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5–25–04 Tuesday
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# Rules and Regulations

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Tuesday, May 25, 2004



## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### 14 CFR Part 39

**[Docket No. 2003–CE–47–AD; Amendment 39–13584; AD 2004–08–15]**

**RIN 2120–AA64**

## Airworthiness Directives; Goodrich Avionics Systems, Inc. TAWS8000 Terrain Awareness Warning System

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Final rule; correction.

**SUMMARY:** This document makes a correction to Airworthiness Directive (AD) 2004–08–15, which was published in the **Federal Register** on April 21, 2004 (69 FR 21393), and applies to all Goodrich Avionics Systems, Inc. (Goodrich) TAWS8000 terrain awareness warning systems (TAWS) that are installed on airplanes. We incorrectly referred to paragraph (d)(1) in the Compliance column of paragraph (e)(2). The correct reference is (e)(1). This action corrects the table in paragraph (e) of AD 2004–08–15, Amendment 39–13584.

**EFFECTIVE DATE:** The effective date of this AD remains June 7, 2004.

**FOR FURTHER INFORMATION CONTACT:** Brenda S. Ocker, Aerospace Engineer, FAA, Chicago Aircraft Certification Office, 2300 East Devon Avenue, Des Plaines, Illinois 60018; telephone: (847) 294–7126; facsimile: (847) 294–7834.

**SUPPLEMENTARY INFORMATION:**

### Discussion

On April 13, 2004, FAA issued AD 2004–08–15, Amendment 39–13584 (69 FR 21393), that applies to all Goodrich TAWS8000 terrain awareness warning systems (TAWS) that are installed on airplanes. This AD requires you to inspect the TAWS installation and modify any TAWS where both the TAWS and any other device are connected to the same baro set potentiometer. This AD also prohibits future installation or reconfiguration of any TAWS8000 TAWS that does not incorporate hardware "Mod C".

### Need for the Correction

The FAA incorrectly referred to paragraph (d)(1) in the Compliance column of paragraph (e)(2). The correct reference is (e)(1). This action corrects the table in paragraph (e) of AD 2004–08–15, Amendment 39–13584.

This correction is needed to ensure that the affected airplane owners/operators do the corrective action after the inspection required in paragraph (e)(1).

### Correction of Publication

■ Accordingly, the publication of April 21, 2004 (69 FR 21393), of Amendment 39–13584; AD 2004–08–15, which was the subject of FR Doc. 04–8792, is corrected as follows:

## PART 39—AIRWORTHINESS DIRECTIVES

**§ 39.13 [Corrected]**

■ On page 21395, in § 39.13 [Amended], 2., replace the text in the Compliance column of paragraph (e)(2) of the AD with the following text: Before further flight after the inspection required in paragraph (e)(1) of this AD."

■ Action is taken herein to correct this reference in AD 2004–08–15 and to add this AD correction to § 39.13 of the Federal Aviation Regulations (14 CFR 39.13).

The effective date remains June 7, 2004.

Issued in Kansas City, Missouri, on May 18, 2004.

**James E. Jackson,**

*Acting Manager, Small Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 04–11704 Filed 5–24–04; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### 14 CFR Part 71

**[Docket No. FAA–2004–17721; Airspace Docket No. 04–ACE–ACE–33]**

## Modification of Class E Airspace; Mosby, MO

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

**ACTION:** Direct final rule; request for comments.

**SUMMARY:** This action amends Title 14 Code of Federal Regulations, part 71 (14 CFR 71) by revising Class E airspace at Mosby, MO. On March 1, 2004, a redefined airport reference point (ARP) for Clay County Regional Airport was published in the National Flight Data Digest. A review of controlled airspace at Mosby, MO revealed the Class E airspace area extending upward from 700 feet Above Ground Level (AGL) does not comply with FAA Orders. This action incorporates the revised ARP, expands the area slightly to comply with the criteria for 700 feet above ground level (AGL) airspace required for diverse departures, modifies the extension and brings the Mosby, MO Class E airspace area into compliance with FAA Orders.

**DATES:** This direct final rule is effective on 0901 UTC, September 30, 2004. Comments for inclusion in the Rules Docket must be received on or before July 26, 2004.

**ADDRESSES:** Send comments on this proposal 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–2004–17721/Airspace Docket No. 04–ACE–33, at the beginning of your comments. You may also submit comments on the Internet at *http://dms.dot.gov*. You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1–800–647–5527) is on the plaza level of the Department of Transportation NASSIF Building at the above address.

**FOR FURTHER INFORMATION CONTACT:** Brenda Mumper, Air Traffic Division, Airspace Branch, ACE–520A, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (816) 329–2524.

**SUPPLEMENTARY INFORMATION:** This amendment to 14 CFR 71 modifies the Class E airspace area extending upward from 700 feet above the surface at Mosby, MO. The Clay County Regional Airport ARP has been redefined. An examination of controlled airspace for Clay County Regional Airport revealed it does not meet the criteria for 700 feet AGL airspace required for diverse departures as specified in FAA Order 7400.2E, Procedures for Handling Airspace Matters. The criteria in FAA Order 7400.2E for an aircraft to reach 1200 feet AGL is based on a standard climb gradient of 200 feet per mile plus the distance from the airport reference point to the end of the outermost runway. Any fractional part of a mile is converted to the next higher tenth of a mile. The review also identified that the extension to the Mosby, MO Class E airspace area is incorrectly defined. This amendment incorporates the revised Clay County Regional Airport ARP into the legal description, expands the airspace area from a 6.4-mile radius to a 6.5-mile radius of Clay County Regional Airport, redefines the centerline of the Mosby, MO Class E airspace area extension as a 343° versus a 340° bearing from the Mosby nondirectional radio beacon (NDB), and brings the legal description of the Mosby, MO Class E airspace area into compliance with FAA Orders 7400.2E and 8260.19C, Flight Procedures and Airspace. This area will be depicted on appropriate aeronautical charts. Class E airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9L, Airspace Designations and Reporting Points, dated September 2, 2003, and effective September 16, 2003, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

### The Direct Final Rule Procedure

The FAA anticipates that this regulation will not result in adverse or negative comment and, therefore, is issuing it as a direct final rule. Previous actions of this nature have not been controversial and have not resulted in adverse comments or objections. Unless a written adverse or negative comment, or a written notice of intent to submit an adverse or negative comment is received within the comment period, the regulation will become effective on the date specified above. After the close of the comment period, the FAA will publish a document in the **Federal Register** indicating that no adverse or negative comments were received and confirming the date on which the final rule will become effective. If the FAA does receive, within the comment period, an adverse or negative comment, or written notice of intent to submit such a comment, a document withdrawing the direct final rule will be published in the **Federal Register**, and a notice of proposed rulemaking may be published with a new comment period.

### Comments Invited

Interested parties are invited to participate in this rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. FAA–2004–17221/Airspace No. 04–ACE–33." The postcard will be date/time stamped and returned to the commenter.

### Agency Findings

The regulations adopted herein will 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. Therefore, it is determined that this final rule does not have federalism implications under Executive Order 13132.

The FAA has determined that this regulation is noncontroversial and unlikely to result in adverse or negative comments. For the reasons discussed in the preamble, I certify that this regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under Department of Transportation (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.

### List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

### Adoption of the Amendment

■ Accordingly, the Federal Aviation Administration amends 14 CFR part 71 as follows:

## PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

### §71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9L, dated September 2, 2003, and effective September 16, 2003, is amended as follows:

* * * * *

*Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.*

* * * * *

**ACE MO E5 Mosby, MO**

Mosby, Clay County Regional Airport, MO
(Lat. 39°19′57″ N., long. 94°18′35″ W.)
Mosby NDB
(Lat. 39°20′46″ N., long. 94°18′27″ W.)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Clay County Regional Airport and within 2.5 miles each side of the 343° bearing from the Mosby NDB extending from the 6.5-mile radius of the airport to 7 miles north of the NDB.

* * * * *

Issued in Kansas City, MO, on May 11, 2004.

**Paul J. Sheridan**

*Acting Manager, Air Traffic Division, Central Region.*

[FR Doc. 04–11788 Filed 5–24–04; 8:45 am]

BILLING CODE 4910–13–M

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### 14 CFR Part 71

**[Docket No. FA–2004–17427; Airspace Docket No. 04–ACE–27]**

### Modification of Class E Airspace; Oshkosh, NE

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

**ACTION:** Direct final rule; request for comments; correction.

**SUMMARY:** This action corrects a direct final rule; request for comments that was publised in the **Federal Register** on Tuesday, May 11, 2004, (69 FR 26029) [FR Doc. 04–10636]. It corrects an error in the legal description.

**DATES:** This direct final rule is effective on 0901 UTC, August 5, 2004.

**FOR FURTHER INFORMATION CONTACT:** Brenda Mumper, Air Traffic Division, Airspace Branch, ACE–520A, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (816) 329–2524.

**SUPPLEMENTARY INFORMATION:**

**History**

**Federal Register** document 04–10636, published on Tuesday, May 11, 2004, (69 FR 26029) modified Class E airspace areas at Oshkosh, NE. The modification corrected discrepancies in the dimensions controlled airspace for diverse departures from Garden County Airport, expanded the area by .5 mile, corrected errors in the location of the Oshkosh, NE nondirectional radio beacon used in the legal description, redefined the extension to the airspace area and brought the legal description of the Oshkosh, NE Class E airspace area into compliance with FAA Order 7400.2E, Procedures for Handling Airspace Matters. However, the line in the legal description identifying the airport was not in the correct format.

■ Accordingly, pursuant to the authority delegated to me, the legal description of Oshkosh, NE Class E airspace, as publised in the **Federal Register** on Tuesday, May 11, 2004, (69 FR 26029) [FR Doc. 04–10636] is corrected as follows:

### PART 71—[AMENDED]

**§ 71.1 [Corrected]**

■ On page 26030, Column 2, third paragraph, second line, change "Garden County Airport, NE" to read "Oshkosh, Garden County Airport, NE".

Issued in Kansas City, MO, on May 13, 2004.

**Paul J. Sheridan,**

*Acting Manager, Air Traffic Division, Central Region.*

[FR Doc. 04–11787 Filed 5–24–04; 8:45 am]

BILLING CODE 4910–13–M

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 165

**[COTP Savannah–04–040]**

**RIN 1625–AA00, AA11**

### Security Zones and Regulated Navigation Area; Savannah River, GA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing temporary security zones and a temporary regulated navigation area, from June 5, 2004, through June 11, 2004, for the G–8 Summit to be held in Sea Island, Georgia. These rules are required to provide for the security of the public, the G–8 Summit and its participants, and the safety of the waterways due to the potential for hostile and violent acts from demonstrators protesting the G–8. These temporary security zones prohibit the entry of all vessels and persons into all waters of the Savannah River from Port Wentworth south, including the Back River, the Elba Island South Channel, and the Intracoastal Waterway Alternate Route in the vicinity of St. Augustine Creek, to the boundary of the temporary regulated navigation area that is located in the vicinity of the south east tip of Elba Island at the western portion of the Lower Flats Range. The temporary regulated navigation area controls the movement of all vessels operating on the Intracoastal Waterway in the vicinity of Fields Cut and south through Elba Island Cut to St. Augustine Creek.

**DATES:** This rule is effective from 8 a.m. on June 5, 2004 until 4 p.m. on June 11, 2004.

**ADDRESSES:** Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket [COTP Savannah 04–040] and are available for inspection or copying at Marine Safety Office Savannah, 100 W. Oglethorpe Ave., Suite 1017, Savannah, Georgia 31401 between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** LTJG Anthony Quirino, Coast Guard Marine Safety Office Savannah, (912) 652–4353, ext 235.

**SUPPLEMENTARY INFORMATION:**

**Regulatory Information**

On April 8, 2004, we published a notice of proposed rulemaking (NPRM) entitled Security Zones and Regulated Navigation Areas; Savannah River, GA in the **Federal Register** (69 FR 18797). We received one letter commenting on the proposed rule. No public hearing was requested, and none was held.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register.** This rule is needed to provide for the security of the public, the G–8 Summit and its participants, and the safety of the waterways due to the potential for hostile and violent acts from demonstrators protesting the G–8. Law enforcement officials require sufficient time to put security measures in place for the start of the G–8 summit on June 8th. Therefore, it is in the public interest to have these regulations effective less than 30 days after publication in the **Federal Register.**

**Background and Purpose**

The G8 (Group of 8) is an informal group of eight countries—Canada, France, Germany, Italy, Japan, Russia, the United Kingdom and the United States—whose leaders meet to discuss broad economic and foreign policies. The 30th G8 summit will be held in Sea Island, Georgia, from June 8 through June 10, 2004.

Cities that have recently hosted conferences or summits similar to the G–8 Summit have experienced significant property damage, and their law enforcement officers and public citizens have sustained personal injuries from a segment of protestors engaged in violent demonstrations against those summits and their agendas. Examples include the September 2003 World Trade Organization (WTO) Ministerial in Cancun, Mexico; the 2003 G–8 Summit in Calgary, Canada, the 2001 G–8 Summit in Genoa, Italy; and the 1999 World Trade Organization in Seattle, Washington. These conferences and summits experienced an influx of protestors, and in particular protest groups opposing international trade who have a propensity for violence and a desire to engage in hostile acts against, among others, summit attendees, conference venues, the general public, business and municipal buildings, and law enforcement officials. Information and intelligence indicates that there is

potential for similar acts to be attempted during the upcoming June G–8 Summit in Savannah, Georgia.

This history has heightened the need for the development and implementation of various security measures in the vicinity of the Savannah River, particularly around venue areas established for the dignitaries and official parties attending the G–8 Summit, critical port facilities and infrastructure, bridges, and the navigable waterways. The Coast Guard has determined from information provided by local, state, and federal law enforcement officials that vessels or persons in close proximity to the G–8 Summit may launch hostile or violent acts from the waterways adjacent to the Summit and from the waterways adjacent to where Summit attendees are staying. The potential for these acts poses a security threat to the public, the G–8 Summit and its participants, and the flow of commerce on the navigable waterways.

The temporary security zones and temporary regulated navigation area (RNA) are necessary to mitigate these threats and protect the public, the G–8 Summit attendees, law enforcement officers, and the flow of commerce on the waterways from persons attempting hostile and violent acts.

The temporary security zones and temporary regulated navigation area are being established to mitigate these threats and are necessary to protect the public, the G–8 conference and attendees, law enforcement officers, the Port of Savannah and commerce within the port from persons attempting hostile and violent acts.

Please note that elsewhere in today's **Federal Register**, we have published another final rule, entitled "Security Zone, St. Simons Sound and the Atlantic Ocean, GA" that is also intended to provide security of the public, the G–8 Summit and its participants, and the safety of the waterways during this same period—June 5, 2004, until 4 p.m. on June 11, 2004.

**Discussion of Comments and Changes**

We received one letter offering support of the rule and the increased security and protection that it provides. The Coast Guard agrees with this comment and no changes to the final rule were made.

**Regulatory Evaluation**

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not "significant" under the regulatory policies and procedures of the Department of Homeland Security (DHS).

We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary. Although the security zone applies to a large section of the Savannah River, traffic will be allowed to pass through the zone with the permission of the Captain of the Port of Savannah or his designated representatives. Before the effective period, we will issue maritime advisories widely available to users of the river.

**Small Entities**

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule will have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities. We did not receive any comments from small entities or other information following our (NPRM) on April 8, 2004 (69 FR 18797) stating that this rule would have a significant economic impact on them.

**Assistance for Small Entities**

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offered to assist small entities in understanding this rule so that they could better evaluate its effects on them and participate in the rulemaking process. Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on the actions by employees of the Coast Guard, call 1–800–REG–FAIR (1–888–734–3247).

**Collection of Information**

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

**Federalism**

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

**Unfunded Mandates Reform Act**

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

**Taking of Private Property**

This rule will not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

**Civil Justice Reform**

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

**Protection of Children**

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not economically significant and does not create environmental risks to health or risks to safety that may disproportionately affect children.

**Indian Tribal Governments**

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

**Energy Effects**

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated them as a significant energy action. Therefore, they do not require a Statement of Energy Effects under Executive Order 13211.

**Environment**

We have analyzed these rules under Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, these rules are categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation.

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

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 Part 165 as follows:

## PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

**Authority:** 33 U.S.C. 1226, 1231; 50 U.S.C. 191, 195; 46 U.S.C. Chapter 701; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. From 8 a.m. on June 5, 2004, until 4 p.m. on June 11, 2004 add a new temporary § 165.T07–040 to read as follows:

**§ 165.T07–040 Temporary Security Zones and Temporary Regulated Navigation Area, Savannah River, GA**

(a) *Locations—*

(1) *Security Zone, Savannah River.* An imaginary line starting at Channel Light 22, (Light List Volume III, Number 5090), at the intersection of the Middle River and the Savannah River and crossing due West over the Savannah River to Port Wentworth at approximate point 32°08′47″ N, 081°06′36″W; then all waters of the Savannah River from shore to shore and surface to bottom south and east of this imaginary line downriver to an imaginary line starting at the south east tip of Elba Island at approximate point 32°04′19″ N, 080°58′27″ W and extending due north across the Savannah River and through Red Buoy #36 to approximate point 32°0′40″ N, 080°58′19″ W. All coordinates are based upon North American Datum 83 (NAD 83).

(2) *Security Zone, Back River.* All waters of the Back River south and east of the Highway 17 bridge from shore to shore and surface to bottom easterly to where the Back River meets the Savannah River.

(3) *Security Zone, South Channel Elba Island.* All waters of the South Channel south of Elba Island, from shore to shore and surface to bottom, from the intersection of the Savannah River and the South Channel and continuing south easterly to an imaginary line starting at the south east tip of Elba Island at approximate point 32°04′19″ N, 080°58′27″ W and extending south westerly following the northern edge of Elba Island Cut channel to the north east tip of McQueen Island at approximate position 32°04′08″ N, 080°58′55″ W. All coordinates are based upon North American Datum 83 (NAD 83).

(4) *Security Zone, Intracoastal Waterway Alternate Route.* All waters of the Intracoastal Waterway Alternate Route from shore to shore and surface to bottom from St. Augustine Creek Day Beacon A18 (Light List, Vol. III, no. 35960) to Day Beacon A12 (Light List, Vol. III, no. 35945).

(5) *Regulated navigation area; Intracoastal Waterway Fields Cut, Savannah River, and St. Augustine Creek.* All waters of the Intracoastal Waterway from shore to shore and surface to bottom from Fields Cut Buoy 48 (Light List, Vol. III, no. 35865) at Wright River south and west to the Savannah River, and including all waters of the Savannah River in the vicinity of Lower Flats Range, from shore to shore and surface to bottom, southeast of an imaginary line starting at the south east tip of Elba Island at approximate point 32°04′19″ N, 080°58′27″ W and extending due north across the Savannah River and through Red Buoy #36 to approximate point 32°04′40″ N, 080°58′19″ W to an imaginary line starting at the western tip of Jones Island at the intersection of the Intracoastal Waterway and extending southwesterly across the Savannah River intersecting through Green buoy "35" to Bird Island at approximate point 32°04′15″ N, 080°58′00″ W, and continuing south and west and including all waters of Elba Island Cut and the Intracoastal waterway, from shore to shore and surface to bottom, to Elba Island Cut Light 10 (Light List, Vol. III no. 35900) at St. Augustine Creek. All coordinates are based upon North American Datum 83 (NAD 83).

(b) *Definitions.*

The following definitions apply to this section:

*Designated Representatives* means Coast Guard Patrol Commanders including Coast Guard coxswains, petty officers and other officers operating Coast Guard vessels, and federal, state, and local officers designated by or assisting the Captain of the Port of Savannah, to regulate the movement of vessels within the RNA and restrict vessels and persons from entering the security zones.

*Slow speed* means the speed at which a vessel proceeds when it is fully off plane, completely settled in the water and not creating excessive wake. Due to the different speeds at which vessels of different sizes and configurations may travel while in compliance with this definition, no specific speed is assigned to slow speed. In no instance should slow speed be interpreted as a speed less than that required to maintain steerageway. A vessel is not proceeding at slow speed if it is:

(1) On a plane;

(2) In the process of coming up onto or coming off a plane; or

(3) Creating an excessive wake.

