposal. In this section III, FDA discusses each of the proposed requirements, the redesignation of certain regulations and revisions to existing requirements.

A. Related Rulemaking

As previously stated, in the **Federal Register** of August 19, 1999 (64 FR 45340), FDA issued, as part of the Blood Initiative, a proposed rule entitled ''Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents'' (the testing proposed rule). In the testing proposed rule, FDA proposed to revise the general biological product standards by adding testing requirements for HCV, and by adding requirements for performing a licensed, supplemental test when a donation is found to be repeatedly reactive for any of the required screening tests for evidence of infection due to communicable disease agents. The testing proposed rule would delete § 610.45, ''Human Immunodeficiency Virus (HIV) requirements,'' because its requirements would be included in the revision of proposed § 610.40. The use of the term ''repeatedly reactive'' in this rulemaking is consistent with the testing proposed rule, which states that ''according to the manufacturer's instructions, initially reactive samples are to be tested again, generally in duplicate, and a sample that is found to be reactive on any single retest (i.e., on one or more of the duplicate retests), is considered to be repeatedly reactive.'' Refer to the testing proposed rule for additional discussion of repeatedly reactive test results in section D., Further Testing. In § 610.40(a) and (c) of the testing proposed rule, FDA would revise the requirements for performance of donor screening tests and for supplemental testing of a donor who tests repeatedly reactive for evidence of infection due to a communicable disease agent, including HCV. As discussed in section III.D, this rule proposes that § 610.40(g), include the proposed requirements to initiate HCV ''lookback'' and requirements to initiate HIV ''lookback'' (currently in § 610.45(d), which would be deleted as part of the testing proposed rule). Initiation of the ''lookback'' processes would be based on results of HIV and HCV testing proposed in § 610.40(a) and (c) of the testing proposed rule. (Refer to section III.D of this document for discussion of the proposed changes to § 610.45(d).)

B. Proposed Revisions to § 606.100(b)(19)

FDA is proposing to amend § 606.100(b)(19), which currently prescribes requirements for SOP's, in accordance with §§ 610.46 and 610.47, to look at in-date prior collections from a donor who later tests repeatedly reactive on a required test for HIV, or is otherwise determined to be unsuitable when tested for HIV, and to notify transfusion recipients. FDA is proposing to amend § 606.100(b)(19) to include requirements for blood establishments to have SOP's, in accordance with proposed §§ 610.48 and 610.49, for HCV ''lookback,'' including procedures for quarantine and testing, and notification of transfusion recipients. The revised regulations would require SOP's to look at prior collections from a donor who has donated blood and later tests repeatedly reactive on a required test for HIV or HCV, or when the blood establishment has been made aware of other test results indicating evidence of HIV or HCV infection, and to notify transfusion recipients, if appropriate.

C. Proposed Revisions to § 606.160

FDA is proposing to amend § 606.160. Section 606.160(b)(1)(viii) currently prescribes requirements for maintaining records of quarantine, notification, testing, and disposition performed under §§ 610.46 and 610.47, whenever a donor subsequently tests repeatedly reactive for evidence of HIV infection. FDA is proposing to revise § 606.160(b)(1)(viii), to include requirements for maintaining records of quarantine, notification, testing, and disposition performed under proposed §§ 610.48 and 610.49, whenever a donor subsequently tests repeatedly reactive for evidence of HCV infection.

Section 606.160(d) currently prescribes that the retention period for required processing records shall be no less than 5 years after completion of the record or 6 months after the latest expiration date for the individual product, whichever is a later date. FDA is proposing to revise § 606.160(d) by increasing the required retention period to no less than 10 years after the records of processing have been completed, or 6 months after the latest expiration date for the individual product, whichever is a later date. FDA is proposing this change in the retention period because advances in medical diagnosis and therapy have created opportunities for disease prevention or treatment many years after recipient exposure to a donor later determined to be at increased risk of transfusion transmitted disease. Additionally, methods of recordkeeping have advanced, improving the ability of blood establishments to more easily maintain and retrieve records.

D. Proposed Revisions to § 610.45

As previously discussed, in the **Federal Register** of August 19, 1999 (64 FR 45340), FDA issued a proposed rule to revise § 610.40, and to delete § 610.45, ''Human Immunodeficiency Virus (HIV) requirements,'' because, except as discussed below, the requirements of § 610.45 would be included in proposed § 610.40.

Section 610.45(d) currently requires blood establishments to comply with §§ 610.46 and 610.47, the HIV ''lookback'' requirements for quarantine, consignee notification, further testing and transfusion recipient notification, when applicable, whenever a donor's ''test results for antibody to HIV are repeatedly reactive or otherwise determined to be unsuitable when tested in accordance with paragraph (a) of this section * * *.'' As previously discussed in section III.A of this document, the testing proposed rule would delete § 610.45. This proposed rule would include the requirements of current § 610.45(d) into proposed § 610.40(g). Proposed § 610.40(g) would require blood establishments to comply with §§ 610.46 and 610.47, and with proposed §§ 610.48 and 610.49, thereby requiring compliance with the HIV and

HCV ''lookback'' regulations, respectively.

E. Proposed Revisions to Headings of §§ 610.46 and 610.47

As a result of the addition of HCV ''lookback'' requirements, FDA is proposing to revise the headings of the sections applicable to the ''lookback'' requirements for HIV. FDA is proposing to revise the heading of § 610.46 to read ''Human Immunodeficiency Virus (HIV) 'Lookback;' quarantine, consignee notification and further testing'' to distinguish it from the new § 610.48, ''Hepatitis C Virus (HCV) '''lookback;''' quarantine, consignee notification and further testing.'' Likewise, FDA is proposing to amend the heading of § 610.47, ''Lookback'' Notification requirements for transfusion services,'' to read ''Human Immunodeficiency Virus (HIV) ''Lookback;'' notification of transfusion recipients'' to distinguish it from the new § 610.49, ''Hepatitis C Virus (HCV) ''Lookback;'' notification of transfusion recipients.'' As previously noted, FDA is proposing to amend § 610.46 for consistency with proposed § 610.48 of this proposed rule, and to amend § 610.47 for consistency with § 610.49 of this proposed rule. The corresponding revisions to § 610.46 and to § 610.47 are noted in the discussion of proposed § 610.48 and proposed § 610.49.

F. Proposed § 610.48(a), Quarantine and Consignee Notification

Proposed § 610.48(a) identifies the circumstances that would trigger the ''lookback'' process when a donor returns to donate and tests repeatedly reactive on a screening test, and states the requirements for quarantine of blood and blood components, notification of consignees, and quarantine of blood and blood components by consignees. Under proposed § 610.48(a)(1), blood establishments would be required to take appropriate action within 3-calendar days after the date on which a donor returns to donate blood or blood components and tests repeatedly reactive for evidence of HCV infection on a required test, performed in accordance with proposed § 610.40(a), or the date on which the blood establishment was made aware of other test results indicating evidence of HCV infection, provided the testing was performed by a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), using a test approved by FDA. In the testing proposed rule (64 FR 45340, August 19, 1999) proposed § 610.40(a) requires tests for specified communicable disease agents, including for HCV, and requirements for further testing of repeatedly reactive samples. For example, a blood establishment completing a screening test on Tuesday afternoon with a repeatedly reactive test result would have until the end of the day on Friday to complete the requirements for quarantine and consignee notification.

FDA is specifically requesting comments on the appropriateness of 3 calendar days proposed for exemptions of the quarantine of prior collections and consignee notification under proposed §§ 10.48(a), (e), and (f) and the conforming amendment to 610.46(a). FDA is also proposing that the ''lookback'' measures specified in § 610.48(a) be initiated by a blood establishment upon receipt of information that a person who has been a donor at that establishment has other test results indicating evidence of HCV infection and that the test was performed by a CLIA-certified laboratory, using a test approved by FDA, regardless of the purpose of the testing. FDA recognizes that blood establishments do not routinely receive such information, but should a blood establishment become aware of such reliable test results, the proposal would require appropriate ''lookback'' measures. State laws and public health practices vary widely, making it impossible to specify all circumstances under which test results may be provided to the blood establishment. However, FDA believes that the blood establishment has the obligation, upon the receipt of such reliable test results, to initiate appropriate action to protect the blood and plasma supply. In addition, the reliability of test results may vary, depending on the quality of the test method used and on the qualifications of the testing facility to perform the test. Accordingly, FDA is proposing to require the initiation of ''lookback'' procedures when the test results originate from a laboratory certified under CLIA and when the laboratory has used FDA-approved tests.

Proposed § 610.48(a) would require blood establishments and their consignees to identify and quarantine all affected blood and blood components collected prior to the donor's repeatedly reactive screening test for HCV. Under proposed § 606.160(d), blood establishments would retain records for ''* * * no less than 10 years * * *'' or, for products that remain in inventory, for 6 months after the latest expiration date of the product, whichever is the later date, and under proposed § 610.48(a) blood establishments would quarantine any in-date prior collections that remain in inventory. If the blood establishment has information to assure that there are no in-date prior collections, there is no need to trace those products.

Proposed § 610.48(a)(1)(i) would require blood establishments to quarantine all in-date prior collections from a donor testing repeatedly reactive for evidence of HCV infection. Proposed § 610.48(a)(1)(ii) would require blood establishments to notify consignees of the repeatedly reactive HCV screening test result so that the consignee may quarantine all in-date prior collections of blood and blood components. Proposed § 610.48(a)(2) would require consignees to quarantine all in-date prior collections of blood and blood components that remain in inventory.

For consistency, FDA is also proposing conforming amendments to the corresponding HIV ''lookback'' requirements of § 610.46(a). FDA is proposing to amend § 610.46(a) by changing the title of the paragraph to ''Quarantine and consignee notification'' and to clarify that blood establishments would be required to complete the quarantine and consignee notification requirements within 3-calendar days after the date on which the donor tests repeatedly reactive for evidence of HIV infection. FDA is proposing to replace the phrase ''or otherwise determined to be unsuitable when tested in accordance with § 610.45'' with ''or when the blood establishment has been made aware of other test results indicating evidence of HIV infection, provided the testing was performed by a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988, using a test approved by FDA'' to eliminate any confusion that might be caused by different wording. Likewise, for clarity and consistency, FDA is proposing to replace ''For Whole Blood, blood components, Source Plasma and Source Leukocytes collected from that donor within the 5 years prior to the repeatedly reactive test, if intended for transfusion, or collected within the 6 months prior to the repeatedly reactive test, if intended for further manufacture into injectable products, * * *.'' with ''For in-date blood and blood components collected from that donor at any time prior to the repeatedly reactive test, whenever records are available, if intended for transfusion or for further manufacture into injectable products, * * *.'' Also, FDA recognizes that it is not necessary for ''lookback'' requirements to distinguish collections intended for transfusion from those intended for further manufacturing. FDA is clarifying that ''lookback'' requirements should be followed for any

prior collection that has not expired because records are held for 6 months after the latest expiration date of the individual product.

G. Proposed § 610.48(b), Further Testing and Consignee Notification of Results

Proposed § 610.48(b) would require further testing whenever a donor returns to donate and tests repeatedly reactive for evidence of HCV infection, as described in § 610.48(a), and notification of consignees of the results of the further testing. Proposed § 610.48(b) would require blood establishments to perform further testing, in accordance with proposed § 610.40(c) of the testing proposed rule (as previously discussed), after a donor with a record of prior collections tests repeatedly reactive for evidence of HCV infection when tested in accordance with proposed § 610.40(a) of the testing proposed rule. Blood establishments would be required to notify consignees of the results of the further testing within 45-calendar days after the day on which the donor tests repeatedly reactive on a screening test for evidence of HCV infection.

FDA is proposing a conforming amendment to § 610.46(b) for HIV ''lookback'' by changing the maximum time provided for a blood establishment to notify consignees of the results of the further testing from 30 to 45 days. This change is proposed for consistency between the HIV and HCV ''lookback'' regulations and in response to comments that although further testing for HIV and HCV can be completed within 30 days, additional time is needed to notify consignees following completion of the further testing.

H. Proposed § 610.48(c), Review of Historical Testing Records and Identification of Donors Tested Using a Multiantigen Screening Test Prior to the Effective Date of this Regulation

As discussed in section I.C of this document in this preamble, blood establishments routinely have been testing blood donations for antibody to HCV since 1990. In the guidance documents issued in March 1998, September 1998 and June 1999, FDA issued recommendations (draft guidance was issued in June 1999) for blood establishments to initiate ''lookback'' procedures consistent with those now being proposed, including when, through a review of historical testing records, previous instances are identified when a donor had tested repeatedly reactive on a multiantigen screening test for evidence of HCV infection. FDA believes that since 1990, many blood establishments have routinely initiated ''lookback'' procedures consistent with the regulations now being proposed, and with the issuance of the recommendations in 1998 and 1999, many additional establishments have undertaken the review of historical testing records and have initiated appropriate ''lookback'' procedures. However, because HCV is a chronic, often asymptomatic disease that may ultimately have serious consequences, FDA believes that it is imperative to identify and notify recipients who have been transfused with blood or blood components for which there is an increased risk of transmission of HCV as determined by subsequent donor testing. Such transfusion recipients should be made aware that they should seek further testing to see if they are infected and, if so, to receive appropriate counseling and medical care.

The requirements of proposed § 610.48(c) and (d) are based on the agency's understanding of current research in hepatitis testing. FDA specifically invites comments on these provisions and requests individuals to submit data in support of the comments. To the extent the data do not support these provisions, FDA would revise the rule accordingly. FDA recognizes that the review of historical testing records (performed in accordance with proposed § 610.48(c) and (d)) will identify tests performed using both licensed and unlicensed tests, HCV EIA 1.0, 2.0, and 3.0, as well as, HCV RIBA 2.0 and 3.0 supplemental tests. For that reason, the proposed requirements for testing performed prior to the effective date of any final rule resulting from this proposal (that is, test results identified in the review of historical testing records) would take into account the use of unlicensed tests, under specific circumstances. In addition, testing performed following the effective date of any final rule resulting from this proposal (such as further testing performed in accordance with proposed § 610.48(h) or (i)) would require use of a currently licensed test, as specified.

The purpose of § 610.48(c) is to identify, through a search of available historical testing records, those prior collections that might have been collected during the window period, that is, a donation that may have been made after the donor became infected with HCV but before it was possible for a screening test to detect antibody to HCV. The identification of prior collections would be based on the multiantigen screening test result and would be followed by appropriate steps to perform quarantine, further testing and notification of consignees and transfusion recipients, as discussed in detail in this and other sections of this proposed rule. Blood establishments would be required to perform a review of historical testing records to identify, within 1 year of the effective date of any final rule resulting from this proposal, prior collections at increased risk of transmitting HCV infection because they are from a donor who later tested repeatedly reactive for evidence of HCV infection on a multiantigen screening test and who either: (1) Has no record of further testing for HCV performed on the repeatedly reactive sample and no record of a negative licensed, multiantigen screening test performed at a later date (as specified in § 610.48(c)(4) and (c)(5); or (2) has a record of further testing (as specified in § 610.48(c)(1), (c)(2), and (c)(3)) that potentially indicates evidence of HCV infection, as discussed in detail later in this proposed rule. As discussed in the following paragraph, after the review of historical testing records, ''lookback'' actions would be triggered for certain prior collections. Blood establishments would be required to quarantine any in-date prior collections still in inventory where records show that they were collected from donors later found to have a repeatedly reactive multiantigen screening test for evidence of HCV infection (unless exempt from quarantine under § 610.48(g)(2)), and to notify consignees to quarantine such prior collections, as specified under proposed § 610.48(e)(2); to perform further testing, as specified in proposed § 610.48(h)(1), on donors identified in accordance with proposed § 610.48(c)(4) and (c)(5); or optionally to perform further testing in accordance with § 610.48(h)(2) on donors identified in accordance with § 610.48(c)(2) and (c)(3); and to notify consignees of the test result, in accordance with proposed § 610.48(h)(3), as described in the following paragraph. Transfusion services notified by blood establishments of prior receipt of blood or blood components at increased risk of transmitting HCV would either notify the transfusion recipients directly or notify the recipient's physician of record (i.e., physician of record or physician who ordered the blood or blood component), as specified in proposed § 610.49(b).

Under proposed § 610.48(c), the review would include records, if available, dating back indefinitely for computerized electronic records, and to January 1988 for other readily retrievable records, or 12 months prior to the donor's most recent negative

multiantigen screening test for antibody to HCV, whichever is the lesser period. This 12-month time period requirement is intended to identify any potential ''window period'' donation. Review of historical testing records dating back indefinitely would not be necessary for prior collections from many donors (i.e., prior collections from donors who have a record of a prior negative multiantigen screening test result because the prior collections would not be considered to be window period donations.) Examples are provided in the following paragraph. In addition, many donors who test repeatedly reactive for evidence of HCV infection are first-time donors with no previous history of donation. Thus, no ''lookback'' action is needed for such a first-time donor because ''lookback'' activity targets prior collections and no prior collections exist for a first time donor.

Proposed § 610.48(c) would limit the review of records to the identification of prior collections dating back to ''the date 12 months prior to the donor's most recent negative multiantigen screening test for HCV.'' FDA believes that this 12-month period prior to the last negative multiantigen screening test for HCV establishes with high confidence that, prior to that date, possible HCV infection would have been detected by a screening test; if any ''window period'' donation was collected, it would have occurred after that date. For example, it would not be necessary to identify collections dating back indefinitely for a donor who has donated every 6 months from January 1983 until testing repeatedly reactive on a screening test for evidence of HCV infection in January 1998, with the last negative multiantigen screening test on July 1, 1997. In this example, the last negative multiantigen screening test for antibody to HCV is July 1, 1997, and 12 months prior to that would be July 2, 1996. Under the proposal, the blood establishment would use the later date of July 2, 1996 (rather than the maximum time period back to January 1983), and the blood establishment would identify donations made on or after July 2, 1996, to July 1, 1997, as possible ''window period'' donations. In this example, donations made prior to July 2, 1996, would not be suspected to be ''window period'' donations, capable of transmitting HCV infection to a transfusion recipient. Note that a negative test result on a single antigen EIA screening test for HCV may not be used as the ''most recent negative multiantigen screening test'' and is not a basis to limit the ''lookback'' activity, as described previously, due to the limited sensitivity of the single antigen HCV EIA test.

FDA is proposing the review of historical testing records to identify five specific instances following a repeatedly reactive multiantigen screening test that should be used to identify increased risk of transmitting HCV from the donor's prior collections. Under § 610.48(c), blood establishments would identify prior collections from donors who tested repeatedly reactive for evidence of HCV infection on a licensed, multiantigen screening test and who: (1) Tested positive on a supplemental test for HCV performed on the repeatedly reactive sample (as specified in § 610.48(c)(1)); or (c)(2) tested indeterminate on a supplemental test for HCV (as specified in § 610.48(c)(2)); or (c)(3) testing repeatedly reactive on licensed HCV EIA 3.0 screening test and negative on a licensed HCV RIBA 2.0 supplemental test but with no records of a negative licensed HCV RIBA 3.0 supplemental test performed on the repeatedly reactive sample or a later sample from the same donor; or (4) tested repeatedly reactive for evidence of HCV infection on an HCV EIA 2.0 screening test with no record of a supplemental test for HCV performed on the repeatedly reactive sample or on a later sample from the donor and no record of a negative licensed HCV EIA 3.0 screening test performed on the repeatedly reactive sample or later on the same donor; or (5) tested repeatedly reactive for evidence of HCV infection on a licensed, HCV EIA 3.0 screening test with no record of a supplemental test for HCV performed on the repeatedly reactive sample or on a later sample from the same donor. As discussed previously, the requirements of proposed § 610.48(c) for review of historical testing records to identify prior collections from affected donors are particular to the testing methods used and exceptions are specified in § 610.48(g), Exemption from Quarantine. Prior collections that would not be identified as possible ''window period'' donations and would not require further action are exempted from quarantine as described in § 610.48(g)(2). For donors identified in accordance with § 610.48(c)(4) and (c)(5) for whom no records of further testing exist to clarify the status of prior collections determined to be at increased risk of transmitting HCV infection, blood establishments would be required, as described under proposed § 610.48(e), to perform quarantine and consignee notification for any in-date prior collections that remain in inventory and to perform further testing, as described under proposed § 610.48(h)(1).

I. Proposed § 610.48(d), Review of Records and Identification of Donors Testing Repeatedly Reactive on a Single Antigen Screening Test Prior to the Effective Date of this Regulation

The purpose of § 610.48(d), which parallels the requirements of § 610.48(c), is to identify, through a review of historical testing records, those prior collections that might have been collected during the window period of HCV infection, based on a single antigen screening test result. Similar to the requirements of § 610.48(c), which is based on the multiantigen screening test, proposed § 610.48(d) would: (1) Require blood establishments to review available historical records of donor testing that occurred prior to the effective date of this regulation to identify prior collections that are potential window period donations; (2) require the review of available historical testing records dating back indefinitely for computerized electronic records and to January 1988 for other readily retrievable records; and (3) require that blood establishments complete the review or historical testing records within 1 year of the effective date of any final rule that results from this proposal.

Under § 610.48(d), blood establishments would identify previously distributed blood and blood components in any of the following four instances: (1) As proposed in § 610.48(d)(1), where the donor tested repeatedly reactive for evidence of HCV infection on the single antigen screening test and repeatedly reactive on an HCV EIA 2.0 or HCV EIA 3.0 screening test for HCV performed on the repeatedly reactive sample or a fresh sample from the same donor; (2) as proposed in § 610.48(d)(2), where the donor tested repeatedly reactive for evidence of HCV infection on the single antigen screening test and either positive or indeterminate on an HCV 2.0 or HCV 3.0 strip immunoblot assay (HCV RIBA 2.0 or HCV RIBA 3.0 supplemental test, respectively) supplemental test for HCV; or (3) as proposed in § 610.48(d)(3), where the donor tested repeatedly reactive for evidence of HCV infection on an HCV EIA 1.0 screening test, with a signal to cut off (S/CO) value less than 2.5 for at least two out of the three EIA tests (i.e., the initial EIA screening test and the duplicate retests) with no record of a supplemental test or multiantigen screening test for HCV performed on the repeatedly reactive sample or on a later sample from the same donor ; or (4) as proposed in § 610.48(d)(4), where the donor tested repeatedly reactive for

evidence of HCV infection on an HCV EIA 1.0 screening test, with a S/CO value equal to or greater than 2.5 for at least two out of the three EIA tests or with no determination of S/CO value for all three EIA tests, and with no record of a supplemental test or multiantigen screening test for HCV performed on the repeatedly reactive sample or on a later sample from the same donor. (The S/CO value for each test result is calculated as the ratio of the absorbency value obtained for the donor sample divided by the absorbency value for the cutoff in that assay run.)

As previously discussed in section I.C of this document, the PHS Advisory Committee met on January 28, 1999, to consider options for expanding the targeted HCV ''lookback'' program to include recipients of blood from donors subsequently identified as repeatedly reactive by the single antigen HCV EIA 1.0 screening test. Approximately 80 percent of the HCV EIA 1.0 repeatedly reactive donations were identified before the first confirmatory test became available. The PHS Advisory Committee concluded that it would be reasonable to limit the ''lookback'' for EIA 1.0 based on the S/CO value of the screening tests in cases where supplemental testing had not been done and further testing of the original repeatedly reactive sample or a later sample from the same donor was impractical. The PHS Advisory Committee concluded that it would be appropriate to perform HCV ''lookback'' on a subset of the donors testing repeatedly reactive on EIA 1.0 screening tests to capture the vast majority of the true positives and minimize the unnecessary false recipient notifications. The requirements proposed in § 610.48(d) and (i) reflect the PHS Advisory Committee's recommendations for use of the S/CO value based on a critical ratio of 2.5 in evaluating risk of HCV transmission under ''lookback'' circumstances identified in the review of historical testing records.

As discussed previously, the requirements of proposed § 610.48(d) for review of historical testing records to identify prior collections from affected donors are particular to the testing methods used and exceptions are specified in § 610.48(g), Exemption from quarantine. Prior collections that would not be identified as possible ''window period'' donations and would not require further action are exempted from quarantine as described in § 610.48(g)(3).

J. Proposed § 610.48(e), Quarantine and Consignee Notification Following the Review of Historical Testing Records Based on Screening Performed Using a Multiantigen Screening Test

The purpose of proposed § 610.48(e) is to require quarantine of prior collections that were identified in the review of historical testing records, based on a multiantigen screening test in accordance with proposed § 610.48(c), until further testing is completed, if necessary, and the blood establishment can make a determination to release the prior collections from quarantine (under proposed § 610.48(j)(2)), or to destroy or relabel them (under proposed § 610.48(k)). Proposed § 610.48(e) would require blood establishments to quarantine certain prior collections until further testing is completed to clarify the status of the prior collections, and to notify consignees so that prior collections they hold can be quarantined. This requirement is intended to prevent the transfusion of a prior collection from a donor identified in the review of records as being at increased risk of transmitting HCV infection while further testing is performed.

Proposed § 610.48(e)(1) would require blood establishments to quarantine in-date prior collections of blood and blood components collected from donors identified in the review of records, under proposed § 610.48(c), while further testing is performed, as required in proposed § 610.48(h)(1) or as optional testing is performed in accordance with § 610.48(h)(2).

As previously mentioned, some exceptions to quarantine are specified in proposed § 610.48(g)(2). Prior collections that meet the criteria under proposed § 610.48(g)(2) would not be suspected as ''window period'' donations and would be exempt from quarantine, as discussed in following sections. If no exemption to quarantine applies, blood establishments would be required to perform quarantine within 3 days of the date on which the establishment identifies a donor's repeatedly reactive multiantigen screening test. All identification performed in accordance with § 610.48(c) and the resulting quarantine and notification must be completed within a maximum of 1 year from the effective date of any final rule resulting from this proposal.

Proposed § 610.48(e)(2) would require blood establishments, within 3-calendar days of the date on which the donor's repeatedly reactive multiantigen screening test is identified, to notify consignees of the donor's test results, including supplemental test results, if available, so that consignees may quarantine all in-date prior collections of blood and blood components subject to quarantine under proposed § 610.48(e)(1). FDA is specifically requesting comments on the appropriateness of the 1-year timeframe to complete all quarantine and notification.

K. Proposed § 610.48(f), Quarantine and Consignee Notification Following the Review of Records Based on Screening Performed Using a Single Antigen Screening Test

The purpose of § 610.48(f), which parallels the requirements of § 610.48(e), is to require quarantine of prior collections that were identified in the review of historical testing records based on single antigen testing, in accordance with proposed § 610.48(d), until further testing is completed, if necessary, and a determination can be made to release the prior collections from quarantine (under proposed § 610.48(j)(3)), or to destroy or relabel them (under proposed § 610.48(k)). Proposed § 610.48(f) would require blood establishments to quarantine certain prior collections until further testing is completed to clarify the status of the prior collections, and to notify consignees so that prior collections they hold can be quarantined. This requirement is intended to prevent the transfusion of a prior collection from a donor identified in the review of records as being at increased risk of transmitting HCV infection while further testing is performed.

Proposed § 610.48(f)(1) would require blood establishments to quarantine in-date prior collections of blood and blood components from donors identified in the review of historical testing records, under proposed § 610.48(d), while further testing is performed, as required in proposed § 610.48(i)(1) or as optional testing is performed in accordance with § 610.48(i)(2).

Under this proposal, blood establishments would be required to perform quarantine within 3 calendar days of the date on which the blood establishment identifies a donor's repeatedly reactive single antigen screening test. All identification performed in accordance with § 610.48(d) and the resulting quarantine and notification must be completed within a maximum of 1 year from the effective date of any final rule resulting from this proposal. As previously mentioned, some exceptions to quarantine are specified in proposed § 610.48(g)(3). Prior collections that

meet the criteria under proposed § 610.48(g)(3) would not be suspected as ''window period'' donations and would, therefore, be exempt from quarantine, as discussed in following sections.

Proposed § 610.48(f)(2) would require blood establishments, within 3-calendar days of the date on which the donor's repeatedly reactive single antigen screening test is identified, to notify consignees of the donor's test results, including supplemental test results, if available, so that consignees may quarantine all in-date prior collections of blood and blood components subject to quarantine under proposed § 610.48(f)(1). FDA is specifically requesting comments on the appropriateness of 3-calendar days proposed for completion of the quarantine of prior collections and consignee notification under § 610.48(f) and the appropriateness of the 1-year timeframe to complete all quarantine and notification.

Proposed § 610.48(f)(3) would require consignees notified in accordance with proposed § 610.48(f)(2) to quarantine all prior collections of blood and blood components subject to quarantine under proposed § 610.48(f)(1), except as provided in proposed § 610.48(g)(3).

L. Proposed § 610.48(g), Exemption From Quarantine

Proposed § 610.48(g) specifies which prior collections are not suspected as being window period donations and, therefore, are not subject to quarantine under proposed § 610.48(a), (e), and (f). Proposed § 610.48(g)(1) would exempt from quarantine certain prior collections otherwise subject to quarantine under proposed § 610.48(a) when a donor tests repeatedly reactive on a multiantigen screening test for evidence of HCV infection. Proposed § 610.48(g)(1)(i) is intended to identify certain donations that are not suspected of being collected during the ''window period'' because they were collected prior to the time a possible window period could have existed, and would not be subject to quarantine under proposed § 610.48(a). Under proposed § 610.48(g)(1)(i), for donations collected more than 12 months prior to the donor's most recent negative multiantigen screening test, a high confidence level exists that no infection could have existed at the time of donation and remain undetected by a screening test, and, therefore, blood establishments would not be required to quarantine blood or blood components ''collected more than 12 months prior to the donor's most recent negative multiantigen screening test when tested for HCV in accordance with § 610.40(a). An explanation of ''window period'' donations and a corresponding example are provided previously in the description of proposed § 610.48(c).

In addition, proposed § 610.48(g)(1)(ii) would provide that when an appropriate licensed supplemental test for HCV (discussed in this section III.L) is found to be negative and is completed within the 3-day time period provided for completion of quarantine and consignee notification, quarantining of prior collections of blood and blood components from that donor would not be required. Thus, if the supplemental test is found negative within 3-calendar days after the date on which the donor tested repeatedly reactive for evidence of HCV infection (the time provided for completion of quarantine and consignee notification), then the repeatedly reactive screening test result would be interpreted as a ''false positive,'' would not indicate HCV infection, and prior collections from that donor would not be considered to be at increased risk of transmitting HCV. If, however, the supplemental testing is completed more than 3 days after the date of the repeatedly reactive screening test result (the time provided for completion of quarantine and consignee notification), the blood and blood components would be quarantined but could then be released from quarantine if the supplemental test is negative, as provided in proposed § 610.48(j).

As specified in proposed § 610.48(g), the supplemental test must be appropriately chosen, i.e., the appropriately chosen supplemental test should contain all the antigens of the screening test that was performed. Under proposed § 610.48(g)(1)(ii), if the repeatedly reactive screening test was obtained using an HCV EIA 2.0 screening test, then an appropriate supplemental test would be either an HCV RIBA 2.0 or an HCV RIBA 3.0. However, if the repeatedly reactive screening test result was obtained using an HCV EIA 3.0 screening test, then the appropriate supplemental test would be an HCV RIBA 3.0. The HCV RIBA 2.0 supplemental test would not be an appropriately chosen supplemental test following an HCV EIA 3.0 screening test because the HCV RIBA 2.0 supplemental test does not include all antigens contained in the HCV EIA 3.0 screening test.

Proposed § 610.48(g)(2) provides for exceptions from quarantine performed in accordance with proposed § 610.48(e) following the review of historical testing records based on screening performed using a multiantigen screening test. Similar to the provisions of proposed § 610.48(g)(1), proposed § 610.48(g)(2) is intended to exempt from quarantine those prior collections that are not suspected as being collected during the ''window period.'' Under proposed § 610.48(g)(2), prior collections of blood and blood components would not be subject to quarantine under proposed § 610.48(e) if they meet any of the following criteria: (1) The prior collection was donated more than 12 months prior to the donor's most recent negative multiantigen screening test for evidence of HCV infection that preceded the repeatedly reactive screening test; or (2) records show that the repeatedly reactive screening test result was obtained using an HCV EIA 2.0 screening test, and either the original sample or a later sample from the same donor was tested and found negative using an HCV RIBA 2.0, or an HCV RIBA 3.0 supplemental test or an HCV EIA 3.0 screening test. (As previously discussed, a negative test result on a single antigen EIA screening test for HCV may not be used as the ''most recent negative multiantigen screening test'' and is not a basis to limit the ''lookback'' activity, as described previously, due to the limited sensitivity of the HCV EIA 1.0 screening test); or (3) records show that the repeatedly reactive screening test result was obtained using an HCV EIA 3.0 screening test, and either the original sample or a later sample from the same donor was tested and found negative using an HCV RIBA 3.0 supplemental test.

Proposed § 610.48(g)(3) provides for exceptions from quarantine (performed in accordance with proposed § 610.48(f)) following the review of records based on screening performed using a single antigen screening test. Similar to the provisions of proposed § 610.48(g)(1) and (g)(2), proposed § 610.48(g)(3) is intended to exempt from quarantine those prior collections that are not suspected as being collected during the ''window period.'' Under proposed § 610.48(g)(3), prior collections of blood and blood components would not be subject to quarantine under proposed § 610.48(f) if they meet any of the following four criteria: (1) Records show that the repeatedly reactive screening test result was obtained using an HCV EIA 1.0 screening test, and either the original sample or a later sample from the same donor was tested and found negative using an HCV EIA 2.0 or an HCV EIA 3.0 screening test (exempted under proposed § 610.48(g)(3)(i)); or (2) records show that the repeatedly reactive screening test result was obtained using an HCV EIA 1.0

screening test, and either the original sample or a later sample from the same donor was tested and found negative using a HCV RIBA 2.0 or a HCV RIBA 3.0 supplemental test (exempted under proposed § 610.48(g)(3)(ii)); or (3) the donor identified in accordance with proposed § 610.48(d)(1), as testing repeatedly reactive on an HCV EIA 2.0 or 3.0 screening test, was further tested using an HCV RIBA 2.0 or HCV RIBA 3.0 supplemental test, using a fresh sample, or frozen sample from the repeatedly reactive donation and the result was negative (exempted under § 610.48(g)(3)(iii)); or (4) the donor identified in accordance with proposed § 610.48(d)(2), as testing indeterminate on an HCV RIBA 2.0 supplemental test, was further tested using either an HCV EIA 3.0 or a HCV RIBA 3.0 supplemental test using a fresh sample, or frozen sample from the repeatedly reactive donation and the result was negative (exempted under proposed § 610.48(g)(3)(iv)).

FDA is also proposing a conforming amendment to § 610.46(c), which specifies requirements for exemption from quarantine for HIV ''lookback,'' for consistency with the HCV ''lookback'' requirements by changing ''Whole Blood, blood components, Source Plasma and Source Leukocytes'' to ''blood and blood components.''

M. Proposed § 610.48(h), Further Testing Following Review of Historical Testing Records and Consignee Notification Based on Screening Performed Using a Multiantigen Screening Test

Proposed § 610.48(h) is intended to require that prior collections identified in accordance with § 610.48(c)(4) and (c)(5), based on multiantigen screening test results, either be further tested and consignees notified so that blood establishments can determine if the prior collection should be released from quarantine (under § 610.48(j)), or destroyed or relabeled (under § 610.48(k)), and if notification of transfusion recipients is necessary (under § 610.49(a)). In addition, blood establishments would have the option to perform further testing for prior collections identified in accordance with § 610.48(c)(2) and (c)(3). Proposed § 610.48(h)(1) would require blood establishments, by 1 year from the effective date of any final rule resulting from this proposal, to perform further testing to clarify the status of prior collections collected from a donor identified, in accordance with § 610.48(c)(4) and (c)(5), as being at increased risk of transmitting HCV. Proposed § 610.48(h)(1) would require that further testing be performed as follows: (1) As proposed in § 610.48(h)(1)(i)(A), if the repeatedly reactive test result was obtained using a licensed HCV EIA 2.0 screening test, blood establishments would perform a licensed supplemental test for HCV on a frozen sample from the repeatedly reactive donation, if it is available. If such a frozen sample is not available, blood establishments would obtain a fresh sample from the donor and perform a licensed supplemental test for HCV; or alternatively, (2) as proposed in § 610.48(h)(1)(i)(B), if the repeatedly reactive test result was obtained using a licensed HCV EIA 2.0 screening test, blood establishments would perform a licensed HCV EIA 3.0 screening test on a frozen sample, if it is available. If such a frozen sample is not available, blood establishments would obtain a fresh sample from the donor and perform a licensed HCV EIA 3.0 screening test and a licensed supplemental test if the HCV EIA 3.0 screening test is repeatedly reactive; or (3) as proposed in § 610.48(h)(1)(ii), if the repeatedly reactive test result was obtained using a licensed HCV EIA 3.0 screening test, blood establishments would perform a licensed supplemental test for HCV on a frozen sample, if available. If such a frozen sample is not available, blood establishments would obtain a fresh sample from the donor and perform a licensed supplemental test for HCV; or (4) as proposed in § 610.48(h)(1)(iii), blood establishments would make a determination that neither a frozen sample from the repeatedly reactive donation nor a fresh sample from the donor is available for further testing. For example, the blood establishment might make a determination that additional testing is not possible because the sample was not stored properly, or the donor could not be located or the donor declined further testing.

Under proposed § 610.48(h)(2), blood establishments would have the option to perform further testing on prior collections identified in accordance with § 610.48(c)(2) and (c)(3). This provision would make it possible to clarify the status of the prior collections and, in some instances, based on further testing, it might not be necessary to destroy the prior collections or notify transfusion recipients. Under proposed § 610.48(h)(2), blood establishments that have performed the review of records and identified prior collections in accordance with proposed § 610.48(c)(2) or (c)(3) of this section may further test a frozen sample from the repeatedly reactive donations or a fresh sample from the same donor by 1 year from the effective date of any final rule resulting from this proposal, as follows: (1) As proposed in § 610.48(h)(2)(i), if the donor was identified in accordance with proposed § 610.48(c)(2) of this section as testing repeatedly reactive using an HCV EIA 2.0 screening test, and indeterminate on a HCV RIBA 2.0 supplemental test, blood establishments have the option to perform further testing using either an HCV EIA 3.0 screening test or a currently available licensed supplemental test for HCV; or (2) as proposed in § 610.48(h)(2)(ii), if the donor was identified in accordance with proposed § 610.48 (c)(2) of this section as testing repeatedly reactive using an HCV EIA 2.0 screening test, indeterminate on a HCV RIBA 2.0 supplemental test, and repeatedly reactive on an HCV EIA 3.0 screening test, blood establishments have the option to perform further testing using an appropriately chosen licensed supplemental test for HCV (refer to section L of this document that discusses proposed § 610.48(g) for more information regarding use of ''an appropriately chosen supplemental test''); or (3) as proposed in § 610.48(h)(2)(iii), if the donor was identified in accordance with (c)(2) of this section as testing repeatedly reactive using an HCV EIA 3.0 screening test, and indeterminate on a HCV RIBA 2.0 supplemental test, blood establishments have the option to perform further testing using an appropriately chosen licensed supplemental test for HCV; or (4) as proposed in § 610.48(h)(2)(iv), if the donor was identified in accordance with proposed § 610.48 (c)(3) of this section as testing repeatedly reactive using an HCV EIA 3.0 screening test, and negative on a HCV RIBA 2.0 supplemental test, blood establishments have the option to perform further testing using an appropriately chosen licensed supplemental test for HCV. Based on the results of the further testing, the blood establishment can make a decision regarding the next appropriate step under proposed § 610.48(j), to release from quarantine, or under proposed § 610.48(k), to destroy or appropriately label prior collections, or under proposed § 610.49(a), to notify any transfusion recipients.

Under proposed § 610.48(h)(3), blood establishments would be required to notify consignees of the results of the additional testing, performed in accordance with proposed § 610.48(h)(1) or (h)(2), upon completing the additional testing and prior to 1 year from the effective date of any final rule resulting from this proposal. Blood

establishments would be required to notify the consignee of any risk of HCV transmission that exists for such prior collections, based on the results of the additional testing. If the prior collection was from a donor identified in the review of historical testing records in accordance with proposed § 610.48(c)(1) through (c)(5), and no additional testing was performed, or if no sample was available for further testing, as provided in proposed § 610.48(h)(1)(iii), the blood establishment would be required, within 1 year from the effective date of a final rule that results from this proposal, to notify consignees of any risk of HCV transmission for such prior collections.

The review of historical testing records identifies those donors whose test results indicate some degree of risk of HCV transmission for prior collections. If the testing records do not include supplemental testing, further testing of the original repeatedly reactive sample or a fresh sample from the donor is needed. The purpose of further testing is to provide the opportunity for blood establishments to evaluate the test results and determine the next appropriate step in the ''lookback'' process. Blood establishments must consider several significant issues when evaluating HCV screening and supplemental tests. Prior collections from donors who subsequently test positive or indeterminate on a supplemental test for HCV (except donors testing indeterminate on a RIBA 3.0 supplemental test as described below), are at increased risk of transmitting HCV. Prior collections from such donors would be destroyed or relabeled as proposed in § 610.48(k), or, if transfused, would trigger notification of recipients because of the increased risk of transmission of HCV infection.

However, in the case of a donor whose screening test was repeatedly reactive by HCV EIA 2.0, if an indeterminate RIBA 2.0 supplemental test result is followed by a negative result on an HCV EIA 3.0 screening test or an HCV RIBA 3.0 supplemental test, prior collections may be released from quarantine, as proposed in § 610.48(j), and transfusion recipients need not be notified. This release from quarantine is based on current research that indicates absence of polymerase chain reaction (PCR) reactivity for HCV RNA in HCV RIBA 2.0 indeterminate/HCV EIA 3.0 negative samples or in HCV RIBA 2.0 indeterminate/HCV RIBA 3.0 negative samples. Conversely, prior collections from donors who subsequently test repeatedly reactive on an EIA screening test and indeterminate on an HCV RIBA 3.0 supplemental test must also be destroyed or relabeled because they represent an increased risk of HCV transmission (under proposed § 610.48(k)). However, if these prior collections have been transfused, consignee notification for the purpose of recipient notification need not be performed (as noted in relevant sections of proposed § 610.49(a)) due to infrequent PCR positivity (only 1.6 percent) in HCV EIA 3.0 repeatedly reactive/HCV RIBA 3.0 indeterminate samples and infrequent (0.5 percent to 4 percent) PCR reactivity in HCV RIBA 2.0 indeterminate/HCV RIBA 3.0 indeterminate samples.

N. Proposed § 610.48(i), Further Testing and Consignee Notification Following Review of Records Based on Screening Performed Using a Single Antigen Screening Test

The purpose of proposed § 610.48(i), which parallels the requirements of proposed § 610.48(h), is to require that prior collections, identified in the review of historical testing records and based on single antigen testing in accordance with § 610.48(d)(4), be further tested and consignees notified so that blood establishments can determine if the prior collections should be released from quarantine (under § 610.48(j)), or destroyed or relabeled (under § 610.48(k)), and if notification of transfusion recipients is necessary (under § 610.49(a)). In addition, blood establishments would have the option to perform further testing for prior collections identified in accordance with § 610.48(d)(1), (d)(2), and (d)(3). Proposed § 610.48(i)(1) would require blood establishments, within 1 year of the effective date of any final rule resulting from this proposal, to perform further testing to clarify the status of prior collections collected from a donor identified, in accordance with § 610.48(d)(4), as being at increased risk of transmitting HCV.

Proposed § 610.48(i)(1) would require that further testing for donors identified in accordance with proposed § 610.48(d)(4) be performed as follows: (1) As proposed in § 610.48(i)(1)(i), blood establishments would be required to perform a licensed supplemental test for HCV on a frozen sample from the repeatedly reactive donation, if available. If such a frozen sample is not available, blood establishments would be required to obtain a fresh sample from the donor and perform a licensed RIBA 3.0 supplemental test for HCV; or (2) as proposed under § 610.48(i)(1)(ii), blood establishments would be required to make a determination that neither a frozen sample from the repeatedly reactive donation nor a fresh sample from the donor is available for further testing. For example, under certain circumstances, the blood establishment could make a determination that additional testing is not possible because the sample was not stored properly, or the donor could not be located or the donor declined further testing.

Under proposed § 610.48(i)(2), blood establishments would have the option to perform further testing on prior collections identified in accordance with § 610.48(d)(1) and (d)(2). This provision would make it possible to clarify the status of the prior collections and, in some instances, based on further testing, it might not be necessary to destroy the prior collections or notify transfusion recipients. Under proposed § 610.48(i), blood establishments that have performed the review of historical testing records and identified prior collections in accordance with proposed § 610.48 (d)(1) or (d)(2) of this section may further test a frozen sample from the repeatedly reactive donation or a fresh sample from the same donor by 1 year from the effective date of any final rule resulting from this proposal, as follows: (1) As proposed under § 610.48(i)(2)(i), if the donor was identified in accordance with proposed § 610.48 (d)(1) of this section as testing repeatedly reactive on an HCV EIA 1.0 screening test and repeatedly reactive on either an HCV EIA 2.0 or HCV EIA 3.0 screening test, blood establishments have the option to perform further testing using an appropriate licensed supplemental test for HCV; or (2) as proposed under § 610.48(i)(2)(ii), if the donor was identified in accordance with paragraph (d)(2) of this section as testing repeatedly reactive on an HCV EIA 1.0 screening test with an indeterminate test result obtained using a HCV RIBA 2.0 supplemental test, blood establishments have the option to perform further testing using a currently available licensed supplemental test for HCV or an HCV EIA 3.0 screening test. If such optional further testing is performed using an HCV EIA 3.0 screening test and the result is repeatedly reactive, blood establishments have the additional option to perform further testing using an appropriately chosen licensed supplemental test for HCV; or (3) as proposed under § 610.48(i)(2)(iii), if the donor was identified in accordance with paragraph (d)(3) of this section as testing repeatedly reactive on an HCV EIA 1.0 screening test with a S/CO value less than 2.5 for at least two out of the three EIA tests, and with no record of a supplemental test or multiantigen

screening test for HCV performed on the repeatedly reactive sample or on a later sample from the same donor, blood establishments have the option to perform further testing using a licensed multiantigen screening test for HCV or a licensed supplemental test for HCV.

Under proposed § 610.48(i)(3), blood establishments would be required to notify consignees of the results of the additional testing, performed in accordance with proposed § 610.48(i)(1) or (i)(2), upon completing the additional testing and prior to 1 year from the effective date of any final rule resulting from this proposal. Blood establishments would be required to notify the consignee of any risk of HCV transmission that exists for such prior collections, based on the results of the additional testing. If the prior collection was from a donor identified in the review of historical testing records in accordance with proposed § 610.48(d)(1) through (d)(4), and no additional testing was performed, or if no sample was available for further testing, as provided in proposed § 610.48(i)(1)(ii), the blood establishment would be required to notify consignees, within 1 year from the effective date of a final rule that results from this proposal, of any risk of HCV transmission for such prior collections.

O. Proposed § 610.48(j), Release From Quarantine

The purpose of proposed § 610.48(j) is to identify those prior collections of blood and blood components intended for transfusion or for manufacture into injectable products that have been quarantined and further tested that may be released from quarantine, based on the results of the additional testing. Under proposed § 610.48(j)(1), those prior collections subject to quarantine under proposed § 610.48(a) would be released for use only if the donor's current, repeatedly reactive sample is further tested using a licensed, supplemental test for HCV, as required in proposed § 610.48(b), and the result of the supplemental test is negative. Because the negative supplemental test result indicates that the repeatedly reactive screening test result was a ''false positive,'' prior collections from the donor are not suspected as being a possible window period donation, are not at increased risk of transmitting HCV and therefore, may be released from quarantine.

Under proposed § 610.48(j)(2), prior collections subject to quarantine under proposed § 610.48(e)(1) (as a result of the review of historical testing records and based on a multiantigen screening test) would be released from quarantine only if such prior collections were not suspected as being ''window'' period donations. Such prior collections, if not exempt from quarantine under proposed § 610.48(g)(2), would be released from quarantine if certain conditions are met as follows: (1) As proposed in § 610.48(j)(2)(i)(A), if the donor's testing records meet the conditions specified in proposed § 610.48(c)(4) (repeatedly reactive HCV EIA 2.0 screening test without additional test results) and further testing was performed in accordance with § 610.48(h)(1)(i)(A) on a frozen sample from the repeatedly reactive donation or a fresh sample from the same donor, and the result of the licensed supplemental test for HCV is negative; or (2) as proposed in § 610.48(j)(2)(i)(B), if the donor's testing records meet the conditions specified in proposed § 610.48(c)(4) and the blood establishment performed further testing in accordance with proposed § 610.48(h)(1)(i)(B) on a frozen sample from the repeatedly reactive donation or a fresh sample from the same donor, using either a licensed HCV EIA 3.0 screening test and the result is negative, or the result of the licensed HCV EIA 3.0 screening test is repeatedly reactive and further testing is performed using a licensed supplemental test for HCV and the result is negative; or (3) as proposed in § 610.48(j)(2)(ii), if the donor's testing records meet the conditions specified in proposed § 610.48(c)(5) (repeatedly reactive HCV EIA 3.0 screening test without additional test results) and the blood establishment performed further testing in accordance with proposed § 610.48(h)(1)(ii) of this section on a frozen sample or a fresh sample from the same donor using a licensed, supplemental test for HCV and the result is negative; or (4) as proposed in § 610.48(j)(2)(iii), if the donor's testing records meet the conditions specified in proposed § 610.48(c)(2) (repeatedly reactive multiantigen screening test and indeterminate supplemental test) and the blood establishment performed further testing in accordance with proposed § 610.48(h)(2), and one of three conditions specified in proposed § 610.48(j)(2)(iii)(A), (j)(2)(iii)(B) or (j)(2)(iii)(C) applies. (Proposed § 610.48(j)(2)(iii)(A) addresses repeatedly reactive sample that was tested using an HCV EIA 2.0 screening test, or a later sample from the same donor that was further tested in accordance with proposed § 610.48(h)(2)(i) of this section using either an HCV EIA 3.0 screening test or a licensed supplemental test for HCV and the result is negative. Proposed § 610.48(j)(2)(iii)(B) addresses the repeatedly reactive sample that was tested using an HCV EIA 2.0 screening test or a later sample from the donor that was further tested in accordance with proposed § 610.48(h)(2)(ii) of this section using a HCV RIBA 3.0 and the result is negative. Proposed § 610.48(j)(2)(iii)(C) addresses the repeatedly reactive sample that was tested using an HCV EIA 3.0 screening test or a later sample from the same donor that was further tested in accordance with proposed § 610.48(h)(2)(iii) of this section using a licensed supplemental test for HCV and the result is negative) or; (5) under proposed § 610.48(j)(2)(iv), if the donor's testing records meet the conditions specified in proposed § 610.48(c)(3) (repeatedly reactive HCV EIA 3.0 screening test and indeterminate HCV RIBA 2.0 supplemental test) and further testing was performed in accordance with proposed § 610.48(h)(2)(iv) of this section on a frozen sample or a fresh sample from the same donor using a licensed supplemental test for HCV and the result is negative.

Under proposed § 610.48(j)(3), prior collections subject to quarantine under proposed § 610.48(f)(1) (as a result of the review of historical testing records and based on a single antigen screening test) would be released from quarantine only if such prior collections were not suspected as being ''window'' period donations. Such prior collections, if not exempt from quarantine under proposed § 610.48(g)(3), would be released from quarantine if certain conditions are met as follows: (1) Under proposed § 610.48(j)(3)(i), if the donor's testing records meet the conditions specified in proposed § 610.48(d)(4) (repeatedly reactive HCV EIA 1.0 screening test with an S/CO value greater than or equal to 2.5) and further testing was performed in accordance with proposed § 610.48(i)(1)(i) on a fresh sample, or frozen sample from the repeatedly reactive donation using a licensed supplemental test for HCV and the result is negative; or (2) under proposed § 610.48(j)(3)(ii), if the donor's testing records meet the conditions specified in proposed § 610.48 (d)(1) (repeatedly reactive HCV EIA 1.0 screening test and repeatedly reactive HCV EIA 2.0 or 3.0 screening test) and further testing was performed in accordance with proposed § 610.48(i)(2)(i) on a fresh sample, or frozen sample from the repeatedly reactive donation and the result of the appropriate supplemental test for HCV is negative; or (3) under proposed § 610.48(j)(3)(iii), if the donor's testing records meet the conditions specified in

proposed § 610.48 (d)(2) and further testing (in the case of a repeatedly reactive HCV EIA 1.0 and indeterminate HCV RIBA 2.0 supplemental test) was performed in accordance with proposed § 610.48 (i)(2)(ii) on a fresh sample, or frozen sample from the repeatedly reactive donation and the result when further tested using either an HCV EIA 3.0 screening test or a licensed supplemental test for HCV is negative; or (4) under proposed § 610.48(j)(3)(iv), if the donor's testing records meet the conditions specified in proposed § 610.48 (d)(3) (repeatedly reactive HCV EIA 1.0 with an S/CO less than 2.5) and further testing was performed in accordance with proposed § 610.48(i)(2)(iii) on a fresh sample, or frozen sample from the repeatedly reactive donation and the result when further tested using a licensed multiantigen screening test for HCV or a licensed supplemental test for HCV is negative.

FDA is proposing a conforming amendment to § 610.46(d), which specifies requirements for release from quarantine for HIV ''lookback,'' for consistency with the HCV ''lookback'' requirements by changing ''Whole Blood, blood components, Source Plasma and Source Leukocytes'' to ''blood and blood components.''

P. Proposed § 610.48(k), Destruction or Labeling of Prior Collections Held in Quarantine

The purpose of proposed § 610.48(k) is to identify prior collections that must be destroyed or appropriately labeled, that is, those prior collections that are not exempt from quarantine under proposed § 610.48(g) and do not meet the conditions for release from quarantine in accordance with proposed § 610.48(j). Proposed § 610.48(k) would require that blood establishments and consignees take appropriate action for prior collections subject to quarantine under proposed § 610.48(a), (e), and (f). Blood establishments would be required to either destroy the quarantined prior collections or appropriately label the collections for in vitro use unless: (1) The prior collection was determined to be exempt from quarantine in accordance with proposed § 610.48(g), or (2) the prior collection was subject to release from quarantine under proposed § 610.48(j). FDA recognizes there may be some limited uses for quarantined prior collections which are not suitable for release from quarantine for the product's original intended use. Such prior collections should not be used for transfusion or for further manufacturing into injectable products. FDA recommends that these prior collections be destroyed as a general practice; however, in limited situations, release for research or manufacture into in-vitro diagnostic reagents may be acceptable. If released for these uses, prior collections should be relabeled consistent with §§ 606.121 and 640.70. In addition, these prior collections must be relabeled as ''Biohazard'' with the cautionary statements as follows:

Collected from a donor who subsequently tested reactive for anti-HCV. An increased risk of transmission of hepatitis C is present.''; in addition, the label must contain one of the following cautionary statements, as appropriate: ''Caution: For Further Manufacturing Into In-Vitro Diagnostic Reagents For Which There Are No Alternative Sources.'' or ''For Laboratory Research Use Only.

FDA is proposing a conforming amendment to § 610.46, the HIV ''lookback'' requirements, for consistency and to clarify the actions to be taken for prior collections subject to quarantine under § 610.46(a). FDA is proposing to redesignate § 610.46(e) as § 610.46(f) and to add new § 610.46(e) *Destruction or labeling of prior collections held in quarantine*, consistent with this proposal.

Q. Proposed § 610.48(l)

Proposed § 610.48(l) specifies that actions taken under proposed § 610.48 do not constitute a recall. This regulation is consistent with current § 610.46(e) applicable to the HIV ''lookback'' requirements (as noted previously, FDA is proposing to redesignate paragraph (e) as paragraph (f)). While there are similarities between the product recall process and ''lookback,'' there are several important differences: (1) The recall procedures described in part 7 (21 CFR part 7) are intended as a guideline while ''lookback'' would be a regulatory requirement; (2) additional steps are required in ''lookback'' which are not ordinarily performed in a product recall; (3) because each ''lookback'' would be initiated due to similar circumstances, a health hazard evaluation and recall classification by the agency (see § 7.41) is unnecessary; and (4) the products being quarantined may not be in violation of applicable laws (see § 7.40). FDA recognizes that a ''lookback'' action does not mean that an establishment has erred or did not meet its obligations under the regulations and the law in assuring the safety of the blood supply. Failure to take appropriate action in accordance with the proposed ''lookback'' regulations, however, would be a violation and FDA would take enforcement action, when appropriate, in such situations.

R. Proposed § 610.49(a), Hepatitis C Virus (HCV) ''Lookback;'' Notification of Transfusion Recipients

The purpose of proposed § 610.49 is to identify the circumstances under which it is necessary to notify transfusion recipients; who is responsible for performing the notification; and the timeframes for completing the notification process. The notification process is intended to result in the notification of transfusion recipients who have received prior collections of blood and blood components from a donor later determined to be at increased risk of transmitting HCV infection because they are possible ''window period'' donations. Refer to the discussion in the description of proposed § 610.48(c) for more information on ''window period'' donations. As previously discussed, there are two sets of circumstances which trigger ''lookback'' activity. The notification of transfusion recipients would be performed as a result of: (1) The identification of a donor who returns to donate again and tests repeatedly reactive for evidence of HCV infection on a licensed multiantigen screening test (as specified in § 610.48(a)) and further testing (performed as specified in proposed § 610.48(b)) indicates an increased risk of transmitting HCV; or (2) the identification of a donor, as a result of the review of historical testing records (in accordance with proposed § 610.48(c) or (d)), and further testing (as shown in historical records or as performed under proposed § 610.48(h) or (i)) indicates an increased risk of transmitting HCV. Under the proposal, transfusion recipient notification need not be performed for prior collections of Source Plasma and Source Leukocytes, because they are intended for further manufacture and not for transfusion. Proposed § 610.49(a), would require transfusion services to take appropriate actions, in accordance with § 610.49(b) and (c), when a transfusion recipient has received blood or blood components, from a donor later determined to be at increased risk of transmitting HCV infection as follows: (1) The donor was identified in accordance with proposed § 610.48(a) and the result of the licensed, supplemental test performed in accordance with proposed § 610.48(b) is positive; or (2) the donor was identified in accordance with proposed § 610.48(c)(1), and the result of the supplemental test identified in the review of records is positive; or (3) the

donor was identified in accordance with proposed § 610.48(c)(2), and the result of the supplemental test identified in the review of records is indeterminate, unless either the historical testing records or further testing (in accordance with proposed § 610.48(h)) show the indeterminate supplemental test result was obtained using a licensed supplemental test, and the initial test result was determined to be a false positive because any of the conditions for exemption from quarantine or release from quarantine have been met ; or (4) the donor was identified in accordance with proposed § 610.48(c)(4) or (c)(5) as testing repeatedly reactive on a multiantigen screening test with no record of further testing and the result of the licensed, supplemental test performed, in accordance with proposed § 610.48(h)(1)(i)(A), (h)(1)(i)(B), or (h)(1)(ii) is positive; or (5) the donor was identified in accordance with proposed § 610.48(c)(4) or (c)(5) as having no record of further testing and no fresh or frozen sample is available for further testing, as specified in proposed § 610.48(h)(1)(iii); or (6) the donor was identified in accordance with proposed § 610.48(d)(1) unless the initial test result was determined to be a false positive because any of the conditions for exemption from quarantine (under proposed § 610.48(g)(3)) or release from quarantine (under proposed § 610.48(j)(3)) have been met, or the donor was further tested in accordance with § 610.48(i)(2)(i) using an appropriately chosen supplemental test for HCV and the result is negative or indeterminate; or (7) the donor was identified in accordance with proposed § 610.48(d)(2) and the result of the supplemental test performed using an HCV RIBA 2.0 or HCV RIBA 3.0 supplemental test is positive as identified in the review of historical testing records; or (8) the donor was identified in accordance with proposed § 610.48(d)(2), and the result of the supplemental test performed using HCV RIBA 2.0 is indeterminate, unless any of the conditions for exemption from quarantine (under proposed § 610.48(g)(3)), or release from quarantine (under proposed § 610.48(j)(3)) have been met, or the donor was further tested in accordance with proposed § 610.48(i)(2)(ii) using a licensed supplemental test for HCV and the result is indeterminate; or (9) the donor was identified in the review of historical testing records in accordance with proposed § 610.48(d)(3) (repeatedly reactive HCV EIA 1.0 with an S/CO value less than 2.5) and the result of the licensed, supplemental test for HCV performed in accordance with proposed § 610.48(i)(2)(iii) is positive; or (10) the donor was identified in the review of historical testing records in accordance with proposed § 610.48(d)(4) (as testing repeatedly reactive on a single antigen screening test with a S/CO value equal to or greater than 2.5 for at least two of the three EIA tests, or the S/CO value can not be calculated, and with no record of further testing) and the result of the licensed, supplemental test for HCV performed in accordance with § 610.48(i)(1) is positive; or (11) the donor was identified in the review of historical testing records, in accordance with § 610.48(d)(4), and no record of further testing is available and no fresh or frozen sample is available for further testing, as specified in § 610.48(i)(1)(ii).

FDA is proposing conforming amendments to HIV ''lookback'' requirements of § 610.47(a) for consistency with the HCV ''lookback'' requirements of proposed § 610.49(a). FDA is proposing to amend § 610.47(a) to clarify that transfusion services shall notify recipients of prior collections of blood and blood components from a donor later determined to be at increased risk of transmitting HIV infection when tested for evidence of HIV infection and the result of the additional tests required in § 610.46(b) are positive.

S. Proposed § 610.49(b), Notification of Recipients of Prior Transfusion

Proposed § 610.49(b) describes the requirements for the process of notification of transfusion recipients. Under proposed § 610.49(b), consistent with requirements for notification in the HIV ''lookback'' regulations in § 610.47, the transfusion service would either notify the physician of record (i.e., the physician of record or physician who ordered the blood) and ask him or her to inform the recipient, or would notify the recipient directly. FDA recognizes that, under certain circumstances, the physician may have developed an ongoing relationship with the patient and may agree to take responsibility for notification and counseling. The transfusion service is ultimately responsible for ensuring that the notification takes place. The transfusion service might seek assistance in the notification process. For example, the transfusion service might determine that such notification and counseling would be best conducted by staff in another department in the hospital, who may be better trained and experienced in counseling patients. Under proposed § 610.49(b) and under the proposed conforming amendment to § 610.47(b), a transfusion service may elect to notify the transfusion recipient directly, without the assistance of the patient's physician of record. FDA specifically requests comment whether the transfusion service should be required to perform concurrent notification of the physician of record whenever the transfusion service notifies the transfusion recipient directly.