(c) *Regulations—*

(1) *Security Zones.* The regulations in this paragraph apply to the zones in paragraph (a)(1) through (a)(4) of this section. Entry into or remaining within the security zones by vessels or persons is prohibited unless authorized by the Coast Guard Captain of the Port, Savannah, Georgia or that officer's designated representatives. Vessels moored, docked or anchored in the security zones when they become effective must remain in place unless ordered by or given permission from the COTP to do otherwise. Vessels or persons desiring to enter or transit the areas encompassed by the security zones may contact the Coast Guard on VHF Channel Marine 16 or at (912) 652–4353 to seek permission to enter or transit the area. If permission is granted, all persons and vessels must comply with the instructions of the Captain of the Port or that officer's designated representatives.

(2) *Regulated Navigation Area.* The regulations in this paragraph apply to the area in paragraph (a)(5) of this section.

(i) All vessels and persons entering and transiting through the regulated navigation area shall proceed continuously and at a slow speed. In no instance should slow speed be interpreted as a speed less than that required to maintain steerageway. Nothing in this rule alleviates vessels or operators from complying with all state and local laws in the area.

(ii) All vessels and persons shall comply with orders from the Coast Guard Captain of the Port of Savannah or that officer's designated representatives, regulating their speed, course, direction and movements within the RNA.

All vessels and persons shall obtain the permission of the Captain of the Port or that officer's designated representatives prior to entering or transiting via VHF Channel 16.

(d) *Effective period:* This section is effective from 8 a.m. on June 5, 2004 until 4 p.m. on June 11, 2004.

Dated: May 17, 2004.

**Harvey E. Johnson, Jr.,**

*Rear Admiral, U.S. Coast Guard, Commander, Seventh Coast Guard District.*

[FR Doc. 04–11887 Filed 5–21–04; 12:12 pm]

BILLING CODE 4910–15–P

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

### 33 CFR Part 165

**[COTP Savannah–04–041]**

**RIN 1625–AA00**

## Security Zone, St. Simons Sound and the Atlantic Ocean, GA

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing security zones, from June 5, 2004, through June 11, 2004, for the G–8 Summit to be held in Sea Island, Georgia. These security zones are required to provide for the security of the public, the G–8 Summit and its participants, and the safety of the waterways due to the potential for hostile and violent acts from demonstrators protesting the G–8 Conference. This rule prohibits the entry of all vessels and persons into the waters in the vicinity of Sea Island, Jekyll Island, and all waters of the Atlantic Ocean from the baselines of Sea Island, St. Simons Island and Jekyll Island extending seaward to a distance of 3 nautical miles, as well as waters on the Hampton River, Jones Creek, Lanier Island, and St. Simons Sound. Additional security zones prohibit entering closer than 100-yards to eight specified bridges located in the vicinity of these waters.

**DATES:** This rule is effective from 8 a.m. June 5, 2004, until 4 p.m. on June 11, 2004.

**ADDRESSES:** Marine Safety Office Savannah maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket [COTP Savannah 04–041] and will be available for inspection or copying at Marine Safety Office Savannah, 100 W. Oglethorpe Ave., Suite 1017, Savannah, Georgia 31401, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** LTJG Anthony Quirino, Coast Guard Marine Safety Office Savannah, (912) 652–4353, ext. 235.

**SUPPLEMENTARY INFORMATION:**

### Regulatory Information

On April 8, 2004, we published a notice of proposed rulemaking (NPRM) entitled Security Zone, St. Simons Sound and the Atlantic Ocean, GA, in the **Federal Register** (69 FR 18794). We received 2 letters commenting on the proposed rule. No public meeting was requested, and none was held.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register.** This rule is necessary to minimize danger and provide security for the public and participants of the G8 Conference. Law enforcement officials require sufficient time to put security measures in place prior to the start of the conference on June 8, 2004. Therefore, it is in the public interest to have these regulations effective less than 30-days after publication in the **Federal Register.**

### Background and Purpose

The G8 (Group of 8) is an informal group of eight countries—Canada; France, Germany, Italy, Japan, Russia, the United Kingdom and the United States—whose leaders meet to discuss broad economic and foreign policies. The 30th G8 Summit will be held in Sea Island, Georgia, from June 8 through June 10, 2004.

Cities that have recently hosted conferences or summits similar to the G–8 Summit have experienced significant property damage, and their law enforcement officers and public citizens have sustained personal injuries from a segment of protestors engaged in violent demonstrations against those summits and their agendas. Examples include the September 2003 World Trade Organization (WTO) Ministerial in Cancun, Mexico; the 2003 G–8 Summit in Calgary, Canada, the 2001 G–8 Summit in Genoa, Italy; and the 1999 World Trade Organization in Seattle, Washington. These conferences and summits experienced an influx of protestors, and in particular protest groups opposing international trade who have a propensity for violence and a desire to engage in hostile acts against, among others, summit attendees, conference venues, the general public, business and municipal buildings, and law enforcement officials. Information and intelligence indicates that there is potential for similar acts to be attempted during the upcoming June G–8 Summit in Savannah, Georgia.

This history has heightened the need for the development and implementation of various security measures in the vicinity of St. Simons Sound. In particular, there is a need for additional security around venue areas established for the dignitaries and official parties attending the G–8 Summit, bridges, and waterways used by commercial shipping. The Coast Guard has determined from information provided by local, state, and federal law enforcement officials that vessels or persons in close proximity to the G–8 Summit may launch hostile or violent acts from the waterways adjacent to the Summit and from the waterways adjacent to where Summit attendees are staying. The potential for these acts poses a security threat to the public, the G–8 Summit and its participants, and the flow of commerce on the navigable waterways.

The security zones mitigate these threats and are necessary to protect the public, the G–8 Summit attendees, law enforcement officers, and the flow of commerce on the waterways from persons attempting hostile and violent acts. Please note that elsewhere in today's **Federal Register**, we have published another final rule, entitled "Security Zones and Regulated Navigation Areas; Savannah River, GA," that is also intended to provide security of the public, the G–8 Summit and its participants, and the safety of the waterways during this same period—June 5, 2004, until 4 p.m. on June 11, 2004.

### Discussion of Rule

In our NPRM (69 FR 18794) we advised vessels transiting the Intracoastal waterway to exit and enter

at Altamaha Sound as an alternate route around the security zone. Due to shoaling in Altamaha Sound, published in Local Notice to Mariners (08/04), vessels should instead use Doboy Sound, 2 miles north, to exit and enter the Intracoastal waterway.

**Discussion of Comments and Changes**

We received two letters offering comments on the proposed rule. One comment recommended using consistent language that prohibits the entry of all vessels and persons throughout the rule. We agree. As a result of this comment, language that prohibits the entry of all vessels and persons is now consistently used throughout this rule.

The other letter requested advance permission to enter and transit the security zones, and commented that the regulation was overbroad because it shut down traffic on the Intracoastal waterway. Granting pre-approval to transit these security zones is impracticable because of the numerous unknown exigencies that may exist. Moreover, numerous alternatives do exist, including transiting offshore of the security zones, weather permitting, or delaying a voyage until after expiration of the security zones. Finally, although authorization to transit the security zone may not be provided in advance, requests for permission to transit the zone immediately may still be granted by the COTP Savannah. This approach provides COTP Savannah the flexibility to enforce this rule as threats and conditions dictate.

Although the G–8 Summit is scheduled to take place from June 8 through June 10, 2004, it is necessary to make the security zones effective from June 5 through June 11, 2004, to provide security for arriving and departing G–8 summit attendees and allow law enforcement officials time to stand up and stand down from patrolling the security zones.

We made one technical change in the text of the regulation. The references in (a)(1) and (a)(2) to the location coordinates being based on North American Datum 83 have been moved into a note for the entire paragraph (a).

**Regulatory Evaluation**

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not "significant" under the regulatory policies and procedures of the Department of Homeland Security (DHS).

We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary.

**Small Entities**

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on a substantial number of small entities.

This rule would affect the following entities, some of which might be small entities: The owners or operators of vessels intending to transit or anchor in a portions of St. Simons Sound, the Intracoastal waterway and the Atlantic Ocean covered by this security zone. We received no comments from owners of such small entities. Therefore, owners are encouraged to contact the Captain of the Port to seek permission to transit these security zones.

**Assistance for Small Entities**

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule affects your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

**Collection of Information**

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

**Federalism**

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

**Unfunded Mandates Reform Act**

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 or more in any one year. Though this rule would not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

**Taking of Private Property**

This rule would not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

**Civil Justice Reform**

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

**Protection of Children**

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

**Indian Tribal Governments**

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

**Energy Effects**

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office

of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

**Environment**

We have analyzed this rule under Commandant Instruction M16475.lD, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction, from further environmental documentation.

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

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

## PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

**Authority:** 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. From 8 a.m. on June 5, 2004, until 4 p.m. on June 11, 2004, add a new temporary § 165.T07–041 to read as follows:

**§ 165.T07–041 Temporary security zones, St. Simons Sound, GA.**

(a) *Locations.* The following areas are security zones:

(1) *Security zone; St. Simons Sound and the Atlantic Ocean.* All waters of St. Simons Sound and the Atlantic Ocean, from surface to bottom, encompassed by a line commencing from the north east point of Little St. Simons Island at 31°15′24″ N, 081°16′55″ W; thence, easterly seaward into the waters of the Atlantic Ocean out to a distance of 3 nautical miles at 31°15′24″ N, 081°11′55″ W; thence southerly following the contour of the baseline at a distance of 3 nautical miles to 31°00′44″ N, 081°19′35″ W; thence westerly to the southern tip of Jekyll Island at 31°00′44″ N, 081°26′03″ W; thence northwesterly to the south side of the Sidney Lanier bridge at 31°06′48″ N, 081°29′40″ W; thence continuing northeasterly to the northern tip of Lanier Island at 31°11′06″ N, 081°25′17″ W; thence continuing northeasterly to the Hampton River at 31°17′36″ N, 081°20′33″ W; thence back to the original point.

(2) *Security zone, Bridges.* All waters from surface to bottom within 100-yards of the following bridges:

| *Roadway* | *Bridge* | *Located at* |
|---|---|---|
| (i) Jekyll Island Causeway | Cedar Creek | 31°05.318′ N, 081°28.780′ W. |
| (ii) Jekyll Island Causeway | Jekyll Creek | 31°02.808′ N, 081°25.347′ W. |
| (iii) Highway 17 | Sidney Lanier | 31°06.982′ N, 081°29.094′ W. |
| (iv) Saint Simons Causeway | Terry Creek | 31°09.697′ N, 081°28.137′ W. |
| (v) Saint Simons Causeway | Back River | 31°09.868′ N, 081°26.766′ W. |
| (vi) Saint Simons Causeway | Little River | 31°10.120′ N, 081°26.200′ W. |
| (vii) Saint Simons Causeway | MacKay River | 31°10.276′ N, 081°25.494′ W. |
| (viii) Saint Simons Causeway | Frederica River | 31°10.050′ N, 081°24.782′ W. |

**Note to § 165.T07–041(a):** All coordinates are based upon North American Datum 83 (NAD 83).

(b) *Definitions.* As used in this section, *designated representatives* means Coast Guard Patrol Commanders including Coast Guard coxswains, petty officers and other officers operating Coast Guard vessels, and federal, state, and local officers designated by or assisting the Captain of the Port of Savannah (COTP) to restrict vessels and persons from entering the security zones.

(c) *Regulations.* Entry into or transiting within the security zones by vessels or persons is prohibited unless authorized by the Coast Guard Captain of the Port, Savannah, Georgia or that officer's designated representatives. Vessels docked, moored, or anchored in security zones when they become effective must remain in place unless ordered by or given permission from the COTP to do otherwise. Vessels or persons desiring to enter or transit the areas encompassed by the security zones may contact the Coast Guard on VHF Channel Marine 16 or at (912) 652–4353 to seek permission to enter or transit the zones. If permission is granted, all persons and vessels must comply with the instructions of the Captain of the Port or that officer's designated representatives.

Dated: May 17, 2004.

**Harvey E. Johnson, Jr.,**

*Rear Admiral, U.S. Coast Guard, Commander, Seventh Coast Guard District.*

[FR Doc. 04–11886 Filed 5–21–04; 12:12 pm]

BILLING CODE 4910–15–P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 62

**[VA141–5075a; FRL–7666–5]**

### Approval and Promulgation of State Air Quality Plans for Designated Facilities and Pollutants, Commonwealth of Virginia; Control of Emissions From Commercial and Industrial Solid Waste Incinerator Units

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

**ACTION:** Direct final rule.

**SUMMARY:** EPA is taking direct final action to approve the commercial and industrial solid waste incinerator (CISWI) section 111(d)/129 plan (the "plan") submitted to EPA on September 8, 2003 by the Virginia Department of Environmental Quality (DEQ). The plan includes supplemental information submitted on August 11, and September 30, 2003, and April 6, 2004. The plan establishes emission limits, monitoring, operating, and recordkeeping requirements for commercial and industrial solid waste incinerator units for which construction commenced on or before November 30, 1999. Submittal and approval of the plan fulfills a Clean Air Act (the Act) requirement for the Commonwealth of Virginia.

**DATES:** This rule is effective on July 26, 2004 without further notice, unless EPA receives written comment by June 24, 2004. If EPA receives such comments, it 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:** Submit your comments, identified by VA141–5075 by one of the following methods:

A. *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

B. *E-mail: wilkie.walter@epa.gov.*

C. *Mail:* Walter Wilkie, Chief, Air Quality Analysis Branch, Mailcode 3AP22, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

*Instructions:* Direct your comments to Docket ID No. VA141–5075. EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The Federal regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; and the Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia 23219.

**FOR FURTHER INFORMATION CONTACT:** James B. Topsale, P.E., at (215) 814–2190, or by e-mail at *topsale.jim@epa.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

Sections 111(d)/129 of the Act require states to submit plans to control certain pollutants (designated pollutants) at existing solid waste combustor facilities (designated facilities) whenever standards of performance have been established under section 111(b) for new sources of the same type, and EPA has established emission guidelines (EG) for such existing sources. A designated pollutant is any pollutant for which no air quality criteria have been issued, and which is not included on a list published under section 108(a) or section 112(b)(1)(A) of the Act, but emissions of which are subject to a standard of performance for new stationary sources. However, section 129 of the Act, also requires EPA to promulgate EG for CISWI units that emit a mixture of air pollutants. These pollutants include organics (dioxins/furans), carbon monoxide, metals (cadmium, lead, mercury), acid gases (hydrogen chloride, sulfur dioxide, and nitrogen oxides) and particulate matter (including opacity). On December 1, 2000 (65 FR 75338), EPA promulgated CISWI unit new source performance standards and EG, 40 CFR part 60, subparts CCCC and DDDD, respectively. The designated facility to which the EG apply is each existing CISWI unit, as stipulated in subpart DDDD, that commenced construction on or before November 30, 1999. *See* 40 CFR 60.2550 for details.

Section 111(d) of the Act requires that "designated" pollutants, regulated under standards of performance for new stationary sources by section 111(b) of the Act, must also be controlled at existing sources in the same source category to a level stipulated in an emission guidelines (EG) document. Section 129 of the Act specifically addresses solid waste combustion and emissions controls based on what is commonly referred to as "maximum achievable control technology" (MACT). Section 129 requires EPA to promulgate a MACT based emission guideline (EG) document for CISWI units, and then requires states to develop plans that implement the EG requirements. The CISWI EG under 40 CFR part 60, subpart DDDD, establish emission and operating requirements under the authority of the Act, sections 111(d) and 129. These requirements must be incorporated into a State plan that is "at least as protective" as the EG, and is Federally-enforceable upon approval by EPA. The procedures for adoption and submittal of State plans are codified in 40 CFR part 60, subpart B.

## II. Review of the Virginia CISWI Plan

EPA has reviewed the Virginia CISWI plan in the context of the requirements of 40 CFR part 60, and subparts B and DDDD. A summary of the review is provided below.

### *A. Identification of Enforceable State Mechanism(s) for Implementing the EG*

On September 8, 2003, the DEQ submitted to EPA the required plan, including an enforceable mechanism, the State Air Pollution Control Board's Regulation for the Control and Abatement of Air Pollution, Emission Standards for Commercial/Industrial Solid Waste Incinerators (Rule 4–45). In addition, related applicable Regulations for General Administration were submitted on August 11, 2003 and April 6, 2004.

### *B. Demonstration of Legal Authority*

DEQ's authority is explained in detail in its August 11, 2003 letter to EPA. The DEQ cites its authority under the Air Pollution Control Law of Virginia at Title 10.1, Chapter 13, Code of Virginia. This is also discussed in the plan narrative, Section I, Legal Authority—State, and the Attorney General's Office certification of authority in a July 1, 1998 letter. The DEQ has sufficient statutory and regulatory authority to implement and enforce the plan.

### *C. Inventory of CISWI Units in Virginia Affected by the EG*

The plan contains a DEQ inventory of known existing CISWI units that are subject to the plan.

### *D. Inventory of Emissions From CISWI Units in Virginia*

The submitted plan contains an estimate of emissions from each affected facility. Emissions estimates are provided for organics (dioxins/furans), carbon monoxide, acid gases (hydrogen chloride, sulphur dioxide, and nitrogen oxides), metals (cadmium, lead, mercury), and particulate matter.

### *E. Emission Limitations for CISWI Units*

The state CISWI regulation, Rule 4–45, includes emission limitation requirements that are at least as protective as those in the EG, subpart DDDD.

### *F. Compliance Schedules*

Rule 4–45 contains an expeditious compliance schedule provision (9 VAC 5–40–6420 A) that requires final compliance on or before October 3,

2004, and it includes separate provisions for extending the compliance date. Both the Federal and Virginia plans require that a compliance date extension must be submitted to the respective implementing air pollution control agency on or before December 3, 2003. Neither air pollution control agency has the authority under the Act and related rules to grant or approve an extension request submitted after December 3, 2003. As the Federal plan implementing agency, EPA has no record of receiving a compliance date extension request. Therefore, under the Virginia plan, final compliance is required on or before October 3, 2004.

*H. Testing, Monitoring, Recordkeeping, and Reporting Requirements*

Rule 4–45 includes the applicable source compliance testing, monitoring, recordkeeping, and reporting requirements of the EG.

*I. A Record of the Public Hearing on the State Plan*

A public hearing for the plan was held in Richmond, Virginia, on August 27, 2003. The DEQ provided evidence of complying with the public notice and other hearing requirements of subpart B.

*J. Provision for Annual State Progress Reports to EPA*

The DEQ will submit to EPA on an annual basis a report which details the progress in the enforcement of the plan. The first progress report will be submitted to EPA within one year after approval of the Virginia plan.

In 1995, Virginia adopted legislation that provides, subject to certain conditions, for an environmental assessment (audit) "privilege" for voluntary compliance evaluations performed by a regulated entity. The legislation further addresses the relative burden of proof for parties either asserting the privilege or seeking disclosure of documents for which the privilege is claimed. Virginia's legislation also provides, subject to certain conditions, for a penalty waiver for violations of environmental laws when a regulated entity discovers such violations pursuant to a voluntary compliance evaluation and voluntarily discloses such violations to the Commonwealth and takes prompt and appropriate measures to remedy the violations. Virginia's Voluntary Environmental Assessment Privilege Law, Va. Code Sec. 10.1–1198, provides a privilege that protects from disclosure documents and information about the content of those documents that are the product of a voluntary environmental assessment. The Privilege Law does not extend to documents or information (1) that are generated or developed before the commencement of a voluntary environmental assessment; (2) that are prepared independently of the assessment process; (3) that demonstrate a clear, imminent and substantial danger to the public health or environment; or (4) that are required by law.

On January 12, 1997, the Commonwealth of Virginia Office of the Attorney General provided a legal opinion that states that the Privilege law, Va. Code Sec. 10.1–1198, precludes granting a privilege to documents and information "required by law," including documents and information "required by Federal law to maintain program delegation, authorization or approval," since Virginia must "enforce Federally authorized environmental programs in a manner that is no less stringent than their Federal counterparts. * * *" The opinion concludes that "[r]egarding § 10.1–1198, therefore, documents or other information needed for civil or criminal enforcement under one of these programs could not be privileged because such documents and information are essential to pursuing enforcement in a manner required by Federal law to maintain program delegation, authorization or approval."