Proposed § 610.49(b) would require the transfusion service to make a minimum of three attempts to notify the transfusion recipient or the recipient's physician of record. The time period provided for completion of the recipient notification would be based on the date of donor testing and the date of receipt of the supplemental test result from the blood establishment. Recipient notification based on donor testing completed after the effective date of the regulation, as specified in the final rule resulting from this proposal, would be required to be completed within a maximum of 12 weeks of receipt of the results of the donor's supplemental test for HCV from the blood establishment. Recipient notification based on donor testing completed prior to the effective date of the regulation, as specified in the final rule resulting from this proposal (historical records of donor testing), would be required to be completed within 1 year of receipt of notification of test results from the blood establishment. FDA is proposing a longer period of time for completion of transfusion recipient notification based on donor testing completed prior to the effective date of the regulation because such notification would be made as a result of the review of historical testing records performed in accordance with proposed § 610.48(c) and (d), and it is possible that a transfusion service could have a large number of notifications to complete. However, FDA believes that the transfusion recipient notification process should begin and be completed as soon as feasible because such a notification will not require a year to complete in all cases. FDA recognizes that many blood establishments may be performing such transfusion recipient notifications consistent with the recommendations of the June 1999 draft guidance. Therefore, FDA believes that if a blood establishment has a limited number of transfusion recipient notifications to perform as a result of this regulation, then the notifications could be completed in less than the 1-year period that would be provided under this proposal. In addition, donors identified in accordance with proposed § 610.48(c)(2) through (c)(5), and proposed § 610.48(d)(1) through (d)(4) generally will be further tested by the

blood establishment in accordance with § 610.48(h) and (i), respectively. In those instances, FDA would require that the notification of recipients based on such a licensed supplemental test, performed after the effective date of the regulation, be completed within 12 weeks of the date of receipt of the supplemental test result from the blood establishment.

Under proposed § 610.49(b), the transfusion service would be responsible for the basic explanation to the recipient, referral for counseling and further testing, and documentation of the notification or attempts to notify the physician of record or the recipient, under § 606.160 of this chapter. Under this proposal, each establishment should have a well-designed system for notification, and would need to develop SOP's that describe each step in the notification system, as well as the required documentation. The SOP would address the need for documentation of person(s) contacted, by whom, when and whether the transfusion recipient was notified directly, or the physician of record agreed to notify the recipient, and the outcome of the notification efforts, including the reasons for inability to notify.

FDA is requesting comment on the appropriateness of requiring a minimum of three attempts to notify affected transfusion recipients as proposed for HIV and HCV ''lookback.'' FDA is proposing to increase the record retention requirement to 10 years (proposed § 606.160(d)) and to increase the length of time for which HIV and HCV ''lookback'' must be initiated, from a maximum of 5 years as currently required in § 610.46(a) for HIV ''lookback'' (for HCV ''lookback'' in proposed § 610.48(a)). In addition, FDA is proposing to require HCV ''lookback'' based on the review of available historical testing records (proposed § 610.48(c) and (d)) for those prior collections'' * * * dating back indefinitely for computerized electronic records and to January 1, 1988, for other readily retrievable records.'' FDA specifically requests comment on the minimum number of attempts which should be required to notify affected transfusion recipients identified in the records that are more than 5 years old and who, therefore, might be more difficult to locate. FDA also requests the submission of data which support a specific number of attempts to notify affected transfusion recipients.

FDA is proposing conforming amendments to HIV ''lookback'' requirements of § 610.47(b) for consistency with the HCV ''lookback'' requirements of proposed § 610.49(b). FDA is proposing to amend § 610.47(b) to clarify that transfusion services have the option of either notifying the transfusion recipient directly or notifying the recipient's physician of record and asking him or her to notify the recipient and that notification (based on donor testing completed after the effective date of the regulation) must be completed within a maximum of 12 weeks.

T. Proposed § 610.49(c), Notification of Legal Representative or Relative

Proposed § 610.49(c) would require the transfusion service or physician to notify a legal representative, designated in accordance with State law, if the transfusion recipient has been adjudged incompetent by a State court. In addition, if the transfusion recipient is competent, but State law permits a legal representative or relative to receive the information on the recipient's behalf, proposed § 610.49(c) would require the transfusion service or physician to notify the recipient, or his or her legal representative or relative. If the transfusion recipient is a minor at the time of notification, the transfusion service would be required to notify the recipient's legal representative. Under proposed § 610.49(c), reasons for notifying the recipient's relative or legal representative on his or her behalf would be documented, as required in the recordkeeping provisions of § 606.160. Proposed § 610.49(c) would not require notification efforts to continue if the recipient is deceased because, as previously discussed, direct percutaneous exposure to infectious blood, particularly in the setting of drug abuse, accounts for the majority of HCV infections acquired in the United States. Secondary transmission of HCV to sexual partners, care providers or others with close contact is very unlikely.

FDA is proposing conforming amendments to HIV ''lookback'' requirements of § 610.47(c) for consistency with the HCV ''lookback'' requirements of proposed § 610.49(c). FDA is proposing to amend § 610.47(c) to clarify that transfusion service or physician would be required to notify the legal representative if the transfusion recipient is a minor at the time of notification and to document the result of the notification or the attempts to complete the notification.

U. Proposed § 610.49(d), Reference Tables

Proposed § 610.49(d) includes four tables intended to assist in identifying the applicable paragraphs of proposed §§ 610.48 and 610.49 and the corresponding ''lookback'' actions. In particular, the requirements of proposed §§ 610.48 and 610.49 that are based on the review of historical testing records require that many different testing sequences be addressed. These tables are intended to clarify the applicable sections and the corresponding steps of the ''lookback'' process that must be considered for a particular sequence of tests.

Table 1 identifies applicable sections for the ''lookback'' process based on current donor testing, for donors identified in accordance with proposed § 610.48(a). For example, a donor that tests repeatedly reactive for HCV upon returning to donate again, would be identified by the blood establishment in accordance with proposed § 610.48(a). Table 1 of proposed § 610.49 lists the subsequent ''lookback'' actions that must be taken and the applicable regulations. Continuing with this example, in addition to other ''lookback'' actions, table 1 shows that such a donor would be further tested in accordance with proposed § 610.48(b), and prior collections could be released from quarantine if the conditions of proposed § 610.48(j)(1) were met.

Tables 2, 3, and 4 of proposed § 610.49 identify applicable sections for the ''lookback'' process based on the review of historical testing records. A different table applies based on the specific screening test that was performed. Table 2 identifies applicable sections based on the review of historical testing records for donors identified in accordance with proposed § 610.48(c) as testing repeatedly reactive using an HCV EIA 3.0 screening test. Table 3 identifies applicable sections based on the review of historical testing records for donors identified in accordance with proposed § 610.48(c) as testing repeatedly reactive using an HCV EIA 2.0 screening test. Table 4 of proposed § 610.49 identifies applicable sections based on the review of historical testing records for donors identified in accordance with proposed § 610.48(d) and tested using a single antigen screening test, HCV EIA 1.0.

IV. Analysis of Impacts and Initial Regulatory Flexibility Analysis

FDA has examined the impacts of the proposed rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic,

environmental, public health and safety, and other advantages; distributive impacts; and equity). The Regulatory Flexibility Act requires agencies to analyze whether a rule may have a significant impact on a substantial number of small entities and, if it does, to analyze regulatory options that would minimize the impact. Section 202(a) of the Unfunded Mandates Reform Act requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation).

The agency has determined that the proposed rule may be a significant action as defined by the Executive Order. The analysis below details FDA's estimate of the potential costs and benefits of the rule. As described in the analysis that follows, the rule is likely to have a significant economic effect on a substantial number of small entities. FDA has therefore prepared an Initial Regulatory Flexibility Analysis. The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for the proposed rule, because the proposed rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation. The current inflation adjusted statutory threshold is about $110 million.

A. Economic Impact

The purpose of the proposed rule is to help ensure the continued safety of the blood supply and to help ensure that information is provided to consignees and recipients of blood products in the event of a repeat donor's seroconversion to positivity for hepatitis C. The proposed action is considered necessary to interdict prior in-date collections at increased risk for transmitting HCV and to help assure that blood product recipients receive counseling and treatment if necessary, as effective therapies become available for hepatitis C. The proposed rule will further support public confidence in safety of the U.S. blood supply, recognizing priorities for the reduction of infectious disease risks to transfusion recipients. The agency further notes that the costs and benefits of the FDA and the Health Care Finance Administration (HCFA) rule are not additive, as the impacts considered in the HCFA rule are also accounted for in the FDA rule.

1. The Number and Type of Entities Affected

The proposed rule will affect establishments that collect, process, and ship blood and blood components, and establishments that transfuse those products. The affected entities include commercial plasma centers, regional and community blood collection or donation centers, hospitals that operate blood collection centers, and facilities that transfuse blood products. The HCFA estimates that there are approximately 6,200 transfusing facilities. FDA's Office of Blood Research and Review (OBRR) has a record of 2,801 registered blood and plasma establishments.

According to a 1992 survey (Ref. 3), U.S. blood establishments collect an annual total of 13,794,000 units of blood. Allogeneic donations (not directed for a specific recipient) accounted for 87.2 percent (12,035,000 units). Approximately 79 percent of allogeneic donations are provided by repeat donors. (This percentage is based on American Red Cross estimates based on donations between January 1996 and June 1997.) FDA's analysis of the HCV ''lookback'' rule focuses on allogeneic donations by repeat donors, and the subset of those donors expected to test repeatedly reactive in a screening test for evidence of HCV infection. As outlined in preceding sections of this document, the proposed rule includes a set of provisions for processes to be performed by blood establishments. In general terms, these provisions concern donor recordkeeping, record review, identification and quarantine of affected units for repeat reactive donors, notification of consignees of unpooled products concerning the HCV status of affected units, and further testing to confirm HCV positivity. The proposed rule also specifies requirements for blood product consignees that relate to quarantine of in-date unpooled products based on blood establishment notifications, and recipient notification when appropriate.

Plasma centers will be affected by the proposed rule only to the extent that these establishments store and distribute unpooled units to consignees that also retain unpooled units in their inventories. FDA currently has little information about the volume of unpooled units retained by plasma centers that would be affected by this proposal. Because this information is essential for the estimation of economic impact, FDA requests detailed industry comment on current practices for recordkeeping and retention of unpooled units of plasma (including estimated numbers of unpooled units), both at collection centers and the facilities to which these units are subsequently shipped. For the purpose of this analysis, FDA has assumed that most units will be pooled prior to the initiation of any ''lookback'' activity and, therefore, that plasma establishments will be minimally affected by the proposed rule. Plasma establishments similarly will not be affected by the proposed requirements for review of historical testing records. FDA, therefore, assumes that the primary impact on plasma establishments will involve the review of the proposed regulation by each establishment to determine how current facility SOP's would be affected.

With the exception of hospitals that both collect and transfuse blood products, most establishments affected by the rule will either act as a blood collection establishment or as a consignee (transfusion service), not as both. To distinguish the impact of the requirements for blood establishments and for consignees, the rule provisions affecting each type of entity will be treated separately in the analysis that follows. Table 1 of this document provides a summary of the estimated one-time versus the yearly costs for blood establishments and blood product consignees. The basis for these estimates are explained in sections IV.A.2 and IV.A.3 of this document.

TABLE 1.—SUMMARY OF ESTIMATED ONE-TIME YEARLY COSTS FOR BLOOD ESTABLISHMENT AND BLOOD PRODUCT CONSIGNEES

Affected Entities (number)	One-Time Cost	Yearly Cost
Blood Establishments (2,800)		
Hepatitis C Virus (HCV) ''Lookback'' Standard Operating Procedures (SOP's)	$2,875,040	
Prospective review		$4,558,442

TABLE 1.—SUMMARY OF ESTIMATED ONE-TIME YEARLY COSTS FOR BLOOD ESTABLISHMENT AND BLOOD PRODUCT CONSIGNEES—Continued

Affected Entities (number)	One-Time Cost	Yearly Cost
Historical review	$33,239,402	
Subtotal	$36,114,442	$4,558,442
Consignees (6,200)		
HCV ''Lookback'' SOP's	$2,546,464	
Prospective review		$2,114,632
Historical Review	$50,106,540	
Subtotal	$52,653,004	$2,114,632
Total	$88,767,446	$6,673,074

2. Estimated Impact on Blood and Plasma Establishments

Many of the provisions of the proposed rule will affect blood establishments. Each establishment will need to review the provisions of the rule in order to reconcile current facility practices for record review, sample quarantine, consignee notification and other related processes, and donor and blood product recordkeeping, with the requirements of the rule. FDA estimates the cost of performing such a one-time review and reconciliation of blood establishment SOP's to be approximately $1,027 per establishment, assuming that the review will require approximately 40 hours per facility and be performed by a staff medical technologist (Ref. 4). This yields a total one-time cost of $2,875,040.

The proposed rule requires that blood establishments extend the retention period for required processing records for blood donors from 5 to 10 years after the records of processing have been completed or 6 months after the latest expiration date for the individual product, whichever is a later date. FDA estimates that this provision will cost approximately $3,110,240 per year, assuming that routine maintenance of donor files for the additional period of time will require approximately 40 hours of additional programming support time per facility per year, at a cost of $27.77 per hour of programmer time, based on 1997 Bureau of Labor Statistics estimates (40 x $27.77 x 2,800).

The proposed rule requires that blood and plasma establishments act within 3-calendar days of receiving the results of an FDA-licensed HCV test performed by a blood establishment or a CLIA-certified laboratory, with repeatedly reactive HCV results for a repeat blood donor. The establishment would retain the records for all in-date products and quarantine any in-date unpooled product that remain in inventory, quarantine all in-date unpooled prior collections, and notify consignees of the repeatedly reactive test result so that they may also quarantine any in-date unpooled prior collections. However, prior collections made more than 12 months prior to the last negative multiantigen HCV screening test are exempt from the required quarantine. Following the repeatedly reactive results of the initial screening tests, the blood establishment would be required to notify consignees of the result of the more specific supplemental HCV test within 45-calendar days after the day on which the donor tests repeatedly reactive in a screening test for evidence of HCV infection. If the result of further testing with a licensed supplemental test is negative, then the initial screening test result can be considered a ''false positive'' and the in-date prior collections can be released from quarantine.

FDA's estimated cost of these provisions is based on an estimated number of consignee notifications multiplied by the unit cost of each notification. First, the number of annual affected blood donations was calculated as the product of 12 million donations, an 80 percent repeat donor rate, and a 0.12 percent HCV positive donor rate. The resulting 11,520 figure was then adjusted upward to 12,816 to reflect the difference found between the number of donors triggering ''lookback'' and the component notifications reported as interim results from a recent survey conducted by the Centers for Disease Control and Prevention (CDC) (Ref. 4). Assuming a cost of $113 per notification based on remarks from a representative of the nation's blood banks (Ref. 5) yields a consignee notification cost to blood banks of $1,448,202 per year (12,816 x $113). Thus, the prospective review in the proposed rule results in a yearly total cost of $4,558,442 ($3,110,240 + $1,448,202) for blood establishments. These costs may be slightly understated, because the CDC survey-based projections extend back only to 1988 records. Nevertheless, because the proposed rule requires pre-1988 searches only for ''computerized electronic records,'' this underestimate would be small.

The proposed rule would also require a review of historical testing records of donations collected prior to the effective date of the rule. Blood establishments will be required to review records from prior collections to identify donors that tested repeatedly reactive in a screening test for evidence of HCV infection, for whom either: (1) There is no record of further testing, (2) the donor tested indeterminate on a supplemental test for HCV (with some exceptions), or (3) the donor tested positive on a supplemental test. The purpose of the record review is to identify prior collections from donors who are likely to be infected in order to notify recipients of such donations, and quarantine affected products that remain in inventory.

Following their review of historical testing records, blood establishments would be required to do the following tasks. If the records show that the repeat donation, testing repeatedly reactive in a screening test for evidence of HCV infection, was followed by an appropriate licensed supplemental test with confirmed negative results, no further action is needed. If the repeat donation, testing repeatedly reactive in a screening test for evidence of HCV infection, was followed by a supplemental test with confirmed positive results, the blood establishment

would notify consignees of blood products from the donor's prior donations and quarantine affected products that remain in inventory. If the records show that the donation, testing repeatedly reactive in a screening test for evidence of HCV infection, was followed by a supplemental test with indeterminate result, or there is no record of supplemental testing to determine the donor's HCV status, the blood establishment would try to perform supplemental testing to clarify the status of prior collections. If a frozen sample from the donation testing repeatedly reactive in a screening test for evidence of HCV infection is available, that sample would be used in supplemental testing; otherwise, the blood establishment would attempt to contact the donor to obtain a fresh sample for testing. If further testing with fresh or frozen samples is accomplished, the blood establishment would be required to notify consignees of the test result. If no frozen sample is available and a fresh sample cannot be retrieved from the donor, the blood establishment would be required to notify consignees of the results of the repeatedly reactive screening test and the inability to clarify the donor's HCV status. Within 1 year of the effective date of the final rule, blood establishments would be required to perform the testing needed to clarify the status of prior collections. Blood establishments would be required to notify consignees of HCV positive test results within 45 days of completion of further testing performed as a result of the review of historical testing records. If no further testing could be performed, consignees would be notified within 1 year.

FDA's estimate of the cost of performing the specified review of historical testing records is based on the CDC estimate of 294,154 attempted notifications (188,448 during the period 1990 to mid-1992 and 105,706 during the period from mid-1992 to 1998) and the estimated cost of $113 per notification (Ref. 5). This yields a one-time review cost of $33,239,402. Again, this estimate does not account for pre-1988 computerized electronic records, but the agency believes there are relatively few.

In total, as shown in table 1, FDA's estimates that blood collection agencies will incur ''lookback'' related one–time costs of about $36.1 million and annual costs of about $4.6 million. As the industry has already initiated this program, it is likely that the greater part of these costs have already been incurred.

3. Estimated Impact on Blood Product Consignees

The proposed rule would require that transfusion services (i.e., consignees) notify transfusion recipients who received prior collections from a donor at increased risk of transmitting HCV. Recipient notification is included in both the prospective ''lookback'' and the review of historical testing records to identify prior collections. The transfusion service may notify the physician of record or notify the recipient directly. If the transfusion recipient is a minor or adjudged incompetent by a State court, the transfusion service or physician would be required to notify the recipient's legal representative. The proposed rule is expected to generate one-time costs and some additional annual costs for blood product consignees. One-time costs include the development of facility SOP's for recipient notification. FDA assumes that these tasks will involve the review of current SOP's (e.g., for HIV ''lookback'') and the adaptation or modification of current procedures to address the provisions of this rule and estimates that they will require an average of 16 hours per facility for facilities that act as consignees. The review would be performed by a staff medical technologist at an estimated cost of $25.67 per hour. Thus, FDA estimates the total one-time cost for the 6,200 transfusing facilities to be $2,546,464.

For notifications resulting from prospective donor testing and required quarantine, the required notification effort would include a minimum of three attempts to notify the transfusion recipient and would be completed within a maximum of 12 weeks of receipt from the blood establishment of the results of the donor's supplemental test for HCV. The agency's estimated cost of compliance with provisions concerning the prospective review and recipient notification is based on the previously described estimate of 11,520 annual affected donations. This figure was adjusted to 12,816 to reflect the CDC survey finding that the number of components sent to transfusion facilities exceeded the number of donors triggering ''lookback'' at blood centers by 11.2 percent. The cost per attempted notification is estimated at $165 which reflects the average cost quoted by a third party contractor for matching, notifying, testing, counciling, and documenting ''lookback'' efforts for over 100 hospitals (Ref. 6). Although the proposed rule does not specifically require hospitals to perform testing and counciling services, many do. These assumptions yield an annual cost of $2,114,632 (12,816 x $165) for blood consignees to conduct prospective ''lookback'' activities.

Notifications resulting from the review of historical testing records and the identification of prior collections are to be completed by the transfusion service within 1 year of receipt of notification from the blood establishment. The recipient notification provided by the transfusion service would include a basic explanation to the recipient, referral for counseling and further testing and documentation of the notification or attempts to notify the physician of record or recipient. The estimated one-time cost of recipient notification associated with the review of historical testing records is $50,106,540. This is based on the CDC estimate of about 303,676 recipients identified for notification (188,448 from 1990 to mid–1992 and 115,228 from 1990 to mid–1992), and the average cost of $165 of staff time per component for recipient notification. Thus, FDA estimates the total one-time cost to blood transfusion facilities to be $52,653,004 ($2,546,464 + $50,106,540) for conducting retrospective ''lookback''.

The cost of targeted HCV ''lookback'' notification in the United States is expected to compare favorably with the experiences reported in earlier efforts, e.g., in Canada (Ref. 7), which were likely based on less automated approaches to recordkeeping. Table 2 of this document shows the cost of the HCV ''lookback'' per recipient notified, using CDC data to project various outcomes of the ''lookback'' effort. As shown in table 2, the assumption that a total of 258,551 transfusion recipients will be identified for notification through the historical ''lookback'' effort translates to an estimated one-time cost of about $642 per recipient identified. CDC further estimates that approximately 57,885 will still be living and notified through the retrospective review. This estimate implies a one-time cost of $1,440 per notified living recipient.

TABLE 2.—ESTIMATED COST PER RECIPIENT NOTIFICATION

	Cost of ''Lookback'' and Notification[1]	Cost Per Recipient Transfused	Cost Per Recipient Notified
Prospective	$6,673,074[2]	$658	$1,541
Historial	$83,345,942	$642	$1,440

[1] Excludes cost of developing SOP's.
[2] Annual cost.

B. Benefits of the Proposed Rule

The proposed rule is intended to help ensure the continued safety and adequacy of the national blood supply. Threats to the safety of the blood supply and the importance of a timely regulatory response to assure public safety have been the focus of numerous review efforts in recent years, by the U.S. House of Representatives Committee on Government Reform and Oversight, Subcommittee on Human Resources and Intergovernment Relations, the General Accounting Office, IOM, and private organizations including the American Liver Foundation and the DHHS Advisory Committee on Blood Safety and Availability. The proposed ''lookback'' effort provides benefits both at the individual level of blood recipients and at a societal level, in terms of both the safety and continued adequacy of the national blood supply. The discussion that follows first addresses individual level benefits and then considers societal benefits.

1. Individual Benefits of HCV ''lookback''

Over the past several years, the improved accuracy of HCV testing, the increased understanding of hepatitis C outcomes, the value of counseling against risk behaviors that worsen outcomes, and the advances in treatment of HCV have collectively created a medical and ethical imperative to inform identified transfusion recipients of their HCV risk. Prior to the widespread use of HCV screening of blood donors, transfusion was one of the most common modes of transmission. Although patients with chronic hepatitis C may remain asymptomatic for a number of years, the consequences of their disease are extremely serious. For example, CDC population-based studies indicate that 40 percent of chronic liver disease is HCV-related, resulting in an estimated 8,000 to 10,000 deaths each year (Ref. 8). Current CDC estimates of medical and work-loss costs of all HCV-related acute and chronic liver disease (including cases resulting from blood transfusion) are in excess of $600 million annually, and HCV-associated end-stage liver disease is the most frequent indication for liver transplantation among adults. The cost of liver transplantation is estimated to be approximately $200,000 in the first year and $20,000 per year for subsequent years; and the cost of treatment for hepatocellular carcinoma, another sequelae of chronic liver disease, is estimated to be $10,000 per year (Ref. 9).

Timely notification of HCV infection benefits the infected blood recipient in several important ways. First, although factors predicting severity of liver disease due to HCV have not been well-defined, recent data indicate that increased alcohol intake is associated with more severe liver disease. According to CDC, even moderate amounts of alcohol in patients with chronic hepatitis C might enhance liver disease. Consequently, an HCV-infected patient identified by the proposed ''lookback'' program could minimize liver damage associated with alcohol consumption by restricting his or her intake.

Next, while other percutaneous exposures currently represent the most common means of infection, some case-control studies have also reported a positive association with sexual contact with a person with a history of hepatitis and acquiring hepatitis C. In fact, 15 to 20 percent of the acute hepatitis C patients reported to CDC's sentinel counties surveillance system have a history of sexual exposure in the absence of other risk factors. Infected patients identified through the proposed ''lookback'' procedures could take steps to protect sexual partners from the risk of infection.

Next, it is important to note that identified infected patients would benefit from treatment with available therapies. Studies of patient characteristics and responsiveness to therapy indicate that best results are achieved if treatment is initiated earlier in the disease, when patients are younger and have not yet developed cirrhosis (Ref. 10). For example, Bennett et al. estimated the cost effectiveness of a single course (6 months) of treatment with alfa interferon and found that patients at age 20 experience an average of 3.1 years of life gained at $500 per year of life extended (YLE); 30-year-old patients have an average gain of 1.9 years of life, at $7,100/YLE; patients starting treatment at age 50 have 6 months of life gained at $7,100/YLE; and 70-year-old patients gain an average of 22 days at $62,000/YLE (Ref. 11).

Next, care providers for the identified infected patient would be aware of the infection and could use additional precautions to avoid the risk of exposure to blood or wounds when providing care to the patient. Finally, identified infected patients would be informed that they must not donate blood.

Currently, the primary treatment for chronic hepatitis C is alfa interferon therapy (Ref. 12). On average, of those patients who undergo interferon treatment, a reported 10 to 20 percent show a sustained response after 6 months of therapy, and 20 to 30 percent a sustained response if therapy is continued for 12 months. Although alfa interferon produces a wide array of adverse side effects (Ref. 13), and some patients experience a relapse of HCV infection despite therapy, the benefits for patients identified for treatment through HCV ''lookback'' are likely to continue to increase as improved therapies are developed. In particular, combination therapy using alfa interferon plus ribavirin has been reported to result in an improved outcome (Ref. 13).

In addition to the ''lookback'' costs discussed previously, the overall cost-effectiveness of the proposed regulation will vary with the cost and effectiveness (i.e., cure rate) of therapy for hepatitis C, and the cost of treatment for chronic liver disease and its sequelae in the absence of, or with failure of treatment for hepatitis C. A single course of alfa interferon therapy has been estimated to cost $2,300 (Ref. 9), but hepatitis C therapy is a rapidly changing area of clinical practice and the cost-effectiveness of treatment can shift dramatically with the introduction of new drugs and the age distribution and the comorbidities of the population receiving treatment. An illustrative example, however, can demonstrate the potential benefits of the increased therapies that might result from this

regulation. Although FDA cannot precisely determine the number of HCV positive individuals that would respond to the notification and seek medical consultation, a projection derived largely from interim findings of the CDC survey indicates that retrospective notification activities might identify about 3,764 cases of previously unidentified chronic HCV. This projection assumes that about 22.4 percent of 258,551 potential recipients are notified, about 13 percent of those notified test positive for HCV, 66.7 percent of the HCV cases are not currently known, and 75 percent of the HCV cases are chronic. Kim et al. (Ref. 9) found that, on average, patients with chronic HCV gain 0.25 discounted (3 percent) quality adjusted life-years (QALY's) from 6 months of interferon-2b treatment. (The authors do not provide estimates for any other discount rates.) On this basis, the above assumptions imply that retrospective ''lookback'' would gain a total of 941 QALY's, at a cost of about $88,573 per QALY.

There is no generally accepted means of valuing life-years saved, although a number of empirical studies indicate a societal willingness-to-pay of from $1.6 million to $11.6 million to avoid a statistical death. Assuming a mid-range estimate of $5 million and annualizing over a 35-year period at 3 percent yields an annual value of $233,000. The above assumptions imply that providing 6 months of interferon- 2b therapy to an additional 3,764 HCV-positive individuals could produce societal willingness-to-pay benefits of $219 million. The additional discounted (3 percent) incremental cost of providing such therapy was estimated by Kim et al. to be about $1,000 per patient, which implies an additional treatment cost of only $3,764,000 (3,764 patients x $1,000). Thus, by this measure, the individual benefits of retrospective HCV ''lookback'' easily exceed their incremental costs.

The benefits of the prospective ''lookback'' provisions can be similarly analyzed. Based on the CDC interim findings, FDA assumed that prospective ''lookback'' notifications would be initiated for 10,894 transfused recipients, of which 48 percent would be successful, 5.4 percent of those who are notified would test positive for HCV, 66.7 percent would be previously unknown, and 75 percent chronic. Thus, 123 patients could potentially gain 0.25 QALY's per year at a cost of roughly $217,011 per QALY. According to the monetization values described above, these health gains could generate annual benefits of $7.2 million, or roughly the level of the prospective ''lookback'' costs.

The agency recognizes the substantial uncertainty that surrounds such estimates. For example, medical cost-effectiveness studies sometimes assume a maximum societal value of about $50,000 per QALY. This modification would imply one-time retrospective ''lookback'' benefits of about $47 million and annual prospective ''lookback'' benefits of about $1.5 million, which would cover over half of the estimated initial costs of compliance. In addition, the figures assume that the distribution of recipient ages would reasonably match those of the Kim et al. study. Other studies of HCV treatment outcomes may project differently. FDA seeks public comment on the above assumptions and estimates.

2. Societal Benefits of HCV ''lookback''

In addition to the direct benefits of medical treatment, the proposed ''lookback'' program will help to boost confidence and trust in the national blood supply. Thus, HCV ''lookback'' will generate societal benefits that are incremental to the health benefits discussed above. Recent public reviews of blood supply issues have recognized the importance of assuring both safety and the perception of safety. For example, reviews suggest that the public trust in the blood supply system was severely shaken by the transmission of HIV by blood products. This effect was exacerbated by the perceived failure of blood collection centers, public health agencies, and health care providers to take timely action to prevent or minimize patient risk. The failure to institute an HIV ''lookback'' program at an early date resulted in a number of cases in which transfusion recipients were unaware of their infection, failed to seek treatment and subsequently infected others (Refs. 13 and 14).

Now that information is available to identify and to offer counseling and treatment options for those confirmed HCV-positive, FDA believes that the public trust demands the timely communication of relevant risk information. Although the agency cannot accurately assess the dollar value of this public trust or the potential impact of its loss, the following discussion, considers the cost of unfavorable shifts in public perception to be a potential indicator of the value of stabilizing public trust in the U.S. blood system. The purpose of the discussion is to provide an order-of-magnitude value assessment to which the estimated costs of HCV ''lookback'' can be compared.

Potential indicator of yearly cost: Changes in the blood donation patterns. The impact of the AIDS epidemic on the perceived safety of the nation's blood supply is believed to have contributed to the reduction in volunteer blood donations and to the dramatic increase in autologous and directed blood donation in subsequent years. The IOM discussion of bioethical issues in risk communication regarding the blood supply describes blood services as special because ''Trust is perhaps uniquely important. You know pretty fast if you have lost the public trust because people stop showing up to donate'' (Ref. 17). This comment suggests two measures of the loss of public trust in the blood supply in the wake of the HIV/AIDS transfusions of the 1980's: The reduction in the volume of allogeneic blood donations and the substantial increase in the volume of autologous blood collections. These shifts have associated opportunity costs and inefficiency costs. Part of the observed changes in blood donation reflect tighter donor screening and more efficient use of the patient's own blood in scheduled surgery. But some of the shift is believed to reflect a distrust of the blood supply not warranted based on objective measures of disease risk. FDA reviewed the extent of the blood donation decline that might be attributable to AIDS-related public mistrust and asked whether a similar round of impacts might result if risk communication about known HCV exposures were perceived as inadequate by the general public.

CDC estimates that the number of donations per donor has dropped from five as recently as 1992 to 1993, to two donations per donor in the period 1996 to 1998. This trend was already apparent in the survey findings of Wallace et al. published in 1995. Their survey compared blood collections in 1989 with collections in 1992, and found that 904,000 fewer allogeneic units and 462,000 more autologous units of blood were collected in 1992 compared with 1989. At an estimated average price of $103 per unit[1], the reduction in (allogeneic) donations represents an annual loss to the nation's blood supply valued at $93.11 million. If the allogeneic donations yielded more than one product per unit donation, the loss of potential supply would be greater.

[1] The estimates of $103 per allogeneic unit and $137 per autologous unit represent midpoint values in the range of blood costs reported by S. L. Lee in ''Patients' Willingness to pay for Autologous Blood Donation'' in *Risk in Perspective*, Harvard Center for Risk Analysis, vol. 6, No. 6, June 1988.

Autologous blood collection presents less risk of infectious disease, but it is not generally considered to be cost-effective, since much of the collected product is ultimately discarded because the patient does not require it. Of the estimated 1,117,000 autologous units collected in 1992, a total of 546,000 was reported as discarded. At an estimated average cost of $137 per unit, this represents an annual loss valued at $74.80 million. These discarded autologous units represent a real cost incurred by either the hospital or other blood establishment (if unrecoverable), by the third-party payer, or by the patient for a product that provided no therapeutic value. The most recent data suggest that the volume of unnecessary autologous collections is starting to decline, with clinical practice changes and regained public trust in the blood supply. Although the shifting patterns of blood collections may largely reflect appropriate responses to actual blood safety risks, if even a fraction of the shifts result from misperceptions, due to perceived failures in government and industry risk communication, then avoidable opportunity and inefficiency costs will be incurred.

FDA cannot assume that the failure to require notification of known exposures to hepatitis C among transfusion recipients would produce a similar second round of blood supply shifts and costs. However, hepatitis C has been characterized in the media, which influences public perception, as being as lethal as AIDS (Ref. 18) and its prevalence is much greater. If timely communication and support for patients, after inadvertent exposure to hepatitis C, were to eliminate as little as 15 percent of the yearly costs associated with the supply shifts described previously, this annual saving of over $25 million would exceed the $19 million in total annualized compliance costs estimated to be imposed by this regulation (calculated over 10 years at 7 percent).

3. Alternatives Considered for HCV ''Lookback''

FDA finds that the targeted ''lookback'' approach proposed is the most effective of several alternatives when evaluated in terms of ethical, cost, and effectiveness criteria. The following provides a discussion of the alternatives that have been considered.

a. *Alternative:* Publication of FDA guidance but no regulatory requirement for ''lookback''. One alternative to regulation involves FDA taking no further action, as the agency has already issued industry guidance concerning HCV ''lookback''. The principle advantage of this approach would be the elimination of FDA expenses related to issuing and later enforcing the rule. However, although the ''lookback'' process described in the guidance is much the same as that required under the proposed rule, the approach would be less effective in achieving the desired benefits. Because FDA would only recommend a process and timeframe, but have no basis for enforcing it, some in industry may elect a more extended timeframe for performing the ''lookback'' based on the review of historical testing records in order to spread the costs of this effort. Such delay, however, would increase each recipient's risk of serious disease complications and speed the spread of infection.

For blood establishments, a potential cost of such delay would be the risk of litigation by blood recipients who discover through other means that they have contracted hepatitis C through transfusion. The risk of litigation, however, appears relatively small. Blood-product related injuries have been removed from the scope of strict liability law by blood shield laws in 47 of the 51 jurisdictions in this country. Although these laws may protect society's interest in assuring an adequate blood supply by shielding providers and manufacturers from liability claims in instances where due care is taken, they have also made it difficult and often impossible for individuals to obtain compensation for infections acquired from blood or blood products. A review of transfusion associated AIDS litigation for the period 1984 through 1993 (Ref. 20) reports only a handful of cases based on failure of a blood establishment to perform ''lookback'' and none were reported won by a plaintiff on this basis. The adoption of an approach involving agency informal action based on the expectation of industry self-regulation to solve problems has been strongly criticized in the IOM review as inadequate to protect the public in the context of HIV/AIDS. FDA believes this view is similiarly applicable to HCV.

b. *Alternative:* Use of general ''lookback.''. An alternative to targeted ''lookback'' is an approach referred to as ''general lookback.'' This approach would be implemented through the general broadcast and other public media and regional medical organizations. The program would be aimed at all patients who received blood before the onset of screening, with the recommendation that they be tested for evidence of infection. Physicians participate in the program by recommending that previously transfused patients be tested for HCV. The program often includes a letter campaign to all previously transfused patients (regardless of the HCV status of the blood donors) from hospitals and other blood consignees who performed the transfusion service.

The cost and ultimate effectiveness of general ''lookback'' would vary depending on the program structure. All of the general ''lookback'' approaches involve reduced costs for blood collection centers, because the identification of infected donors would no longer be required. Nevertheless, if the general ''lookback'' involves a consignee letter campaign, the record review needed to identify current addresses for all transfusion recipients could be as great or greater than that required to identify only those recipients of blood products who are at higher risk of HCV.

A recent Canadian effort involving general letter ''lookback'' is estimated to have cost $1,654 per identified and confirmed positive recipient ($2,123 including HCV testing) (Ref. 7). Another Canadian hospital had completed a general letter ''lookback'' for HCV when the Canadian Red Cross Society began targeted ''lookback'' in 1995. By April of 1998, at least 13 new seropositive recipients had been identified by targeted ''lookback'' who were missed by general ''lookback.'' As a result, targeted ''lookback'' raised the number of HCV-positive recipients tested at that hospital by at least 9 percent over general ''lookback.''

A general approach without letter notification can be less costly. A 1990 electronic media program in Cincinnati, for example, was estimated to have cost the blood center only $13,370, or $209 per identified positive recipient; although the authors note that ''costs to the notified recipients may far exceed those of the Center'' (Ref. 19). Despite the vigorous public information campaign, less than 5 percent of these recipients sought testing (Ref. 24). The CDC also is undertaking a program of general ''lookback'' media activities, but evidence of effectiveness is not yet available.

At this time, FDA believes that although general ''lookback'' may be less costly, it is unlikely to communicate the relevant risk message to the majority of affected transfusion recipients. The effectiveness of a general ''lookback'' program requires that patients: (1) Be reached by the program, (2) be aware of the transfusion episode, and (3) seek testing even though the average risk per recipient is small. Experience suggests that a substantial share of patients and families are not

aware of earlier transfusions. A review of general ''lookback'' efforts in Canada, for example, found that 25 to 32 percent of pediatric patients and their families were unaware of an earlier transfusion. FDA agrees that general ''lookback'' activities can be important, particularly by reaching the population at risk due to parenteral drug use or other risk behaviors not involving blood transfusion. General ''lookback'' activities can also reinforce the effectiveness of targeted ''lookback.'' The agency believes, however, that by itself, general ''lookback'' does not adequately inform all affected recipients of blood transfusions.

c. *Proposed: Use of targeted ''lookback.''* The ''lookback'' provisions of the proposed rule can be characterized as a ''targeted lookback'' program, meaning that the notification of infection risk is limited to or targeted at individuals identified as recipients of blood from donors subsequently found to be infected with HCV. Targeted ''lookback'' requires that the transfusion service be aware that the donor subsequently tested positive, donor and product disposition records be available to link blood components with the identified donors, and the physician or transfusion service know the recipient's current whereabouts. Blood consignees would locate recipient records for all transfused units from an affected donor, and have current recipient or physician address information available so that notifications can be delivered. Ideally, the recipient will still be alive and be able to receive testing and treatment, if appropriate.

Recent experiences among Canadian facilities implementing HCV ''lookback'' suggest that the effectiveness of targeted ''lookback'' may vary, depending on the extent to which these conditions for success hold true within a community. For example, a Canadian Red Cross Center in Toronto reported that although able to identify 5,301 affected components, trace 3,209 of those to hospitals, obtain responses for 2,807 (87 percent) of the units, and identify 2,437 as having been transfused, the establishment found that 45 percent of the transfused patients had already died. Of those remaining, only 184 patients (8 percent of the transfused) were finally tested as a result of the ''lookback'' effort, although as many as 68 percent of those tested were found to be HCV positive (Ref. 21).

Despite the difficulties of implementing targeted ''lookback,'' FDA concludes that it remains a valuable means of reaching patients at high risk for HCV. As noted previously, a comparison of Canadian efforts in targeted ''lookback'' versus general ''lookback'' through physician and public education found that a large number of targeted patients and families were unaware of the transfusion episode. These recipients would not have been reached through the general ''lookback'' effort (Ref. 7). Similar experiences have occurred with HIV ''lookback'' efforts (Ref. 22).

C. Small Business Impact

Because of the lack of information to characterize the relevant volumes of affected blood and plasma products, the impact on those establishments and consignees that might qualify as small entities is uncertain. The FDA has therefore prepared an Initial Regulatory Flexibility Analysis. The blood establishments and blood product consignees affected by the proposed rule are included under the major SIC (standard industrialization classification) group 80 for providers of Health Services. According to Section 601 of the Regulatory Flexibility Act of 1980, the term ''small entity'' encompasses the terms ''small business,'' ''small organization'' and ''small governmental jurisdiction.'' According to the Small Business Administration (SBA), a small business within the blood industry is an enterprise with less than $5 million in annual receipts. A small organization is a not-for-profit enterprise which is independently owned and operated and is not dominant in its field. A ''small governmental jurisdiction'' generally means governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than 50,000.

The FDA registry of blood establishments does not provide an indication of the size of the registered entities. Although uncertain, it is likely that some smaller facilities may experience significant costs as a result of compliance with the proposed rule. According to the 1996 directory of the American Association of Blood Banks (AABB), only 34 regional and community blood centers have annual revenues of less than $5 million and each collect no more than 30,000 donations per year. Based on their survey of the blood industry in 1992, Wallace et al. (Ref. 3) estimate an annual total of 12,035,000 units of allogeneic blood were collected by blood establishments. Each small blood center would therefore account for approximately 0.2 percent (30,000/12,035,000) of all collections. Assuming that the one-time and annual costs of HCV ''lookback'' for blood collection facilities (see table 1 of section IV of this document) will be proportionate to the volume of collections, this implies that the small centers would each experience a one-time cost of approximately $72,229 ($36,114,442 x 0.002) and yearly costs of approximately $9,117 ($4,558,442 x 0.002). Based on an estimated average price of $103 per allogeneic unit (see footnote 1) this one-time cost would represent approximately 2 percent ($72,229/($103 x 30,000)) of annual average revenues. The yearly costs of on-going prospective ''lookback'' would represent approximately 0.3 percent of average annual revenues ($9,117/($103 x 30,000)).

Hospitals are expected to be the primary entity affected by the proposed requirements for transfusion services, but the extent of the small business impact is uncertain. Although the details of transfusion activities at hospitals are not available, FDA examined other data to develop a preliminary assessment of small business impact. The size of U.S. hospitals varies substantially. The 1998 American Hospital Association (AHA) survey data indicate a total of 5,134 U.S. registered community hospitals grouped into eight bed size categories. The average annual revenues for facilities in these bed size categories range from approximately $5.5 million to $513 million. However, since many hospitals are not-for-profit or are operated by state and local governments, the SBA annual receipts criteria for small businesses would not apply to these facilities. Of the 5,134 U.S. community hospitals included in the AHA report 1,330 are under the control of State and local government, 3,045 are nonprofit institutions and the remaining 759 are reported to be investor-owned.

The number of hospitals that would meet at least one of the various SBA definitions for small entities is uncertain. According to the AHA statistics for 1998, the smallest reported hospital size category includes 262 hospitals with 6 to 24 beds, and total gross revenues of $1.43 billion, yielding average revenues of $5.46 million. FDA assumes that the 11 facilities reported to be investor-owned within this bed size category could qualify as small entities. Although it is possible that all nonprofit hospitals may qualify as small entities, it appears that a number of facilities might be excluded from that definition because they are reported to be hospitals in a system. According to the AHA survey definition, ''hospitals in a system'' refer to those ''hospitals belonging to a corporate body that owns and/or manages health provider facilities or health-related subsidiaries;

the system may also own non-health-related facilities'' (Ref. 23). The AHA currently has record of 1,592 hospitals that are non-Federal and nonprofit (including State and local government controlled) that are hospitals in a system. If these facilities were excluded, FDA estimates that 2,783 (1,330 State and local + 3,045 nonprofit − 1,592 in-a-system) non-Federal, nonprofit hospitals may qualify as small entities. Thus, a total of 2,794 (2,783 + 11) hospitals might qualify as small entities.

The agency does not know how many of the estimated affected transfusion recipients received their transfusion as part of care provided at a hospital qualifying as a ''small entity.'' The following analysis of potential impact by size of hospital suggests that, regardless of hospital size, the cost impact may be limited if the number of affected transfusion recipients is proportionate to the number of inpatient surgeries performed by hospitals in different size categories. Table 3 of this document estimates the percentage of all inpatient hospital surgeries, based on the number of inpatient surgeries reported to AHA as performed by hospitals in different bed size categories. This percentage is used to estimate a share of the total 303,676 retrospective recipient notification activities initiated by hospitals in each category. The number of transfusion recipients to be contacted per hospital within a bed size category is based on the total estimated recipients per bed size category divided by the number of hospitals reported for each category. These estimates are presented in the right-most column of table 3. (Note that estimated values are rounded).

TABLE 3.—ESTIMATED NUMBER OF AFFECTED BLOOD RECIPIENTS PER HOSPITAL, BASED ON ESTIMATED NUMBER OF FACILITIES AND DISTRIBUTION OF IMPORTANT SURGERIES BY HOSPITAL SIZE CATEGORY (RETROSPECTIVE REVIEW)

Bed Size Category	Non-Federal Hospitals	Estimated Percent Inpatient Surgeries	Estimated Share of Recipients	Estimated Recipients per Hospital
6 to 24	262	0.21	627	2
25 to 49	906	2.02	6,121	7
50 to 99	1,128	6.03	18,315	16

Table 4 presents estimates of the cost per hospital, which are derived from estimates of the number of transfusion recipients per hospital (as shown in table 3) and the estimated notification cost of $165 per recipient. To provide additional perspective on relative impact, table 4 includes the notification cost shown as a percentage of average annual gross revenues per hospital. The notification cost is estimated to be approximately 0.01 percent of the average annual gross revenues for every size category.

TABLE 4.—ESTIMATED NOTIFICATION COST AS A PERCENT OF GROSS ANNUAL REVENUE, BASED ON ESTIMATES OF AVERAGE ANNUAL HOSPITAL REVENUE

Bed Size Category	Cost per Hospital for Retrospective Notification	Gross Annual Revenue per Hospital	Notification Cost as Percent of Gross Annual Revenue
6 to 24	$395	$5.459 million	0.01 percent
25 to 49	$1,115	$12.606 million	0.01 percent
50 to 99	$2,679	$27.711 million	0.01 percent
100 to 199	$7,256	$74.803 million	0.01 percent

A similar analysis of the yearly cost impact of prospective on-going notification, that would involve an estimated 12,816 affected components distributed across all hospitals, produces costs per hospital per year ranging from $17 per facility for the smallest hospital size category, to approximately $1,936 per facility for hospitals in the 500 + bed size category. For all bed size categories, the estimated yearly costs represent less than one-thousandth of a percent of average annual revenues.

These findings of the Initial Regulatory Flexibility Analysis suggests that the relative cost impact may be fairly consistent across hospitals of different sizes, if the number of affected transfusion recipients per hospital is proportionate to the number of inpatient surgeries performed by hospitals in different size categories. However, the distribution of affected transfusion recipients across hospitals of different size and types of ownership is currently unknown. Because this information is essential for the estimation of the economic impact on small entities, FDA requests industry comment on the anticipated numbers of affected transfusion recipients, the ability to trace transfused products, and the volume of transfused products handled by consignees, particularly those that can be classified as small entities.

In general, it is expected that the regulatory costs for blood establishments will be a function of the volume of donors, the number of donations testing repeatedly reactive in a screening test for evidence of HCV infection, the volume of donor blood components that must be traced, the quality of facility recordkeeping and the number of different consignees to which the collection facility distributes blood products. These factors are likely to be larger and generate higher potential costs for larger blood establishments. Yet careful screening is already in place in most facilities, which will minimize the number of affected units over time. It is similarly expected that transfusing facilities will already have recordkeeping systems and SOP's in place that can be readily adapted to HCV ''lookback.'' Also, recordkeeping and procedures to support targeted ''lookback'' for HIV are expected to provide a ready capability to trace donations and components affected by the proposed rule. FDA anticipates therefore that most of the information infrastructure needed for HCV ''lookback'' will already be in place for both blood establishments and blood transfusion services. For both types of establishments, the cost of compliance will primarily involve additional staff time.

As described earlier, FDA has considered several alternatives, and considers that a targeted ''lookback'' will be the most effective approach to contacting affected recipients of HCV-infected blood products. However, within that approach the agency allows for flexibility in the facility's individual approach to compliance, to help minimize the resource impact. For example, the particular design and systems for record-keeping and standard operating procedures developed in response to the proposed rule are under the control of the facility, as is the approach taken to notification. This will enable each facility to develop procedures that are most appropriate and cost-effective given the resources available. In addition, the agency has specified a limited time frame for notification, and a maximum required number of attempts, in order to provide a clear endpoint to facility efforts related to the ''lookback.''

Although FDA has obtained initial estimates of the number of blood centers that would be classified as small entities, the agency currently does not have data on the distribution of repeat donors, donations testing repeatedly reactive in a screening test for evidence of HCV infection, and affected blood components, for those establishments that would qualify as small business entities. Because this information is essential for the estimation of the economic impact on small businesses, FDA requests industry comment on the current recordkeeping, the ability to trace products, and the volumes of donation units and components handled by these facilities.

V. The Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in section V of this document with an estimate of the annual reporting and recordkeeping burden. Included in this estimate is the time for reviewing the procedures, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Reporting and recordkeeping requirements within Current Good Manufacturing Practices for Blood and Blood Components: Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk for Transmitting HCV Infection (''lookback'').

Description: This proposed rule would require that blood establishments prepare and follow written procedures when the blood establishments have collected Whole Blood, blood components, Source Plasma, and Source Leukocytes later determined to be at risk for transmitting HCV infections. Under the proposed rule, blood establishments would be required to include procedures that are similar to procedures now in effect for HIV ''lookback'' (§§ 610.46 and 610.47), for clarifying the status of the donor who later tests repeatedly reactive in a licensed screening test for HCV, quarantining prior collections from such donors, and notifying transfusion recipients, as appropriate, based on further testing of the donor. When a donor who previously donated blood is tested in accordance with § 610.40 on a later donation, and tests repeatedly reactive for antibody to HCV, the blood establishment would be required to perform a supplemental test using a licensed test, and notify consignees who received Whole Blood, blood components, Source Plasma, and Source Leukocytes from prior collections so that appropriate action is taken. Blood establishments and consignees would be required to quarantine previously collected Whole Blood, blood components, Source Plasma and Source Leukocytes from such donors (some exemptions apply), and where appropriate, consignees would notify transfusion recipients.

Under the proposed rule, blood establishments additionally would be required to perform a one-time retrospective review of historical HCV testing records that will identify prior collections from donors at increased risk for transmitting HCV. The retrospective review of HCV testing records would be limited to a period of time that is 12 months prior to the last negative licensed multiantigen screening test, whenever there is a record of such a prior test. Blood establishments would be required to notify consignees of the risk of HCV transmission that exists for prior collections based on the retrospective review of HCV testing records and the results of the supplemental HCV testing performed before or as a result of the retrospective review of testing records. Blood establishments would notify consignees of the risk of HCV transmission that exists for prior collections from a donor who tested repeatedly reactive on a screening test for HCV and for whom the blood establishment has no record of further testing and further testing is impractical or infeasible (an exception may apply). Under this proposal, consignees would notify the transfusion recipients.

FDA is also proposing conforming amendments to certain provisions of §§ 610.46 and 610.47, the HIV ''lookback'' regulations (61 FR 47413, September 9, 1996). The proposed revisions to §§ 610.46 and 610.47, discussed under the corresponding sections of this proposal, are intended to clarify and provide consistency between the HIV and HCV ''lookback'' requirements but do not include a requirement for the retrospective review of historical HIV testing records. The agency is issuing this proposed rule to help ensure that the blood supply continues to be safe, that information is provided to users of blood and blood components, and that transfusion recipients of blood and blood components at risk for transmitting HCV will be notified, as appropriate.

Description of Respondents: Blood establishments (Business and Not-for-Profit) and consignees of blood establishments, including hospitals, transfusion services and physicians.

The total reporting and recordkeeping burden for the first year is estimated to be 492,148 hours. However, of this total approximately 470,237 hours would be expended on a one-time basis for establishing the written procedures and doing the one-time retrospective review of historical HCV testing records. Therefore, 21,911 hours is estimated as the ongoing annual burden related to this proposed regulation. The total ongoing annual burden for blood collection facilities under §§ 610.46(a), 610.46(b), 610.47(b) and 606.160(b)(1)(viii) for HIV ''lookback'' is estimated to be 1,843 hours. The total ongoing annual burden for blood collection facilities under §§ 610.48(a)(1)(ii), 610.48(b), 610.49(b), 610.49(c) and 606.160(b)(1)(viii) for

HCV ''lookback'' is estimated to be 20,698 hours.

Based on information previously discussed in section IV of this document, there are approximately 2,800 FDA registered blood establishments in the United States that collect approximately 12 million allogeneic donations annually. The CDC estimates there are approximately 9,628,000 donations from repeat donors per year. The following reporting and recordkeeping estimates are based on information provided by industry, and FDA experience.

1. HIV Reporting Burden

In table 5, it is estimated that approximately 3,500 repeat donors (an annual average of 1.25 repeat donors per establishment) will test repeatedly reactive on a screening test for HIV. Under proposed §§ 610.46(a) and (b), this estimate results in 3,500 notifications of the HIV screening test results to consignees by blood establishments for the purpose of quarantine of affected units, and another 3,500 notifications to consignees of subsequent test results. FDA estimates an average of 10 minutes per notification of consignees.

In addition, it is estimated that 180 transfusion services not subject to HCFA regulations will be required under § 610.47(b) to notify physicians, or in some cases recipients, an average of 0.14 times per year resulting in a total number of 25 notifications. The estimate of one-half hour for notifications under § 610.47(b) is based on the minimum requirement of three attempts to notify recipients by transfusion services. FDA estimates that each repeat donor has donated two previous times and two components were made from each donation. The estimates for HIV ''lookback'' provided in the tables differ from the estimates for HIV ''lookback'' provided in a notice published in the **Federal Register** of November 4, 1999 (64 FR 60212) because FDA has new, updated information from industry representatives from which to base its estimates.

2. HCV Reporting Burden

Based on the interim results from a recent CDC survey (ref. 4), CDC estimates that 11,520 repeat donors per year would test repeatedly reactive for antibody to HCV. Under proposed §§ 610.48(a)(1)(ii) and 610.48(b), blood establishments would notify the consignee two times for each of the 12,816 components prepared from these donations, once for quarantine purposes and again with additional HCV test results for a total 25,632 notifications as an annual ongoing burden. Under proposed § 610.49(b) and (c), FDA estimates that approximately 6,200 transfusion services would notify two recipients annually.

A. HCV One-time Reporting Burden

Based on estimates from CDC, FDA expects that for the one-time retrospective review of historical testing records, as many as 303,676 blood components would be at increased risk for transmitting HCV. For each of these products, under §§ 610.48(e)(2), 610.48(f)(2), 610.48(h)(3)(i) and (ii), and 610.48(i)(3)(i) and (ii), blood establishments would notify consignees to quarantine these products and report additional HCV test results to consignees, and, under § 610.49(b) and (c), consignees would notify transfusion recipients or recipients' physicians of record. CDC estimated that there could be approximately 258,125 transfusion recipients that would be notified after a one-time retrospective review of historical test results for HCV screening. The numbers in the hours per response column are based on FDA's knowledge and experience regarding notification.

B. HCV Ongoing Annual Reporting Burden

Under § 610.49(b) and (c), it is estimated that transfusion services may be expected to notify approximately 10,894 transfusion recipients per year, as previously discussed. The estimated average 0.5 hours to complete notification under §§ 610.47(b), 610.49(b) and (c) is based on FDA's knowledge and experience. The estimates of 13 hours, 5,447 hours, and 129,063 hours, respectively, allow for a consignee to make up to three attempts to complete the notification process.

3. HIV and HCV Recordkeeping Burden

In the recordkeeping charts, the numbers in the hours per record column are based on FDA's estimate of the time to complete one record. FDA estimates that it will take blood collection facilities approximately 40 hours to establish the written procedures proposed under § 606.100(b)(19) and consignees approximately 16 hours to establish written procedures in accordance with proposed § 610.49(b) and (c). In table 7, the estimate of 154 recordkeepers and 175 total annual records are based on the estimate that the HIV ''lookback'' requirements of § 610.47(b) are already implemented voluntarily by more than 95 percent of the facilities, which collect 98 percent of the Nation's blood supply. FDA estimates that it takes transfusion services approximately 10 minutes to document and maintain the records to relate the donor with the unit number of each previous donation. The time required for recordkeeping under § 606.160(b)(1)(viii) is estimated to be approximately 10 minutes for each HIV or HCV repeatedly reactive donation record and approximately 10 minutes per transfusion recipient record required under §§ 610.47(b) and 610.49(b) and (c).

FDA estimates the burden for this collection of information as follows:

TABLE 5.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
610.46(a)	2,800	1.25	3,500	.17	600
610.46(b)	2,800	1.25	3,500	.17	600
610.47(b)	180	0.14	25	.50	13
610.48(a)(i)(ii)	2,800	4.6	12,816	.17	2,179
610.48(b)	2,800	4.6	12,816	.17	2,179
610.49(b)and (c)	6,200	2	10,894	.50	5,447
Total					11,018

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 6.—ESTIMATED ONE-TIME REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Respondents	Hours per Response	Total Hours
610.48(e)(2)	2,800	41	115,228	.1	11,523
610.48(f)(2)	2,800	67	188,448	.1	18,845
610.48(h)(3)(i) and (h)(3)(ii)	2,800	41	115,228	.1	11,523
610.48(i)(3)(i) and (i)(3)(ii)	2,800	67	188,448	.1	18,845
610.49(b) and (c)	6,200	42	258,125	.5	129,063
Total					189,799

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 7.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
606.160(b)(1)(viii)					
HIV	154	1.14	175	.17	30
HIV	2,800	1.25	3,500	.17	600
HCV	2,800	9	25,632	.17	4,357
606.160(b)(1)(viii)	6,200	4	25,632	.17	4,357
610.49(b) and (c)	6,200	2	12,816	.17	2,179
Total					11,523

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 8.—ESTIMATED ONE-TIME RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Frequency of Recordkeeping	Total Records	Hours per Record	Total Hours
606.100(b)(19)	2,800	1	2,800	40	112,000
606.100(b)(19)	6,200	1	6,200	16	99,200
606.160(b)(1)(viii)	2,800	108	303,676	0.08	24,294
606.160(b)(1)(viii)	6,200	49	303,676	0.08	24,294
610.49(b) and (c)	6,200	42	258,125	0.08	20,650
Total					280,438

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

There are no capital costs or operating and maintenance costs associated with this collection of information.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to submit written comments regarding information collection by December 18, 2000, to the Office of Information and Regulatory Affairs, OMB (address above), Attention: Wendy Taylor, Desk Officer for FDA.

VI. Request for Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this proposed rule by February 14, 2001. 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.

VII. Proposed Effective Date

The agency is proposing that any final rule that may issue based upon this proposed rule become effective 180 days after its date of publication in the **Federal Register**.

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Alter, M., ''Epidemiology of Hepatitis C,'' *Hepatology*, 26:62S–65S, 1997.

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4. Alter, M., CDC Survey Interim Results.

5. MacPherson, J., America's Blood Centers, ''Advisory Committee on Blood Safety and Availability'' Tenth Meeting, vol. II, p. 7.

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7. Goldman, M., S. Juodvalkis, P. Gill, and G. Spurll, ''Hepatitis C Lookback,'' *Transfusion Medicine Review*, vol. 12, No. 2: 84–93, 1998.

8. U.S. Department of Health and Human Services, Center for Disease Control and Prevention, ''Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV–Related Chronic Disease,'' *Morbidity and Mortality Weekly Report*, vol. 47, No. RR–19, October 16, 1998.

9. Kim, W. R., J. J. Poterucha, J. E. Hermans, T. M. Therneau, E. R. Dickson, R. W. Evans, and J. B. Gross, ''Cost-Effectiveness of 6 and 12 Months of Interferon-alfa Therapy for Chronic Hepatitis C,'' *Annals of Internal Medicine*, vol. 127, No. 10, November 1997.

10. Davis, G. L., and J. Y. N. Lau, ''Factors Predictive of a Beneficial Response to Therapy of Hepatitis C,'' *Hepatology*, vol. 26, No. 3, Suppl.1: 122s–126s.

11. Bennett, W. G., Y. Inoue, J. R. Beck, J. B Wong, S. G. Pauker, and G. L. Davis, ''Estimates of the Cost-Effectiveness of a Single Course of Interferon-alfa2b in Patients with Histologically Mild Chronic Hepatitis C,'' *Annals of Internal Medicine*, vol. 127, No. 10, November 1997.

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Hepatology, vol. 26, No. 3, Suppl. 1:2s–10s, 1997.

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14. J. G. McHutchison et al., *New England Journal of Medicine*, 339: 1485, 1998.

15. Leveton, L. B., H. C. Sox, Jr., and M. A. Stoto, editors, *HIV and the Blood Supply: An Analysis of Crisis Decisionmaking*, Chapter 7, Institute of Medicine, National Academy Press, Washington, DC, 1995.

16. Ottosen, J. S., *The Blood Conspiracy: How to Avoid Getting AIDS and Hepatitis in a Transfusion*, Aspen Leaf Press, Woodland Park, CO, 1993.

17. Moreno, J. D., ''Attitudes Toward Risk: The Right to Know and the Right to Give Informed Consent'' in *Blood and Blood Products: Safety and Risk*, Institute of Medicine, National Academy Press, Washington, DC, 1996.

18. Groopman, J., ''The Shadow Epidemic'' *The New Yorker*, May 11, 1998.

19. Zuck, T. F., G. A. Rose, U. J. Dumaswala, N. J. Geer, ''Experience with a Transfusion Recipient Education Program about Hepatitis C,'' *Transfusion*, vol. 30, No. 8, 761, 1990.