Virginia's Immunity law, Va. Code Sec. 10.1–1199, provides that "[t]o the extent consistent with requirements imposed by Federal law," any person making a voluntary disclosure of information to a state agency regarding a violation of an environmental statute, regulation, permit, or administrative order is granted immunity from administrative or civil penalty. The Attorney General's January 12, 1997 opinion states that the quoted language renders this statute inapplicable to enforcement of any Federally authorized programs, since "no immunity could be afforded from administrative, civil, or criminal penalties because granting such immunity would not be consistent with Federal law, which is one of the criteria for immunity."

Therefore, EPA has determined that Virginia's Privilege and Immunity statutes will not preclude the Commonwealth from enforcing its section 111(d)/129 program consistent with the Federal requirements. In any event, because EPA has also determined that a state audit privilege and immunity law can affect only state enforcement and cannot have any impact on Federal enforcement authorities, EPA may at any time invoke its authority under the Clean Air Act, including, for example, sections 113, 167, 205, 211 or 213, to enforce the requirements or prohibitions of the state plan, independently of any state enforcement effort. In addition, citizen enforcement under section 304 of the Clean Air Act is likewise unaffected by this, or any, state audit privilege or immunity law.

## III. Final Action

EPA is approving the Virginia CISWI plan for controlling designated pollutants under sections 111(d) and 129 of the Act. Accordingly, EPA is amending 40 CFR part 62 to reflect this action. As a result, the Federal plan is no longer applicable, as of the effective date of this action.

This approval is based on the rationale discussed above and in further detail in the technical support document (TSD) associated with this action. The DEQ has committed, as part of the plan, to consult with EPA and obtain its concurrence before implementing certain actions as described in the plan narrative, section J, Discretionary Authority, and Regulation for General Administration (9 VAC 5–20–80), Relationship of state regulations to Federal regulations.

As stated above, EPA has no record of receiving a CISWI unit compliance date extension request on or before December 3, 2003, as required by the Federal plan. As a result, neither EPA or the DEQ now have the authority to approve an extension request submitted to either agency after the noted date. Therefore, EPA is taking no action to approve those provisions of Rule 4–45 that relate to a compliance date extension request, sections 9 VAC 5–40–6420 B through 6421 and 6422 B.2. Final compliance or closure for all affected units must be achieved on or before October 3, 2004.

There are other Rule 4–45 provisions that are not relevant or germane to this plan approval action. Those provisions, for example, include requirements relating to odor control. A listing of the Commonwealth rule provisions that are not part of the plan, except for those noted in the previous paragraph, are identified in the plan, Attachment A, and DEQ's April 6, 2004 letter, Attachment C.

As provided by 40 CFR 60.28(c), any revisions to the Virginia plan will not be considered part of the applicable plan until submitted by the DEQ in accordance with 40 CFR 60.28(a) or (b), as applicable, and until approved by EPA in accordance with 40 CFR part 60, subpart B.

EPA is publishing this rule without prior proposal because the Agency views this as a noncontroversial amendment and anticipates no adverse

comments. This action simply reflects already existing Federal requirement for state air pollution control agencies and existing CISWI units that are subject to the provisions of 40 CFR part 60, subparts B and DDDD, respectively. However, in the "Proposed Rules" section of today's **Federal Register**, EPA is publishing a separate document that will serve as the proposal to approve the 111(d) plan should relevant adverse or critical comments be filed. This rule will be effective July 26, 2004 without further notice unless the Agency receives relevant adverse comments by June 24, 2004. If EPA receives adverse comments, EPA will publish a timely withdrawal in the **Federal Register** informing the public that the rule did not take effect. EPA will address all public comments in a subsequent final rule based on the proposed rule. The EPA will not institute a second comment period on this action. Any parties interested in commenting must 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.

## III. Administrative Requirements

### *A. General 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. For this reason, this action is also not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001). 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). This rule also does not have tribal implications because it will not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000). This action also does not have Federalism implications because it does 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). This action 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 "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because it is not economically significant.

In reviewing 111(d)/129 plan 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 111(d)/129 plan submission for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a 111(d)/129 plan submission, to use VCS in place of a 111(d)/129 plan 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. 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.*).

### *B. Submission to Congress and the Comptroller General*

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 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**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

### *C. Petitions for Judicial Review*

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 July 26, 2004. 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, approving the Virginia CISWI plan, may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

**List of Subjects in 40 CFR Part 62**

Environmental protection, Administrative practice and procedure, Air pollution control, Aluminum, Fertilizers, Fluoride, Intergovernmental relations, Paper and paper products industry, Phosphate, Reporting and recordkeeping requirements, Sulfur oxides, Sulfur acid plants, Waste treatment and disposal.

Dated: May 18, 2004.

**Richard J. Kampf,**

*Acting Regional Administrator, Region III.*

■ 40 CFR part 62 is amended as follows:

## PART 62—[AMENDED]

■ 1. The authority citation for part 62 continues to read as follows:

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

## Subpart VV—Virginia

■ 2. A new center heading, after § 62.11620, consisting of §§ 62.11621, 62.11622, 62.11623 is added to read as follows:

Emissions From Existing Commercial Industrial Solid Waste Incinerators (CISWI) Units—Section 111(d)/129 Plan

### § 62.11621 Identification of plan.

Section 111(d)/129 CISWI plan submitted on September 8, 2003, including related supplemental information submitted on August 11, and September 30, 2003, and April 6, 2004.

### § 62.11622 Identification of sources.

The plan applies to all affected CISWI units for which construction commenced on or before November 30, 1999.

**§ 62.11623 Identification of plan.**

Effective date of the plan is July 26, 2004.

[FR Doc. 04–11771 Filed 5–24–04; 8:45 am]
BILLING CODE 6560–50–P

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

### 44 CFR Part 65

**[Docket No. FEMA –B–7446]**

### Changes in Flood Elevation Determinations

**AGENCY:** Federal Emergency Management Agency (FEMA), Emergency Preparedness and Response Directorate, Department of Homeland Security.

**ACTION:** Interim rule.

**SUMMARY:** This interim rule lists communities where modification of the Base (1% annual-chance) Flood Elevations (BFEs) is appropriate because of new scientific or technical data. New flood insurance premium rates will be calculated from the modified BFEs for new buildings and their contents.

**DATES:** These modified BFEs are currently in effect on the dates listed in the table below and revise the Flood Insurance Rate Maps in effect prior to this determination for the listed communities.

From the date of the second publication of these changes in a newspaper of local circulation, any person has ninety (90) days in which to request through the community that the Mitigation Division Director for the Emergency Preparedness and Response Directorate reconsider the changes. The modified BFEs may be changed during the 90-day period.

**ADDRESSES:** The modified BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

**FOR FURTHER INFORMATION CONTACT:** Doug Bellomo, P.E. Hazard Identification Section, Mitigation Division, Emergency Preparedness and Response Directorate, FEMA, 500 C Street, SW., Washington, DC 20472, (202) 646–2903.

**SUPPLEMENTARY INFORMATION:** The modified BFEs are not listed for each community in this interim rule. However, the address of the Chief Executive Officer of the community where the modified BFE determinations are available for inspection is provided.

Any request for reconsideration must be based on knowledge of changed conditions or new scientific or technical data.

The modifications are made pursuant to Section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR Part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified BFEs are the basis for the floodplain management measures that the community is required to either adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program (NFIP).

These modified BFEs, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by the other Federal, State, or regional entities.

The changes BFEs are in accordance with 44 CFR 65.4.

**National Environmental Policy Act**

This rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Consideration. No environmental impact assessment has been prepared.

**Regulatory Flexibility Act**

The Mitigation Division Director for the Emergency Preparedness and Response Directorate certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because modified BFEs are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are required to maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

**Regulatory Classification**

This interim rule is not a significant regulatory action under the criteria of Section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

**Executive Order 12612, Federalism**

This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

**Executive Order 12778, Civil Justice Reform**

This rule meets the applicable standards of Section 2(b)(2) of Executive Order 12778.

**List of Subjects in 44 CFR Part 65**

Flood insurance, Floodplains, Reporting and recordkeeping requirements.

■ Accordingly, 44 CFR Part 65 is amended to read as follows:

## PART 65—[AMENDED]

■ 1. The authority citation for Part 65 continues to read as follows:

**Authority:** 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

**§ 65.4 [Amended]**

■ 2. The tables published under the authority of § 65.4 are amended as follows:

| State and county | Location and case No. | Date and name of newspaper where notice was published | Chief executive office of community | Effective date of modification | Community No. |
|---|---|---|---|---|---|
| Arizona: Maricopa | City of Phoenix (04–09–0654X). | March 18, 2004, March 25, 2004, *Arizona Business Cazette.* | The Honorable Skip Rimsza, Mayor, City of Phoenix, 200 West Washington Street, 11th Floor, Phoenix, Arizona 85003–1611. | June 24, 2004 ..... | 040051 |
| Pima ..... | Town of Marana (04–09–0750P). | March 25, 2004, April 1, 2004, *Daily Territorial.* | The Honorable Bobby Sutton, Jr., Mayor, Town of Marana, 13251 North Lon Adams Road, Marana, Arizona 85653. | April 22, 2004 ..... | 040118 |

| State and county | Location and case No. | Date and name of newspaper where notice was published | Chief executive office of community | Effective date of modification | Community No. |
|---|---|---|---|---|---|
| Pima | Town of Marana (03–09–0698P). | March 25, 2004, April 1, 2004, *Daily Territorial.* | The Honorable Bobby Sutton Jr., Mayor, Town of Marana, 13251 North Lon Adams Road, Marana, Arizona 85653. | July 1, 2004 | 040118 |
| Pima | City of Tucson (03–09–1711P). | April 8, 2004, April 15, 2004, *Daily Territorial.* | The Honorable Bob Walkup, Mayor, City of Tucson, City Hall, 255 West Alameda Street, Tucson, Arizon 85701. | July 15, 2004 | 040076 |
| Pima | Unicorporated Areas (03–09–0698P). | March 25, 2004, April 1, 2004, *Daily Territorial.* | The Honorable Sharon Bronson, Chair, Pima County Board of Supervisors, 130 West Congress Street, 11th Floor, Tucson, Arizona 85701. | July 1, 2004 | 040073 |
| California: | | | | | |
| Humboldt | City of Arcata (03–09–0824P). | February 10, 2004, February 17, 2004, *Arcata Eye.* | The Honorable Robert Ornelas, Mayor, City of Arcata, 736 F Street, Arcata, California 95521. | May 18, 2004 | 060061 |
| Los Angeles | City of Burbank | February 11, 2004, February 18, 2004, *Burbank Leader.* | The Honorable Stacey Murphy, Mayor, City of Burbank, P.O. Box 6459, Burbank, California 91510–6459. | May 19, 2004 | 065018 |
| Los Angeles | City of Los Angeles (04–09–0102P). | March 11, 2004, March 18, 2004, *Los Angeles Times.* | The Honorable James K. Hahn, Mayor, City of Los Angeles, 200 North Spring Street, Room 303, Los Angeles, California 90012. | June 17, 2004 | 060137 |
| Placer | Unincorporated Areas (03–09–1212P). | February 4, 2004, February 11, 2004, *The Rocklin Placer Herald.* | The Honorable Rex Bloomfield, Chairman, Placer County, Board of Supervisors, 175 Fulweiler Avenue, Auburn, California 95603. | January 8, 2004 | 060239 |
| Riverside | City of Moreno Valley (04–09–0122P). | April 1, 2004, April 8, 2004, *Press—Enterprise.* | The Honorable Frank West, Mayor, City of Moreno Valley, 14177 Frederick Street, Moreno Valley, California 92552. | July 8, 2004 | 065074 |
| San Diego | City of Chula Vista (03–09–0900P). | March 5, 2004, March 12, 2004, *Chula Vista Star News.* | The Honorable Stephen C. Padilla, Mayor, City of Chula Vista, City Hall, 276 Fourth Avenue, Chula Vista, California 91910. | June 11, 2004 | 065021 |
| San Diego | City of Oceanside (04–09–0309P). | April 1, 2004, April 8, 2004, *North County Times.* | The Honorable Terry Johnson, Mayor, City of Oceanside, 300 North Coast Highway, Oceanside, California 92054. | July 8, 2004 | 060294 |
| San Diego | City of San Diego (04–09–0108P). | April 8, 2004, April 15, 2004, *San Diego Daily Transcript.* | The Honorable Dick Murphy, Mayor, City of San Diego, 202 C Street, 11th Floor, San Diego, California 92101. | July 15, 2004 | 060295 |
| San Diego | Unincorporated Areas (03–09–1209P). | April 8, 2004, April 15, 2004, *San Diego Union-Tribune.* | The Honorable Dianne Jacob, Chairwoman, San Diego County Board of Supervisors, 1600 Pacific Highway, San Diego, California 92101. | July 15, 2004 | 060284 |
| Ventura | City of Simi Valley (04–09–0234P). | February 12, 2004, February 19, 2004, *Ventura County Star.* | The Honorable William Davis, Mayor, City of Simi Valley, 2929 Tapo Canyon Road, Simi Valley, California 93063–2199. | January 30, 2004 | 060421 |
| Colorado: | | | | | |
| Adams | City of Brighton (03–08–0621P). | February 4, 2004, February 11, 2004, *Brighton Standard Blade.* | The Honorable Jan Pawlowski, Mayor, City of Brighton, 22 South Fourth Avenue, Brighton, Colorado 80601. | May 12, 2004 | 080004 |
| Adams | Unincorporated Areas (03–08–0621P). | February 4, 2004, February 11, 2004, *Brighton Standard Blade.* | The Honorable Elaine T. Valente, Chair, Adams County Board of Commissioners, 450 South Fourth Avenue, Brighton, Colorado 80601. | May 12, 2004 | 08001 |
| Adams | Unincorporated Areas (02–08–398P). | February 6, 2004, February 13, 2004, *Eastern Colorado News.* | The Honorable Elaine T. Valente, Chair, Adams County Board of Commissioners, 450 South Fourth Avenue, Brighton, Colorado 80601. | May 14, 2004 | 08001 |

| State and county | Location and case No. | Date and name of newspaper where notice was published | Chief executive office of community | Effective date of modification | Community No. |
|---|---|---|---|---|---|
| Arapahoe | City of Littleton (03–08–0691P). | March 11, 2004, March 18, 2004, *Littleton Independent.* | The Honorable John Ostermiller, Mayor, City of Littleton, 2255 West Berry Avenue, Littleton, Colorado 80165. | March 1, 2004 | 080017 |
| Douglas | Town of Parker (04–08–0033P). | February 19, 2004, February 26, 2004, *Douglas County News Press.* | The Honorable Gary Lasater, Mayor, Town of Parker, 20120 East Mainstreet, Parker, Colorado 80138. | May 27, 2004 | 080310 |
| El Paso | Unincorporated Areas (03–08–0406P). | March 10, 2004, March 17, 2004, *El Paso County News.* | The Honorable Chuck Brown, Chair, El Paso County Board of Commissioners, 27 East Vermijo Avenue, Colorado Springs, Colorado 80903–2208. | June 16, 2004 | 080059 |
| El Paso | Unincorporated Areas (03–08–0449P). | March 17, 2004, March 24, 2004, *El Paso County News.* | The Honorable Chuck Brown, Chair, El Paso County Board of Commissioners, 27 East Vermijo Avenue, Colorado Springs, Colorado 80903–2208. | June 23, 2004 | 080059 |
| El Paso | Unincorporated Areas (03–08–0617P). | March 17, 2004, March 24, 2004, *El Paso County News.* | The Honorable Chuck Brown, Chair, El Paso County Board of Commissioners, 27 East Vermijo Avenue, Colorado Springs, Colorado 80903–2208. | June 23, 2004 | 080059 |
| Jefferson | City of Lakewood (03–08–0305P). | March 25, 2004, April 1, 2004, *Lakewood Sentinel.* | The Honorable Steve Burkholder, Mayor, City of Lakewood, Lakewood Civic Center South, 480 South Allison Parkway, Lakewood, Colorado 80226. | July 1, 2004 | 085075 |
| Jefferson | Unincorporated Areas (03–080479P). | February 25, 2004, March 3, 2004, *Evergreen Canyon Courier.* | The Honorable Michelle Lawrence, Chairperson, Jefferson County Board of Commissioners, 100 Jefferson County Parkway, Golden, Colorado 80419–5550. | June 2, 2004 | 080087 |
| Jefferson | City of Westminster (03–08–0520P). | January 29, 2004, February 5, 2004, *Westminster Window.* | The Honorable Ed Moss, Mayor, City of Westminster, 4800 West 92nd Avenue, Westminster, Colorado 80031. | May 6, 2004 | 080008 |
| Hawaii: | | | | | |
| Hawaii | Hawaii County (03–09–1531P). | February 12, 2004, February 19, 2004, *Hawaii Tribune Herald.* | The Honorable Harry Kim, Mayor, Hawaii County, 25 Aupuni Street, Hilo, Hawaii 96720. | January 20, 2004 | 155166 |
| Maui | Maui County (03–09–0438P). | March 25, 2004, April 1, 2004, *Maui News.* | The Honorable Alan M. Arawaka, Mayor, Maui County, 200 South High Street, Wailuku, Hawaii 96793–2155. | July 1, 2004 | 150003 |
| Utah: Sevier | City of Salina (04–08–0072P). | February 25, 2004, March 3, 2004, *Richfield Reaper.* | The Honorable Marilyn S. Anderson, Mayor, City of Salina, P.O. Box 69, Salina, Utah 84654. | June 2, 2004 | 490132 |
| Washington: King | City of Bellevue (03–10–0399P). | February 26, 2004, March 4, 2004, *King County Journal.* | The Honorable Connie Marshall, Mayor, City of Bellevue, P.O. Box 90012, Bellevue, Washington 98009–9012. | June 3, 2004 | 530074 |

(Catalog of Federal Domestic Assistance No. 83.100, "Flood Insurance.")

Dated: May 18, 2004.

**Anthony S. Lowe,**

*Mitigation Division Director, Emergency Preparedness and Response Directorate.*

[FR Doc. 04–11760 Filed 5–24–04; 8:45 am]

BILLING CODE 9110–11–P

## DEPARTMENT OF TRANSPORTATION

### Federal Railroad Administration

### 49 CFR Part 232

[FRA Docket No. PB–9; Notice No. 22]

RIN 2130–AB52

## Brake System Safety Standards for Freight and Other Non-Passenger Trains and Equipment; End-of-Train Devices

**AGENCY:** Federal Railroad Administration (FRA), DOT.

**ACTION:** Final rule; adjustment of schedule of civil penalties.

**SUMMARY:** This document amends the schedule of civil penalties for violations of part 232 to make it consistent with the primary final rule in this proceeding or with subsequent changes made in the text of the regulation in response to petitions for reconsideration. These changes are technical amendments made solely to the schedule of civil penalties contained in appendix A to part 232, are a statement of agency policy, and are consistent with FRA's

intent when issuing the final rule and its response to petitions for reconsideration in this proceeding. The adjustments will enhance FRA's safety enforcement program by ensuring that the regulated community is fully aware of its potential civil penalty liability and by ensuring that appropriate civil penalties are assessed when taking enforcement actions.

**DATES:** *Effective Date:* The revision of Appendix A to part 232 is effective May 25, 2004.

**ADDRESSES:** Any petition for reconsideration should reference FRA Docket No. PB–9, Notice No. 22, and be submitted in triplicate to the FRA Docket Clerk, Office of Chief Counsel, RCC–10, 1120 Vermont Avenue, NW., Mail Stop 10, Washington, DC 20590.

**FOR FURTHER INFORMATION CONTACT:** James Wilson, FRA Office of Safety, RRS–14, 1120 Vermont Avenue, NW., Stop 25, Washington, DC 20590 (telephone 202–493–6259), or Thomas Herrmann, Trial Attorney, Office of the Chief Counsel, RCC–10, 1120 Vermont Avenue, NW., Stop 10, Washington, DC 20590 (telephone 202–493–6053).