20. Kern, J. M., and B. B. Croy, ''A Review of Transfusion-Associated AIDS Litigation: 1984 Through 1993,'' *Transfusion*, vol. 34, No. 6, 1994.

21. Wall, A., W. Lau, J. Lewis, J. A. Chiavetta, S. Mohammad, and R. Herst, ''Hepatitis C Virus (HCV) Targeted Lookback Program,'' *Transfusion*, vol. 37 Suppl. s392, 1997.

22. Gill, M. J., D. Towns, S. Allaire, and G. Meyers, ''Transmission of Human Immunodeficiency Virus Through Blood Transfusion: The Use of Lookback and Traceback Approaches to Optimize Recipient Identification in a Regional Population,'' *Transfusion*, vol. 37, 513–516, 1997.

23. Healthcare InfoSource, Inc., a subsidiary of the American Hospital Association, *Hospital Statistics*, 1998 ed., Chicago IL.

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List of Subjects

21 CFR Part 606

Blood, Labeling, Laboratories, Reporting and recordkeeping requirements.

21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 606 and 610 be amended as follows:

PART 606—CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

1. The authority citation for 21 CFR part 606 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

2. Section 606.100 is amended by revising paragraph (b)(19) to read as follows:

§ 606.100 Standard operating procedures.

* * * * *

(b) * * *

(19) Procedures in accordance with §§ 610.46 and 610.48 of this chapter to look at prior donations of blood and blood components from a donor who has donated blood and subsequently tests repeatedly reactive for evidence of human immunodeficiency virus (HIV) infection or hepatitis C virus (HCV) infection when tested in accordance with § 610.40 of this chapter or when a blood establishment has been made aware of other test results indicating evidence of HIV or HCV infection. Procedures to quarantine in-date blood and blood components, intended for further manufacture into injectable products that were obtained from such donors; procedures to notify consignees regarding the need to quarantine such products; procedures to determine the suitability for release of such products; procedures to notify consignees of blood and blood components from such donors of the results of the HIV and HCV testing performed on such donors; procedures in accordance with §§ 610.47 and 610.49 of this chapter to notify physician of record so that recipients of transfusion with blood or blood components are informed that they may have received blood or blood components at increased risk of transmitting HIV and HCV, respectively.

* * * * *

3. Section 606.160 is amended by revising paragraph (b)(1)(viii) and the second sentence of paragraph (d) to read as follows:

§ 606.160 Records.

* * * * *

(b) * * *

(1) * * *

(viii) Records of quarantine, consignee notification, further testing, transfusion recipient notification, and disposition performed under §§ 610.46, 610.47, 610.48, and 610.49 of this chapter.

* * * * *

(d) * * * The retention period shall be no less than 10 years after the records of processing have been completed or 6 months after the latest expiration date for the individual product, whichever is the later date. * * *

* * * * *

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

4. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

5. Section 610.40 is amended by adding paragraph (g) to read as follows:

§ 610.40 Test for hepatitis B surface antigen.

* * * * *

(g) For a donor whose test result for HIV or HCV is repeatedly reactive when tested in accordance with paragraphs (a), (c), and (d) of this section, or when a blood establishment has been made aware of other test results indicating evidence of HIV or HCV infection, the blood establishment shall comply, as applicable, with §§ 610.46, 610.47, 610.48, and 610.49.

6. Section 610.46 is amended by revising the section heading and paragraph (a), the heading for paragraph (b), the first sentence of paragraphs (b) and (c), and paragraph (d); by redesignating paragraph (e) as paragraph (f); by revising newly redesignated paragraph (f); and by adding new paragraph (e) to read as follows:

§ 610.46 Human Immunodeficiency Virus (HIV) ''Lookback;'' quarantine, consignee notification and further testing.

(a) *Quarantine and consignee notification.* (1) All blood and plasma establishments shall take appropriate action when a donor of blood or blood components tests repeatedly reactive for evidence of HIV infection on a screening test in accordance with § 610.40(a), or when the blood establishment has been made aware of other test results indicating evidence of HIV infection, provided the testing was performed by a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988, using a test approved by FDA. For blood and blood components collected from that donor at any time prior to the repeatedly reactive test, whenever records are available, if intended for transfusion or for further manufacture into injectable products, except those products exempt from quarantine in accordance with paragraph (c) of this section, the blood establishment shall, within 3-calendar days after the date on which the donor tested repeatedly reactive for evidence of HIV infection or after the date on which the blood establishment was made aware of other test results

indicating evidence of HIV infections, identify the prior collections from that donor and:

(i) Quarantine all such prior collections of blood and blood components; and

(ii) Notify consignees of the repeatedly reactive HIV screening test result so that the consignee may quarantine all such prior collections of blood and blood components.

(2) Consignees notified in accordance with paragraph (a)(1)(ii) of this section shall quarantine all such prior collections of blood and blood components held at that establishment, except as provided in paragraph (c) of this section.

(b) *Further testing and consignee notification of results.* Blood establishments shall perform further testing on the donor's blood, as specified in § 610.40(c), and shall notify the consignee(s) of the results of this test within 45-calendar days after the date on which the donor tested repeatedly reactive for evidence of HIV infection on a screening test. * * *

(c) *Exemption from quarantine.* Prior collections otherwise subject to quarantine under paragraph (a) of this section need not be held in quarantine if a determination has been made that the blood or blood component was collected more than 12 months prior to the donor's most recent negative screening test when tested for HIV in accordance with § 610.40(a). * * *

(d) *Release from quarantine.* Prior collections of blood and blood components intended for transfusion or further manufacture into injectable products which have been quarantined under paragraph (a) of this section may be released if the donor's current repeatedly reactive sample is subsequently tested for antibody to HIV as provided in paragraph (b) of this section and the test result is negative, absent other informative test results.

(e) *Destruction or labeling of prior collections held in quarantine.* Blood establishments and consignees shall destroy or appropriately label for in vitro use prior collections of blood and blood components otherwise subject to quarantine in accordance with paragraphs (a) and (d) of this section, unless such prior collections are determined to be exempt from quarantine in accordance with paragraph (c) of this section or subject to release from quarantine in accordance with paragraph (d) of this section. Quarantined prior collections made available for in vitro use shall be appropriately relabeled consistent with §§ 606.121 and 640.70 of this chapter. In addition, these units must be relabeled as ''Biohazard'' with the cautionary statement as follows:

''Collected from a donor who subsequently tested positive for anti-HIV. An increased risk for transmission of human immunodeficiency virus is present;'' in addition, the label must contain one of the following cautionary statements, as appropriate: ''Caution: For Further Manufacturing Into In Vitro Diagnostic Reagents For Which There Are No Alternative Sources.'' or ''For Laboratory Research Use Only.''

(f) *Actions under this section.* Actions under this section do not constitute a recall as defined in § 7.3 of this chapter.

7. Section 610.47 is revised to read as follows:

§ 610.47 Human Immunodeficiency Virus (HIV) ''Lookback;'' notification of transfusion recipients.

(a) *Appropriate actions following further testing.* Transfusion services that are not subject to the Health Care Financing Administration's regulations on conditions of Medicare participation for hospitals (42 CFR part 482) are required to take appropriate action in accordance with paragraphs (b) and (c) of this section when a recipient has received prior collections of blood or blood components from a donor later determined to be unsuitable when tested for evidence of infection due to HIV and the result of the additional tests as provided for in § 610.46(b) are positive.

(b) *Notification of recipients of prior transfusion.* If the transfusion service has administered blood or blood components as described in paragraph (a) of this section, the transfusion service shall either notify the recipient directly or notify the recipient's physician of record (i.e., physician of record or physician who ordered the blood or blood component) and ask him or her to inform the recipient of the need for HIV testing and counseling. If the physician is not available or declines to notify the recipient, the transfusion service shall notify the recipient and inform the recipient of the need for HIV testing and counseling. The notification process shall include a minimum of three attempts to notify the recipient, or the recipient's physician, and be completed within a maximum of 12 weeks of receipt of the result of the licensed, more specific test for HIV from the blood establishment. The transfusion service is responsible for notification, including basic explanations to the recipient and referral for counseling and further testing, and shall document the notification and the result of attempts to notify the recipient and the recipient's physician of record, if contacted, under § 606.160 of this chapter.

(c) *Notification of legal representative or relative.* If the transfusion recipient has been adjudged incompetent by a State court, the legal representative, designated in accordance with State law, shall be notified. If the transfusion recipient is competent, but State law permits a legal representative or relative to receive the information on the recipient's behalf, the transfusion service or the physician who agreed to perform the notification on behalf of the transfusion service shall notify the recipient or his or her legal representative or relative. If the transfusion recipient is a minor at the time of notification, the transfusion service or physician, as described in this paragraph, shall notify the recipient's legal representative or relative. If the transfusion recipient is deceased, the transfusion service or physician, as described in this paragraph, shall continue the notification process and inform the deceased recipient's legal representative or relative. The transfusion service is responsible for notification, including basic explanations to the recipient's legal representative or relative and referral for counseling and further testing of the recipient, and shall document the notification and the result of attempts to notify the recipient's legal representative or relative and the recipient's physician of record, if contacted, under § 606.160 of this chapter. Reasons for notifying the recipient's relative or legal representative on his or her behalf shall be documented under § 606.160 of this chapter.

8. Section 610.48 is added to subpart E to read as follows:

§ 610.48 Hepatitis C Virus (HCV) ''Lookback;'' quarantine, consignee notification and further testing.

(a) *Quarantine and consignee notification.* (1) *Repeatedly reactive screening test.* All blood and plasma establishments shall take appropriate action when a donor of blood or blood components tests repeatedly reactive for evidence of HCV infection on a screening test, in accordance with § 610.40(a), or when the blood establishment has been made aware of other test results indicating evidence of HCV infection, provided the testing was performed by a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988, using a test approved by FDA. For in-date blood and blood components collected from that donor at any time prior to the repeatedly reactive test,

whenever records are available, if intended for transfusion, or if intended for further manufacture into injectable products, except those products exempt from quarantine in accordance with paragraph (g)(1) of this section, the blood establishment shall, within 3-calendar days after the date on which the donor tested repeatedly reactive for evidence of HCV infection or after the date on which the blood establishment was made aware of other test results indicating evidence of HCV infection, identify the prior collections from that donor and:

(i) Quarantine all such prior collections of blood and blood components; and

(ii) Notify consignees of the repeatedly reactive HCV screening test result so that the consignee may quarantine all such prior collections of blood and blood components.

(2) *Quarantine by consignee*. Consignees notified in accordance with paragraph (a)(1)(ii) of this section shall quarantine all such prior collections of blood and blood components held at that establishment, except as provided in paragraph (g)(1) of this section.

(b) *Further testing and consignee notification of results*. In the case of a donor with a repeatedly reactive screening test for HCV, blood establishments shall perform further testing on the donor's blood, as specified in § 610.40(c). Where prior collections from the same donor were distributed, blood establishments shall notify the consignee(s) of the results of this test within 45-calendar days after the date on which the donor tested repeatedly reactive for evidence of HCV infection on a screening test.

(c) *Review of historical testing records and identification of donors tested using a multiantigen screening test prior to* [*the effective date of the final rule*]. Blood establishments shall review records of donor testing completed prior to [the effective date of the final rule] in order to identify donors who tested repeatedly reactive for evidence of HCV infection on a multiantigen screening test for HCV and to identify prior collections from such donors. Blood establishments shall, by (date 1 year from the effective date of the final rule), identify previously distributed blood and blood components from such donors, based on available required records maintained in accordance with § 606.160 of this chapter, dating back indefinitely for computerized electronic records and to January 1, 1988, for other readily retrievable records, or to the date 12 months prior to the donor's most recent negative multiantigen screening test for antibody to HCV, whichever is the lesser period. Blood establishments shall identify previously distributed blood and blood components from such donors in any of the following instances:

(1) *First instance*. Where the donor tested repeatedly reactive for evidence of HCV infection on the multiantigen screening test and positive on a supplemental test for HCV performed on the repeatedly reactive sample;

(2) *Second instance*. Where the donor tested repeatedly reactive for evidence of HCV infection on the multiantigen screening test and indeterminate on a supplemental test for HCV performed on the repeatedly reactive sample;

(3) *Third instance*. Where the donor tested repeatedly reactive for evidence of HCV infection on an HCV EIA 3.0 multiantigen screening test and negative on a HCV 2.0 strip immunoblot assay (HCV RIBA 2.0 supplemental test) with no record of a negative licensed HCV 3.0 strip immunoblot assay (RIBA 3.0 supplemental test) performed on the repeatedly reactive sample or a later sample from the same donor.

(4) *Fourth instance*. Where the donor tested repeatedly reactive for evidence of HCV infection on a licensed HCV EIA 2.0 screening test with no record of a supplemental test for HCV performed on the repeatedly reactive sample or on a later sample from the same donor and no record of a negative licensed HCV EIA 3.0 screening test performed on the repeatedly reactive sample or a later sample from the same donor; or

(5) *Fifth instance*. Where the donor tested repeatedly reactive for evidence of HCV infection on a licensed HCV EIA 3.0 screening test with no record of a supplemental test for HCV performed on the repeatedly reactive sample or on a later sample from the same donor.

(d) *Review of historical testing records and identification of donors tested using a single antigen screening test prior to [the effective date of the final rule]*. Blood establishments shall review records of donor testing completed prior to [the effective date of the final rule] in order to identify donors who tested repeatedly reactive for evidence of HCV infection on a single antigen screening test for HCV and to identify prior collections from such donors. Blood establishments shall, by (date 1 year from the effective date of the final rule), identify previously distributed blood and blood components from such donors, based on available required records maintained in accordance with § 606.160 of this chapter, dating back indefinitely for computerized electronic records and to January 1, 1988, for other readily retrievable records, or to the date 12 months prior to the donor's most recent negative multiantigen screening test for antibody to HCV, whichever is the lesser period, in any of the following instances:

(1) *First instance*. Where the donor tested repeatedly reactive for evidence of HCV infection on the single antigen screening test and repeatedly reactive on an HCV EIA 2.0 or HCV EIA 3.0 screening test performed on the repeatedly reactive sample or a fresh sample from the same donor;

(2) *Second instance*. Where the donor tested repeatedly reactive for evidence of HCV infection on the single antigen screening test and either positive or indeterminate on an HCV 2.0 or HCV 3.0 strip immunoblot assay (HCV RIBA 2.0 or HCV RIBA 3.0, respectively) supplemental test for HCV performed on the repeatedly reactive sample or a fresh sample from the same donor;

(3) *Third instance*. Where the donor tested repeatedly reactive for evidence of HCV infection on an HCV EIA 1.0 screening test, with a signal to cutoff (S/CO) value less than 2.5 for at least two out of the three EIA tests (i.e., the initial EIA screening test and the duplicate retests), with no record of a supplemental test or multiantigen screening test for HCV performed on the repeatedly reactive sample or on a later sample from the same donor; or

(4) *Fourth instance*. Where the donor tested repeatedly reactive for evidence of HCV infection on an HCV EIA 1.0 screening test, with a S/CO value equal to or greater than 2.5 for at least two out of the three EIA tests (i.e., the initial EIA screening test and the duplicate retests) or with no determination of S/CO value for all three EIA tests, and with no record of a supplemental test or multiantigen screening test for HCV performed on the repeatedly reactive sample or on a later sample from the same donor.

(e) *Quarantine and consignee notification following the review of historical testing records based on screening performed using a multiantigen screening test*. Blood establishments shall, by (date 1 year from the effective date of the final rule), complete all quarantine and consignee notification requirements for prior collections from donors identified in the review of historical testing records in accordance with paragraph (c) of this section as follows:

(1) *Quarantine*. Blood establishments shall, within 3-calendar days of the date of the identification of the donor's repeatedly reactive multiantigen screening test for HCV, quarantine all in-date prior collections of blood and blood components collected from such a donor at any time prior to the

repeatedly reactive multiantigen screening test and identified in accordance with paragraph (c) of this section, if intended for transfusion, or if intended for further manufacture into injectable products, except those products exempt from quarantine in accordance with paragraph (g)(2) of this section.

(2) *Consignee notification.* Blood establishments shall, within 3-calendar days of the date of identification of the donor's repeatedly reactive multiantigen screening test for HCV, notify consignees of the donor's test results, including the supplemental test results, if available, so that consignees may quarantine all in-date prior collections of blood and blood components subject to quarantine under paragraph (e)(1) of this section.

(3) *Quarantine by consignees.* Consignees notified in accordance with paragraph (e)(2) of this section shall quarantine all in-date prior collections of blood and blood components subject to quarantine under paragraph (e)(1) of this section, except as provided in paragraph (g)(2) of this section.

(f) *Quarantine and consignee notification following the review of historical testing records based on screening performed using a single antigen screening test.* (1) *Quarantine.* Blood establishments shall, by (date 1 year from the effective date of the final rule) and within 3-calendar days of the date of the identification of the donor's repeatedly reactive single antigen screening test for HCV, quarantine all in-date prior collections of blood and blood components collected from such a donor at any time prior to the repeatedly reactive single antigen screening test and identified in accordance with paragraph (d) of this section, if intended for transfusion, or if intended for further manufacture into injectable products, except those products exempt from quarantine in accordance with paragraph (g)(3) of this section.

(2) *Consignee notification.* Blood establishments shall, within 3-calendar days of the date of identification of the donor's repeatedly reactive single antigen screening test for HCV, notify consignees of the donor's test results, including the supplemental test results, if available, so that consignees may quarantine all in-date prior collections of blood and blood components subject to quarantine under paragraph (f)(1) of this section.

(3) *Quarantine by consignees.* Consignees notified in accordance with paragraph (f)(2) of this section shall quarantine all in-date prior collections of blood and blood components subject to quarantine under paragraph (f)(1) of this section, except as provided in paragraph (g)(3) of this section.

(g) *Exemption from quarantine.* As used in § 610.48, an appropriately chosen licensed supplemental test is one which includes all antigens contained in the screening test that was performed.

(1) *Prior collections subject to quarantine under paragraph (a) of this section.* Prior collections otherwise subject to quarantine under paragraph (a) of this section need not be placed in quarantine if a determination has been made that:

(i) The blood or blood component was collected more than 12 months prior to the donor's most recent negative multiantigen screening test when tested for HCV in accordance with § 610.40(a); or

(ii) An appropriately chosen licensed supplemental test for HCV, performed in accordance with paragraph (b) of this section has been completed within 3-calendar days of the date of the donor's repeatedly reactive screening test and the result is negative.

(2) *Prior collections subject to quarantine under paragraph (e)(1) of this section.* Prior collections otherwise subject to quarantine under paragraph (e)(1) of this section need not be placed in quarantine if a determination has been made that:

(i) The blood or blood component was collected more than 12 months prior to the donor's most recent negative multiantigen screening test for HCV that preceded the repeatedly reactive screening test; or

(ii)(A) The repeatedly reactive screening test result was obtained using an HCV EIA 2.0 screening test, and either the original sample or a later sample from the same donor was tested and found negative using an HCV RIBA 2.0 or HCV RIBA 3.0 supplemental test or an HCV EIA 3.0 screening test; or

(B) The repeatedly reactive screening test result was obtained using an HCV EIA 3.0 screening test, and either the original sample or a later sample from the same donor was tested and found negative using an HCV RIBA 3.0 supplemental test;

(3) *Prior collections subject to quarantine under paragraph (f)(1) of this section.* Prior collections otherwise subject to quarantine under paragraph (f)(1) of this section need not be placed in quarantine if the donor's testing records show that:

(i) The repeatedly reactive screening test result was obtained using an HCV EIA 1.0 screening test, and either the original sample or a later sample from the same donor was further tested and found negative using an HCV EIA 2.0 or 3.0; or

(ii) The repeatedly reactive screening test result was obtained using an HCV EIA 1.0 screening test, and either the original sample or a later sample from the same donor was tested and found negative using an HCV RIBA 2.0 or HCV RIBA 3.0 supplemental test ; or

(iii)(A) The donor, identified in accordance with paragraph (d)(1) of this section, as testing repeatedly reactive on an HCV EIA 2.0, was further tested using a HCV RIBA 2.0 or HCV RIBA 3.0 supplemental test, on a fresh sample, or frozen sample from the repeatedly reactive donation and the result was negative; or

(B) The donor, identified in accordance with paragraph (d)(1) of this section, as testing repeatedly reactive on an HCV EIA 3.0, was further tested using an HCV RIBA 3.0 supplemental test, on a fresh sample, or frozen sample from the repeatedly reactive donation and the result was negative; or

(iv) The donor identified in accordance with paragraph (d)(2) of this section, as testing indeterminate on a HCV RIBA 2.0 supplemental test, was further tested using either an HCV EIA 3.0 or a HCV RIBA 3.0 supplemental test on a fresh sample, or frozen sample from the repeatedly reactive donation and the result was negative.

(h) *Further testing following review of historical testing records and consignee notification based on screening performed using a multiantigen screening test.* (1) *Further testing.* Blood establishments that have performed the review of records and identified prior collections in accordance with paragraphs (c)(4) and (c)(5) of this section shall, by (date 1 year from the effective date of the final rule):

(i)(A) If the repeatedly reactive test result was obtained using a HCV EIA 2.0 screening test, perform a licensed supplemental test for HCV on a frozen sample from the repeatedly reactive donation, if available; or if such a frozen sample is not available, obtain a fresh sample from such a donor and perform a licensed supplemental test for HCV; or

(B) If the repeatedly reactive test result was obtained using a HCV EIA 2.0 screening test, perform a licensed HCV EIA 3.0 screening test on a frozen sample, if available, or on a fresh sample from such a donor and perform a licensed supplemental test if the HCV EIA 3.0 screening test is repeatedly reactive; or

(ii) If the repeatedly reactive test result was obtained using a HCV EIA 3.0 screening test, perform a licensed supplemental test for HCV on a frozen

sample, if available, or on a fresh sample from such a donor; or

(iii) Make a determination that neither a frozen sample from the repeatedly reactive donation nor a fresh sample from the donor is available for further testing.

(2) *Options for further testing.* Blood establishments that have performed the review of records and identified certain prior collections in accordance with paragraphs (c)(2) or (c)(3) of this section, and as described in paragraphs (h)(2)(i) through (h)(2)(iv) of this section may further test a frozen sample from the repeatedly reactive donation or a fresh sample from the same donor by (date 1 year from the effective date of the final rule), as follows:

(i) Donors identified in accordance with paragraph (c)(2) of this section as testing repeatedly reactive using an HCV EIA 2.0 screening test, and indeterminate on an HCV RIBA 2.0 supplemental test, may be further tested using either a licensed HCV EIA 3.0 screening test or a currently available licensed supplemental test for HCV;

(ii) Donors identified in accordance with paragraph (c)(2) of this section as testing repeatedly reactive using an HCV EIA 2.0 screening test, indeterminate on a HCV RIBA 2.0 supplemental test, and repeatedly reactive on an HCV EIA 3.0 screening test, performed in accordance with paragraph (h)(2)(i) of this section, may be further tested using an appropriately chosen licensed supplemental test for HCV;

(iii) Donors identified in accordance with paragraph (c)(2) of this section as testing repeatedly reactive using an HCV EIA 3.0 screening test, and indeterminate on a HCV RIBA 2.0 supplemental test, may be further tested using an appropriately chosen licensed supplemental test for HCV;

(iv) Donors identified in accordance with paragraph (c)(3) of this section as testing repeatedly reactive using an HCV EIA 3.0 screening test, and negative on a HCV RIBA 2.0 supplemental test with no record of a negative HCV RIBA 3.0 supplemental test, may be further tested using an appropriately chosen licensed supplemental test for HCV.

(3) *Consignee notification.* Except for blood and blood components exempt from quarantine in accordance with paragraph (g)(2) of this section, blood establishments shall:

(i) Within 45 days following completion of additional testing and prior to (date 1 year from the effective date of the final rule), notify consignees of the results of the additional licensed screening test and/or the licensed, supplemental test performed in accordance with paragraphs (h)(1) and (h)(2) of this section; or

(ii) Prior to (date 1 year from the effective date of the final rule), notify consignees of the test results for a donor who was identified in the review of historical testing records, in accordance with paragraphs (c)(1) through (c)(5) of this section.

(i) *Further testing following review of historical testing records and consignee notification based on screening performed using a single antigen screening test.* (1) *Further testing.* Blood establishments that have performed the review of records and identified prior collections in accordance with paragraph (d)(4) of this section shall, by (date 1 year from the effective date of the final rule):

(i) Perform a licensed, supplemental test for HCV on a frozen sample from the repeatedly reactive donation, if available; or if such a frozen sample is not available, obtain a fresh sample from such a donor and perform a licensed supplemental test for HCV; or

(ii) Make a determination that neither a frozen sample from the repeatedly reactive donation nor a fresh sample from the donor is available for further testing.

(2) *Options for further testing.* Blood establishments that have performed the review of records and identified certain prior collections in accordance with paragraphs (d)(1) or (d)(2) of this section and described in paragraphs (i)(2)(i) through (i)(2)(iii) of this section may further test a frozen sample from the repeatedly reactive donation or a fresh sample from the same donor, by (date 1 year from the effective date of the final rule), as follows:

(i) Donors identified in accordance with paragraph (d)(1) of this section as testing repeatedly reactive on an HCV EIA 1.0 screening test and repeatedly reactive on either an HCV EIA 2.0 or HCV EIA 3.0 screening test may be further tested using an appropriately chosen licensed supplemental test for HCV; or

(ii) Donors identified in accordance with paragraph (d)(2) of this section as testing repeatedly reactive on an HCV EIA 1.0 screening test with an indeterminate test result obtained using an HCV RIBA 2.0 supplemental test, may be further tested using a currently available licensed supplemental test for HCV or an HCV EIA 3.0. If such optional further testing is performed using an HCV EIA 3.0 and the result is repeatedly reactive, blood establishments may perform further testing using an appropriately chosen licensed supplemental test for HCV.

(iii) Donors identified in accordance with paragraph (d)(3) of this section as testing repeatedly reactive on an HCV EIA 1.0 screening test with a S/CO value less than 2.5 for at least two out of the three EIA tests, and with no record of a supplemental test or multiantigen screening test for HCV performed on the repeatedly reactive sample or on a later sample from the same donor, may be further tested using a licensed multiantigen screening test for HCV or a licensed supplemental test for HCV.

(3) *Consignee notification.* Except for blood and blood components exempt from quarantine in accordance with paragraph (g)(3) of this section, blood establishments shall:

(i) Within 45 days following completion of additional testing and prior to (date 1 year from the effective date of the final rule), notify consignees of the results of the additional licensed screening test and/or the licensed, supplemental test performed in accordance with paragraphs (i)(1) and (i)(2) of this section; or

(ii) Prior to (date 1 year from the effective date of the final rule), notify consignees of the test results for a donor who was identified in the review of historical testing records in accordance with paragraphs (d)(1) through (d)(4) of this section.

(j) *Release from quarantine.* (1) *Prior collections subject to quarantine under paragraph (a) of this section.* Prior collections of blood and blood components intended for transfusion or further manufacture into injectable products which are subject to quarantined under paragraph (a) of this section may be released if the donor's current, repeatedly reactive sample is subsequently tested using a licensed, supplemental test for HCV as provided in paragraph (b) of this section and the result is negative.

(2) *Prior collections subject to quarantine under paragraph (e)(1) of this section.* Prior collections of blood and blood components, which are not exempt from quarantine under paragraph (g)(2) of this section, and are otherwise subject to quarantine under paragraph (e)(1) of this section may be released from quarantine if:

(i)(A) The donor's testing records meet the conditions specified in paragraph (c)(4) of this section and further testing was performed in accordance with paragraph (h)(1)(i)(A) of this section on a frozen sample from the repeatedly reactive donation or a fresh sample from the same donor using a licensed supplemental test for HCV, and the result of the licensed supplemental test for HCV is negative; or

(B) The donor's testing records meet the conditions specified in paragraph (c)(4) of this section and further testing was performed in accordance with paragraph (h)(1)(i)(B) of this section on a frozen sample from the repeatedly reactive donation or a fresh sample from the same donor using a licensed, HCV EIA 3.0 screening test and the result is negative, or using a licensed, supplemental test if the HCV EIA 3.0 screening test is repeatedly reactive and the result of the licensed, supplemental test is negative; or

(ii) The donor's testing records meet the conditions specified in paragraph (c)(5) of this section and further testing was performed in accordance with paragraph (h)(1)(ii) of this section on a frozen sample or a fresh sample from the same donor using a licensed, supplemental test for HCV and the result is negative; or

(iii) The donor's testing records meet the conditions specified in paragraph (c)(2) of this section and further testing was performed, in accordance with paragraph (h)(2) of this section, as follows:

(A) The repeatedly reactive sample (test performed using an HCV EIA 2.0 screening test), or a later sample from the donor was further tested in accordance with paragraph (h)(2)(i) of this section using either a licensed HCV EIA 3.0 screening test or a licensed supplemental test for HCV and the result is negative; or

(B) The repeatedly reactive sample (test performed using an HCV EIA 2.0 screening test) or a later sample from the donor was further tested in accordance with paragraph (h)(2)(ii) of this section using an licensed supplemental test for HCV and the result is negative; or

(C) The repeatedly reactive sample (test performed using an HCV EIA 3.0 screening test) or a later sample from the donor was further tested in accordance with paragraph (h)(2)(iii) of this section using a licensed supplemental test for HCV and the result is negative; or

(iv) The donor's testing records meet the conditions specified in paragraph (c)(3) of this section and further testing was performed in accordance with paragraph (h)(2)(iv) of this section on a frozen sample or a fresh sample from the same donor using a licensed supplemental test for HCV and the result is negative.

(3) *Prior collections subject to quarantine under paragraph (f)(1) of this section.* Prior collections of blood and blood components, which are not exempt from quarantine under paragraph (g)(3) of this section, and are otherwise subject to quarantine under paragraph (f)(1) of this section may be released from quarantine if:

(i) The donor's testing records meet the conditions specified in paragraph (d)(4) of this section and further testing was performed in accordance with paragraph (i)(1)(i) of this section on a fresh sample, or frozen sample from the repeatedly reactive donation using a licensed supplemental test for HCV and the result is negative; or

(ii) The donor's testing records meet the conditions specified in paragraph (d)(1) of this section and further testing was performed in accordance with paragraph (i)(2)(i) of this section on a fresh sample, or frozen sample from the repeatedly reactive donation and the result of the an appropriately chosen licensed supplemental test for HCV is negative; or

(iii) The donor's testing records meet the conditions specified in paragraph (d)(2) of this section and further testing was performed in accordance with paragraph (i)(2)(ii) of this section on a fresh sample, or frozen sample from the repeatedly reactive donation and the result when further tested using either a licensed HCV EIA 3.0 screening test or a licensed supplemental test for HCV is negative;

(iv) The donor's testing records meet the conditions specified in paragraph (d)(3) of this section and further testing was performed in accordance with paragraph (i)(2)(iii) of this section on a fresh sample, or frozen sample from the repeatedly reactive donation and the result when further tested using a licensed multiantigen screening test for HCV or a licensed supplemental test for HCV is negative.

(k) *Destruction or labeling of prior collections held in quarantine.* Blood establishments and consignees shall destroy or appropriately label for in vitro use prior collections of blood and blood components otherwise subject to quarantine in accordance with paragraphs (a), (e), and (f) of this section, unless such prior collections are determined to be exempt from quarantine in accordance with paragraph (g) of this section or subject to release from quarantine in accordance with paragraph (j) of this section. Quarantined prior collections made available for in vitro use shall be appropriately relabeled consistent with §§ 606.121 and 640.70 of this chapter. In addition, these units must be relabeled as ''Biohazard'' with the cautionary statement as follows:

''Collected from a donor who subsequently tested reactive for anti-HCV. An increased risk of transmission of hepatitis C virus is present.''; in addition, the label must contain one of the following cautionary statements as appropriate: ''Caution: For Further Manufacturing Into In-Vitro Diagnostic Reagents For Which There Are No Alternative Sources'' or ''For Laboratory Research Use Only.''

(l) *Recalls.* Actions under this section do not constitute a recall as defined in § 7.3 of this chapter.

9. Section 610.49 is added to subpart E to read as follows:

§ 610.49 Hepatitis C Virus (HCV) ''Lookback;'' notification of transfusion recipients.

(a) *Appropriate actions following further testing.* Transfusion services are required to take appropriate action in accordance with paragraphs (b) and (c) of this section when a recipient has received prior collections of blood or blood components from a donor later determined to be at increased risk of transmitting HCV infection when tested for evidence of infection due to HCV and:

(1) The result of the licensed, supplemental test, performed as prescribed in § 610.48(b) and in accordance with the testing requirements specified in § 610.40(c), is positive;

(2) The result of the supplemental test identified in the review of historical testing records is positive, as specified in § 610.48(c)(1);

(3) The result of the supplemental test identified in the review of historical testing records in accordance with § 610.48(c)(2) is indeterminate, unless:

(i) The review of historical testing records shows the supplemental test was performed using an HCV RIBA 3.0 supplemental test; or

(ii) Any of the conditions for exemption from quarantine specified in § 610.48(g)(2) have been met; or

(iii) The donor was further tested in accordance with § 610.48(h)(2)(i), (h)(2)(ii), or (h)(2)(iii) and any of the conditions for release from quarantine specified in § 610.48(j)(2)(iii) have been met; or

(iv) The donor was further tested in accordance with § 610.48(h)(2)(ii) or (h)(2)(iii) using a supplemental test for HCV and the result is indeterminate;

(4) The result of the licensed supplemental test performed in accordance with § 610.48(h)(1)(i)(A), (h)(1)(i)(B), or (h)(1)(ii) is positive for a donor identified in the review of historical testing records in accordance with § 610.48(c)(4) and (c)(5), as testing repeatedly reactive on a multiantigen screening test in the past with no record of further testing;

(5) No record of further testing is available for a donor identified in the

review of historical testing records, in accordance with § 610.48(c)(4) and (c)(5), and no fresh or frozen sample is available for further testing, as specified in § 610.48(h)(1)(iii);

(6) The result of the additional test using HCV EIA 2.0 or 3.0 identified in the review of historical testing records is repeatedly reactive, as specified in § 610.48(d)(1), unless:

(i) Any of the conditions for exemption from quarantine specified in § 610.48(g)(3) have been met; or

(ii) The donor was further tested in accordance with § 610.48(i)(2)(i) and any of the conditions for release from quarantine specified in § 610.48(j)(3) have been met; or

(iii) The donor was further tested in accordance with § 610.48(i)(2)(i) using an appropriately chosen licensed supplemental test for HCV and the result is indeterminate; or

(7) The result of the supplemental test performed using an HCV RIBA 2.0 or HCV RIBA 3.0 is positive for a donor identified in the review of historical testing records in accordance with § 610.48(d)(2);

(8) The result of the supplemental test performed using an HCV RIBA 2.0 is indeterminate, for a donor identified in the review of historical testing records in accordance with § 610.48(d)(2), unless:

(i) Any of the conditions for exemption from quarantine specified in § 610.48(g)(3) have been met; or

(ii) The donor was further tested in accordance with § 610.48(i)(2)(ii) and any of the conditions for release from quarantine specified in § 610.48(j)(3) have been met; or

(iii) The donor was further tested in accordance with § 610.48(i)(2)(ii) using a licensed supplemental test for HCV and the result is indeterminate; or

(9) The result of the licensed, supplemental test for HCV or a licensed multiantigen screening test performed in accordance with § 610.48(i)(2)(iii) is positive for a donor identified in the review of historical testing records, in accordance with § 610.48(d)(3); or

(10) The result of the licensed, supplemental test for HCV performed in accordance with § 610.48(i)(1) is positive for a donor identified in the review of historical testing records, in accordance with § 610.48(d)(4), as testing repeatedly reactive on a single antigen screening test with a S/CO value equal to or greater than 2.5 for at least two of the three EIA tests, or the S/CO value can not be calculated, and with no record of further testing; or

(11) No record of further testing is available for a donor identified in the review of historical testing records, in accordance with § 610.48(d)(4), and no fresh or frozen sample is available for further testing, as specified in § 610.48(i)(1)(ii).

(b) *Notification of recipients of prior transfusion*. If the transfusion service has administered blood or blood components later determined to be at increased risk of transmitting HCV infection, as described in paragraph (a) of this section, the transfusion service shall either notify the recipient directly or notify the recipient's physician of record (i.e., physician of record or physician who ordered the blood or blood component) and ask him or her to inform the recipient of the need for HCV testing and counseling. If the physician is not available or declines to notify the recipient, the transfusion service shall notify the recipient and inform the recipient of the need for HCV testing and counseling. The notification of transfusion recipients based on donor testing completed after (the effective date of the final rule) shall include a minimum of three attempts to notify the recipient or the recipient's physician of record and be completed within a maximum of 12 weeks of receipt of the result of the supplemental test for HCV from the blood establishment. The notification of transfusion recipients based on donor testing completed prior to (the effective date of the final rule) shall include a minimum of three attempts to notify the recipient or the recipient's physician of record and be completed within 1 year of the date on which the transfusion service received notification from the blood establishment. The transfusion service is responsible for notification, including basic explanations to the recipient and referral for counseling and further testing, and shall document the notification and the result of attempts to notify the recipient and the recipient's physician of record, if contacted, under § 606.160 of this chapter.

(c) *Notification of legal representative or relative*. If the transfusion recipient has been adjudged incompetent by a State court, the legal representative, designated in accordance with State law, shall be notified. If the transfusion recipient is competent, but State law permits a legal representative or relative to receive the information on the recipient's behalf, the transfusion service or the physician who agreed to perform the notification on behalf of the transfusion service shall notify the recipient or his or her legal representative or relative. If the transfusion recipient is a minor at the time of notification, the transfusion service or physician, as described in this paragraph, shall notify the recipient's legal representative or relative. If the transfusion recipient is deceased, the transfusion service or physician, as described in this paragraph, may discontinue the notification process. The transfusion service is responsible for notification, including basic explanations to the recipient's legal representative or relative and referral for counseling and further testing of the recipient, and shall document the notification and the result of attempts to notify the recipient's legal representative or relative and the recipient's physician of record, if contacted, under § 606.160 of this chapter. Reasons for notifying the recipient's relative or legal representative on his or her behalf shall be documented under § 606.160 of this chapter.

(d) *Reference tables*. Tables 1 through 4 of this paragraph show the various tests performed for HCV (including both current donor testing shown in table 1 of this paragraph and tests identified in the review of historical testing records in tables 2 through 4 of this paragraph), steps of the ''lookback'' process, and applicable provisions of §§ 610.48 and 610.49. Based on the initial screening test select the appropriate table from the following:

TABLE 1.—OUTLINE OF PROVISIONS OF § 610.48 FOR HEPATITIS C VIRUS (HCV) ''LOOKBACK'' BASED ON CURRENT DONOR TESTING

Actions to be taken	Applicable section(s):
Identify prior collections	610.48(a)(1)
Quarantine prior in-date collections	610.48(a)(1)(i)
Notify consignees to quarantine	610.48(a)(1)(ii)
Consignees perform quarantine of prior collections	610.48(a)(2)
Exemptions from quarantine	610.48(g)(1)(i) 610.48(g)(1)(ii)
Perform further testing	610.48(b)
Notify consignees of test results	610.48(b)
Release prior collections from quarantine	610.48(j)(1)[1]
Destroy or label prior collections	610.48(k)
Notify transfusion recipients	610.49(a)(1)[2]

[1] If the licensed supplemental test for HCV is negative.
[2] If the licensed supplemental test for HCV is positive.

TABLE 2.—OUTLINE OF PROVISIONS OF § 610.48 FOR HEPATITIS C VIRUS (HCV) ''LOOKBACK'' BASED ON REVIEW OF HISTORICAL TESTING RECORDS AND IDENTIFICATION OF DONORS TESTING REPEATEDLY REACTIVE USING AN HCV EIA[1] 3.0 SCREENING TEST

Results of Further Testing:	RIBA 2.0[2] Positive or RIBA 3.0[3] Positive	RIBA 2.0 Negative	RIBA 2.0 Indeterminate	RIBA 3.0 Negative	RIBA 3.0 Indeterminate	No Supplemental Test Done	
Actions To Be Taken:	Applicable Sections						
Identify prior collections	610.48(c)(1)	610.48(c)(3)	610.48(c)(2)		610.48(c)(2)	610.48(c)(5)	
Quarantine prior in-date collections	610.48(e)(1), (e)(2), (e)(3)	610.48(e)(1), (e)(2), (e)(3)	610.48(e)(1), (e)(2), (e)(3)		610.48(e)(1), (e)(2), (e)(3)	610.48(e)(1), (e)(2), (e)(3)	
Notify consignees to quarantine							
Consignees perform quarantine of prior collections							
Exemptions from quarantine	610.48(g)(2)(i)	610.48(g)(2)(i)	610.48(g)(2)(i)	610.48(g)(2)(ii)(B)	610.48(g)(2)(i)	610.48(g)(2)(i)	
Perform further testing						610.48(h)(1)(ii)[4]	610.48(h)(1)(iii)[6]
Perform optional further testing		610.48(h)(2)(iv)[4]	610.48(h)(2)(iii)[4]				
Notify consignees of test results	610.48(h)(3)(ii)	610.48(h)(3)(i) 610.48(h)(3)(ii)	610.48(h)(3)(i) 610.48(h)(3)(ii)		610.48(h)(3)(ii)	610.48(h)(3)(i) 610.48(h)(3)(ii)	610.48(h)(3)(i) 610.48(h)(3)(ii)
Release prior collections from quarantine		610.48(j)(2)(iv)[5]	610.48(j)(2)(iii)(C)[5]			610.48(j)(2)(ii)[5]	
Destroy or label prior collections	610.48(k)	610.48(k)	610.48(k)		610.48(k)	610.48(k)	610.48(k)
Notify transfusion recipients	610.49(a)(2)		610.49(a)(3)			610.49(a)(4)[7]	610.49(a)(5)

[1] ''EIA'' means enzyme linked immunosorbant assay.
[2] ''RIBA 2.0'' means HCV 2.0 strip immunoblot assay.
[3] ''RIBA 3.0'' means HCV 3.0 strip immunoblot assay.
[4] Using a licensed supplemental test for HCV.
[5] If the licensed supplemental test for HCV is negative.
[6] No frozen or fresh sample is available for further testing.
[7] If the licensed supplemental test for HCV is positive.

TABLE 3.—OUTLINE OF PROVISIONS OF § 610.48 FOR HEPATITIS C VIRUS (HCV) ''LOOKBACK'' BASED ON REVIEW OF HISTORICAL TESTING RECORDS AND IDENTIFICATION OF DONORS TESTING REPEATEDLY REACTIVE USING AN HCV EIA[1] 2.0 SCREENING TEST

Results of Further Testing:	RIBA 2.0[2] Positive or RIBA 3.0[3] Positive	RIBA 2.0 Negative	RIBA 2.0 Indeterminate		RIBA 3.0 Negative	RIBA 3.0 Indeterminate	No Supplemental Test Done		
Actions to be Taken:	Applicable Sections								
Identify prior collections	610.48(c)(1)		610.48(c)(2)			610.48(c)(2)	610.48(c)(4)		
Quarantine prior in-date collections	610.48(e)(1), (e)(2), (e)(3)		610.48(e)(1), (e)(2), (e)(3)			610.48(e)(1), (e)(2), (e)(3)	610.48(e)(1), (e)(2), (e)(3)		
Notify consignees to quarantine									
Consignees perform quarantine of prior collections									
Exemptions from quarantine	610.48(g)(2)(i)	610.48(g)(2)(ii)(A)	610.48(g)(2)(i)		610.48(g)(2)(ii)(A)	610.48(g)(2)(i)	610.48(g)(2)(i)		
Perform further testing							610.48(h)(1)(i)(A)[9]	610.48(h) (1)(i)(B)[10]	610.48(h) (1)(iii)[11]
Perform optional further testing			610.48(h) (2)(i)[4] 610.48(h)(2)(ii)[5]	610.48(h) (2)(i)[6]					
Notify consignees of test results	610.48(h)(3)(ii)		610.48(h)(3)(i) 610.48(h) (3)(ii)	610.48(h)(3)(i) 610.48(h) (3)(ii)		610.48(h) (3)(ii)	610.48(h)(3)(i) 610.48(h)(3)(ii)	610.48(h)(3)(i) 610.48(h)(3)(ii)	610.48(h)(3)(i) 610.48(h)(3)(ii)
Release prior collections from quarantine			610.48(j)(2)(iii)(A)[7] 610.48(j)(2)(iii)(B)[8]	610.48(j) (2)(iii)(A)[8]			610.48(j)(2)(i)(A)[12]	610.48(j)(2) (i)(B)[13]	
Destroy or label prior collections	610.48(k)		610.48(k)	610.48(k)		610.48(k)	610.48(k)	610.48(k)	610.48(k)
Notify transfusion recipients	610.49(a)(2)		610.49(a)(3)	610.49(a)(3)			610.49(a)(4)[14]	610.49(a)(4)[14]	610.49(a)(5)

[1] ''EIA'' means enzyme linked immunosorbant assay.
[2] ''RIBA 2.0'' means HCV 2.0 strip immunoblot assay.
[3] ''RIBA 3.0'' means HCV 3.0 strip immunoblot assay.
[4] Using an HCV EIA 3.0 screening test.
[5] If the HCV EIA 3.0 screening test is repeatedly reactive, may perform a licensed supplemental test for HCV.
[6] Using a licensed supplemental test for HCV.
[7] If the HCV EIA 3.0 screening test is negative.
[8] If the licensed supplemental test for HCV is negative.
[9] Perform a licensed supplemental test for HCV.
[10] Perform an HCV EIA 3.0 screening test and perform a licensed supplemental test for HCV if the HCV EIA 3.0 screening test is repeatedly reactive.
[11] No frozen or fresh sample is available for further testing.
[12] If the licensed supplemental test for HCV is negative.
[13] If the HCV EIA 3.0 screening is negative; or, if it is repeatedly reactive, the licensed supplemental test for HCV is negative.
[14] If the licensed supplemental test for HCV is positive.

TABLE 4.—OUTLINE OF PROVISIONS OF § 610.48 FOR HEPATITIS C VIRUS (HCV) ''LOOKBACK'' BASED ON REVIEW OF HISTORICAL TESTING RECORDS AND IDENTIFICATION OF DONORS TESTING REPEATEDLY REACTIVE USING AN HCV EIA [1] 1.0 SCREENING TEST

RESULTS OF FURTHER TESTING:	EIA 2.0[2] Repeatedly Reactive	EIA 3.0[3] Repeatedly Reactive	EIA 2.0 Negative or EIA 3.0 Negative	RIBA 2.0 Positive or RIBA 3.0 Positive	RIBA 2.0 Indeterminate	RIBA 3.0 Indeterminate	RIBA 2.0 Negative or RIBA 3.0 Negative	S/CO[4] < 2.5	S/CO >2.5 or No Determination of S/CO	
ACTIONS TO BE TAKEN:	Applicable Sections									
Identify prior collections	610.48(d)(1)	610.48(d)(1)		610.48(d)(2)	610.48(d)(2)	610.48(d)(2)		610.48(d)(3)	610.48(d)(4)	
Quarantine prior in-date collections	610.48(f)(1), (f)(2), (f)(3)	610.48(f)(1), (f)(2), (f)(3)		610.48(f)(1), (f)(2), (f)(3)	610.48(f)(1), (f)(2), (f)(3)	610.48(f)(1), (f)(2), (f)(3)		610.48(f)(1), (f)(2), (f)(3)	610.48(f)(1), (f)(2), (f)(3)	
Notify consignees to quarantine										
Consignees perform quarantine of prior collections										
Exemptions from quarantine	610.48(g)(3)(iii)[5]	610.48(g)(3)(iii)[5]	610.48(g)(3)(i)		610.48(g)(3)(iv)[7]		610.48(g)(3)(ii)			
Perform further testing									610.48(i)(1)(i)[13]	610.48(i)(1)(ii)[14]
Perform optional further testing	610.48(i)(2)(i)[6]	610.48(i)(2)(i)[6]			610.48(i)(2)(ii)[8]			610.48(i) (2)(iii)[10]		
Notify consignees of test results	610.48(i)(3)(i) 610.48(i)(3)(ii)	610.48(i)(3)(i) 610.48(i)(3)(ii)		610.48(i)(3)(ii)	610.48(i)(3)(i) 610.48(i)(3)(ii)	610.48(i)(3)(ii)		610.48(i)(3)(i) 610.48(i)(3)(ii)	610.48(i)(3)(i) 610.48(i)(3)(ii)	610.48(i)(3)(i) 610.48(i)(3)(ii)
Release prior collections from quarantine	610.48(j)(3)(ii)[5]	610.48(j)(3)(ii)[5]			610.48(j)(3)(iii)[9]			610.48(j)(3)(iv)[11]	610.48(j)(3)(i)[15]	
Destroy or label prior collections	610.48(k)	610.48(k)		610.48(k)	610.48(k)	610.48(k)		610.48(k)	610.48(k)	610.48(k)
Notify transfusion recipients	610.49(a)(6)	610.49(a)(6)		610.49(a)(7)	610.49(a)(8)			610.49(a)(9)[12]	610.49(a)(10)[16]	610.49(a)(11)

[1] ''EIA'' means enzyme linked immunosorbant assay.
[2] ''RIBA 2.0'' means HCV 2.0 strip immunoblot assay.
[3] ''RIBA 3.0'' means HCV 3.0 strip immunoblot assay.
[4] ''S/CO'' means ''Signal to cut off.''
[5] If further testing using an appropriately chosen supplemental test for HCV was performed and the result was negative.
[6] May perform further testing using an appropriately chosen licensed supplemental test for HCV.
[7] If further testing using an HCV EIA 3.0 screening test or an HCV RIBA 3.0 supplemental test was performed and the result was negative.
[8] May perform further testing using an HCV EIA 3.0 screening test or a licensed supplemental test for HCV. If an HCV EIA 3.0 screening test is performed and is repeatedly reactive, may perform further testing using a licensed supplemental test for HCV.
[9] If further testing using an HCV EIA 3.0 screening test or a licensed supplemental test for HCV was performed and the result was negative.
[10] May perform further testing using a licensed multiantigen screening test for HCV or a licensed supplemental test for HCV.
[11] If further testing using a licensed multiantigen screening test for HCV or a licensed supplemental test for HCV was performed and the result was negative.
[12] If further testing using a licensed multiantigen screening test for HCV or a licensed supplemental test for HCV was performed and the result was positive.
[13] Using a licensed supplemental test for HCV.
[14] No frozen or fresh sample is available for further testing.
[15] If the licensed supplemental test for HCV is negative.
[16] If the licensed supplemental test for HCV is positive.

Dated: December 3, 1999.

Jane E. Henney,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 00–28907 Filed 11–15–00; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 482

[HCFA–3014–P]

RIN 0938–AJ29

Medicare and Medicaid Programs; Hospital Conditions of Participation: Laboratory Services

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would require hospitals that transfuse blood and blood products to prepare and follow written procedures for appropriate action when it is determined that blood and blood products the hospitals received and transfused are at increased risk for transmitting hepatitis C virus (HCV); quarantine prior collections from a donor who is at increased risk for transmitting HCV infection; notify transfusion recipients, as appropriate, of the need for HCV testing and counseling; and extend the records retention period to 10 years.

These changes are based on recommendations by the Secretary's Advisory Committee on Blood Safety and Availability. The intent is to aid in the prevention of HCV infection and to create opportunities for disease prevention many years after recipient exposure to a donor.

DATES: We will consider written comments if we receive them at the appropriate address, as provided below, no later than 5 p.m. on or before January 16, 2001.

ADDRESSES: Mail written comments (one original and three copies) to the following address: Health Care Financing Administration, U.S. Department of Health and Human Services, P.O. Box 8010, Attention: HCFA–3014–P, 7500 Security Boulevard, Baltimore, Maryland 21244–8010.

If you prefer, you may deliver your written comments (one original and three copies) to one of the following addresses:

Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or,

Room C5–09–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Because of staffing and resource limitations, we cannot accept audio, visual, or facsimile (FAX) copies of comments. In commenting, please refer to file code HCFA–3014–P. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in room 443–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

FOR FURTHER INFORMATION CONTACT: Mary Collins, (410) 786–3189.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 1861(e) of the Social Security Act (the Act), hospitals must meet certain conditions in order to participate in the Medicare program. These conditions are intended to protect patient health and safety and ensure that high-quality care is provided. Hospitals receiving payment under Medicaid must meet the Medicare conditions of participation.

Regulations containing the Medicare conditions of participation for hospitals are located in the Code of Federal Regulations at 42 CFR part 482. The condition of participation for hospital laboratory services at § 482.27 (c) currently specifies the steps hospitals must take when they become aware they have administered potentially human immunodeficiency virus (HIV) infectious blood or blood products to a patient. The more detailed requirements for laboratories appear in 42 CFR part 493, which sets forth requirements for all laboratories participating in the Medicare, Medicaid, and Clinical Laboratory Improvement Amendments (CLIA) programs.

The Health Care Financing Administration (HCFA) and the Food and Drug Administration (FDA) are responsible for ensuring the safety of blood and blood products.

Blood banks (referred to as blood establishments in FDA regulations) are subject to the FDA regulations for current good manufacturing practices and additional standards for the manufacture of blood and blood components under 21 CFR parts 211, 600, 601, 606, 610, and 640. Laboratories that provide transfusion services are subject to CLIA requirements for quality control and health and safety standards (42 CFR part 493, subpart K). Laboratories in hospitals are also subject to the hospital conditions of participation for adequacy of laboratory services (42 CFR 482.27). HCFA coordinates inspections of hospital-based blood banks with the FDA to minimize duplication of effort and reduce the burden on affected facilities.

Hepatitis C virus (HCV) was first discovered and established as a causative agent of transfusion-associated hepatitis in the late 1980s. In October 1989, FDA's Blood Products Advisory Committee (BPAC) first discussed steps to identify and quarantine potentially HCV infectious blood and blood products remaining in storage and notify recipients of the blood. (These steps are known as ''lookback.'') BPAC advised that there was insufficient information available concerning HCV infection to propose either product quarantine or notification of recipients transfused with products prepared from prior collections from donors later determined to be at increased risk for transmitting HCV.

In 1996, the Tenth Report of the U.S. House of Representatives Committee on Government Reform and Oversight (H. Rpt. No. 104–746) focused attention on the significant public health problem that HCV infections pose for the nation. HCV infection is the most common blood-borne infection in the United States. The Centers for Disease Control and Prevention (CDC) estimate that during the 1980s, as many as 180,000 new HCV infections occurred each year. Since 1989, the annual number of new infections has declined by 80 percent. Currently approximately 4 million individuals in the United States are believed to be chronically infected with HCV.

In 1996, however, data from the Third National Health and Nutritional Examination Survey conducted from 1988 to 1994 indicated that chronically infected persons may not be aware of their infection. Despite progression of the disease, HCV infection is usually asymptomatic for about 20 years, but in many cases causes serious liver injury that is thought to be the leading cause of late stage liver failure and cirrhosis in the United States. HCV is also thought to play a significant role in the development of liver cancer. Between 8,000 and 12,000 deaths annually result from HCV-related chronic liver disease.

HCV can be transmitted in a number of ways, including sharing of drug use equipment among injection drug users, blood transfusion and solid organ

transplants from infectious donors, hemodialysis, occupational exposure to blood, perinatal exposure of infants to infected mothers, and unprotected sex.

In response to scientific data that show that HCV is transmissible through infectious blood and blood products, FDA has implemented an extensive system of donor screening and testing procedures performed before, during, and after a donation takes place to help prevent the transfusion of blood and blood products that are infected with HCV.

Blood establishments are currently testing each donation of blood and blood components for the antibody to HCV. FDA restricts the use, for transfusion or further manufacture, of donations testing repeatedly reactive for the antibody to HCV. Repeatedly reactive means that the initial HCV antibody screening test is reactive (in which case it is retested in duplicate), and that one or both of the duplicate tests are reactive.

As a result of the FDA blood donor screening and testing procedures, the risk of transmitting HCV infections through blood transfusion is very low. Despite the best practices of blood establishments, however, a person may donate blood early in the infection process when the antibody to HCV is not detectable by the screening test but is nevertheless present in the donor's blood (a so-called ''window'' period). If the donor attempts to donate blood at a later date, the test for the antibody to HCV may at that time be repeatedly reactive. Under these circumstances, previously collected blood and blood products would be at increased risk for transmitting HCV, and a recipient of a blood product collected during the window period would not know whether the donor was infected with HCV at the time of the previous donations. Approximately 7 percent of the 3.9 million Americans believed to be chronically infected with HCV were infected as a result of transfusion of blood components before the availability of donor screening tests or due to past use of non-viral-inactivated plasma derivative products. [1]

As a result of advances in identifying the presence of HCV, the window period continues to shrink. The FDA proposed rule titled ''Current Good Manufacturing Practice for Blood and Blood Components: Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV Infection ('Lookback'),'' published elsewhere in this issue of the **Federal Register,** provides more information on the length of the window period and discusses various diagnostic modalities for HCV infection.

The incidence of transfusion-transmitted HCV infection has decreased markedly since the implementation of donor screening for HCV and viral inactivation of clotting factors and intravenous immune globulins. Blood establishments implemented donor screening tests after a single antigen, enzyme linked immunosorbent assay (EIA) for antibody to HCV (HCV EIA 1.0 screening test) was licensed in May 1990. FDA issued a memorandum to all registered blood establishments in November 1990, ''Testing for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV),'' recommending use of approved donor screening tests for antibody to HCV. A lookback program was not recommended because: (1) Screening tests available at the time could not distinguish between on-going infection and recovery, thus rendering unclear the meaning of a reactive test for any one individual; (2) donor screening for antibody to HCV did not include confirmatory testing, and most notification would have been based on false positive donor test results; (3) there was limited knowledge of routes of transmission for HCV other than parenteral; and (4) no potential long-term benefits of therapy were known.

A significantly more sensitive multiantigen screening test (HCV EIA 2.0 screening test) was licensed in March 1992. In June 1993, FDA licensed an HCV 2.0 strip immunoblot assay (HCV RIBA 2.0), also known as recombinant immunoblot assay (RIBA), a supplemental test for antibody to HCV. Supplemental tests for antibody to HCV are used to distinguish false positive test results from true repeatedly reactive screening test results. Following the December 1993 BPAC meeting, BPAC recommended product quarantine of prior collections from a donor who later tests repeatedly reactive for the antibody to HCV and tests positive or indeterminate on a supplemental test; however, BPAC only marginally endorsed consignee notification for the purpose of transfusion recipient notification because the public health benefit of the notification was not clear.

The Public Health Service Advisory Committee on Blood Safety and Availability (PHS Advisory Committee) discussed improvements in the treatment and management of HCV infection and improvements in testing for the antibody to HCV at public meetings held on April 24, 1997 and on August 11 and 12, 1997. The PHS Advisory Committee also discussed the public health benefits of notifying transfusion recipients receiving prior collections from a donor who subsequently tests repeatedly reactive for evidence of HCV infection. Following the Department of Health and Human Services' acceptance of recommendations from the PHS Advisory Committee, the FDA developed guidance, published in March 1998, regarding procedures for testing blood for HCV, quarantining blood and blood products, and notifying patients who may have received HCV-infected blood and blood products.

At public meetings on November 24, 1998 and January 28, 1999, the PHS Advisory Committee reconsidered the issue of recipient notification related to repeatedly reactive results on the single antigen screening test. The PHS Advisory Committee recommended that targeted lookback should be initiated based on a repeatedly reactive HCV EIA 1.0 screening test result on a repeat donor unless a supplemental test was performed and the result did not indicate increased risk of HCV infection, or, in the absence of a supplemental test result, unless the signal to cut off value of the repeatedly reactive HCV EIA 1.0 screening test was less than 2.5 or follow-up testing of the donor was negative.

FDA published a notice in the **Federal Register** on June 22, 1999 (64 FR 33309) announcing the availability of a draft guidance titled ''Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Prior Collections from Donors with Repeatedly Reactive Screening Tests for Hepatitis C Virus (HCV); (2) Supplemental Testing, and the Notification of Consignees and Transfusion Recipients of Donor Test Results for Antibody to HCV (Anti-HCV).'' Consistent with the recommendations of the PHS Advisory Committee, this revised draft guidance addressed lookback actions related to donor screening by HCV EIA 1.0 and also recommended that the search of historical testing records of prior donations from donors with repeatedly reactive EIA 1.0, EIA 2.0, or EIA 3.0 screening tests for HCV should extend back indefinitely to the extent that electronic or other retrievable records exist.

In the proposed rule titled ''Medicare and Medicaid Programs; Hospital Conditions of Participation; Provider Agreements and Supplier Approval'' (HCFA–3745–P), published on

[1] M.J. Alter, ''Epidemiology of Hepatitis C,'' Hepatology 26.3 (1997): 62s–65s.

December 19, 1997 in the **Federal Register** (62 FR 66726), we proposed to revise the hospital conditions of participation to focus on patient care outcomes, reflect a cross-functional view of the hospitals' organization and patient treatment, encourage flexibility in meeting quality standards, and eliminate outdated and redundant evaluation criteria. The lookback requirement for HIV infectious blood and blood products was the only lookback under this proposed condition. The HIV requirement was restated without change in the existing § 482.27(c). This requirement would merely be redesignated under this proposed rule. We are still in the process of analyzing comments we received on the December 19, 1997 proposed rule as we develop the final rule.

Should the restructuring of part 482 in the December 19, 1997 proposed rule become final before we publish this proposed rule (HCFA–3014–P) as a final rule, the provisions dealing with potentially HCV infectious blood and blood products would be set forth in the final rule (HCFA–3014–F) as a revision to § 482.145.

II. Provisions of This Proposed Rule

In order to have consistent industry standards for potentially infectious blood and blood products, we propose to adopt as our requirements for hospitals the procedures for HIV and HCV proposed by the FDA published elsewhere in this issue of the **Federal Register**. Since our proposed rule is in concert with the FDA's proposed rule, we will consider comments we receive in conjunction with the FDA. We specifically request comments on the reasonableness of our adopting the FDA requirements.

The FDA proposed rule for HCV lookback would require the search of historical testing records of prior donations from donors with repeatedly reactive EIA 1.0, EIA 2.0, or EIA 3.0 screening tests for HCV to extend back indefinitely for computerized electronic records and to January 1, 1998 for other retrievable records. Under the FDA rule, the blood establishment would notify the hospital if it supplied the hospital with potentially HIV or HCV infectious blood.