**SUPPLEMENTARY INFORMATION:**

## Background

On January 17, 2001, FRA published a final rule revising the Federal safety standards governing braking systems and equipment used in freight and other non-passenger railroad train operations. *See* 66 FR 4104–217. The effective date of the final rule was May 31, 2001. *See* 66 FR 9906 (February 12, 2001) and 66 FR 29501 (May 31, 2001). The final rule contained staggered implementation dates with the majority of the rule becoming applicable on April 1, 2004. *See* 49 CFR 232.1(b) and 66 FR 4193. In response to the final rule, FRA received six petitions for reconsideration from seven parties raising various issues related to a number of the provisions contained in the final rule.

On August 1, 2001, FRA published an initial response to the petitions for reconsideration of the final rule addressing those issues raised in the petitions related to the periodic maintenance and testing requirements prescribed in subpart D of the final rule. *See* 66 FR 39683. FRA believed that it was necessary to address these issues as quickly as possible because the periodic maintenance and testing requirements prescribed in subpart D of the final rule had a compliance date of August 1, 2001. Due to the complexity of some of the issues raised in the petitions for reconsideration on other provisions of the final rule, FRA decided to address the issues related to subpart D in its initial response to the petitions and then issue a follow-up response addressing the issues pertaining to other portions of the final rule. *See id.* On April 10, 2002, FRA published its second response to petitions for reconsideration addressing all other outstanding issues raised in the petitions for reconsideration. *See* 67 FR 17556–85.

This document amends the schedule of civil penalties contained in appendix A to part 232 to make it consistent with the January 2001 final rule or with the changes made in the text in response to petitions for reconsideration. These changes are technical adjustments or corrections made solely to the schedule of civil penalties contained in Appendix A to part 232, are a statement of agency policy, and are consistent with FRA's intent when issuing the final rule and its response to petitions for reconsideration in this proceeding. The adjustments will enhance FRA's safety enforcement program by ensuring that the regulated community is fully aware of its potential civil penalty liability and by ensuring appropriate civil penalties are assessed when taking enforcement actions.

## Discussion of Corrections and Modifications

This document is making six corrections or adjustments to the schedule of civil penalties contained in Appendix A to part 232. First, the listed civil penalties associated with § 232.205 are being corrected to reflect the changes made to this section by FRA second response to petitions for reconsideration. In that response, a new paragraph (b) was added to this section to clarify the inspection requirements related to the addition of solid blocks of cars, and paragraph (f) of the section was removed to avoid duplication. *See* 69 FR 17573–75, 17582. Thus, what were paragraphs (b) through (e) of this section in the January 2001 final rule are now paragraphs (c) through (f). However, the penalty schedule was never modified to reflect these changes. Consequently, FRA is correcting the penalty schedule items for this section to reflect the above-noted amendments.

Secondly, a typographical error in the penalty schedule amount associated with § 232.207(a) is also being corrected. The January 2001 final rule showed the civil penalty for a complete failure to perform a Class IA brake test as $15,000. *See* 66 FR 4212. This should have read $5,000 and is being so corrected.

Third, the penalty schedule items associated with the Class II brake test provisions of § 232.209 are being adjusted by adding a clarifying citation for paragraph (d) of this section. Paragraph (d) of this section requires the performance of a Class I brake test on any car added to a train via a Class II brake test at the next forward location where facilities are available for performing such a test. The clarifying adjustment directs the reader to the footnote following the schedule of civil penalties, which makes clear that the penalties associated with the failure to perform a proper Class I brake test would be applicable in these instances.

Fourth, FRA is also amending the penalty schedule items associated with Class III brake tests requirements contained in § 232.211. When issuing its second response to petitions for reconsideration of the final rule, FRA added a paragraph (d) containing a modified Class III brake test in those instances where the continuity of a train's brake pipe is broken or interrupted with the train otherwise remaining unchanged. *See* 67 FR 17583. However, at the time the provision was added, no specific civil penalty was associated to a violation of the new provision. This document amends the schedule of civil penalties by adding a specific reference to paragraph (d) of this section and assigns a certain civil penalty consistent with a partial failure to perform a Class III brake test.

Fifth, the items in the schedule related to the extended haul train provisions of § 232.213 are being clarified to include a potential civil penalty amount for the general operation provision of paragraph (b) of this section. This penalty is currently applied to situations where an extended haul train is operated outside the restrictions contained in paragraph (a) that are not otherwise specifically covered by the penalties associated with that paragraph. For example, this would include such acts as exceeding the allowable number of pick-ups or set-outs with an extended haul train.

Finally, FRA is making corrections to the penalty items associated with §§ 232.213(a)(2)–(3), (5)(i), and (8), and 232.217(c). The items associated with these sections direct the reader to footnote (2) at the end of the schedule of civil penalties. Because there is only one footnote at the end of the penalty schedule, the reference for the above-noted provisions is being corrected to cite to footnote (1).

## General Information

As the amendments contained in this document are minor corrections or adjustments to the existing schedule of civil penalties associated with part 232, which constitutes a general statement of agency policy relating potential civil penalty assessment amounts, FRA is

issuing this document as a final rule. FRA views the amendments as technical corrections to a general statement of agency policy and not a substantive rule. Consequently, FRA believes that, pursuant to 5 U.S.C. 553(b)(3)(A) and (B), this action is both exempted from the requirement for prior public notice and that good cause exists for finding that prior public notice of this action is unnecessary.

**Regulatory Impact**

*Executive Order 12866 and DOT Regulatory Policies and Procedures*

This final rule has been evaluated in accordance with Executive Order 12866 and DOT policies and procedures. The modifications contained in this final rule are not considered significant because they are intended merely to correct and adjust the schedule of civil penalties associated with part 232 consistent with FRA's intent when publishing the primary final rule in this proceeding on January 17, 2001. No changes or modifications are being made to any regulatory provision contained in part 232. There is no economic impact caused by the corrections and clarifications contained in this final rule.

*Regulatory Flexibility Act*

The Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) requires a review of rules to assess their impact on small entities. FRA certifies that this final rule does not have a significant impact on a substantial number of small entities. Because the modifications contained in this final rule merely correct and adjust the schedule of civil penalties associated with part 232 and because no changes or modifications are being made to any regulatory provision contained in part 232, FRA has concluded that there are no substantial economic impacts on small units of government, businesses, or other organizations.

*Paperwork Reduction Act*

Because the modifications contained in this final rule merely correct and adjust the schedule of civil penalties associated with part 232 and because no changes or modifications are being made to any regulatory provision contained in part 232, this final rule does not change any of the information collection requirements contained in part 232.

*Environmental Impact*

FRA has evaluated this final rule in accordance with its "Procedures for Considering Environmental Impacts" (FRA's Procedures) (64 FR 28545, May 26, 1999) as required by the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), other environmental statutes, Executive Orders, and related regulatory requirements. FRA has determined that this document is not a major FRA action (requiring the preparation of an environmental impact statement or environmental assessment) because it is categorically excluded from detailed environmental review pursuant to section 4(c) of FRA's Procedures.

*Federalism Implications*

FRA believes it is in compliance with Executive Order 13132. Because the modifications contained in this final rule merely correct and adjust the schedule of civil penalties associated with part 232 and because no changes or modifications are being made to any regulatory provision contained in part 232, this document will not have a substantial 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. This final rule will not have federalism implications that impose any direct compliance costs on State and local governments.

*Unfunded Mandates Reform Act of 1995*

Pursuant to Section 201 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 2 U.S.C. 1531), each Federal agency "shall, unless otherwise prohibited by law, assess the effects of Federal regulatory actions on State, local, and tribal governments, and the private sector (other than to the extent that such regulations incorporate requirements specifically set forth in law)." Section 202 of the Act (2 U.S.C. 1532) further requires that "before promulgating any general notice of proposed rulemaking that is likely to result in the promulgation of any rule that includes any Federal mandate that may result in expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year, and before promulgating any final rule for which a general notice of proposed rulemaking was published, the agency shall prepare a written statement" detailing the effect on State, local, and tribal governments and the private sector. The statutory figure of $100,000,000 has been adjusted upward for inflation to $120,700,000. Because the modifications contained in this final rule merely correct and adjust the schedule of civil penalties associated with part 232 and because no changes or modifications are being made to any regulatory provision contained in part 232, this document will not result in the expenditure, in the aggregate, of $120,700,000 or more in any one year, and thus preparation of such a statement is not required.

*Energy Impact*

Executive Order 13211 requires Federal agencies to prepare a Statement of Energy Effects for any "significant energy action." 66 FR 28355 (May 22, 2001). Under the Executive Order, a "significant energy action" is defined as any action by an agency (normally published in the **Federal Register**) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking: (1)(i) That is a significant regulatory action under Executive Order 12866 or any successor order, and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) that is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. FRA has evaluated this final rule in accordance with Executive Order 13211. Because the modifications contained in this final rule merely correct and adjust the schedule of civil penalties associated with part 232 and because no changes or modifications are being made to any regulatory provision contained in part 232, FRA has determined that this document will not have a significant adverse effect on the supply, distribution, or use of energy. Consequently, FRA has determined that this regulatory action is not a "significant energy action" within the meaning of Executive Order 13211.

**List of Subjects in 49 CFR Part 232**

Penalties, Railroad power brakes, Railroad safety.

**Adoption of the Amendments**

■ For the reasons set forth in the preamble, part 232 of chapter II, subtitle B of title 49 of the Code of Federal Regulations is amended to read as follows:

**PART 232—[AMENDED]**

■ 1. The authority citation for part 232 is revised to read as follows:

**Authority:** 49 U.S.C. 20102–20103, 20107, 20133, 20141, 20301–20303, 20306, 21301–21302, 21304; 28 U.S.C. 2461, note; 49 CFR 1.49 (c), (m).

■ 2. Appendix A to part 232 is revised to read as follows:

## APPENDIX A TO PART 232.—SCHEDULE OF CIVIL PENALTIES [1]

| Section | Violation | Willful violation |
|---|---|---|
| **Subpart A—General** | | |
| 232.15 Movement of power brake defects: | | |
| (a) Improper movement, general | ([1]) | ([1]) |
| (11) Failure to make determinations and provide notification of en route defect | $2,500 | $5,000 |
| (b) Complete failure to tag | 2,500 | 5,000 |
| (1) Insufficient tag or record | 1,000 | 2,000 |
| (2), (4) Improper removal of tag | 2,000 | 4,000 |
| (3) Failure to retain record of tag | 2,000 | 4,000 |
| (c) Improper loading or purging | 2,500 | 5,000 |
| (e) Improper placement of defective equipment | 2,500 | 5,000 |
| 232.19 Availability of records | ([1]) | ([1]) |
| **Subpart B—General Requirements** | | |
| 232.103 All train brake systems: | | |
| (a)–(c), (h)–(i) Failure to meet general design requirements | 2,500 | 5,000 |
| (d) Failure to have proper percentage of operative brakes from Class I brake test | 5,000 | 7,500 |
| (e) Operating with less than 85 percent operative brakes | 5,000 | 7,500 |
| (f) Improper use of car with inoperative or ineffective brakes | 2,500 | 5,000 |
| (g) Improper display of piston travel | 2,500 | 5,000 |
| (m) Failure to stop train with excess air flow or gradient | 2,500 | 5,000 |
| (n) Securement of unattended equipment: | | |
| (1) Failure to apply sufficient number of hand brakes; failure to develop or implement procedure to verify number applied | 5,000 | 7,500 |
| (2) Failure to initiate emergency | 2,500 | 5,000 |
| (3) Failure to apply hand brakes on locomotives | 2,500 | 5,000 |
| (4) Failure to adopt or comply with procedures for securing unattended locomotive | 5,000 | 7,500 |
| (o) Improper adjustment of air regulating devices | 2,500 | 5,000 |
| (p) Failure to hold supervisors jointly responsible | 2,500 | 5,000 |
| 232.105 Locomotives: | | |
| (a) Air brakes not in safe and suitable condition | 1,000–5,000 | 2,000–7,500 |
| (b) Not equipped with proper hand or parking brake | 5,000 | 7,500 |
| (c)(1) Failure to inspect/repair hand or parking brake | 2,500 | 5,000 |
| (2) Failure to properly stencil, tag, or record | 2,000 | 4,000 |
| (d) Excess leakage from equalizing reservoir | 2,500 | 5,000 |
| (e) Improper use of feed or regulating valve braking | 2,500 | 5,000 |
| (f) Improper use of passenger position | 2,500 | 5,000 |
| (g) Brakes in operative condition | 2,500 | 5,000 |
| 232.107 Air sources/cold weather operations: | | |
| (a)(1), (2) Failure to adopt or comply with monitoring program for yard air sources | 5,000 | 7,500 |
| (3) Failure to maintain records | 2,500 | 5,000 |
| (b) Failure to blow condensation | 2,500 | 5,000 |
| (c) Use of improper chemicals | 5,000 | 7,500 |
| (d) Failure to equip or drain yard air reservoirs | 2,500 | 5,000 |
| (e) Failure to adopt or comply cold weather operating procedures | 5,000 | 7,500 |
| 232.109 Dynamic brakes: | | |
| (a) Failure to provide information | 5,000 | 7,500 |
| (b) Failure to make repairs | 5,000 | 7,500 |
| (c) Failure to properly tag | 2,500 | 5,000 |
| (d) Failure to maintain record of repair | 2,000 | 4,000 |
| (e) Improper deactivation | 2,500 | 5,000 |
| (f) Improper use of locomotive as controlling unit | 2,500 | 5,000 |
| (g) Locomotive not properly equipped with indicator | 2,500 | 5,000 |
| (h) Rebuilt locomotive not properly equipped | 2,500 | 5,000 |
| (j) Failure to adopt or comply with dynamic brake operating rules | 5,000 | 7,500 |
| (k) Failure to adopt or comply with training on operating procedures | 5,000 | 7,500 |
| 232.111 Train handling information: | | |
| (a) Failure to adopt and comply with procedures | 5,000 | 7,500 |
| (b) Failure to provide specific information | 2,500 | 5,000 |
| **Subpart C—Inspection and Testing Requirements** | | |
| 232.203 Training requirements: | | |
| (a) Failure to develop or adopt program | 7,500 | 11,000 |
| (b)(1)–(9) Failure to address or comply with specific required item or provision of program | 5,000 | 7,500 |
| (c) Failure to adopt or comply with two-way EOT program | 5,000 | 7,500 |
| (d) Failure to adopt or comply with retaining valve program | 5,000 | 7,500 |
| (e) Failure to maintain adequate records | 5,000 | 7,500 |
| (f) Failure to adopt and comply with periodic assessment plan | 7,500 | 11,000 |
| 232.205 Class I brake test—initial terminal inspection: | | |
| (a) Complete failure to perform inspection | ([1])10,000 | 15,000 |
| (c)(1)–(4), (6)–(8) Partial failure to perform inspection | 5,000 | 7,500 |
| (c)(5) Failure to properly adjust piston travel (per car) | 2,500 | 5,000 |
| (d) Failure to use carman when required | 5,000 | 7,500 |

APPENDIX A TO PART 232.—SCHEDULE OF CIVIL PENALTIES [1]—Continued

| Section | Violation | Willful violation |
|---|---|---|
| (e) Failure to provide proper notification | 2,500 | 5,000 |
| (f) Failure to void compressed air | 2,500 | 5,000 |
| 232.207 Class IA brake tests—1,000-mile inspection: | | |
| (a) Complete failure to perform inspection | [1]5,000 | 7,500 |
| (b)(1)–(6) Partial failure to perform inspection | 2,500 | 5,000 |
| (c) Failure to properly designate location | 5,000 | 7,500 |
| (c)(1) Failure to perform at designated location | 5,000 | 7,500 |
| (c)(2) Failure to provide notification | 2,500 | 5,000 |
| 232.209 Class II brake tests—intermediate inspection: | | |
| (a) Complete failure to perform inspection | [1]5,000 | 7,500 |
| (b)(1)–(5), (c) Partial failure to perform inspection | 2,500 | 5,000 |
| (d) Failure to conduct Class I after Class II pick-up | [1] | [1] |
| 232.211 Class III brake tests—trainline continuity inspection: | | |
| (a) Complete failure to perform inspection | 5,000 | 7,500 |
| (b)(1)–(4), (c) Partial failure to perform inspection | 2,500 | 5,000 |
| (d) Failure to restore air pressure at rear | 2,500 | 2,500 |
| 232.213 Extended haul trains: | | |
| (a)(1) Failure to properly designate an extended haul train | 5,000 | 7,500 |
| (a)(2)–(3), (5)(i), (8) Failure to perform inspections | [1] | [1] |
| (a)(4) Failure to remove defective car (per car) | 2,000 | 4,000 |
| (a)(5)(ii), (6) Failure to conduct inbound inspection | 5,000 | 7,500 |
| (a)(7) Failure to maintain record of defects (per car) | 2,000 | 4,000 |
| (b) Improper movement or use of extended haul train | 5,000 | 7,500 |
| 232.215 Transfer train brake tests: | | |
| (a) Failure to perform inspection | 5,000 | 7,500 |
| (b) Failure to perform on cars added | 2,500 | 5,000 |
| 232.217 Train brake system tests conducted using yard air: | | |
| (a) Failure to use suitable device | 2,500 | 5,000 |
| (b) Improper connection of air test device | 5,000 | 7,500 |
| (c) Failure to properly perform inspection | [1] | [1] |
| (d) Failure to calibrate test device | 2,500 | 5,000 |
| (e) Failure to use accurate device | 2,500 | 5,000 |
| 232.219 Double heading and helper service: | | |
| (a) Failure to perform inspection or inability to control brakes | 2,500 | 5,000 |
| (b) Failure to make visual inspection | 2,500 | 5,000 |
| (c) Use of improper helper link device | 2,500 | 5,000 |
| **Subpart D—Perlodic Maintenance and Testing Requirements** | | |
| 232.303 General requirements: | | |
| (b)–(d) Failure to conduct inspection or test when car on repair track | 2,500 | 5,000 |
| (e) Improper movement of equipment for testing | 2,500 | 5,000 |
| (e)(1) Failure to properly tag equipment for movement | 2,000 | 5,000 |
| (e)(2)–(4) Failure to retain record or improper removal of tag or card | 2,000 | 4,000 |
| (f) Failure to stencil or track test information | 2,500 | 5,000 |
| 232.305 Repair track air brake tests: | | |
| (a) Failure to test in accord with required procedure | 2,500 | 5,000 |
| (b)–(d) Failure to perform test | 2,500 | 5,000 |
| 232.307 Single car tests: | | |
| (a) Failure to test in accord with required procedure | 2,500 | 5,000 |
| (b)–(c) Failure to perform test | 2,500 | 5,000 |
| 232.309 Repair track air brake test and single car test equipment and devices: | | |
| (a)–(f) Failure to properly test or calibrate | 2,500 | 5,000 |
| **Subpart E—End-of-Train Devices** | | |
| 232.403 Design standards for one-way devices: | | |
| (a)–(g) Failure to meet standards | 2,500 | 5,000 |
| 232.405 Design standards for two-way devices: | | |
| (a)–(i) Failure to meet standards | 2,500 | 5,000 |
| 232.407 Operating requirements for two-way devices: | | |
| (b) Failure to equip a train | 5,000 | 7,500 |
| (c) Improper purchase | 2,500 | 5,000 |
| (f)(1) Failure of device to be armed and operable | 5,000 | 7,500 |
| (f)(2) Insufficient battery charge | 2,500 | 5,000 |
| (f)(3) Failure to activate the device | 2,500 | 5,000 |
| (g) Improper handling of en route failure, freight or other non-passenger | 5,000 | 7,500 |
| (h) Improper handling of en route failure, passenger | 5,000 | 7,500 |
| 232.409 Inspection and testing of devices: | | |
| (a) Failure to have unique code | 2,500 | 5,000 |
| (b) Failure to compare quantitative values | 2,500 | 5,000 |
| (c) Failure to test emergency capability | 5,000 | 7,500 |
| (d) Failure to properly calibrate | 2,500 | 5,000 |

APPENDIX A TO PART 232.—SCHEDULE OF CIVIL PENALTIES [1]—Continued

| Section | Violation | Willful violation |
|---|---|---|
| **Subpart F—Introduction of New Brake System Technology** | | |
| 232.503 Process to introduce new technology: | | |
| (b) Failure to obtain FRA approval | 10,000 | 15,000 |
| 232.505 Pre-revenue service acceptance testing plan: | | |
| (a) Failure to obtain FRA approval | 5,000 | 7,500 |
| (b) Failure to comply with plan | 2,500 | 5,000 |
| (f) Failure to test previously used technology | 5,000 | 7,500 |

[1] A penalty may be assessed against an individual only for a willful violation. Generally, when two or more violations of these regulations are discovered with respect to a single unit of equipment that is placed or continued in service by a railroad, the appropriate penalties set forth above are aggregated up to a maximum of $11,000 per day. An exception to this rule is the $15,000 penalty for willful violation of § 232.503 (failure to get FRA approval before introducing new technology) with respect to a single unit of equipment; if the unit has additional violative conditions, the penalty may routinely be aggregated to $15,000. Although the penalties listed for failure to perform the brake inspections and tests under § 232.205 through § 232.209 may be assessed for each train that is not properly inspected, failure to perform any of the inspections and tests required under those sections will be treated as a violation separate and distinct from, and in addition to, any substantive violative conditions found on the equipment contained in the train consist. Moreover, the Administrator reserves the right to assess a penalty of up to $22,000 for any violation where circumstances warrant. *See* 49 CFR part 209, appendix A.

Failure to observe any condition for movement of defective equipment set forth in § 232.15(a) will deprive the railroad of the benefit of the movement-for-repair provision and make the railroad and any responsible individuals liable for penalty under the particular regulatory section(s) concerning the substantive defect(s) present on the equipment at the time of movement.

Failure to provide any of the records or plans required by this part pursuant to § 232.19 will be considered a failure to maintain or develop the record or plan and will make the railroad liable for penalty under the particular regulatory section(s) concerning the retention or creation of the document involved.

Failure to properly perform any of the inspections specifically referenced in § 232.209, § 232.213, and § 232.217 may be assessed under each section of this part or this chapter, or both, that contains the requirements for performing the referenced inspection.

Issued in Washington, DC, on May 18, 2004.

**Allan Rutter,**

*Federal Railroad Administrator.*

[FR Doc. 04–11696 Filed 5–24–04; 8:45 am]

BILLING CODE 4910–06–P

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

### 50 CFR Part 17

**RIN 1018–AT64**

## Withdrawal of Regulations Governing Incidental Take Permit Revocation

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Final rule.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), withdraw the regulations in part 17 of title 50 of the Code of Federal Regulations (CFR) regarding the revocation of incidental take permits issued under the authority of the Endangered Species Act (ESA). On December 11, 2003, the U.S. District Court for the District of Columbia in *Spirit of the Sage Council* v. *Norton*, Civil Action No. 98–1873 (D.D.C.), invalidated 50 CFR 17.22(b)(8) and 17.32(b)(8), the regulations addressing Service authority to revoke incidental take permits under certain circumstances. The court ruled that we did not follow the public notice and comment procedures required by the Administrative Procedure Act (APA). This rule affects only 50 CFR 17.22(b)(8) and 17.32(b)(8). In the Proposed Rules section of today's **Federal Register** is a rulemaking proposal to reestablish the provisions of 50 CFR 17.22(b)(8) and 17.32(b)(8).

**DATES:** This rule is effective May 25, 2004.

**ADDRESSES:** The complete file for this rule is available, by appointment, during normal business hours, at 4401 North Fairfax Drive, Room 420, Arlington, VA 22203. You may call 703/358–2171 to make an appointment to view the files.

**FOR FURTHER INFORMATION CONTACT:** Rick Sayers, Chief, Branch of Consultation and Habitat Conservation Planning, at 4401 North Fairfax Drive, Room 420, Arlington, VA 22203 (Telephone 703/358–2106, Facsimile 703/358–1735).

**SUPPLEMENTARY INFORMATION:** This rule applies to the U.S. Fish and Wildlife Service only. Therefore, the use of the terms "Service" and "we" in this notice refers exclusively to the U.S. Fish and Wildlife Service.

This rule applies only to 50 CFR 17.22(b)(8) and 17.32(b)(8), which pertain to revocation of incidental take permits. Regulations in 50 CFR 17.22(c) and 17.32(c) that pertain to Safe Harbor Agreements (SHAs) and in 50 CFR 17.22(d) and 17.32(d) that pertain to Candidate Conservation Agreements with Assurances (CCAAs) are not affected by this final rule.

### Background

On June 12, 1997 (62 FR 32189), we published proposed revisions to our general permitting regulations in 50 CFR part 13 to identify the situations in which permit provisions in part 13 would not apply to individual incidental take permits. On June 17, 1999 (64 FR 32706), we published final regulations that included a provision, hereafter referred to as the Permit Revocation Rule, that described circumstances under which incidental take permits could be revoked. The Permit Revocation Rule, which was codified at 50 CFR 17.22(b)(8) (endangered species) and 17.32(b)(8) (threatened species), provided that an incidental take permit "may not be revoked * * * unless continuation of the permitted activity would be inconsistent with the criterion set forth in 16 U.S.C. 1539(a)(2)(B)(iv) and the inconsistency has not been remedied in a timely fashion." The criterion in 16 U.S.C. 1539(a)(2)(B)(iv)—that "the taking will not appreciably reduce the likelihood of the survival and recovery of the species in the wild"—is substantially identical to the definition of "jeopardize the continued existence of" in the joint Department of the Interior/Department of Commerce regulations implementing section 7 of the Endangered Species Act (50 CFR 402.02). In essence, the Permit Revocation Rule authorized the Service to revoke an incidental take permit if continuation of the permitted activity would jeopardize the continued existence of the listed species and the

jeopardy situation is not remedied in a timely fashion. On September 30, 1999 (64 FR 52676), we published a correction to the regulations promulgated in our June 17, 1999 (64 FR 32706), final rule; however, the correction was not associated with permit revocation.

On February 11, 2000 (65 FR 6916), we published a request for additional public comment on specific regulatory changes included in the June 17, 1999 (64 FR 32706), final rule, including the Permit Revocation Rule. Based on our review of the comments we received in response to the February 11, 2000 (65 FR 6916), request for comments, we published a notice on January 22, 2001 (66 FR 6483), that affirmed the provisions of the June 17, 1999 (64 FR 32706), final rule, including the Permit Revocation Rule.

The plaintiffs in *Spirit of the Sage Council* v. *Norton,* Civil Action No. 98–1873 (D.D.C.), challenged the validity of the Permit Revocation Rule. On December 11, 2003, the court ruled that the public notice and comment procedures followed by the Service when promulgating the Permit Revocation Rule were in violation of the APA. The court vacated and remanded the Permit Revocation Rule to the Service for further consideration consistent with section 553 of the APA. In compliance with the court's order, we therefore withdraw the Permit Revocation Rule (50 CFR 17.22(b)(8) and 17.32(b)(8)).

**Effective Date**

In accordance with 5 U.S.C. 553(d)(3), we find good cause to make this rule effective upon publication. Moreover, in accordance with 5 U.S.C. 553(b)(3)(B), we find good cause that notice and public procedure for this rulemaking action are impracticable, unnecessary, or contrary to the public interest. We must remove the text identified in this rule from 50 CFR 17 because the December 11, 2003, court order in *Spirit of the Sage Council* v. *Norton,* Civil Action No. 98–1873 (D.D.C.) vacated this text.

**List of Subjects in 50 CFR Part 17**

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

**Regulation Promulgation**

■ For the reasons set out in the preamble, we amend title 50, chapter I, subchapter B of the Code of Federal Regulations, as set forth below.

## PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

**Authority:** 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

**§ 17.22 [Amended]**

■ 2. Amend § 17.22 by removing paragraph (b)(8).

**§ 17.32 [Amended]**

■ 3. Amend § 17.32 by removing paragraph (b)(8).

Dated: April 12, 2004.

**Craig Manson,**

*Assistant Secretary for Fish and Wildlife and Parks.*

[FR Doc. 04–11740 Filed 5–24–04; 8:45 am]

BILLING CODE 4310–55–P

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### 50 CFR Part 679

**[Docket No. 031124287–4060–02; I.D. 051804B]**

## Fisheries of the Exclusive Economic Zone Off Alaska; Rock Sole in the Bering Sea and Aleutian Islands Area

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

**ACTION:** Apportionment of reserve; request for comments.

**SUMMARY:** NMFS apportions amounts of the non-specified reserve of groundfish in the Bering Sea and Aleutian Islands management area (BSAI) to rock sole. This action is necessary to account for previous harvest of the total allowable catch (TAC). It is intended to promote the goals and objectives of the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area (FMP).

**DATES:** Effective May 25, 2004. Comments must be received no later than 4:30 p.m., Alaska local time, June 8, 2004.

**ADDRESSES:** Send comments to Sue Salveson, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region, NMFS, Attn: Lori Durall. Comments may be submitted by:

- Mail: P.O. Box 21668, Juneau, AK 99802–1668;
- Hand Delivery to the Federal Building: 709 West 9th Street, Room 420A, Juneau, AK;
- Fax: 907–586–7557;
- E-mail: *bsairel04__1@noaa.gov* Include in the subject line of the e-mail comment the document identifier: bsairel04__1; or
- Webform at the Federal eRulemaking Portal: *http:www.regulations.gov*. Follow the instructions at that site for submitting comments.

**FOR FURTHER INFORMATION CONTACT:** Josh Keaton, 907–586–7228.

**SUPPLEMENTARY INFORMATION:** NMFS manages the groundfish fishery in the BSAI according to the FMP prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The Administrator, Alaska Region, NMFS, has determined that the initial TAC for rock sole in the BSAI, specified in the final 2004 harvest specifications (69 FR 9242, February 27, 2004) needs to be supplemented from the non-specified reserve in order to continue operations and account for prior harvest.

Therefore, in accordance with § 679.20(b)(3), NMFS proposes to apportion 3,075 metric tons from the non-specified reserve to the rock sole initial TAC in the BSAI. These proposed apportionments are consistent with § 679.20(b)(1)(ii) and do not result in overfishing of a target species because the revised initial TAC is equal to or less than the specification of the acceptable biological catch (69 FR 9242, February 27, 2004).

**Classification**

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA, (AA) finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) and 679.20 (b)(3)(iii)(A) as such a requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent the agency from responding to the most recent fisheries data in a timely fashion and would delay the apportionment of the reserves to the rock sole fishery, thus preventing full utilization of the TAC of rock sole,

cause disruption to the industry and potential economic harm through unnecessary discards. This action will allow for the orderly conduct and efficient operation of the BSAI groundfish fishery. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of May 4, 2004.

The AA also finds good cause to waive the 30–day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

Under § 679.20(b)(3)(iii), interested persons are invited to submit written comments on this action (see **ADDRESSES**) until June 8, 2004.

This action is required by 50 CFR 679.20 and is exempt from review under Executive Order 12866.

**Authority:** 16 U.S.C. 1801, *et seq.*

Dated: May 19, 2004.

**Bruce C. Morehead,**

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

[FR Doc. 04–11799 Filed 5–24–04; 8:45 am]

BILLING CODE 3510–22–S

# Proposed Rules

Federal Register
Vol. 69, No. 101
Tuesday, May 25, 2004

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 AGRICULTURE

### Agricultural Marketing Service

### 7 CFR Part 989

**[Docket No. FV04–989–610 REVIEW]**

### Raisins Produced From Grapes Grown in California

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

**ACTION:** Notice of regulatory review and request for comments.

**SUMMARY:** This document announces that the Agricultural Marketing Service (AMS) plans to review Marketing Order No. 989 for raisins produced from grapes grown in California, under criteria contained in section 610 of the Regulatory Flexibility Act (RFA).

**DATES:** Written comments on this notice must be received by July 23, 2004.

**ADDRESSES:** Interested persons are invited to submit written comments concerning this notice of review. Comments must be sent to the Docket Clerk, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or E-mail: *moab.docketclerk@usda.gov* or *http://www.regulations.gov*. All comments should reference the docket number and the date and page number of this issue of the **Federal Register** and will be made available for public inspection in the Office of the Docket Clerk during regular business hours, or may be viewed at *http://www.ams.usda.gov/fv/moab.html*.

**FOR FURTHER INFORMATION CONTACT:** Martin Engeler, Assistant Regional Manager, or Maureen T. Pello, Senior Marketing Specialist, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 2202 Monterey Street, Suite 102B, Fresno, CA 93721; telephone: (559) 487–5901; Fax: (559) 487–5906; E-mail: *Martin.Engeler@usda.gov* or *Maureen.Pello@usda.gov*; or George Kelhart, Technical Advisor, Marketing Order Administration Branch, Fruit and Vegetable Programs, AMS, USDA, 1400 Independence Avenue, SW., STOP 0237, Washington, DC 20250–0237; telephone: (202) 720–2491; Fax: (202) 720–8938; or E-mail: *George.Kelhart@usda.gov*.

**SUPPLEMENTARY INFORMATION:** Marketing Order No. 989, as amended (7 CFR part 989), regulates the handling of raisins produced from grapes grown in California. The marketing order is effective under the Agricultural Marketing Agreement Act of 1937 (AMAA), as amended (7 U.S.C. 601–674).

AMS initially published in the **Federal Register** (63 FR 8014; February 18, 1999), its plan to review certain regulations, including Marketing Order No. 989, under criteria contained in section 610 of the Regulatory Flexibility Act (RFA; 5 U.S.C. 601–612). Updated plans were published in the **Federal Register** on January 4, 2002 (67 FR 525), and again on August 14, 2003 (68 FR 48574). Because many AMS regulations impact small entities, AMS has decided, as a matter of policy, to review certain regulations which, although they may not meet the threshold requirement under section 610 of the RFA, warrant review.

The purpose of the review will be to determine whether the marketing order for raisins produced from grapes grown in California should be continued without change, amended, or rescinded (consistent with the objectives of the AMAA) to minimize the impacts on small entities. In conducting this review, AMS will consider the following factors: (1) The continued need for the marketing order; (2) the nature of complaints or comments received from the public concerning the marketing order; (3) the complexity of the marketing order; (4) the extent to which the marketing order overlaps, duplicates, or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and (5) the length of time since the marketing order has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the marketing order.

Written comments, views, opinions, and other information regarding the raisin marketing order's impact on small businesses are invited.

Dated: May 19, 2004.

**A.J. Yates,**

*Administrator, Agricultural Marketing Service.*

[FR Doc. 04–11742 Filed 5–24–04; 8:45 am]

**BILLING CODE 3410–02–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### 14 CFR Part 39

**[Docket Nos. 2002–CE–05–AD and 2002–CE–57–AD]**

**RIN 2120–AA64**

### Airworthiness Directives; Cessna Aircraft Company Models 401, 401A, 401B, 402, 402A, 402B, 402C, 411, 411A, and 414A Airplanes

**AGENCY:** Federal Aviation Administration, DOT.

**ACTION:** Proposed rules; Withdrawal.

**SUMMARY:** This document withdraws two notices of proposed rulemaking (NPRMs) that would have applied to Cessna Aircraft Company (Cessna) Models 401, 401A, 401B, 402, 402A, 402B, 402C, 411, 411A, and 414A airplanes. The proposed ADs would have superseded existing ADs and would have required you to repetitively inspect the wing spar caps of all airplanes for fatigue cracks and repair or replace as necessary and incorporate a spar strap modification on each wing spar on certain airplanes. The FAA has decided not to issue the new ADs as proposed. We will propose ADs after alternative solutions are developed.

**ADDRESSES:** You may view the AD dockets at FAA, Central Region, Office of the Regional Counsel, Attention: Rules Docket No. 2002–CE–05–AD or Rules Docket No. 2002–CE–57–AD, 901 Locust, Room 506, Kansas City, Missouri 64106. Office hours are 8 a.m. to 4 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Paul Nguyen, Aerospace Engineer, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Mid-Continent Airport, Wichita, Kansas 67209; telephone: (316) 946–4125; facsimile: (316) 946–4107.

**SUPPLEMENTARY INFORMATION:**

**Discussion**

*What action has FAA taken to date?* We issued proposals to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include two ADs that would apply to Cessna Models 401, 401A, 401B, 402, 402A, 402B, 402C, 411, and 411A, 414A airplanes. These proposals (Docket Nos. 2002–CE–05–AD and 2002–CE–57–AD) were published in the **Federal Register** as notices of proposed rulemaking (NPRMs) on May 15, 2003 (68 FR 26239 and 68 FR 26244). The NPRMs proposed the following:

• Docket No. 2002–CE–05–AD: applies to Cessna Models 401, 401A, 401B, 402, 402A, 402B, 411, and 411A airplanes and proposed to supersede AD 79–10–15 R2 with a new AD that would require one of the following (depending on the aircraft configuration):

—*For airplanes that do not incorporate one of the specified Cessna Service Kits:* Repetitively inspect the wing spar caps for fatigue cracks and repair or replace the wing spar caps as necessary and incorporate a spar strap modification on each wing spar; or

—*For airplanes that incorporate one of the specified Cessna Service Kits:* Repetitively inspect the wing spar caps for fatigue cracks and repair or replace the wing spar caps as necessary.

• Docket No. 2002–CE–57–AD: applies to Cessna Models 402C and 414A airplanes and proposed to supersede AD 2000–23–01 with a new AD that would require you to:

—Inspect the wing spar caps for fatigue cracks;

—Repair or replace the wing spar caps as necessary; and

—Incorporate a spar strap modification on each wing spar.

*Was the public invited to comment?* The FAA invited interested persons to participate in the making of these amendments during the original 75-day comment periods. We extended the comment periods for another 30 days and then reopened the comment periods for another 60 days. We received numerous comments on the NPRMs.

In addition, we held a public meeting on March 3 and 4, 2004, in Herndon, Virginia. The public meeting allowed an open flow of communication among the FAA, the public, and industry on issues related to the NPRMs.

*What is FAA's determination of the best course of action?* After analyzing all information related to this subject, the FAA has decided not to issue the ADs as proposed. We have determined that the best way to address the unsafe condition is for FAA, the public, and industry to develop alternative solutions to address the unsafe condition. We will repropose ADs after alternative solutions are developed.

**Future Action**

*Does this mean the FAA cannot take regulatory action in the future?* No. Withdrawal of these NPRMs does not prevent us from issuing other regulatory action in the future, and it does not commit us to any future action. In fact, we plan to propose and issue further rulemaking on this subject after alternative solutions are identified and developed. We fully expect one of the options in such a proposed action would be the incorporation of the Cessna service information and repetitive inspections with appropriate compliance schedules.

*How can I be part of the solution?* The FAA, the public, and industry need to continue the discussion on this issue. The FAA is planning a second public meeting. Details of this meeting will be published in the **Federal Register** and made available on the Internet.

**Regulatory Impact**

*Does this AD involve a significant rule or regulatory action?* Since this action only withdraws two proposed ADs, it is not an AD and, therefore, is not covered under Executive Order 12866, the Regulatory Flexibility Act, or DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979).

**List of Subjects in 14 CFR Part 39**

Air transportation, Aircraft, Aviation safety, Safety.

**The Withdrawal**

Accordingly, FAA withdraws the following notices of proposed rulemaking:

• Docket No. 2002–CE–05–AD, which was published in the **Federal Register** on May 15, 2003 (68 FR 26239); and

• Docket No. 2002–CE–57–AD, which was published in the **Federal Register** on May 15, 2003 (68 FR 26244).

Issued in Kansas City, Missouri, on May 18, 2004.

**James E. Jackson,**

*Acting Manager, Small Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 04–11705 Filed 5–24–04; 8:45 am]

BILLING CODE 4910–13–P

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### 26 CFR Part 1

[REG–106590–00; REG–138499–02]

RIN 1545–AX95; RIN 1545–BB05

## Depreciation of MACRS Property That Is Acquired in a Like-Kind Exchange or as a Result of an Involuntary Conversion; Hearing Cancellation

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Cancellation of public hearing on proposed rulemaking.

**SUMMARY:** This document relates to a cancellation of a public hearing for proposed regulations that provide guidance on how to depreciate MACRS property acquired in a like-kind exchange under section 1031 or as a result of an involuntary conversion under section 1033 when both the acquired and relinquished property are subject to MACRS in the hands of the acquiring taxpayer.