Our proposed rule would amend the hospital conditions of participation to require a hospital to develop agreements with outside blood banks under which the blood bank would notify the hospital when it has supplied the hospital with potentially HCV infectious blood and blood products. This proposed rule would establish a lookback, similar to that now in effect for HIV, requiring hospitals, when notified by blood banks, to quarantine prior collections from a donor who later tests repeatedly reactive for evidence of HCV infection, and to notify transfusion recipients based on further testing of such a donor, as appropriate.

In existing § 482.27, we propose to remove the designation for paragraph (a) and redesignate paragraphs (b) and (c) as (a) and (b), respectively. In addition, we would add a definition of potentially HCV infectious blood and blood products as prior collections from a donor who tested repeatedly reactive for evidence of HCV infection on a single antigen screening test with a signal to cut off value equal to or greater than 2.5 for at least two of the three EIA tests, or the signal to cut off value cannot be calculated, and with no record of further testing; who tests or tested repeatedly reactive for evidence of HCV infection and positive on a multiantigen supplemental test licensed at an earlier or later date by FDA; who tested repeatedly reactive for evidence of HCV infection and indeterminate on a supplemental test for HCV, unless an indeterminate RIBA 3.0 supplemental test result was obtained or a negative EIA 3.0 or negative RIBA 3.0 test result was subsequently obtained; who tested repeatedly reactive for evidence of HCV infection on a multiantigen screening test with no record of further testing; or who tested repeatedly reactive for evidence of HCV infection on a single antigen screening test and repeatedly reactive on a subsequent multiantigen screening test, unless a negative supplemental test result or an indeterminate RIBA 3.0 supplemental test result was obtained. (See proposed § 482.27(b)(2).)

Our regulations currently require that a hospital that regularly uses the services of an outside blood bank have an agreement with the blood bank that requires the blood bank to notify the hospital if the blood bank has supplied the hospital with potentially HIV infectious blood. This proposed rule would amend that provision to also require notification in the case of potentially HCV infectious blood. (See proposed § 482.27(b)(3).) In addition, we would revise our regulations to include HCV-relevant testing required by FDA. (See proposed § 482.27(b)(3)(ii).)

As a new provision, we would require hospitals to include in agreements with blood banks that the blood bank notify the hospital under FDA's proposed 21 CFR 610.48(h)(3)(i) and (h)(3)(ii), and (i)(3)(i) and (i)(3)(ii). The FDA's proposed rule would require hospitals to perform a lookback of blood or blood products collected from a donor extending back indefinitely for computerized electronic records and to January 1, 1998 for other retrievable records, or to the date 12 months before the donor's most recent negative multiantigen screening test for the antibody to HCV, whichever is the later date. (See proposed § 482.27(b)(3)(ii) and (b)(3)(iii).)

We would also revise our regulations to apply the provisions regarding the quarantine of potentially HIV infectious blood and blood products currently set forth at § 482.27(c)(3) to potentially HCV infectious blood and blood products. In addition, we would require hospitals to destroy or label prior collections of blood or blood products held in quarantine as set forth in FDA's proposed 21 CFR 610.48(k). (See proposed § 482.27(b)(4).)

Hospitals are currently required to maintain clinical records on all patients for 5 years. We would add a new provision requiring hospitals to maintain adequate records of the source and disposition of all units of blood and blood products for at least 10 years from the date of disposition. Hospitals would be required to increase the record retention period yearly until 10 years of records from the date of disposition have accrued. (For example, the first year after the effective date of this regulation, hospitals would have 6 years of records, the second year after the effective date, 7 years, etc., until 10 years have been reached.) Hospitals would then be able and expected to maintain 10 years of patient records. (See proposed § 482.27(b)(5).) This is necessary to increase opportunities for disease prevention or treatment years after a recipient has been exposed to a donor later determined to be at risk of transmitting a disease through transfusion.

The FDA has proposed changes in its requirement for patient notification to allow transfusion services to make three attempts to either notify patients directly or notify the attending physician or the physician who ordered the blood. We are proposing that hospitals follow the same notification procedures with regard to potentially HIV and HCV infectious blood and blood products. For consistency, we are also proposing that the HIV lookback requirements be changed to conform to the requirements for HCV lookback. (See proposed § 482.27(b)(6).)

We propose to add a new paragraph (c) requiring hospitals to comply with FDA regulations pertaining to the appropriate testing and quarantining of infectious blood and blood products and to the notification and counseling of

recipients that may have received infectious blood and blood products.

Note that our Medicaid regulations at § 441.17 (''Laboratory services'') provide that the State plan must pay for laboratory services furnished by a hospital-based laboratory meeting the requirements for Medicare participation set forth in § 482.27. Therefore, the provisions of this proposed rule would also affect the Medicaid program. That is, in order for the laboratory services furnished by a hospital-based laboratory under Medicaid to be covered under the State plan, the hospital would have to meet the new requirements set forth in this proposed rule.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, agencies are required to provide a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3506(c)(2)(A)) requires that we solicit comment on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency's estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on each of these issues for the provisions summarized below that contain information collection requirements:

Section 482.27 Condition of participation: Laboratory services

In summary, § 482.27(b)(3) requires a hospital that regularly uses the services of an outside blood bank to establish and maintain a written agreement with the blood bank that governs the procurement, transfer, and availability of blood and blood products. This section also requires the blood bank to notify the hospital within 3 calendar days after the date on which the donor tested repeatedly reactive for evidence of HCV infection or after the date on which the blood establishment was made aware of other test results indicating evidence of HCV infection, as outlined in (i) through (iii).

In summary, § 482.27(b)(5) requires a hospital to maintain, in a manner that permits prompt retrieval, adequate records of the source and disposition of all units of blood and blood products for at least 10 years from the date of disposition. In addition, this section requires a hospital to maintain a fully funded and documented plan that demonstrates how the hospital will transfer these records to another hospital or other entity if the former hospital ceases operation for any reason.

In summary, § 482.27(b)(6) requires a hospital that has administered potentially HIV or HCV infectious blood or blood products (either directly through its own blood bank or under an agreement), or released the blood or blood products to another entity or individual, to make at least three attempts to notify the patient, or to notify the attending physician or the physician who ordered the blood or blood product and ask the physician to notify the patient, that potentially HIV or HCV infectious blood or blood products were transfused to the patient. Time frame and notification requirements are outlined in §§ 482.27(b)(6), (b)(7), and (b)(8).

In summary, § 482.27(b)(9) requires a hospital to maintain policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for confidentiality and medical records.

In summary, § 482.27(b)(10) requires a physician or hospital, if the patient has been adjudged incompetent by a State court, to notify a legal representative designated in accordance with State law. If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf, the physician or hospital must notify the patient or his or her legal representative or relative. If the patient is deceased, the physician or hospital must continue the notification process and inform the deceased patient's legal representative or relative. If the patient is a minor, the legal guardian must be notified.

While all of the information collection requirements referenced above are subject to the Paperwork Reduction Act, the burden associated with these requirements is captured and discussed in the FDA's proposed regulation titled ''Current Good Manufacturing Practice for Blood and Blood Components: Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting HCV Infection ('Lookback'),'' Docket No. 98N–0609. Therefore, we are assigning 1 token hour of burden to these requirements.

The FDA's rule assigns a one-time burden of 16 hours for hospitals to develop procedures to conduct lookback activities. HCFA also requires hospitals that currently receive blood from an outside blood bank to have an agreement with the blood bank that governs the procurement, transfer, and availability of blood and blood products for HIV. Our proposed rule would require those hospitals to modify their current agreements to include HCV. Although the FDA does not require hospitals to have this agreement, we believe that the time necessary to perform this task would be minimal and is already captured in the 16 hours allotted in the FDA rule.

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirement. These requirements are not effective until they have been approved by OMB. A notice will be published in the **Federal Register** when approval is obtained.

If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following:

Health Care Financing Administration, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850. Attn: John Burke, HCFA–3014–P, Fax number: (410) 786–0262,

and,

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503. Attn.: Allison Herron Eydt, HCFA Desk Officer, Fax numbers: (202) 395–6974 or (202) 395–5167.

IV. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of the proposed rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more annually). Because the projected cost of this proposed rule falls below the threshold for a major rule, we have determined that this proposed rule is not a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $5 million or less annually. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year. We believe that this proposed rule is not an economically significant rule as described in the Executive Order, nor a significant action as defined in the Unfunded Mandates Reform Act. Aggregate impacts of the rule, and aggregate expenditures caused by the rule, would not reach $100 million for either the public or the private sector. As discussed in the following paragraphs, because of the lack of information to characterize the number and volumes of affected blood and blood products in hospitals that might qualify as small business entities, the impact on small business establishments is uncertain.

It is clear that a number of hospitals that provide blood transfusions will be affected by the implementation of this proposed rule and that a substantial number of those entities will be required to make changes in their operations. For these reasons, we have prepared the following voluntary analysis. This analysis, in combination with the rest of the preamble, is consistent with the analysis set forth by the RFA.

B. Anticipated Effects

1. Effects on Hospitals

This proposed rule would require hospitals that transfuse blood and blood products to (1) prepare and follow written procedures for appropriate action when it is determined that blood and blood products the hospitals received and transfused are at increased risk for transmitting HCV; (2) quarantine prior collections from a donor who is at increased risk for transmitting HCV infection; (3) notify transfusion recipients, as appropriate, of the need for HCV testing and counseling; and (4) extend the records retention period to 10 years.

The proposed rule would affect hospitals that transfuse blood and blood components. We estimate that there are approximately 6,200 Medicare- and Medicaid-participating hospitals. The CDC estimates that 303,676 recipients may need to be notified due to the historical review.

As indicated previously, the proposed rule would require hospitals to notify transfusion recipients who received prior collections from a donor at increased risk for transmitting HCV. The hospital may notify the attending physician or notify the recipient directly. If the transfusion recipient is a minor or adjudged incompetent by a State court, the hospital or physician would be required to notify the recipient's legal representative. The proposed rule is expected to generate one-time costs and some additional annual costs for hospitals. One-time costs include the development of procedures and policies for recipient notification and the agreement a hospital should have with a blood bank if it uses the services of an outside bank. We assume that these tasks will involve a review of current procedures and policies (for example, for HIV lookback) and the adaptation or modification of current procedures and policies to address the provisions of this rule, and we estimate, in consultation with the FDA, that the tasks will require an average of 16 hours per facility. The Bureau of Labor Statistics estimates that the total hourly compensation in 1997 for a staff medical technologist performing the review would be $25.67. Thus, we estimate the total one-time cost for all 6,200 hospitals to develop HCV lookback procedures to be $2,546,464 (16 x $25.67 x 6,200). (See Table in this section.)

For notifications resulting from donors tested on or after the effective date of the final rule under FDA's proposed § 610.48(a)(b), the hospital's required notification effort must include a minimum of three attempts to notify the transfusion recipient, and the hospital must complete the process within a maximum of 12 weeks from the time it receives from the blood establishment the results of the donor's supplemental test for HCV. The following estimated cost for compliance with provisions concerning the prospective review and recipient notification is based on: (1) FDA's estimation of the number of recipient notification multiplied by the unit cost of each notification. First, the number of annual affected blood donations was calculated as the product of 12 million donations, an 80 percent donor rate, and a 12 percent HCV positive donor rate. (2) The resulting 11,520 figure was then adjusted upward to 12,816 to reflect the difference found between the number of donors triggering lookback and the component notifications reported as interim results from a recent survey conducted by the Centers for Disease Control and prevention (CDC). (3) The cost per attempted notification is estimated at $165, which reflects the average cost quoted by a third party contractor for matching, notifying, testing, counseling, and documenting lookback efforts for over 100 hospitals.[2] Although the proposed rule does not specifically require hospitals to perform testing and counseling services many do. These assumptions yield an annual cost of $2,114,640 (12,816 × $165) for hospitals to conduct prospective lookback activities. (See Table in this section.)

For notifications resulting from donors tested before the effective date of the final rule under FDA's proposed § 610.48(c)(d), the hospital must complete the notification effort within 1 year from the time it receives notification from the blood establishment. The recipient notification provided by the hospital

[2] Richard Quattrocchi, Home Access Health Corporation.

must include a basic explanation to the recipient, referral for counseling and further testing, and documentation of the notification or attempts to notify the attending physician or recipient. Notification resulting from the review of historical testing records and the identification of prior collections are to be completed by the hospital within one year of receipt of notification from the blood establishment. The recipient notification provided by the hospital would include a basic explanation to the recipient, referral for counseling and further testing and documentation of the notification or attempts to notify the physician of record or recipient. The estimated one-time cost of recipient notification associated with the review of historical testing records is $50,106,540. This is based on the CDC estimate of blood components of about 303,676 recipients identified for notification produced from donations (188,448 from 1990 to mid-1992 and 115,228 from 1990 to mid-1992), and the average cost of $165 of staff time per component for recipient notification. Thus, the total one-time cost to hospitals for conducting the historical ''lookback'' efforts is estimated to be $52,653,004 ($2,546,464 to develop procedures and $50,106,540 for recipient notification). (See Table in this section.)

SUMMARY OF ESTIMATED COST OF PROPOSED RULE

Type of cost	Total one-time cost	Total annual cost
Development of HCV Lookback Procedures	[1] $2,546,464.00	
Prospective Review		[3] $2,114,640.00
Historical Review	[2] 50,106,540.00	
Total	52,653,004.00	2,114,640.00

[1] Based on 6,200 hospitals.
[2] Based on the CDC estimate of the total number of blood products (303,676).
[3] Based on the CDC estimate of 12,816 repeat-donor repeatedly reactive donations per year.

2. Effects on Beneficiaries

Timely notification of HCV infection benefits beneficiaries, both directly and indirectly, in several important ways. First, although factors predicting the severity of liver disease due to HCV have not been well defined, recent data indicate that increased alcohol intake is associated with more severe liver disease. According to CDC, even moderate amounts of alcohol in patients with chronic HCV might exacerbate liver disease. Consequently, an HCV-infected patient identified by the proposed lookback program could minimize liver damage associated with alcohol consumption by restricting his or her intake.

Furthermore, while other percutaneous exposures currently represent the most common means of infection, some case-control studies have also reported that HCV can be transmitted through sexual contact. In fact, 15 to 25 percent of the acute HCV patients who were reported to CDC's sentinel counties surveillance system have a history of sexual exposure in the absence of other risk factors. Infected patients identified through the proposed lookback procedures could take steps to protect sexual partners from the risk of infection.

It is also important to note that identified infected patients would benefit from counseling and treatment with available therapies. Studies of patient characteristics and responsiveness to therapy indicate that best results are achieved if treatment is initiated earlier in the disease, when patients are younger and have not yet developed cirrhosis.[3] For example, Bennett et al. estimated the cost effectiveness of a single course (6 months) of treatment with interferon alfa and found that patients at age 20 gained an average of 3.1 years of life, at $500 per year of life extended (YLE); 30-year-old patients gained an average of 1.9 years of life, at $1200/YLE; patients starting treatment at age 50 gained 6 months of life, at $2900/YLE; and 70-year-old patients gained an average of 22 days, at $62,000/YLE.[4]

Another benefit of timely notification is that care providers for the infected patient would be aware of the infection and could use additional precautions to avoid the risk of exposure to blood or wounds when providing care.

Finally, infected patients would be informed that they must not donate blood. The proposed lookback program would, therefore, help to ensure the safety and continued availability of the national blood supply.

3. Effects on Medicaid and Medicare Programs

We expect this proposed rule to generate a one-time cost to develop procedures for recipient notification. We estimate that this cost will be less than $5 million. Finally, the total one-time cost for the development of HCV lookback procedures and for recipient notification associated with the review of historical testing records is estimated to be $52,653,004 ($2,546,464 + $50,106,540). These one-time costs would likely be distributed among health programs as follows: Medicare, 33.3 percent; private health insurance, 30.5 percent; Federal Medicaid, 9.8 percent; State Medicaid, 5.8 percent; other private funds, 7.9 percent; other Federal funds, 6.9 percent; and other State and local funds, 5.7 percent. The total Federal distribution would be 50 percent; that is, 33.3 percent for Medicare, 9.8 percent for Medicaid, and 6.9 percent for other Federal sources. The degree to which the Federal programs fund these amounts will vary: Medicaid providers may be able to pass on costs through the States depending on the method of payment the State Medicaid program has adopted, while Medicare payments could be limited because of the hospital outpatient prospective payment system and increase only in accordance with specific rules regarding coverage of HCV testing for patients who have been exposed to HCV-infected blood, including those identified through the FDA lookback process.

It is important to note that, although this proposed rule presents the costs that would be imposed on all payers of hospital services, including the Medicare and Medicaid programs, it merely conforms to the FDA's proposed rule and has no additional economic impact. It simply repeats the analysis performed in the FDA companion rule

[3] G.L. Davis and J.Y.N. Lau, ''Factors Predictive of a Beneficial Response to Therapy of Hepatitis C,'' Hepatology 26.3 (1997): 122s–126s.

[4] W.G. Bennett et al., ''Estimates of the Cost-Effectiveness of a Single Course of Interferon-alfa2b in Patients with Histologically Mild Chronic Hepatitis C,'' Annals of Internal Medicine, 127.10 (1997): 855–865.

and presents the same total costs to hospitals.

C. Alternatives Considered

The PHS Advisory Committee discussed improvements in the treatment and management of HCV infection and improvements in testing for the HCV antibody at public meetings held in April and August 1997. The Advisory Committee recommended that blood establishments and hospitals notify previous recipients of blood components from donors who tested positive for HCV upon a subsequent donation.

Following the Department of Health and Human Services' acceptance of recommendations from the PHS Advisory Committee, FDA developed industry guidelines for testing blood for HCV, quarantining blood and blood products, and notifying patients who may have received HCV-infected blood and blood products. We explored the possibility of using a program memorandum to notify hospitals that they are required to follow FDA guidelines. We believe, however, that we should promulgate an enforceable regulation.

The following discussion considers some key elements of successful lookback efforts, describes certain challenges identified in lookback programs already in operation, and reviews the value of targeted recipient notification and treatment efforts.

The lookback provisions of the proposed rule can be characterized as a ''targeted lookback'' program, meaning that the notification of infection risk is limited to, or targeted at, individuals identified as recipients of blood from donors subsequently found to be infected with HCV. This program is distinct from ''general lookback'' programs, which are aimed at all patients who received blood before the onset of screening and which include the recommendation that the patients be tested for evidence of infection. General and targeted lookback programs may be complementary. General lookback can be conducted in a variety of ways, including use of the broadcast media, education, and letter campaigns addressed to physicians or patients. By contrast, targeted lookback can only be performed successfully if the transfusion service is aware that the donor subsequently tested positive, if donor and product disposition records are available to link blood components with the identified donors, and if the physician or hospital knows the recipient's current whereabouts. Hospitals would locate recipient records for all transfused units from an affected donor and would have current recipient or physician address information available so that the hospitals could deliver notifications. Ideally, the recipient would still be alive and would respond to the notification for testing and treatment, if appropriate.

However, recent experiences among Canadian facilities implementing HCV lookback suggest that the effectiveness of targeted lookback may vary depending on the extent to which conditions for success exist within a community. For example, an analysis of targeted lookback in Quebec province found that, because the records were inadequate or the whereabouts of recipients were unknown, hospitals could provide information on only approximately 50 percent of the components involved.[5] A Canadian Red Cross Center in Toronto reported on another lookback challenge. Although the establishment was able to identify 5,301 affected components, trace 3,209 of those to hospitals, obtain responses for 2,807 (87 percent) of the units, and identify 2,437 as having been transfused, 45 percent of the transfused patients had already died. Of those remaining, the Canadian facilities finally tested only 184 patients (8 percent of the transfused patients) as a result of the lookback effort although as many as 68 percent of those tested were found to be HCV positive.[6]

Despite the difficulties of implementing targeted lookback, it is considered a valuable means of reaching patients at high risk for HCV. For example, a comparison of Canadian efforts in targeted lookback with general lookback through physician and public education found that a large number of patients and families were unaware of the transfusion episode. These recipients would not have been reached through the general lookback effort.[7]

Timely notification is important because studies of patient characteristics and responsiveness to therapy indicate that the best results are achieved if patients receive treatment when they are younger and have not yet developed cirrhosis.[8] The primary treatment for chronic HCV is alfa interferon therapy.[9] Of those patients who undergo interferon treatment, a reported 10 to 20 percent show a sustained response (SR) after 6 months of therapy, and 20 to 30 percent show an SR if therapy is continued for 12 months. However, alfa interferon produces a wide array of adverse side effects,[10] and some patients experience a relapse after therapy. Still, the benefits for patients identified for treatment through HCV lookback are likely to continue to increase as improved therapies are developed. For example, recent reports based on pilot studies and completed randomized controlled trials indicate that the combination of interferon alfa and ribavirin leads to higher virological SR rates (40 to 50 percent) than interferon alfa alone, which was administered in 6-month clinical trials.[11] FDA has recently approved the use of this combination therapy for HCV patients who suffer a relapse after initial therapy with interferon alone.

As discussed in section I of this document, the BPAC and PHS Advisory Committee have met a number of times to discuss HCV testing and other issues related to ''HCV lookback.'' The PHS Advisory Committee made recommendations after considering alternative procedures to notify transfusion recipients. Alternative approaches for lookback are available but are not considered fully effective. Because of the importance of a safe national blood supply and because our mission is to protect the public health, we accepted the recommendations of the PHS Advisory Committee and did not select an alternative approach.

D. Conclusion

In addition to the prospective HIV lookback that hospitals are currently required to perform, hospitals would be required to conduct a lookback of transfusion recipients of potentially HCV-infected blood. This proposed rule would also require hospitals to have in their agreements with blood banks that blood banks notify hospitals after performing the FDA-mandated lookback. Therefore, we have prepared a voluntary analysis consistent with the analysis set forth by the RFA. We solicit public comments on the extent that any of the entities would be significantly economically affected by these provisions.

[5] M. Goldman *et al.*, ''Hepatitis C Lookback,'' Transfusion Medicine Review 12.2 (1998): 84–93.

[6] A. Wall *et al.*, ''Hepatitis C Virus (HCV) Targeted Lookback Program,'' Transfusion 37 (1997): 392s.

[7] M. Goldman *et al.*, ''Hepatitis C Lookback,'' Transfusion Medicine Review 12.2 (1998): 84–93.

[8] G.L. Davis and J.Y.N. Lau, ''Factors Predictive of a Beneficial Response to Therapy of Hepatitis C,'' Hepatology 26.3 (1997): 122s–126s.

[9] A. Wall *et al.*, ''Hepatitis C Virus (HCV) Targeted Lookback Program,'' Transfusion 37 (1997): 392s.

[10] G. Duscheiko, ''Side Effects of Alpha interferon in Chronic Hepatitis C,'' Hepatology 26.3 (1997): 112s–119s.

[11] National Institutes of Health (NIH) Consensus Development Conference Panel Statement: Management of Hepatitis C, Hepatology 26.3 (1997): 2s–10s.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by OMB.

We have reviewed this proposed rule under the threshold criteria of Executive Order 13132, Federalism. We have determined that it would not significantly affect the rights, roles, and responsibilities of States.

List of Subjects in 42 CFR Part 482

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

Accordingly, for the reasons set forth in the preamble, 42 CFR part 482 would be amended as set forth below:

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

1. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. In § 482.27, the designation for paragraph (a) is removed; paragraphs (b) and (c) are redesignated as paragraphs (a) and (b), respectively; redesignated paragraph (b) is revised; and a new paragraph (c) is added to read as follows:

§ 482.27 Condition of participation: Laboratory services.

* * * * *

(b) *Standard: Potentially infectious blood and blood products*—(1) Definition. Potentially human immunodeficiency virus (HIV) infectious blood and blood products are prior collections from a donor—

(i) Who tested negative at the time of donation but tests repeatedly reactive for the antibody to HIV on a later donation;

(ii) Who tests positive on the FDA-licensed, more specific test or other followup testing required by FDA; and

(iii) For whom the timing of seroconversion cannot be precisely estimated.

(2) *Definition.* Potentially hepatitis C virus (HCV) infectious blood and blood products are prior collections from a donor—

(i) Who tested repeatedly reactive for evidence of HCV infection on a single antigen screening test with a signal to cut off value equal to or greater than 2.5 for at least two of the three enzyme linked immunosorbent assay (EIA) tests, or the signal to cut off value cannot be calculated, and with no record of further testing;

(ii) Who tests or tested repeatedly reactive for evidence of HCV infection and positive on a multiantigen supplemental test licensed at an earlier or later date by FDA;

(iii) Who tested repeatedly reactive for evidence of HCV infection and indeterminate on a supplemental test for HCV, unless an indeterminate recombinant immunoblot assay (RIBA) 3.0 supplemental test result was obtained or a negative EIA 3.0 or negative RIBA 3.0 test result was subsequently obtained;

(iv) Who tested repeatedly reactive for evidence of HCV infection on a multiantigen screening test with no record of further testing; or

(v) Who tested repeatedly reactive for evidence of HCV infection on a single antigen screening test and repeatedly reactive on a subsequent multiantigen screening test, unless a negative supplemental test result or an indeterminate RIBA 3.0 supplemental test result was obtained.

(3) *Services furnished by an outside blood bank.* If a hospital regularly uses the services of an outside blood bank, it must have an agreement with the blood bank that governs the procurement, transfer, and availability of blood and blood products. The agreement must require that the blood bank notify the hospital—

(i) Within 3 calendar days if the blood bank supplied blood and blood products collected from a donor who tested negative at the time of donation but tests repeatedly reactive for the antibody to HIV or HCV on a later donation or who is determined to be at increased risk for transmitting HIV or HCV infection;

(ii) Within 45 days of the test, of the results of the FDA-licensed, more specific test for HIV or HCV, as relevant, or other followup testing required by FDA; and

(iii) Within 3 calendar days if the blood bank supplied blood and blood products collected from a donor, whenever records are available, as set forth in FDA's 21 CFR 610.48(h)(3)(ii) and (i)(3)(ii), in instances in which the donor—

(A) Tested repeatedly reactive on the screening test and positive on a supplemental test for HCV performed on the repeatedly reactive sample;

(B) Tested repeatedly reactive on the screening test and indeterminate on a supplemental test for HCV; or

(C) Tests repeatedly reactive on the screening test with no record of a supplemental test for HCV performed on the repeatedly reactive sample and no record of a negative licensed screening test performed on the same donor.

(4) *Quarantine and disposition of blood and blood products pending completion of testing.* If the blood bank (either internal or under an agreement) notifies the hospital of the repeatedly reactive HIV or HCV screening test results, the hospital must determine the disposition of the blood or blood product and quarantine all blood and blood products from previous donations in inventory.

(i) If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other followup testing required by FDA is negative, absent other informative test results, the hospital may release the blood and blood products from quarantine.

(ii) If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other followup testing required by FDA is positive, the hospital must—

(A) Dispose of the blood and blood products; and

(B) Notify the transfusion recipients as set forth in paragraph (b)(6) of this section.

(iii) If the blood bank notifies the hospital that the result of the FDA-licensed, more specific test or other followup testing required by FDA is indeterminate, the hospital must destroy or label prior collections of blood or blood products held in quarantine as set forth in FDA's 21 CFR 610.48(k).

(5) *Recordkeeping by the hospital.* The hospital must maintain—

(i) Adequate records of the source and disposition of all units of blood and blood products for at least 10 years from the date of disposition;

(ii) The records in a manner that permits prompt retrieval; and

(iii) A fully funded plan to transfer these records to another hospital or other entity if the former hospital ceases operation for any reason.

(6) *Patient notification.* If the hospital has administered potentially HIV or HCV infectious blood or blood products (either directly through its own blood bank or under an agreement) or released the blood or blood products to another entity or individual, the hospital must take the following actions:

(i) Make at least three attempts to notify the patient, or to notify the attending physician or the physician who ordered the blood or blood product and ask the physician to notify the patient, that potentially HIV or HCV infectious blood or blood products were transfused to the patient.

(ii) Immediately notify the patient, or other individual as permitted under paragraph (b)(10) of this section, of the need for HIV or HCV testing and counseling.

(iii) If the physician is unavailable or declines to make the notification, make at least three attempts to give this

notification to the patient or other individual.

(iv) Document in the patient's medical record the notification or attempts to give the required notification.

(7) *Timeframe for notification.* (i) *For donors tested on or after [effective date of final regulation].* For notifications resulting from donors tested on or after [effective date of final regulation] as set forth in FDA's 21 CFR 610.48(a)(b), the notification effort begins when the blood bank notifies the hospital that it received potentially HIV or HCV infectious blood and blood products and continues for 12 weeks unless—

(A) The patient is located and notified; or

(B) The hospital is unable to locate the patient and documents in the patient's medical record the extenuating circumstances beyond the hospital's control that caused the notification timeframe to exceed 12 weeks.

(ii) *For donors tested before [effective date of final regulation].* For notifications resulting from donors tested before [effective date of final regulation] as set forth in FDA's 21 CFR 610.48(c)(d), the notification effort begins when the blood bank notifies the hospital that it received potentially HCV infectious blood and blood products. The hospital must make at least three attempts to give notification and must complete the actions within 1 year of the date on which the hospital received notification from the outside blood service.

(8) *Content of notification.* The notification must include the following information:

(i) A basic explanation of the need for HIV or HCV testing and counseling.

(ii) Enough oral or written information so that the transfused patient can make an informed decision about whether to obtain HIV or HCV testing and counseling.

(iii) A list of programs or places where the patient can obtain HIV or HCV testing and counseling, including any requirements or restrictions the program may impose.

(9) *Policies and procedures.* The hospital must establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for the confidentiality of medical records and other patient information.

(10) *Notification to legal representative or relative.* If the patient has been adjudged incompetent by a State court, the physician or hospital must notify a legal representative designated in accordance with State law. If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf, the physician or hospital must notify the patient or his or her legal representative or relative. If the patient is deceased, the physician or hospital must continue the notification process and inform the deceased patient's legal representative or relative. If the patient is a minor, the legal guardian must be notified.

(c) *General blood safety issues.* Hospitals must comply with regulations of the FDA as they pertain to blood safety issues in the following areas:

(1) Appropriate testing and quarantining of infectious blood and blood products.

(2) Notification and counseling of recipients that may have received infectious blood and blood products.

Authority: Sections 1818(d)(2) and 1818A(d)(2) of the Social Security Act (42 U.S.C. 1395i–2(d)(2) and 1395i–2a(d)(2)).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance)

Dated: September 22, 1999.

Michael M. Hash,

Deputy Administrator, Health Care Financing Administration.

Dated: March 27, 2000.

Donna E. Shalala,

Secretary.