**DATES:** The public hearing originally scheduled for June 3, 2004, at 10 a.m., is cancelled.

**FOR FURTHER INFORMATION CONTACT:** Robin R. Jones of the Publications and Regulations Branch, Legal Processing Division at (202) 622–7180 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:** A notice of proposed rulemaking and notice of public hearing that appeared in the **Federal Register** on Monday, March 1, 2004 (69 FR 9560), announced that a public hearing was scheduled for June 3, 2004, at 10 a.m., in the auditorium. The subject of the public hearing is proposed regulations under section 168 of the Internal Revenue Code. The public comment period for these regulations expired on June 1, 2004. The outlines of oral comments were due on May 13, 2004.

The notice of proposed rulemaking and notice of public hearing instructed those who are interested in testifying at the public hearing to submit an outline of the topics to be addressed. As of Wednesday, May 19, 2004, no one has requested to speak. Therefore, the public hearing scheduled for June 3, 2004, is cancelled.

**Cynthia E. Grigsby,**

*Acting Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).*

[FR Doc. 04–11809 Filed 5–24–04; 8:45 am]

BILLING CODE 4830–01–P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

**[MD166–3111; FRL–7666–4]**

## Approval and Promulgation of Air Quality Implementation Plans; Maryland; Control of VOC Emissions From AIM Coatings

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

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of Maryland. This revision pertains to the control of volatile organic compound (VOC) emissions from architectural and industrial maintenance (AIM) coatings.

**DATES:** Written comments must be received on or before June 24, 2004.

**ADDRESSES:** Submit your comments, identified by MD166–3111 by one of the following methods:

A. *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the on-line instructions for submitting comments.

B. *E-mail: morris.makeba@epa.gov*.

C. *Mail:* Makeba Morris, Chief, Air Quality Planning Branch, Mailcode 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

*Instructions:* Direct your comments to Docket ID No. MD166–3111. EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The Federal regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; and Maryland Department of the Environment, 1800 Washington Boulevard, Suite 705, Baltimore, Maryland 21230.

**FOR FURTHER INFORMATION CONTACT:** Rose Quinto, (215) 814–2182, or by e-mail at *quinto.rose@epa.gov*.

**SUPPLEMENTARY INFORMATION:** On March 19, 2004, the Maryland Department of the Environment (MDE) submitted a revision to its State Implementation Plan (SIP). The SIP revision consists of COMAR 26.11.33 Architectural Coatings which pertains to the control of VOC emissions from AIM coatings (the AIM Rule).

### I. Background

In December 1999, EPA identified emission reduction shortfalls in several one-hour ozone nonattainment areas in the Ozone Transport Region (OTR) and required those areas to address the shortfalls. The Ozone Transport Commission (OTC) developed model rules of control measures for a number of source categories. The OTC AIM coatings model rule was based on the existing rules developed by the California Air Resources Board, which were analyzed and modified by the OTC workgroup to address VOC reduction needs in the OTR. The standards and requirements contained in Maryland's AIM coatings rule are consistent with the OTC model rule.

### II. Summary of SIP Revision

The Maryland AIM Rule applies to any person who supplies, sells, offers for sale, or manufactures any AIM coating for the use in Maryland; as well as a person who applies or solicits the application of any AIM coating within Maryland. The rule does not apply to the following: (1) Any AIM coating that is sold or manufactured for use outside of Maryland, or for shipment to other manufacturers for reformulation or repackaging; (2) any aerosol coating product; or (3) any architectural coating that is sold in a container with a volume of one liter (1.057 quarts) or less. The rule sets specific VOC content limits, in grams per liter, for AIM coating categories with a compliance date of January 1, 2005. Manufacturers would ensure compliance with the limits by reformulating coatings and substituting coatings with compliant coatings that are already in the market. The rule contains VOC content requirements for a wide variety of field-applied coatings, including graphic art coatings, lacquers, primers and stains. The rule also contains administrative requirements for labeling and reporting. There are a number of test methods that would be used to demonstrate compliance with this rule. Some of these test methods include those promulgated by EPA and South Coast Air Quality Management District of California. The test methods used to test coatings must be the most current approved method at the time testing is performed. In addition, the rule includes good faith efforts to be used by a retailer in safeguarding against the sale of a non-compliant product, in the course of business, ensure that the products meet the applicable State requirements.

### III. Proposed Action

EPA is proposing to approve COMAR 26.11.33 for the control of VOC emission from AIM Coatings submitted on March 19, 2004. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

### IV. Statutory and Executive Order Reviews

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this proposed action is not a "significant regulatory action" and therefore is not subject to review by the Office of Management and Budget. For this reason, this action is also not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355 (May 22, 2001)). This action merely proposes to approve State law as meeting Federal requirements and imposes no additional requirements beyond those imposed by State law. Accordingly, the Administrator certifies that this proposed 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 proposes to approve 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). This proposed rule also does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it 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 proposes to approve 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 proposed 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 proposed 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 proposed rule pertaining to Maryland's AIM 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.*).

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

Environmental protection, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

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

Dated: May 18, 2004.

**Richard J. Kampf,**

*Acting Regional Administrator, Region III.*

[FR Doc. 04–11773 Filed 5–24–04; 8:45 am]

BILLING CODE 6560–50–P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 62

**[VA141–5075b; FRL–7666–6]**

### Approval and Promulgation of State Air Quality Plans for Designated Facilities and Pollutants; Commonwealth of Virginia; Control of Emissions From Existing Commercial/Industrial Incineration (CISWI) Units

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

**ACTION:** Proposed rule.

**SUMMARY:** EPA proposes to approve the commercial and industrial solid waste incinerator 111(d)/129 plan (the "plan") submitted by the Virginia Department or Environmental Quality (DEQ). The plan was submitted to EPA by the DEQ on September 8, 2003, and supplemental information on August 11, and September 30, 2003, and April 6, 2004. In the "Final Rules" section of this **Federal Register**, EPA is approving the Commonwealth of Virginia's CISWI plan submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial action and anticipate no adverse comments. A more detailed description of the state submittal and EPA's evaluation are included in a Technical Support Document (TSD) prepared in support of this rulemaking action. A copy of the TSD is available, upon request, from the EPA Regional Office listed in the **ADDRESSES** section of this document. If no adverse comments are received in response to this action, no further activity is contemplated. If EPA receives 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.

**DATES:** Comments must be received in writing by June 24, 2004.

**ADDRESSES:** Submit your comments, identified by VA141–5075 by one of the following methods:

A. *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

B. *E-mail: wilkie.walter@epa.gov.*

C. *Mail:* Walter Wilkie, Chief, Air Quality Analysis Branch, Mailcode 3AP22, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

*Instructions:* Direct your comments to Docket ID No. VA141–5075. EPA's policy is that all comments received will be included in the public docket without change, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The Federal regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division,

U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103; and the Virginia Department of Environmental Quality, 629 East Main Street, Richmond, Virginia, 23219.

**FOR FURTHER INFORMATION CONTACT:** James B. Topsale, P.E., at (215) 814–2190, or by e-mail at *topsale.jim@epa.gov*.

**SUPPLEMENTARY INFORMATION:** For further information, please see the information provided in the direct final action, with the same title, that is located in the "Rules and Regulations" section of this **Federal Register** publication. 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.

Dated: May 18, 2004.

**Richard J. Kampf,**

*Acting Regional Administrator, Region III.*

[FR Doc. 04–11772 Filed 5–24–04; 8:45 am]

**BILLING CODE 6560–50–P**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Parts 1, 43 and 63

**[IB Docket No. 04–112; FCC No. 04-70]**

### Reporting Requirements for U.S. Providers of International Telecommunications Services

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This document is a summary of the Notice of Proposed Rulemaking adopted by the Commission in this proceeding. The Commission seeks comment on the continued need for traffic and revenue reports and facilities-use reports and on proposals that simplify and the reports that carriers must file. The Commission also seeks comment of the elimination of requirement that international telegraph carriers file their contracts with their foreign correspondents.

**DATES:** Comments are due to be filed by July 26, 2004, and reply comments are due to be filed by August 23, 2004. OMB, the general public, and other Federal agencies are invited to comment on the information collection requirements on or before July 26, 2004.

**FOR FURTHER INFORMATION CONTACT:** David Krech or John Copes, Policy Division, International Bureau, (202) 418–1460. For information concerning the information collection(s) contained in this document, contact Judith B. Herman at 202–418–0214, or via the Internet at *JudithB.Herman@fcc.gov*.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's *Notice of Proposed Rulemaking* in IB Docket No. 04–112, FCC 04–70, adopted March 24, 2004. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room CY–A257), 445 12th Street, SW. Washington, DC 20554. The document is also available for download over the Internet at *http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC–04–70.pdf*. The complete text may also be purchased from the Commission's copy contractor, Qualex International, in person at 445 12th Street, SW., Room CY–B402, Washington, DC. 20554, via telephone at (202) 863–2893, via facsimile at (202) 863–2898, or via e-mail at *qualexint@aol.com*. This Notice of Proposed Rulemaking (NPRM) contains proposed new or modified information collections subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–3. It will be submitted to the Office of Management and Budget (OMB) for review under section 3507(d) of the PRA. OMB, the general public, and other Federal agencies are invited to comment on the modified information collections contained in this proceeding.

#### Summary of Notice of Proposed Rulemaking

On March 24, 2004, the Commission adopted a Notice of Proposed Rulemaking in the Matter of Reporting Requirements for U.S. Providers of International Telecommunications Services; Amendment of Part 43 of the Commission's Rule (NPRM). In the NPRM, the Commission undertakes a comprehensive review of the reporting requirements to which carriers providing U.S. international services are subject under part 43 of the rules. The NPRM seeks comment on changes to simplify the reporting requirements and to ensure the usefulness of the data collected by the Commission.

The NPRM seeks comment on whether to retain the annual traffic and revenue reporting requirements. Currently, § 43.61(a) requires international telecommunications carriers to file annual reports setting forth their traffic and revenues for each international service they provide. Section 43.82 of the Commission's rules requires facilities-based U.S. international telecommunications carriers to file annual circuit-status reports that detail, as of December 31st each year, the number of circuits they own or lease to each country they serve and the services for which they use each such circuit. The NPRM seeks comment on whether to retain the § 43.53 telegraph carrier report.

The NPRM tentatively concludes that the § 43.61 traffic and revenue reports and the § 43.82 circuit-status reports continue to be needed and proposes to retain them. The NPRM, however, proposes certain simplifications to lessen the burden on the carries of filing the reports and, in a few cases, proposes to expand the information carriers are required to file to make the reports more useful under current conditions in the international telecommunications market.

The NPRM proposes a number of ways to simplify the § 43.61 traffic and revenue reports and § 43.82 circuit-status report. For example, the NPRM proposes to eliminate the current requirement in the annual traffic and revenue report that carriers file the number of messages they carry to and from the foreign countries they serve, requiring only that they continue to report the number of minutes they handle and the amount of revenues associated with those minutes. Second, the NPRM proposes to eliminate the current requirement that carriers file traffic and revenue information or circuit-status information for services they offer between the U.S. Mainland and offshore U.S. points such as Hawaii and Puerto Rico or traffic carried between two such offshore U.S. points. Third, the NPRM proposes to establish a $5 million annual revenue threshold for reporting U.S. international resale telephone services. That is, U.S. carriers that provide international telephone service on a resale basis do not have to file an annual traffic and revenue report unless their annual resale revenues exceed $5 million. Similarly, the NPRM proposes to implement a $5 million annual revenue threshold also for "miscellaneous" international services, *i.e.*, services other than international telephone service. The NPRM includes a staff proposal that recommends a number of ways to simplify the information that international carriers must report on covered services. The staff proposal is available for download over the Internet at *http://hraunfoss.fcc.gov/edocs_public/attachmatch/FCC–04–70A1.pdf*.

The NPRM also seeks comment on the need to retain the § 43.61(b) and § 43.61(c) quarterly traffic and revenue reports. If the Commission ultimately

concludes that it should retain the quarterly reports, the simplifications proposed for the annual traffic and revenue reports would apply to the retained quarterly reports as well.

The NPRM proposes to require all carriers that own international transmission facilities to file the annual circuit-status reports. At present, only common-carrier service providers are required to file circuit-status information. The NPRM proposes to require owners of non-common-carrier international transmission facilities also to file. Since the circuit-status report was adopted, the mix of common-carrier and non-common-carrier international transmission facilities has shifted so that currently common-carrier facilities represent less than 10 percent of all international transmission facilities. To keep the Commission informed about the availability and usage of international transmission facilities, it will be necessary for it to have information on both common-carrier and non-common-carrier facilities.

The NPRM also proposes to eliminate the § 43.53 telegraph carriers reporting requirement. The NPRM notes that international telegraph services have sharply declined in importance and that no useful purpose would be served by requiring such carriers to file their overseas contracts.

**Procedural Matters**

*Initial Paperwork Reduction Act Analysis*

This NPRM contained proposed new information collections. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the Office of Management and Budget (OMB) to comment on the information collection(s) contained in this NPRM, as required by the Paperwork Reduction Act (PRA) of 1995, Public Law 104–13. Public and agency comments are due July 26, 2004. PRA comments should address: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

*OMB Control Number:* 3060–0106.

*Title:* Section 43.61—Reports of Overseas Telecommunications Traffic.

*Form No.:* Not Applicable.

*Type of Review:* Revision of a currently approved collection.

*Respondents:* Businesses or other for-profit entities.

*Number of Respondents:* 134.

*Estimated Time Per Response:* 18 hours.

*Frequency of Response:* Quarterly, Annual, on occasion.

*Total Annual Burden:* 2412 hours.

*Total Annual Costs:* $216,524.

*Needs and Uses:* The information will be used by the Commission staff for international planning, facility authorization, monitoring emerging developments in communications services, analyzing market structures, tracking the balance of payments in international communications services, and market analysis purposes. The reported data enables the Commission to fulfill its regulatory responsibilities.

*OMB Control Number:* 3060–0572.

*Title:* Filing Manual for Annual International Circuit Status Reports.

*Form No.:* Not Applicable.

*Type of Review:* Revision of a currently approved collection.

*Respondents:* Business and other for-profit entities.

*Number of Respondents:* 138.

*Estimated Time Per Response:* 11 hours.

*Frequency of Response:* Annual reporting requirement.

*Total Annual Burden:* 1,540 hours.

*Total Annual Costs:* $42,600.

*Needs and Uses:* The information will enable the Commission to discharge its obligation to authorize the construction and use of international common carrier transmission facilities. The information will be used by the Commission and the industry as to whether an international common carrier is providing direct or indirect service to countries and to assess industry trends in the use of international transmission facilities. The information is extremely valuable because it is not available from any other source.

**Final Regulatory Flexibility Act Analysis**

As required by the Regulatory Flexibility Act (RFA), as amended, the Commission has prepared this Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities by the policies and rules proposed in this Notice of Proposed Rulemaking (NPRM). (*See* 5 U.S.C. 603. The RFA, *see* 5 U.S.C. 601–612, has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), Pub. L. 104–121, Title II, 110 Stat. 857 (1996).)

Written public comments are requested on this IRFA. Comments must be identified as responses to the IRFA and must be filed by the deadlines for comments on the Notice July 26, 2004. The Commission will send a copy of the Notice, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration. In addition, the Notice and IRFA will be published in the **Federal Register**

*A. Need for, and Objectives of, the Proposed Rules*

The Commission initiated this comprehensive review of the reporting requirements imposed on U.S. carriers providing international telecommunications services. The Commission believes that the proposals contained in the NPRM will make it easier for carriers, both small and large, to provide the information required by the rules. In addition, section 11 of the Telecommunications Act of 1996 directs the Commission to undertake, in every even-numbered year beginning in 1998, a review of all regulations issued under the Communications Act of 1934, as amended.

The objective of this proceeding is to improve the reporting requirements of §§ 43.61 and 43.82 imposed on carriers providing international telecommunications services. Specifically, the NPRM proposes to simplify, consolidate, and revise the annual traffic and revenue reporting requirements and the circuit-status reporting requirements. Also, the NPRM proposes to eliminate several reporting requirements.

Currently, § 43.61 requires that all international telecommunications carriers file an annual report of their traffic and revenues. In addition, § 43.61 sets forth additional reporting requirements for specific carriers that meet the criteria set forth in the rule. Under § 43.82, facilities-based common carriers providing international telecommunications services must file an annual report on the status of their circuits. The information derived from the international revenue and traffic report and circuit-status report is critical in understanding the international telecommunications market. These reports are the only source of publicly available information of this nature.

The information obtained from these reports is used extensively by the Commission, the industry, other government agencies, and the public. The Commission uses the information to evaluate applications for international facilities, track market developments and the competitiveness of each service and geographical market to formulate

rules and policies consistent with the public interest, monitor compliance with those rules and policies, and gauge the competitive effect of its decisions on the market. The information is used to ensure compliance with the Commission's international rules and policies. The information enables the Commission to tailor policies to respond to the market developments on a particular route. The Commission also uses the information to identify those routes for which settlement rates are at a level low enough to permit relief from certain regulatory requirements, including the prohibition on the use of private lines for the provision of switched, basic services ("ISR"). Carriers use the information to track the balance of payments in international communications services and for market analysis purposes. Carriers and potential entrants use the information for, among other things, assessment of market opportunities and to monitor competition in markets. The Commission, along with other government agencies, uses the information in merger analyses and negotiations with foreign countries. In addition, the information contained in the circuit-stateus report allows the Commission to comply with the statutory requirements of the Omnibus Budget Reconciliation Act of 1993.

*B. Legal Basis*

The NPRM is adopted pursuant to sections 1, 4(i) and (j), 11, 201–205, 211, 214, 219, 220, 330(r), 309, and 403 of the Communications Act of 1934 as amended, 47 U.S.C. 151, 154(i), 154(j), 161, 201–205, 211, 214, 219, 220, 303(r), 309, and 403.

*C. Description and Estimate of the Number of Small Entities to Which the Proposals Will Apply*

The RFA directs agencies to provide a description of, and, where feasible, an estimate of the number of small entities that may be affected by the proposals, if adopted. The RFA generally defines the term "small entity" as having the same meaning as the terms "small business," "small organization," and "small governmental jurisdiction." In addition, the term "small business" has the same meaning as the term "small business concern" under the Small Business Act. A small business concern is one that: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the Small Business Administration (SBA).

The proposals in the NPRM apply only to entities providing international common carrier services pursuant to section 214 of the Communications Act; entities providing domestic or international wireless common carrier services under section 309 of the Act; entities providing common carrier or non-common carrier satellite services under section 309 of the Act; and entities licensed to construct and operate submarine cables under the Cable Landing License Act on a common carrier or non-common carrier basis. The Commission has not developed a definition of small entities applicable to these entities. Therefore, the applicable definition of small entity is the definition under the SBA rules applicable to Telecommunications Services (*see* 13 CFR 121.201, NAICS Code.) According to the SBA definition, wired telecommunications carriers, cellular and other wireless providers, and telecommunications resellers would be considered small entities if they employ 1,500 employees or less. The definition also considers satellite or other telecommunications providers as small entities if they have $12.5 million or less in annual receipts. (*See* 13 CFR 121.201, NAICS Code at Subsector 517—Telecommunications.)

We have included small incumbent local exchange carriers in this present RFA analysis. As noted above, a "small business" under the RFA is one that, *inter alia*, meets the pertinent small business size standard (*e.g.*, a telephone communications business having 1,500 or fewer employees), and "is not dominant in its field of operation." The SBA's Office of Advocacy contends that, for RFA purposes, small incumbent local exchange carriers are not dominant in their field of operation because any such dominance is not "national" in scope. (*See* Letter from Jere W. Glover, Chief Counsel for Advocacy, SBA, to William E. Kennard, Chairman, FCC (May 27, 1999). The Small Business Act contains a definition of "small-business concern," which the RFA incorporates into its own definition of "small business." 15 U.S.C. 632(a) (Small Business Act); 5 U.S.C. 601(3) (RFA). SBA regulations interpret "small business concern" to include the concept of dominance on a national basis. 13 CFR 121.102(b). We have therefore included small incumbent local exchange carriers in this RFA analysis, although we emphasize that this RFA action has no effect on Commission analysis and determinations in other, non-RFA contexts.

The carriers required to file the traffic and revenue and circuit-status reports are both large and small entities. In the 2001 annual traffic and revenue report, 625 carriers reported that they provided international message telephone service (IMTS) on a pure resale basis. (*See* FCC, Wireline Competition Bureau, Industry Analysis and Technology Division, "2001 International Telecommunications Data" at page 1, Statistical Findings (January 2003). FCC Web site location *http://www.fcc.gov/wcb/iatd/intl.html.*) Pure resale providers resell the services of underlying U.S. facilities-based and facilities-resale carriers. Pure resale service is primarily provided by small businesses. For example, of the 625 carriers, 277 carriers had revenues less than $10,000; 482 had revenues less than $500,000; and 513 had revenues less than $1 million. The report also shows that 52 U.S. facilities-based and facilities-resale carriers reported that they billed $10.8 billion for IMTS service, $1.4 billion for private line services, and $0.2 billion for international telex, telegraph, and other miscellaneous services. These carriers would be considered large entities under the SBA definition. (*See* 13 CFR 121.201, NAICS Code at Subsector 517—Telecommunications.) According to the 2002 Circuit-Status Report, 79 U.S. international facility-based carriers filed information pursuant to § 43.82. (*See International Bureau Releases 2002 Year-End Circuit Status Report for U.S. Facilities-Based International Carriers; Capacity Use Shows Modest Growth*, rel. Dec. 24, 2003. The report is available on the FCC Web site at *http://www.fcc.gov/ib/pd/pf/csmanual.html.*)

The report does not yield employee or revenue statistics, so it is impossible for use to determine how many carriers could be considered small entities. Although it is quite possible that a carrier could report a small amount of capacity and have significant revenues, we will consider those carriers small entities at this time. Thus, of the 79 carriers filing the annual circuit-status report for 2002, there were at least 8 carriers that could be considered small entities because they did not have any circuits in 2002.

*D. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements*

The NPRM proposes to retain the annual traffic and revenue reporting requirements and the circuit-status reporting requirements because the collection and public reporting of this information continues to be necessary in the public interest. The NPRM, however, proposes to simplify and clarify the reporting requirements to reduce the burdens for both small and large carriers. Because carriers currently are required to file annual traffic and

revenue and circuit-status reports, the proposals contained in the NPRM will not impose any significant economic burden on small carriers. The information contained in the proposed reporting requirements is the same information that the carriers collect and maintain during the routine course of business. The NPRM contains a staff recommendation on the proposed reporting requirements, including eight proposed schedules that show the specific information that carries would be required to report and how they would report it. The proposed reporting requirements are described below. However, because the Commission may change the reporting proposed in the NPRM based on comments received in this proceeding, consequently, the schedules would also change.

Schedule 1 contains a proposed summary report that applies to all entities, both small and large. This report would be a one-page form that international section 214 authorization holders would be required to file annually. The generic form would require a carrier to provide basic information about its international section 214 authorization. Specifically, the carrier would be required to provide its name, its Form 499–A identification number, its Commission Registration System (CORES) identification number, and a list of the international section 214 authorizations that it holds. In addition, the carrier would provide basic information about the services that it provided the previous year. Based on the services the responding carriers reported, the schedule would inform the carrier which other schedules, if any, the carrier would be required to complete. The schedule would provide the carriers with information on which of its entities are required to file, including subsidiaries of the authorization holder that might need to file separately.

Proposed Schedules 2 and 3 would require carriers to submit information on IMTS and seek country-by-country traffic and revenue information. Schedule 2 will require carriers to provide the information on "outbound" IMTS traffic, whereas Schedule 3 will require carriers to provide the information on "inbound" IMTS traffic. Under Schedule 2, carriers would report, their minutes and revenues/payouts if the "source of traffic" is from end users or another U.S. carrier and the carrier terminates those minutes with a foreign carrier, on the spot marked, or self terminates in the foreign country.

Proposed Schedule 3 would require carriers to report, on a country-by-country basis, the number of inbound minutes of IMTS carriers receive from their overseas correspondents and the dollar amounts they receive for terminating that traffic. Also, carriers would be required to continue to separate the inbound traffic they receive under the traditional settlement arrangements from inbound traffic they receive under all other arrangements, such as ISR, hubbing, etc.

Proposed Schedule 4 would require carries to provide additional detail on a world total basis for the IMTS minutes and revenues for traffic billed to U.S. customers and for traffic billed to others. Carriers would be required to report the minutes of collect calls, international toll-free calls, country-beyond calls, and country-direct calls they handle. When reporting this information, carriers would be required to provide separate data for the minutes they receive from foreign carriers for traditional IMTS transit traffic, refilled traffic, and traffic received from spot markets.

Proposed Schedule 5 would require pure resale carriers with over $5 million in revenue from international services to report their U.S.-customer minutes and revenues separately for U.S. end-user traffic, traffic handled for other U.S. carriers, and traffic re-originated for foreign carriers.

Proposed Schedule 6 would require carriers to provide country-by-country information on their international private-line services. Carriers would be required to report separately service provided over facilities they own and service provided over resold circuits. Proposed Schedule 6 includes a new category called "Data Services" to ensure proper reporting of several new services that carriers have begun to offer in recent years.

Proposed Schedule 7 would require carriers to provide information regarding miscellaneous services. Services other than IMTS and private-line service would be considered miscellaneous services. Carriers would be required to provide a minimal amount of information on the new services, such as the name of each service and the total annual revenues the carriers derived from the service.

Proposed Schedule 8 would require carriers to provide a snapshot of their active and idle circuits as of December 31st of each year. Carriers would be required to report their circuit capacity on the basis of the type of facilities they use to provide service—submarine cables, satellites, and terrestrial links. Carriers would be required to report their circuit use in units of 64 Kilobit per second (Kbps) equivalent circuits.

*E. Steps Taken To Minimize Significant Economic Impact on Small Entities, and Significant Alternatives Considered*

The RFA requires an agency to describe any significant, specifically small business, alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): "(1) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rule for small entities; (3) the use of performance, rather than design, standards; and (4) an exemption from coverage or the rule, or any part thereof, for small entities."

The NPRM seeks comment on a number of proposals to simplify and consolidate the reporting requirements for carriers providing international telecommunications services. The proposals in the NPRM are designed to reduce the regulatory requirements for both small and large carriers, while maintaining and enhancing the goals the reports serve. The Commission will also consider other additional significant alternatives developed in the record.

The possible change to the reporting requirements with the most significant impact on small carriers is the proposal to exempt pure resale carriers with less then $5 million in revenues from international services the preceding year from filing reports. Based on the number of carriers filing the annual traffic and revenue report in 2001, the majority of carriers would be considered small carriers. (*See* FCC, Wireline Competition Bureau, Industry Analysis and Technology Divison, "2001 International Telecommunications Data" at page 1, Statistical Findings (January 2003). FCC Web site location *http://www.fcc.gov/wcb/iatd/intl.html.*) This proposal would benefit a substantial number of small entities by relieving them from certain reporting requirements.

The NPRM proposes to simplify the information that the carriers, both small and large, must submit for any traffic and revenue reports. First, the NPRM proposes to eliminate the requirement that carriers provide information on the number of messages that they carried the previous year. Second, the NPRM proposes to eliminate the requirement that carriers use the billing codes set out in the § 43.61 Filing Manual and the Public Notices. Currently, carriers report international telephone traffic under 12 different billing codes, and the various

billing codes have presented recurring problems for carriers filing the reports as well as those who review the reports. Third, the NPRM proposes a set of schedules for the reporting of the traffic and revenue and circuit-status information in lieu of the two filing manuals that are currently used. The Notice proposes to streamline some of the reporting categories, which will reduce the reporting requirements on both small and large entities.

The NPRM proposes to consolidate § 43.61 (traffic and revenue reporting requirement) and § 43.82 (circuit-status reporting requirement) into one rule. Consolidating the rules will eliminate the requirement that carriers file two separate reports—one for traffic and revenue data and one for circuit-status data. The Notice proposes that one filing manual be developed that will satisfy the reporting requirements of the new rule. One consolidated filing manual for both reports would be less confusing and less time-consuming for both small and large carriers.

The NPRM also proposes to require carriers to file the report earlier than currently required in order to improve the timeliness of the resulting report. In selecting a proposed filing date, the Commission tried to balance the need for more expeditious filing with any burden an earlier filing would place on carriers. In addition, with more timely-filed data, it would be unnecessary for carriers to file corrected traffic and revenue data. The proposed new filing date minimizes any burden on the carriers because it does not coincide with any other reporting requirements. Also, carriers will not be burdened with filing another report with corrected data.

The NPRM proposes changes in the format under which the carriers file the reports. The NPRM proposes replacing the current DOS-based filing procedures with spreadsheet-based reporting thereby allowing carriers to file their data using a commercial spread sheet program. This proposal should substantially reduce the burden on all carriers, both small and large, in preparing their data submissions. Also, carriers filing schedules that do not require country-by-country data could easily prepare and submit such information online. This, too, would substantially reduce the burden on the filing carrier, facilitate interactive edit checks, and allow data to be automatically loaded into the Commission's database programs.

The NPRM seeks comment on whether it would significantly speed and facilitate the submission of data if the Commission were to encourage or mandate carriers to submit their data electronically. Electronic filing would lessen the burden of filing the reports for both small and large carriers. Because carriers maintain the data electronically, it would be practicable for carriers to submit the data in the same format rather than convert the data into a different format.

The NPRM proposes a general report that will make it very simple for a carrier to determine which, if any, reporting requirements are applicable to the carrier. In addition, this proposal will simplify a carrier's compliance with other reporting requirements, such as the Form 499–A.

*F. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules*

None.

Ordering Clauses

Accordingly, pursuant to the authority contained in sections 1, 4(i), 4(j), 11, 201–205, 211, 214, 219, 220, 303(r), 309, and 403 of the Communications Act of 1934, as amended, 47 U.S.C. Sections 151, 154(i), 154(j), 161, 201–205, 211, 214, 219, 220, 303(r), 309 and 403, this notice of proposed rulemaking is hereby adopted and comments are requested as described above.

The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, shall send a copy of this notice of proposed rulemaking, including the Initial Regulatory Flexibility Act Analysis, to the Chief Counsel for Advocacy of the Small Business Administration in accordance with section 603(a) of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*

**List of Subjects in 47 CFR Parts 1, 43 and 63**

Communications common carriers, Reporting and recordkeeping requirements, Telecommunications.

Federal Communications Commission.

**Marlene H. Dortch,**

*Secretary.*

**Rule Changes**

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR parts 1, 43 and 63 as follows:

## PART 1—PRACTICE AND PROCEDURE

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

**Authority:** 47 U.S.C. 151, 154(i), 154(j), 155, 225, 303(r), 309 and 325(e).

**§ 1.789 [Removed]**

2. Remove § 1.789.

## PART 43—REPORTS OF COMMUNICATION COMMON CARRIERS AND CERTAIN AFFILIATES

3. The authority citation for part 43 continues to read as follows:

**Authority:** 47 U.S.C. 154; Telecommunications Act of 1996, Pub. L.104–104, secs. 402(b)(2)(B), (c), 110 Stat. 56 (1996) as amended unless otherwise noted. 47 U.S.C. 211, 219, 220 as amended.

**§ 43.53 [Removed]**

4. Remove § 43.53.

5. Section 43.61 is revised to read as follows:

**§ 43.61 Reporting requirements for U.S. international carriers.**

(a) *Annual traffic and revenue reports.* Each carrier engaged in providing international telecommunications service between the area comprising the continental United States, Alaska, Hawaii, and off-shore U.S. points and any country or point outside that area shall file a report with the Commissions not later than May 1, of each year showing traffic and revenue fro international services provided in the preceding calendar year.

(b) *Quarterly traffic reports for facilities-based carriers.* (1) Each common carrier engaged in providing international telecommunications service between the area comprising the continental United States, Alaska, Hawaii, and off-shore U.S. points and any country or point outside that area shall file with the Commission, in addition to the report required by paragraph (a) of this section, actual traffic and revenue data for each calendar quarter in which the carrier's quarterly minutes exceed the corresponding minutes for all carriers by one or more of the following tests:

(i) The carrier's aggregate minutes of facilities-based or private-line resale switched telephone traffic for service billed in the United States are greater than 1.0 percent of the total of such minutes of international traffic for all U.S. carriers published in the Commission's most recent § 43.61 annual report of international telecommunications traffic;

(ii) The carrier's aggregate minutes of facilities-based or private-line resale switched telephone traffic for service billed outside the United States are greater than 1.0 percent of the total of such minutes of international traffic for all U.S. carriers published in the Commission's most recent § 43.61 annual report of international telecommunications traffic;

(iii) The carrier's aggregate minutes of facilities-based or private-line resale switched telephone traffic for service billed in the United States for any foreign country are greater than 2.5 percent of the total of such minutes of international traffic for that country for all U.S. carriers published in the Commission's most recent § 43.61 annual report of international telecommunications traffic; or

(iv) The carrier's aggregate minutes of facilities-based or private-line resale switched telephone traffic for service billed outside the United States for any foreign country are greater than 2.5 percent of the total of such minutes of international traffic for that country for all U.S. carriers published in the Commission's most recent § 43.61 annual report of international telecommunications traffic.

(2) Except as provided in this paragraph, the quarterly reports required by paragraph (b)(1) of this section shall be filed in the same format as, and in conformance with, the filing procedures for the annual reports required by paragraph (a) of this section.

(i) Carriers filing quarterly reports shall include in those reports only their provision of switched, facilities-based telephone service and switched, private-line resale telephone service.

(ii) The quarterly reports required by paragraph (b)(1) of this section shall be filed with the Commission no later than April 30 for the prior January through March quarter; no later than July 31 for the prior April through June quarter; no later than October 31 for the prior July through September quarter; and no later than January 31 for the prior October through December period.

(c) *Quarterly Traffic Reports for resale carriers.* Each common carrier engaged in the resale of international switched services that is affiliated with a foreign carrier that has sufficient market power on the foreign end of an international route to affect competition adversely in the U.S. market and that collects settlement payments from U.S. carriers shall file a quarterly version of the report required in paragraph (a) of this section for its switched resale services on the dominant route within 90 days from the end of each calendar quarter. Commercial Mobile Radio Service (CMRS) carriers, as defined in § 20.9 of this chapter, are not required to file reports pursuant to this paragraph.

(d) *Circuit status reports.* Each facilities-based carrier engaged in providing international telecommunications service between the area comprising the continental United States, Alaska, Hawaii, and off-shore U.S. points and any country or point outside that area shall file a circuit status report with the Commission not later than May 1, each year showing the status of its circuits used to provide international services as of December 31, of the preceding calendar year.

(e) *Filing manual.* The information required under this section shall be furnished in conformance with the instructions and reporting requirements prepared under the direction of the Chief, International Bureau, prepared and published as a filing manual.

(f) *Definitions.* (1) Two entities are *affiliated* with each other if one of them, or any entity that controls one of them, directly or indirectly owns more than 25 percent of the capital stock of, or controls, the other one, Also, a U.S. carrier is *affiliated* with two or more foreign carriers if the foreign carriers, or entities that control them, together directly or indirectly own more than 25 percent of the capital stock of, or control. the U.S. carrier and those foreign carriers are parties to, or the beneficiaries of, a contractual relation (*e.g.,* a joint venture or market alliance) affecting the provision or marketing of international basic telecommunications services in the United States.

(2) *Facilities-based carrier* means a carrier that holds an ownership, indefeasible-right-of-user, or leasehold interest in bare capacity in the U.S. end of an international facility, regardless of whether the underlying facility is a common carrier or non-common carrier submarine cable or a satellite system.

(3) *Foreign carrier* is defined as any entity that is authorized within a foreign country to engage in the provision of international telecommunications services offered to the public in that country within the meaning of the International Telecommunication Regulations, see Final Acts of the World Administrative Telegraph and Telephone Conference, Melbourne, 1988 (WATTC–88), Art. 1, which includes entities authorized to engage in the provision of domestic telecommunications services if such carriers have the ability to originate or terminate telecommunications services to or from points outside their country.

**§ 43.82 [Removed]**

6. Remove § 43.82.

## PART 63—EXTENSION OF LINES, NEW LINES AND DISCONTINUANCE, REDUCTION, OUTAGE AND IMPAIRMENT OF SERVICE BY COMMON CARRIERS; AND GRANTS OF RECOGNIZED PRIVATE OPERATING AGENCY STATUS

7. The authority citation for part 63 continues to read as follows:

**Authority:** Sections 1, 4(i), 4(j), 10, 11, 201, 205, 214, 218, 403 and 651 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 154(i), 154(j), 160, 201, 205, 214, 218, 403, and 571, unless otherwise noted.

**§ 63.23 [Amended]**

8. Section 63.23 is amended by removing paragraph (e) and redesignating paragraph (f) as paragraph (e).

[FR Doc. 04–10837 Filed 5–24–04; 8:45 am]
BILLING CODE 6712–01–M

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

### 50 CFR Part 17

**RIN 1018–AT64**

## Endangered Species Act Incidental Take Permit Revocation Regulations

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Proposed rule.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), propose to amend part 17 of title 50 of the Code of Federal Regulations (CFR) to add regulations that describe circumstances in which the Service may revoke incidental take permits issued under the authority of the Endangered Species Act (ESA). On December 11, 2003, the U.S. District Court for the District of Columbia in *Spirit of the Sage Council* v. *Norton,* Civil Action No. 98–1873 (D. D.C.), invalidated 50 CFR 17.22(b)(8) and 17.32(b)(8), the regulations addressing Service authority to revoke incidental take permits under certain circumstances. The court ruled that we had adopted these regulations without adequately complying with the public notice and comment procedures required by the Administrative Procedure Act (APA) and remanded the regulations to us for further proceedings consistent with the APA. In the Rules and Regulations section of today's **Federal Register** is a final rule withdrawing the permit revocations regulations in 50 CFR 17 vacated by the court order. In this document, we are requesting public comments on our proposal to reestablish the permit revocation regulations vacated by the court.

**DATES:** Comments must be received by July 26, 2004.

**ADDRESSES:** You may submit comments, identified by RIN number 1018–AT64, by any of the following methods: (1)

Mail or hand delivery to the Chief, Division of Consultation, Habitat Conservation Planning, Recovery and State Grants, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 420, Arlington, VA 22203; (2) FAX: 703/358–2229; (3) E-mail: *pprr@fws.gov;* or (4) through the Federal eRulemaking Portal: *http://www.regulations.gov*. All submissions must include the identification number RIN 1018–AT64. The complete file for this proposed rule, including public comments, is available, by appointment, during normal business hours at the same address. You may call 703/358–2171 to make an appointment to view the files.

**FOR FURTHER INFORMATION CONTACT:** Rick Sayers, Chief, Branch of Consultation and Habitat Conservation Planning, at the above address (Telephone 703/358–2171, Facsimile 703/358–1735).

**SUPPLEMENTARY INFORMATION:** This notice of proposed rulemaking applies to the U.S. Fish and Wildlife Service only. Therefore, the use of the terms "Service" and "we" in this notice refers exclusively to the U.S. Fish and Wildlife Service.

This proposed rule applies only to 50 CFR 17.22(b) and 17.32(b), which pertain to incidental take permits. Regulations in 50 CFR 17.22(c) and 17.32(c) that pertain to Safe Harbor Agreements (SHAs) and in 50 CFR 17.22(d) and 17.32(d) that pertain to Candidate Conservation Agreements with Assurances (CCAAs) are not affected by this proposed rule.

## Background

### *Promulgation of the "Permit Revocation Rule"*

The Service administers a variety of conservation laws that authorize the issuance of permits for otherwise prohibited activities. In 1974, we published 50 CFR part 13 to consolidate the administration of various permitting programs. Part 13 established a uniform framework of general administrative conditions and procedures that would govern the application, processing, and issuance of all Service permits. We intended the general part 13 permitting provisions to be in addition to, and not in lieu of, other more specific permitting requirements of Federal wildlife laws.

We subsequently added many wildlife regulatory programs to title 50 of the CFR. For example, we added part 18 in 1974 to implement the Marine Mammal Protection Act; modified and expanded part 17 in 1975 to implement the Endangered Species Act of 1973; and added part 23 in 1977 to implement the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). The regulations in these parts contain their own specific permitting requirements that supplement the general permitting provisions of part 13.