[FR Doc. 00–28908 Filed 11–15–00; 8:45 am]

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November 16, 2000

Part III

Department of Transportation

Federal Aviation Administration

14 CFR Parts 91 and 103

Temporary Flight Restrictions; Proposed Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 91 and 103

[Docket No. FAA–2000–8274; Notice No. 00–13]

RIN 2120–AH13

Temporary Flight Restrictions

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to add a new temporary flight restriction regulation to address specific traffic management procedures for aircraft operations in the vicinity of aerial demonstrations or major sporting events. In addition, this action proposes to change the title of the regulation used to manage aircraft operations near hazard or disaster areas. This action also proposes to clarify the operating requirements for temporary flight restrictions in the vicinity of national disaster areas in the state of Hawaii. Finally this action proposes to amend the Ultralight Vehicle regulations to include all applicable references to temporary flight restrictions. The FAA is proposing these actions to enhance the safe and efficient use of airspace and to prevent any unsafe congestion of sightseeing and other aircraft operations in the vicinity of hazard areas, disaster areas, aerial demonstrations, or major sporting events.

DATES: Send your comments on or before January 16, 2001.

ADDRESSES: Address your comments to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590–0001. You must identify the docket number FAA–2000–8274 at the beginning of your comments, and you should submit two copies of your comments. If you wish to receive confirmation that FAA received your comments, include a self-addressed, stamped postcard.

You may also submit comments through the Internet to http://dms.dot.gov. You may review the public docket containing comments to these proposed regulations in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. The Dockets Office is on the plaza level of the NASSIF Building at the Department of Transportation at the above address. Also, you may review public dockets on the Internet at http://dms.dot.gov.

FOR FURTHER INFORMATION CONTACT: Sheri Edgett Baron, Airspace and Rules Division, ATA–400, Office of Air Traffic Airspace Management, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments relating to the environmental, energy, federalism, or economic impact that might result from adopting the proposals in this document are also invited. Substantive comments should be accompanied by cost estimates. Comments must identify the regulatory docket or notice number and be submitted in duplicate to the DOT Rules Docket address specified above.

All comments received, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking, will be filed in the docket. The docket is available for public inspection before and after the comment period closing date.

All comments received on or before the closing date will be considered by the Administrator before taking action on this proposed rulemaking. Comments filed late will be considered as far as possible without incurring expense or delay. The proposals in this document may be changed in light of the comments received.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must include a pre-addressed, stamped postcard with those comments on which the following statement is made: ''Comments to Docket No. FAA–2000–XXXX.'' The postcard will be date stamped and mailed to the commenter.

Availability of NPRMs

An electronic copy of this document may be downloaded using a modem and suitable communications software from the FAA regulations section of the Fedworld electronic bulletin board service (telephone: 703–321–3339) or the Government Printing Office (GPO) electronic bulletin board service (telephone: 202–512–1661).

Internet users may reach the FAA's web page at http://www.faa.gov/avr/arm/nprm.htm or GPO's webpage at http://www.access.gpo.gov/nara for access to recently published rulemaking documents.

Any person may obtain a copy of this NPRM by submitting a request to the Federal Aviation Administration, Office of Rulemaking, ARM–1, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267–9680. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should request from the above office a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, that describes the application procedure.

Background

Petitions

On May 20, 1999, the Department of Defense (DoD) request that the FAA establish a temporary flight restriction (TFR) to prohibit all non-participating aircraft from operating over or within airspace used by the military aerial demonstration teams such as the United States Air Force Air Demonstration Squadron (the Thunderbirds), the United States Naval Flight Demonstration Team (the Blue Angels), the United States Army Parachute Team (the Golden Knights), or other DoD aircraft teams, while practicing or performing aerial demonstrations. DoD explains that when pilots are executing aerobatic manuevers, they operate aircraft in close formations and perform opposing solo maneuvers at high speeds. DoD contends that in those circumstances, the pilot reaction time necessary to safely ''see and avoid'' non-participating aircraft could be reduced. In the absence of a TFR, non-participating aircraft can enter, and have entered, both aerial demonstration practice area airspace and airshow airspace. DoD contends that the primary potential safety hazards experienced during air shows were non-participating aircraft that enter the airspace area used for aerial demonstration events.

Operators of DoD aircraft conduct their aerial demonstrations pursuant to a waiver of the requirements listed in 14 Code of Federal Regulations (CFR) part 91, including maximum airspeed and minimum altitude restrictions. In addition, specific DoD-issued requirements are applicable. However, DoD believes that using TFRs over aerial demonstration areas will provide sanitized airspace in which to conduct their aerobatic operations and formally prohibit non-participating aircraft from entering this airspace.

On July 19, 1999, the International Council of Air Shows (ICAS) petitioned the FAA to amend 14 CFR to include regulations that would provide for a safe airspace environment for air show operations (Docket Number 29664).

ICAS states that the high speeds and complex maneuvers common in today's air show performances make it impossible for the participating and nonparticipating aircraft to rely completely on the ''see and avoid'' method of collision avoidance. ICAS believes that TFRs would prevent a midair collision and protect spectators on the ground from possible death or injury and protect property from damage that could result from a non-participating aircraft intruding into aerial demonstration events. ICAS states that it received 48 reports of intrusions, between July 1989 and June 1997, by non-participating aircraft into airspace used by air shows or practice sessions for aerial demonstrations.

In addition, the FAA has received requests from Major League Baseball officials, Summer/Winter Olympics officials, the Tournament of Roses Football Game Committee, and others to temporarily restrict aircraft operations over various major sporting events such as the Olympic Games, the Tournament of Roses Football Game, and the Kodak Albuquerque International Balloon Fiesta.

The FAA has determined that the issues identified by DoD, ICAS, and others have merit. Therefore, the FAA believes a new section pertaining to the management of aircraft operations in the vicinity of aerial demonstrations or major sporting events is warranted. In addition, the FAA considers that this proposed rulemaking responds to the ICAS petition for rulemaking and considers the ICAS petition closed.

Past Practices

On January 25, 1971, the FAA issued the Temporary Flight Restrictions Final Rule (36 FR 1467). This rule amended 14 CFR § 91.91 (since re-codified as 14 CFR § 91.137) to provide for the issuance of a Notice to Airmen (NOTAM) that would implement a TFR over a designated disaster or hazard area. In the preamble to the final rule, the FAA stated that the intent of the rule was to prevent hazardous congestion of sightseeing aircraft over the site of an aircraft or train accident, forest fire, earthquake, flood, or other disaster of substantial magnitude. In the past the FAA has used TFRs for major sporting events and aerial demonstrations based on an interpretation of the scope of § 91.137(a)(3) contained in FAA Order 7210.3R. The order indicates that a TFR may be issued for sporting events or aerial demonstrations generating a high degree of public interest, citing § 91.137(a)(3) as regulatory authority. The FAA has reviewed the regulatory history of § 91.137, and has concluded that it is limited to disaster or hazard areas and was not intended to be used for planned events.

The FAA's proposal to add regulations covering TFRs for major sporting events would overturn the practice of using § 91.137(a)(3). If this proposal is adopted, the FAA Advisory Circulars and FAA Orders addressing TFRs would be modified accordingly.

Special Federal Aviation Regulations

In addition to using § 91.137 for planned events, the FAA has also issued Special Federal Aviation Regulations (SFAR) to establish TFRs in the vicinity of certain major sporting events to address the management of aircraft operations in the vicinity of such events and to prevent unsafe congestion of aircraft that are sightseeing over and around such events. These SFAR were for specific events and had a specific duration. Most recently, for example, on May 18, 1999, the FAA published a Notice of Proposed Rulemaking (NPRM) for an SFAR to establish TFRs for the Kodak Albuquerque International Balloon Fiesta in Albuquerque, NM (64 FR 27160). The proposed restrictions addressed Balloon Fiesta operations for the periods October 2 through October 10, 1999, and October 7 through October 15, 2000. The FAA did not receive any comments on the NPRM, and on August 17, 1999, the FAA published the final SFAR to institute the TFRs (64 FR 44814). The FAA previously published a proposed SFAR for the Kodak Albuquerque International Balloon Fiesta on July 15, 1998 (63 FR 38236) and a final SFAR to implement the TFRs on September 28, 1998 (63 FR 51768). Again, these TFRs were for a specific event and had a short duration while the event was going on. The FAA has issued similar TFRs for other specific events such as the Olympics and Goodwill Games.

In an effort to streamline its processes, the FAA is proposing to establish a rule that will allow the FAA to address the management of aircraft operations in the vicinity of aerial demonstrations and sporting events so that individual SFARs will not have to be issued.

Section-by-Section Discussion of the Proposal

The FAA is proposing several changes to part 91 and part 103. The proposed changes are to:

(1) Change the title of § 91.137 to clarify that the regulation concerns aircraft operations near hazard or disaster areas;

(2) Clarify the operating requirements detailed in § 91.138; and

(3) Add a new section (§ 91.145) that would address the management of aircraft operations in the vicinity of aerial demonstrations and major sporting events.

(4) Amend part 103, Ultralight Vehicles, to include all applicable references to TFRs.

Section 91.137

Section 91.137 is currently titled ''Temporary Flight Restrictions,'' and prescribes operating requirements to be followed when flight restrictions are issued in accordance with this particular section. However, the title of this section of the regulation is not specific enough in conveying the intent of the regulation, leading to misinterpretation of the purpose of the rule. Currently, the FAA receives many requests for TFRs that do not meet the intent of the rule. To address this issue, the FAA proposes to retitle § 91.137 as ''Temporary Flight Restrictions in the Vicinity of Disaster/Hazard Areas,'' since this title better describes the intent and activities addressed by this section.

Section 91.138 Temporary Flight Restrictions in National Disaster Areas in the State of Hawaii

The FAA proposes to clarify the operating requirements detailed in § 91.138 by modifying subparagraph (b) to read: ''When a NOTAM has been issued in accordance with this section, no person may operate an aircraft within the designated airspace unless at least one of the following conditions is met.'' The current language could be misinterpreted to mean that all of the conditions must be met before operating an aircraft within the designated airspace. Clarifying this section will help to avoid any potential confusion.

Section 91.145 Temporary Flight Restrictions in the Vicinity of Aerial Demonstrations or Major Sporting Events

The FAA has determined that the issues identified by DoD, ICAS, and others, as discussed earlier in the preamble, have merit. Accordingly, the FAA is proposing to add a new section to part 91 that would prohibit a person from operating an aircraft or device, or engage in any activity within the designated airspace area, except in accordance with the authorizations, terms, and conditions of the temporary flight restriction in the NOTAM, unless otherwise authorized by: (1) Air traffic control; or (2) A Flight Standards Certificate of Waiver or Authorization issued for the demonstration or event. In addition, the new section proposes to authorize the Administrator to exclude

the following flights from a flight restriction issued under the proposed § 91.145: (1) Essential military; (2) Medical and rescue; (3) Presidential and Vice Presidential; (4) Visiting heads of state; (5) Law enforcement and security; and (6) Public health and welfare.

When a TFR of this type is issued, aircraft management procedures for the event would be published in a National Flight Data Center (FDC) NOTAM that would detail, for example, general procedures to include altitudes; times; frequency; point of contact; Air Traffic Control facility; special clearances; and any other pertinent information.

The FAA intends to employ this type of TFR for specific events. Examples of the events that would be covered by the proposed TFR include, but are not limited to the following: the Blue Angels, Thunderbirds, and Golden Knights air demonstration teams; the Summer/Winter Olympic Games; the annual Tournament of Roses Football Game; World Cup Soccer; Major League Baseball All-Star Game; the World Series; the Kodak Albuquerque Internationl Balloon Fiesta; the Sandia Classic Hang Gliding Competition; and the Indianapolis 500 Mile Race. These types of events may be of such a magnitude that would warrant the use of a TFR to prevent the unsafe congestion of aircraft operations in the affected area, and to ensure the safety of persons and property on the ground.

The amount of airspace needed to provide a safe environment for aerial demonstrations/major sporting events would vary depending on the event. The area that would be restricted would normally be limited to the minimum airspace area/altitude/time required to manage participating and non-participating aircraft in the area. For example, during the 1999 Olympic games held in Atlanta, GA, the FAA implemented special traffic management procedures within the airspace overlying competition venues from three hours before to three hours after each event. The TFR areas generally were circular areas of 1 to 4 nautical miles in radius from the surface to approximately 2500 feet above ground level.

During the 1999 Kodak Albuquerque International Balloon Fiesta held in Albuquerque, NM, the FAA implemented special traffic management procedures within a 4 nautical mile radius, extending from the surface up to but not including 8,000 feet mean sea level. The TFR area was in effect between the hours of 0530 Mountain Daylight Time (MDT) and 1200 MDT, and from 1600 MDT until 2200 MDT on October 2 through October 10, 1999, and October 7 through October 15, 2000.

To prevent an unsafe congestion of sightseeing aircraft above an event that may generate a high degree of public interest, the FAA would consider factors such as: The area where the event will be held; effect flight restrictions will have on known aircraft operations; any existing Air Traffic Control (ATC) airspace traffic management restrictions; estimated duration of the event; degree of public interest; number of spectators; provisions for spectator safety, number and types of participating aircraft; use of mixed height and low performance aircraft; impact on non-participating aircraft; weather minimums; and emergency procedures that will be in effect.

Part 103, Section 103.20 Flight Restrictions in the Proximity of Certain Areas Designated by Notice to Airmen

The FAA proposes to revise this section by adding references to §§ 91.137, 91.138, and 91.145. This proposal will ensure that all applicable references to temporary flight restrictions are included in the requirements.

Notice to Airmen Information

Time-critical aeronautical information that is of a temporary nature, or is not sufficiently known in advance to permit publication on aeronautical charts or in other operational publications, receives immediate dissemination via the NOTAM system. All domestic operators planning to fly in the vicinity of aerial demonstrations or major sporting events would need to pay attention to NOTAMS and FDC NOTAM information.

A NOTAM contains information on airports, runways, navigational aids, radar services, and other information essential to flight. A FDC NOTAM contains information that is regulatory in nature, such as amendments to aeronautical charts and restrictions to flight.

Pilots and operators need to consult the monthly NOTAM Domestic/International publication. This publication contains FDC NOTAMs and NOTAMs. Special information, including graphics, would be published in the monthly publication in advance of the event. For more detailed information concerning the NOTAM system, refer to the Aeronautical Information manual ''Preflight'' section.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d) requires that the FAA consider the impact of paperwork and other information collection burdens imposed on the public. We have determined that there are no new information collection requirements associated with this proposed rule.

International Compatibility

In keeping with U.S. obligations under the Convention on International Civil Aviation, it is FAA policy to comply with International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable. The FAA has reviewed the corresponding ICAO Standards and Recommended Practices and has identified no differences with these proposed regulations.

Executive Order 12866 and DOT Regulatory Policies and Procedures

Executive Order 12866, Regulatory Planning and Review, directs the FAA to assess both the costs and benefits of a regulatory change. The FAA is not allowed to propose or adopt a regulation unless a reasoned determination is made that the benefits of the intended regulation justify the costs. The FAA's assessment of this proposal indicates that its economic impact would be minimal. Since its costs and benefits do not make it a ''significant regulatory action'' as defined in the Order, the FAA has not prepared a ''regulatory evaluation,'' which is the written cost/benefit analysis ordinarily required for all rulemaking proposals under the DOT Regulatory Policies and Procedures. The FAA does not need to do the latter analysis where the economic impact of a proposal is minimal. The major economic impact of having a temporary flight restriction would be the inconvenience of circumnavigation to operators who may want to operate in the area of the TFR. An aircraft operator could avoid the restricted airspace by flying over it or by circumnavigating the restricted airspace. Because the possibility of such occurrences is for a limited time and the restricted areas are limited in size, circumnavigation costs would be negligible.

The benefits of establishing a TFR would primarily be a lowered risk of midair collisions between participating and non-participating aircraft. While benefits cannot be quantified, the FAA believes the benefits would be commensurate with the costs attributed to the temporary inconvenience of the flight restrictions for operators near the TFR area.

Regulatory Flexibility Determination

The Regulatory Flexibility Act of 1980 (RFA) establishes ''as a principle of regulatory issuance that agencies shall

endeavor, consistent with the objective on the rule and of applicable statutes, to fit regulatory and informational requirements to the scale of the businesses, organizations, and governmental jurisdictions subject to regulation.'' To achieve that principle, the RFA requires agencies to solicit and consider flexible regulatory proposals and to explain the rationale for their actions. The RFA covers a wide-range of small entities, including small businesses, not-for-profit organizations, and small governmental jurisdictions.

Agencies must perform a review to determine whether a proposed or final rule will have a significant economic impact on a substantial number of small entities. If the determination is that it will, the agency must prepare a regulatory flexibility analysis as described in the RFA.

However, if an agency determines that a proposed or final rule is not expected to have a significant economic impact on a substantial number of small entities, section 605(b) of the 1980 act provides that the head of the agency may so certify and a regulatory flexibility analysis is not required. The certification must include a statement providing the factual basis for this determination, and the reasoning should be clear.

The major economic impact of having a temporary flight restriction would be the inconvenience of circumnavigation to operators who may want to operate in the area of the TFR. An aircraft operator could avoid the restricted airspace by flying over it or by circumnavigating the restricted airspace. Because the possibility of such occurrences would be for a limited time and the restricted areas would be limited in size, circumnavigating costs would be negligible. Consequently, the FAA certifies that the proposed rule would not have a significant economic impact on a substantial number of small entities.

International Trade Impact Analysis

The Trade Agreement Act of 1979 prohibits Federal agencies from engaging in any standards or related activities that create unnecessary obstacles to the foreign commerce of the United States. Legitimate domestic objectives, such as safety, are not considered unnecessary obstacles. The statute also requires consideration of international standards and where appropriate, that they be the basis for U.S. standards. In addition, consistent with the Administration's belief in the general superiority and desirability of free trade, it is the policy of the Administration to remove or diminish to the extent feasible, barriers to international trade, including both barriers affecting the export of American goods and services to foreign countries and barriers affecting the import of foreign goods and services into the United States.

In accordance with the above statute and policy, the FAA has assessed the potential effect of this proposed rule and has determined that it would have only a domestic impact and therefore no affect on any trade-sensitive activity.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 (the Act), enacted as Public Law 104–4 on March 22, 1995, is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local, and tribal governments.

Title II of the Act requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed or final agency rule that may result in a $100 million or more expenditure (adjusted annually for inflation) in any one year by State, local, and tribal governments, in the aggregate, or by the private section; such a mandate is deemed to be a ''significant regulatory action.''

This proposed rule does not contain such a mandate. Therefore, the requirements of Title II of the Unfunded Mandates Reform Act of 1995 do not apply.

List of Subjects in 14 CFR Part 91

Aircraft flight, Airspace, Aviation safety, Air Traffic Control.

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend parts 91 and 103 of Title 14, Code of Federal Regulations as follows:

PART 91—AIR TRAFFIC AND GENERAL OPERATING RULES

1. The authority citation for 14 CFR part 91 continues to read as follows:

Authority: 49 U.S.C. 106(g), 1155, 40103, 40113, 40120, 44101, 44111, 44701, 44709, 44711, 44712, 44715, 44716, 44717, 44722, 46306, 46315, 46316, 46502, 46504, 46506, 46507, 47122, 47508, 47528–47531.

2. Amend § 91.137 by revising the title as follows:

§ 91.137 Temporary flight restrictions in the vicinity of disaster/hazard areas.

* * * * *

3. Amend § 91.138 by revising paragraph (b) to read as follows:

§ 91.138 Temporary flight restrictions in national disaster areas in the State of Hawaii.

* * * * *

(b) When a NOTAM has been issued in accordance with this section, no person may operate an aircraft within the designated area unless at least one of the following conditions is met:

(1) That person has obtained authorization from the official in charge of associated emergency or disaster relief response activities, and is operating the aircraft under the conditions of that authorization.

(2) The aircraft is carrying law enforcement officials.

(3) The aircraft is carrying persons involved in an emergency or a legitimate scientific purpose.

(4) The aircraft is carrying properly accredited newspersons, and that prior to entering the area, a flight plan is filed with the appropriate FAA or ATC facility specified in the NOTAM and the operation is conducted in compliance with the conditions and restrictions established by the official in charge of on-scene emergency response activities.

(5) The aircraft is operating in accordance with an ATC clearance or instruction.

* * * * *

4. Add § 91.145 to subpart B as follows:

§ 91.145 Management of aircraft operations in the vicinity of aerial demonstrations and major sporting events.

(a) The FAA will issue a Notice to Airmen (NOTAM) designating an area of airspace in which a temporary flight restriction applies when it determines that a TFR is necessary to protect persons or property on the surface or in the air, to maintain air safety and efficiency, or to prevent the unsafe congestion of aircraft in the vicinity of an aerial demonstration or major sporting event.

These demonstrations and events include:

(1) United States Naval Flight Demonstration Team (Blue Angels);

(2) United States Air Force Air Demonstration Squadron (Thunderbirds);

(3) United States Army Parachute Team (Golden Knights);

(4) Summer/Winter Olympic Games;

(5) Annual Tournament of Roses Football Game;

(6) World Cup Soccer;

(7) Major League Baseball All-Star Game;

(8) World Series;

(9) Kodak Albuquerque International Balloon Fiesta;

(10) Sandia Classic Hang Gliding Competition;

(11) Indianapolis 500 Mile Race;

(12) Any other aerial demonstration or sporting event the FAA determines to need a temporary flight restriction in accordance with paragraph (b) of this section.

(b) In deciding whether a temporary flight restriction is necessary for an aerial demonstration or major sporting event not listed in paragraph (a) of this section, the FAA considers the following factors:

(1) Area where the event will be held.

(2) Effect flight restrictions will have on known aircraft operations.

(3) Any existing ATC airspace traffic management restrictions.

(4) Estimated duration of the event.

(5) Degree of public interest.

(6) Number of spectators.

(7) Provisions for spectator safety.

(8) Number and types of participating aircraft.

(9) Use of mixed high and low performance aircraft.

(10) Impact on non-participating aircraft.

(11) Weather minimums.

(12) Emergency procedures that will be in effect.

(c) A NOTAM issued under this section will state the name of the aerial demonstration or sporting event and specify the effective dates and times, the geographic features or coordinates, and any other restrictions or procedures governing flight operations in the designated airspace.

(d) When a NOTAM has been issued in accordance with this section, no person may operate an aircraft or device, or engage in any activity within the designated airspace area, except in accordance with the authorizations, terms, and conditions of the temporary flight restriction published in the NOTAM, unless otherwise authorized by:

(1) Air traffic control; or

(2) A Flight Standards Certificate of Waiver or Authorization issued for the demonstration or event.

(e) For the purpose of this section:

(1) *Flight restricted airspace area for an aerial demonstration*—The amount of airspace needed to protect persons and property on the surface or in the air, to maintain air safety and efficiency, or to prevent the unsafe congestion of aircraft will vary depending on the aerial demonstration and the factors listed in paragraph (b) of this section. The restricted airspace area will normally be limited to a 5 nautical mile radius from the center of the demonstration and an altitude 17000 mean sea level (for high performance aircraft) or 13000 feet above the surface (for certain parachute operations), but will be no greater than the minimum airspace necessary for the management of aircraft operations in the vicinity of the specified area.

(2) *Flight restricted area for a major sporting event*—The amount of airspace needed to protect persons and property on the surface or in the air, to maintain air safety and efficiency, or to prevent the unsafe congestion of aircraft will vary depending on the size of the event and the factors listed in paragraph (b) of this section. The restricted airspace will normally be limited to a 3 nautical mile radius from the center of the event and 2500 feet above the surface but will not be greater than the minimum airspace necessary for the management of aircraft operations in the vicinity of the specified area.

(f) A NOTAM issued under this section will be issued at least 30 days in advance of an aerial demonstration or a major sporting event, unless the FAA finds good cause for a shorter period and explains this in the NOTAM.

(g) When warranted, the FAA Administrator may exclude the following flights from the provisions of this section;

(1) Essential military.

(2) Medical and rescue.

(3) Presidential and Vice Presidential.

(4) Visiting heads of state.

(5) Law enforcement and security.

(6) Public health and welfare.

PART 103—ULTRALIGHT VEHICLES

5. The authority citation for 14 CFR part 103 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103–40104, 40113, 44701.

6. Section 103.20 is revised as follows:

§ 103.20 Flight restrictions in the proximity of certain areas designated by notice to airmen.

No person may operate an ultralight vehicle in areas designated in a Notice to Airmen under § 91.137, § 91.138, § 91.141, § 91.143 or § 91.145 of this chapter, unless authorized by ATC.

Issued in Washington, DC on November 2, 2000.

John Walker,

Program Director, Air Traffic Airspace Management Program.

[FR Doc. 00–29318 Filed 11–15–00; 8:45 am]

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BE-82; annual survey of financial services transactions between U.S. financial services providers and unaffiliated foreign persons; comments due by 11-20-00; published 9-21-00

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LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with ''P L U S'' (Public Laws Update Service) on 202–523–6641. This list is also available online at http://www.nara.gov/fedreg.

The text of laws is not published in the **Federal Register** but may be ordered in ''slip law'' (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO Access at http://www.access.gpo.gov/nara/index.html. Some laws may not yet be available.

H.R. 1235/P.L. 106–467
To authorize the Secretary of the Interior to enter into contracts with the Solano County Water Agency, California, to use Solano Project facilities for impounding, storage, and carriage of nonproject water for domestic, municipal, industrial, and other beneficial purposes. (Nov. 9, 2000; 114 Stat. 2026)

H.R. 2780/P.L. 106–468
Kristen's Act (Nov. 9, 2000; 114 Stat. 2027)

H.R. 2884/P.L. 106–469
Energy Act of 2000 (Nov. 9, 2000; 114 Stat. 2029)

H.R. 4312/P.L. 106–470
Upper Housatonic National Heritage Area Study Act of 2000 (Nov. 9, 2000; 114 Stat. 2055)

H.R. 4646/P.L. 106–471
To designate certain National Forest System lands within the boundaries of the State of Virginia as wilderness areas. (Nov. 9, 2000; 114 Stat. 2057)

H.R. 4788/P.L. 106–472
Grain Standards and Warehouse Improvement Act of 2000 (Nov. 9, 2000; 114 Stat. 2058)

H.R. 4794/P.L. 106–473
Washington-Rochambeau Revolutionary Route National Heritage Act of 2000 (Nov. 9, 2000; 114 Stat. 2083)

H.R. 4846/P.L. 106–474
National Recording Preservation Act of 2000 (Nov. 9, 2000; 114 Stat. 2085)

H.R. 4864/P.L. 106–475
Veterans Claims Assistance Act of 2000 (Nov. 9, 2000; 114 Stat. 2096)

H.R. 4868/P.L. 106–476
Tariff Suspension and Trade Act of 2000 (Nov. 9, 2000; 114 Stat. 2101)

H.R. 5110/P.L. 106–477
To designate the United States courthouse located at 3470 12th Street in Riverside, California, as the ''George E. Brown, Jr. United States Courthouse''. (Nov. 9, 2000; 114 Stat. 2182)

H.R. 5302/P.L. 106–478
To designate the United States courthouse located at 1010 Fifth Avenue in Seattle, Washington, as the ''William Kenzo Nakamura United States Courthouse''. (Nov. 9, 2000; 114 Stat. 2183)

H.R. 5331/P.L. 106–479
To authorize the Frederick Douglass Gardens, Inc., to establish a memorial and gardens on Department of the Interior lands in the District of Columbia or its environs in honor and commemoration of Frederick Douglass. (Nov. 9, 2000; 114 Stat. 2184)

H.R. 5388/P.L. 106–480
To designate a building proposed to be located within the boundaries of the Chincoteague National Wildlife Refuge, as the ''Herbert H. Bateman Education and Administrative Center''. (Nov. 9, 2000; 114 Stat. 2186)

H.R. 5410/P.L. 106–481
Library of Congress Fiscal Operations Improvement Act of 2000 (Nov. 9, 2000; 114 Stat. 2187)

H.R. 5478/P.L. 106–482
To authorize the Secretary of the Interior to acquire by donation suitable land to serve as the new location for the home of Alexander Hamilton, commonly known as the Hamilton Grange, and to authorize the relocation of the Hamilton Grange to the acquired land. (Nov. 9, 2000; 114 Stat. 2192)

H.J. Res. 102/P.L. 106–483
Recognizing that the Birmingham Pledge has made a significant contribution in fostering racial harmony and reconciliation in the United States and around the world, and for other purposes. (Nov. 9, 2000; 114 Stat. 2193)

S. 484/P.L. 106–484
Bring Them Home Alive Act of 2000 (Nov. 9, 2000; 114 Stat. 2195)

S. 610/P.L. 106–485
To direct the Secretary of the Interior to convey certain land under the jurisdiction of the Bureau of Land Management in Washakie County and Big Horn County, Wyoming, to the Westside Irrigation District, Wyoming, and for other purposes. (Nov. 9, 2000; 114 Stat. 2199)

S. 698/P.L. 106–486
To review the suitability and feasibility of recovering costs of high altitude rescues at Denali National Park and Preserve in the State of Alaska, and for other purposes. (Nov. 9, 2000; 114 Stat. 2201)

S. 710/P.L. 106–487
Vicksburg Campaign Trail Battlefields Preservation Act of 2000 (Nov. 9, 2000; 114 Stat. 2202)

S. 748/P.L. 106–488
To improve Native hiring and contracting by the Federal Government within the State of Alaska, and for other purposes. (Nov. 9, 2000; 114 Stat. 2205)

S. 893/P.L. 106–489
To amend title 46, United States Code, to provide equitable treatment with respect to State and local income taxes for certain individuals who perform duties on vessels. (Nov. 9, 2000; 114 Stat. 2207)

S. 1030/P.L. 106–490
To provide that the conveyance by the Bureau of Land Management of the surface estate to certain land in the State of Wyoming in exchange for certain private land will not result in the removal of the land from operation of the mining laws. (Nov. 9, 2000; 114 Stat. 2208)

S. 1367/P.L. 106–491
To amend the Act which established the Saint-Gaudens National Historic Site, in the State of New Hampshire, by modifying the boundary and for other purposes. (Nov. 9, 2000; 114 Stat. 2209)

S. 1438/P.L. 106–492
National Law Enforcement Museum Act (Nov. 9, 2000; 114 Stat. 2210)

S. 1778/P.L. 106–493
To provide for equal exchanges of land around the Cascade Reservoir. (Nov. 9, 2000; 114 Stat. 2213)

S. 1894/P.L. 106–494
To provide for the conveyance of certain land to Park County, Wyoming. (Nov. 9, 2000; 114 Stat. 2214)

S. 2069/P.L. 106–495
To permit the conveyance of certain land in Powell, Wyoming. (Nov. 9, 2000; 114 Stat. 2216)

S. 2425/P.L. 106–496
Bend Feed Canal Pipeline Project Act of 2000 (Nov. 9, 2000; 114 Stat. 2218)

S. 2872/P.L. 106–497
Indian Arts and Crafts Enforcement Act of 2000 (Nov. 9, 2000; 114 Stat. 2219)

S. 2882/P.L. 106–498
Klamath Basin Water Supply Enhancement Act of 2000 (Nov. 9, 2000; 114 Stat. 2221)

S. 2951/P.L. 106–499
To authorize the Secretary of the Interior to conduct a study to investigate opportunities to better manage the water resources in the Salmon Creek watershed of the Upper Columbia River. (Nov. 9, 2000; 114 Stat. 2223)

S. 2977/P.L. 106–500
To assist in establishment of an interpretive center and museum in the vicinity of the Diamond Valley Lake in southern California to ensure the protection and interpretation of the paleontology discoveries made at the lake and to develop a trail system for the lake for use by pedestrians and nonmotorized vehicles. (Nov. 9, 2000; 114 Stat. 2224)

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