With respect to the ESA, the combination of the general permitting provisions in part 13 and the specific permitting provisions in part 17 has worked well in most instances. However, the Service has found that, in some areas of permitting policy under the Act, the "one size fits all" approach of part 13 has been inappropriately constraining and narrow. These areas include specifically the Habitat Conservation Planning, Safe Harbor Agreement, and Candidate Conservation Agreement with Assurances programs. Incidental take permitting under section 10(a)(1)(B) of the ESA is one such area.

On June 12, 1997 (62 FR 32189), we published proposed revisions to our general permitting regulations in 50 CFR part 13 to identify, among other things, the situations in which the permit provisions in part 13 would not apply to individual incidental take permits. On June 17, 1999 (64 FR 32706), we published a final set of regulations that included two provisions that relate to revocation of incidental take permits. The first provides that the general revocation standard in 50 CFR 13.28(a)(5) will not apply to several types of ESA permits, including incidental take permits. The second provision, hereafter referred to as the Permit Revocation Rule, described circumstances under which incidental take permits could be revoked. On September 30, 1999 (64 FR 52676), we published a correction to the regulations promulgated in our June 17, 1999 (64 FR 32706), final rule; however, the correction was not associated with permit revocation.

The Permit Revocation Rule, which was codified at 50 CFR 17.22(b)(8) (endangered species) and 17.32(b)(8) (threatened species), provided that an incidental take permit "may not be revoked * * * unless continuation of the permitted activity would be inconsistent with the criterion set forth in 16 U.S.C. 1539(a)(2)(B)(iv) and the inconsistency has not been remedied in a timely fashion." The criterion in section 10(a)(2)(B)(iv) of the ESA (16 U.S.C. 1539(a)(2)(B)(iv)) that "the taking will not appreciably reduce the likelihood of the survival and recovery of the species in the wild" is one of the statutory criteria that incidental take permit applicants must meet in order to obtain a permit. The criterion is substantively identical to the definition of "jeopardize the continued existence of" in the joint Department of the Interior/Department of Commerce regulations implementing section 7 of the ESA (50 CFR 402.02). In essence, the Permit Revocation Rule authorizes the Service to revoke an incidental take permit if continuation of the permitted activity would jeopardize the continued existence of a listed species and the jeopardy situation is not remedied in a timely fashion.

On February 11, 2000 (65 FR 6916), we published a request for additional public comment on several specific regulatory changes included in the June 17, 1999 (64 FR 32706), final rule, including the Permit Revocation Rule. Based on our review of the comments we received in response to the February 11, 2000, request for comments, we published a notice on January 22, 2001 (66 FR 6483), that affirmed the provisions of the June 17, 1999 (64 FR 32706), final rule, including the Permit Revocation Rule.

### *The "No Surprises" Rule Litigation and the Order To Vacate the Permit Revocation Rule*

On February 23, 1998 (63 FR 8859), the Service and the National Marine Fisheries Service jointly promulgated the so-called No Surprises Rule, which provides certainty to holders of incidental take permits by placing limits on the agencies' ability to require additional mitigation after an incidental take permit has been issued. The No Surprises Rule is codified by the Service at 50 CFR 17.22(b)(5) (endangered species) and 17.32(b)(5) (threatened species) and by the National Marine Fisheries Service at 50 CFR 222.307(g). For both agencies, the No Surprises Rule was added to pre-existing regulations pertaining to incidental take permits.

In July 1998, a group of environmental plaintiffs challenged the No Surprises Rule in *Spirit of the Sage Council* v. *Norton*, Civil Action No. 98–1873 (D. D.C.). After the Service promulgated the Permit Revocation Rule on June 17, 1999 (64 FR 32706), the government referred to that rule in its briefs in the No Surprises Rule case to demonstrate that the agencies retained the ability to revoke incidental take permits notwithstanding the assurances in the No Surprises Rule. The plaintiffs subsequently amended their complaint to challenge the Permit Revocation Rule.

On December 11, 2003, the court ruled that the public notice and comment procedures followed by the Service when promulgating the Permit Revocation Rule were in violation of the APA. The court vacated and remanded the Permit Revocation Rule to the Service for further consideration consistent with section 553 of the APA.

The court did not rule on the validity of the No Surprises Rule, but found that the Permit Revocation Rule is relevant to the court's review of the No Surprises Rule. The court, therefore, ordered the Service to consider the No Surprises Rule together with the Permit Revocation Rule in any new rulemaking proceedings concerning revocation of incidental take permits containing No Surprises assurances.

We are taking two rulemaking actions in response to the court order. First, in the Rules and Regulations section of today's **Federal Register** is a final rule withdrawing the permit revocation regulations, 50 CFR 17.22(b)(8) and 17.32(b)(8), vacated by the court order. Second, in this notice we request public comments on our proposal to reestablish the permit revocation regulations the court vacated.

**Summary of Previously Received Comments**

The following are comments we previously received on the Permit Revocation Rule; we will address these and other relevant issues in our final decision regarding this proposal. We received numerous comments on the provisions addressing permit revocation. The comments ranged widely, but generally fell into two categories: The agency did not go far enough with the revocation provision and the agency went too far with the revocation provision. With respect to comments that the revocation provision did not go far enough, many of the commenters stated that they did not see any reason why the old provision in § 13.28(a) should be replaced with a standard they viewed as less protective. These commenters also stated that the revocation provision should have mandatory language like the word "shall" to indicate that revocation is not discretionary. Many commenters questioned why the Service should have to step in at public expense to remedy jeopardy situations before a permit can be revoked. Some questioned what the standard "in a timely fashion" means. One commenter suggested that the revocation provision should also contain a reference to adverse modification of critical habitat, while another commenter recommended that the word "jeopardy" be used instead of "appreciable reduction in the likelihood of survival and recovery" because the commenter viewed "jeopardy" to be a higher standard.

With respect to comments expressing concern that the Service has gone too far, a number of commenters stated that the revocation provision undermined the No Surprises Rule. These commenters strongly opposed any further expansion of the revocation provision and suggested further expansion would be contrary to congressional intent. A number of commenters requested that the Service reaffirm the principles of No Surprises and noted that revocation should be "an action of last resort." Another commenter requested that we limit revocation to instances where the permittee is not in compliance with the permit or, at a minimum, add to the revocation provision a statement to indicate that the burden is on the agency to establish that the conditions for revocation exist.

**Request for Public Comments**

This notice seeks public comment on our proposal to reestablish the Permit Revocation Rule as originally promulgated in June 1999. We specifically invite public comment on the following issues:

1. The proposal to reestablish the Permit Revocation Rule. This rule would allow the Service to revoke an incidental take permit as a last resort in the unexpected and unlikely situation in which continuation of the permitted activities would likely jeopardize the continued existence of a species covered by the permit and the Service is not able to remedy the situation through other means in a timely fashion.

2. The interrelationship of the Permit Revocation Rule and the No Surprises Rule, including whether the revocation standard in the Permit Revocation Rule is appropriate in light of the regulatory assurances contained in the No Surprises Rule.

3. Whether the revocation standard in 50 CFR 13.28(a)(5) or some other revocation standard would be more appropriate for incidental take permits with No Surprises assurances.

**Required Determinations**

*Executive Order 12866*

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

(1) Are the requirements in the rule clearly stated?

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

(3) Does the format of the rule (grouping and order of sections, use of headings, paragraphing, *etc.*,) aid or reduce its clarity?

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

(5) Is the description of the rule in the **SUPPLEMENTARY INFORMATION** section of the preamble helpful in understanding the rule?

(6) What else could we do to make the rule easier to understand?

Send a copy of any comments that concern how we could make this rule easier to understand to: Office of Regulatory Affairs, Department of the Interior, Room 7229, 1849 C Street, NW., Washington, DC 20240.

*Regulatory Planning and Review*

In accordance with Executive Order 12866, this document is a significant proposed rule because it may raise novel legal or policy issues, and was reviewed by the Office of Management and Budget (OMB) in accordance with the four criteria discussed below.

(a) This proposed rule will not have an annual economic effect of $100 million or more or adversely affect an economic sector, productivity, jobs, the environment, or other units of government.

(b) This proposed rule is not expected to create inconsistencies with other agencies' actions. These regulations would amend potentially conflicting permitting regulations established for a voluntary program, Habitat Conservation Planning, for non-Federal property owners and would not create inconsistencies with the actions of non-Federal agencies.

(c) This regulation is not expected to significantly affect entitlements, grants, user fees, loan programs, or the rights and obligations of their recipients.

(d) OMB has determined that this rule may raise novel legal or policy issues and, as a result, this rule has undergone OMB review. The proposed rule is a direct response to a previous legal challenge.

*Regulatory Flexibility Act*

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.*, small businesses, small organizations, and small government jurisdictions), unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The Regulatory Flexibility Act requires Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant

economic impact on a substantial number of small entities.

Pursuant to the Regulatory Flexibility Act, we certified to the Small Business Administration that these regulations would not have a significant economic impact on a substantial number of small entities. The proposed changes clarify the circumstances under which an incidental take permit issued under the authority of section 10(a)(1)(B) of the Endangered Species Act might be subject to revocation. As of February 29, 2004, the Service has issued 327 incidental take permits, and none have required revocation. As identified in the preamble, the specific circumstances under which the proposed regulations would provide for revocation are expected to be extraordinarily rare.

*Small Business Regulatory Enforcement Fairness Act*

This regulation will not be a major rule under 5 U.S.C. 801 *et seq.*, the Small Business Regulatory Enforcement Fairness Act.

(a) This regulation would not produce an annual economic effect of $100 million.

(b) This regulation would not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions.

(c) This regulation would not have a significant adverse effect on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

*Executive Order 13211*

On May 18, 2001, the President issued an Executive Order (E.O. 13211) on regulations that significantly affect energy supply, distribution, and use. Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. Although this rule is a significant action under Executive Order 12866, it is not expected to significantly affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action and no Statement of Energy Effects is required.

*Unfunded Mandates Reform Act*

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*):

(a) The Service has determined and certifies pursuant to the Unfunded Mandates Reform Act, 2 U.S.C. 1502 *et seq.*, that this proposed rulemaking will not impose a cost of $100 million or more in any given year on local or State governments or private entities. No additional information will be required from a non-Federal entity solely as a result of the proposed rule. These regulations implement a voluntary program; no incremental costs are being imposed on non-Federal landowners.

(b) These regulations will not produce a Federal mandate of $100 million or greater in any year; that is, this rule is not a "significant regulatory action" under the Unfunded Mandates Reform Act.

*Takings*

In accordance with Executive Order 12630, these regulations do not have significant takings implications concerning taking of private property by the Federal Government. These regulations pertain to a voluntary program that does not require individuals to participate unless they volunteer to do so. Therefore, these regulations have no impact on personal property rights.

*Federalism*

These regulations will not have substantial direct effects on the States, in the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among various levels of government. Therefore, in accordance with Executive Order 13132, the Service has determined that this rule does not have sufficient federalism implications to warrant a Federalism Assessment.

*Civil Justice Reform*

In accordance with Executive Order 12988, the Department of the Interior has determined that this proposed rule does not unduly burden the judicial system and meets the applicable standards provided in sections 3(a) and 3(b)(2) of the Order.

*Paperwork Reduction Act*

This rule would not impose any new requirements for collection of information associated with incidental take permits other than those already approved for incidental take permits under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). This rule will not impose new recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. We 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.

*National Environmental Policy Act*

The Department of the Interior has determined that the issuance of the proposed rule is categorically excluded under the Department's NEPA procedures in 516 DM 2, Appendix 1.10.

*Government-to-Government Relationship With Indian Tribes*

In accordance with the Secretarial Order 3206, "American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act" (June 5, 1997); the President's memorandum of April 29, 1994, "Government-to-Government Relations with Native American Tribal Governments" (59 FR 22951); E.O. 13175; and the Department of the Interior's Manual at 512 DM 2, we understand that we must relate to recognized Federal Indian Tribes on a Government-to-Government basis. However, these regulations pertain to voluntary agreements, Habitat Conservation Plans, in which Tribes and individuals are not required to participate unless they volunteer to do so. Therefore, these regulations may have effects on Tribal resources and Native American Tribes, but solely at their discretion, should those Tribes or individuals choose to participate in the voluntary program.

**List of Subjects in 50 CFR Part 17**

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

**Proposed Regulation Promulgation**

For the reasons set out in the preamble, we propose to amend title 50, chapter I, subchapter B of the Code of Federal Regulations, as set forth below.

## PART 17—[AMENDED]

1. The authority citation for part 17 continues to read as follows:

**Authority:** 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

2. Amend § 17.22 by adding a new paragraph (b)(8) to read as follows:

**§ 17.22 Permits for scientific purposes, enhancement of propagation or survival, or for incidental taking.**

* * * * *

(b) * * *

(8) *Criteria for revocation.* A permit issued under paragraph (b) of this section may not be revoked for any reason except those set forth in § 13.28(a)(1) through (4) of this subchapter or unless continuation of the permitted activity would be inconsistent with the criterion set forth in 16 U.S.C. 1539(a)(2)(B)(iv) and the inconsistency

has not been remedied in a timely fashion.

* * * * *

3. Amend § 17.32 by adding a new paragraph (b)(8) to read as follows:

**§ 17.32 Permits—general.**

* * * * *

(b) * * *

(8) *Criteria for revocation.* A permit issued under paragraph (b) of this section may not be revoked for any reason except those set forth in § 13.28(a)(1) through (4) of this subchapter or unless continuation of the permitted activity would be inconsistent with the criterion set forth in 16 U.S.C. 1539(a)(2)(B)(iv) and the inconsistency has not been remedied in a timely fashion.

* * * * *

Dated: April 12, 2004.

**Craig Manson,**

*Assistant Secretary for Fish and Wildlife and Parks.*

[FR Doc. 04–11741 Filed 5–24–04; 8:45 am]

BILLING CODE 4310–55–P

# Notices

Federal Register
Vol. 69, No. 101
Tuesday, May 25, 2004

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

### Advisory Committee on Voluntary Foreign Aid; Notice of Meeting

Pursuant to the Federal Advisory Committee Act, notice is hereby given of a meeting of the Advisory Committee on Voluntary Foreign Aid (ACVFA).

*Date:* June 23, 2004 (8:30 a.m. to 1 p.m.).
*Location:* The Hilton Washington, 1919 Connecticut Avenue, NW., Washington, DC 20009.

This meeting will feature discussion on development and humanitarian assistance lessons learned in post-conflict and reconstruction. A session with Millennium Challenge Corporation CEO Paul Applegarth, will also take place. Participants will have an opportunity to ask questions of the speakers and participate in the discussion.

The meeting is free and open to the public. Persons wishing to attend the meeting can register online at *http://www.ACVFA.com* or e-mail their name to Ashley Mattison at *Ashley.Mattison@triumph-tech.com.*

Dated: May 13, 2004.

**Adele Liskov,**

*Acting Executive Director, Advisory Committee on Voluntary Foreign Aid (ACVFA).*

[FR Doc. 04–11794 Filed 5–24–04; 8:45 am]

**BILLING CODE 6116–01–P**

## DEPARTMENT OF AGRICULTURE

### Farm Service Agency

### Notice of Funds Availability; Tree Assistance Program for California Tree Losses Due to Wild Fires

**AGENCY:** Farm Service Agency, USDA.

**ACTION:** Notice.

**SUMMARY:** This notice announces the availability of $12,500,000 for the Tree Assistance Program (TAP) to compensate tree-fruit growers in disaster counties in California who had fruit tree losses as a result of the 2003 wild fires that occurred in southern California.

**DATES:** Applications by eligible persons may be submitted April 19, 2004 through May 28, 2004, or such other date as announced by the Deputy Administrator for Farm Programs of the Farm Service Agency (FSA).

**FOR FURTHER INFORMATION CONTACT:** Eloise Taylor, Chief, Compliance Branch, Production, Emergencies and Compliance Divisions, FSA/USDA, Stop 0517, 1400 Independence Avenue SW., Washington, DC 20250–0517; telephone (202) 720–9882; e-mail: *Eloise_Taylor@wdc.usda.gov.* and *http://www.regulations.gov.* Persons with disabilities who require alternative means for communication of regulatory information, (Braille, large print, audiotape, etc. should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

**SUPPLEMENTARY INFORMATION:**

#### Background

TAP was authorized but not funded by section 10201 of the Farm Security and Rural Investment Act of 2002 (Pub. L. 107–171) (7 U.S.C. 8201) to provide assistance to eligible orchardists to replant trees, bushes and vines that were grown for the production of an annual crop and were lost due to a natural disaster. This notice sets out a special program within TAP for certain fruit tree losses due to wild fires in California. Section 102(e) of Division H of the Consolidated Appropriations Act, 2004 (Pub. L. 108–199) appropriated $12,500,000 to provide assistance under TAP to compensate tree-fruit growers in those counties that suffered losses due to the wild fires that occurred in southern California in the fall of 2003. Consistent with other subsections of the same legislation and what is understood to be Congressional intent, assistance will be limited to four counties. Assistance will be provided subject to regulations and restrictions governing the new TAP provided for in the 2002 Act. Those regulations were published March 2, 2004 (69FR9744) and are found at 7 CFR part 783. Also, the restrictions of the statute apply. They include a requirement of replanting, a limitation on payments by "person", a limitation on acres for which relief can be claimed, a requirement that the loss be tied to a natural disaster, and others. If after the claims filed during the allowed period set out in this notice are received, and the available funds are less than the eligible claims, a proration will be made. Claims are limited to the lesser of the established practice rates or 75 percent of actual costs for eligible replantings after adjusting for normal mortality. Reimbursement for those plantings cannot exceed the reasonable cost of those replantings as determined by FSA. In addition, under current law, no "person" as defined by reference to program regulations can receive, cumulatively, for all TAP claims over the life of the program as administered pursuant to the general authority of the 2002 Act, a total of $75,000. Also, and cumulatively, no person for all TAP claims for all commodities over the life of the administration of the program can, under current law, receive benefits for losses on more than 500 acres. All other restrictions of the TAP regulations and statute apply as well. Other requirements may also apply.

#### Applications

Applications will be accepted until May 28, 2004, or such other date as announced by the Deputy Administrator for Farm Programs of FSA. Only producers with losses in eligible counties in California may file an application. The counties are Los Angeles, Riverside, San Diego, and San Bernardino for 2003 wild fire losses.

Application forms are available for TAP at FSA county offices or on the Internet at *www.fsa.usda.gov.* A complete application for TAP benefits and related supporting documentation must be submitted to the county office before the deadline.

A complete application will include all of the following:

(1) A form provided by FSA;

(2) A written estimate of the number of fruit trees lost or damaged which is prepared by the owner or someone who is a qualified expert, as determined by the FSA county committee;

(3) The number of acres on which the loss was suffered; and

(4) Sufficient evidence of the loss to allow the county committee to calculate whether an eligible loss occurred.

(5) Other information as requested or required by regulation.

Signed at Washington, DC April 27, 2004.

**Michael W. Yost,**

*Acting Administrator, Farm Service Agency.*

[FR Doc. 04–11743 Filed 5–24–04; 8:45 am]

BILLING CODE 3410–05–P

## DEPARTMENT OF AGRICULTURE

### Forest Service

### Notice of Public Meeting, Davy Crockett National Forest Resource Advisory Committee Meeting

**AGENCY:** Forest Service, Agriculture.

**ACTION:** Notice of public meeting.

**SUMMARY:** In accordance with the Secure Rural Schools and Community Self Determination Act of 2000 (Pub. L. 106–393) and the Federal Advisory Committee Act of 1972 (FACA), the U.S. Department of Agriculture, Forest Service, Davy Crockett National Forest Resource Advisory Committee (RAC) will meet as indicated below.

**DATES:** The Davy Crockett National Forest RAC meeting will be held June 24, 2004.

**ADDRESSES:** The Davy Crockett National Forest RAC meeting will be held at the Davy Crockett Ranger Station located on State Highway 7, approximately one quarter mile west of FM 227 in Houston County, Texas. The meeting will begin at 6 p.m. and adjourn at approximately 9 p.m. A public comment period will be at 8:45 p.m.

**FOR FURTHER INFORMATION CONTACT:** Raoul Gagne, District Ranger, Davy Crockett National Forest, Rt. 1, Box 55 FS, Kennard, Texas 75847: Telephone: 936–655–2299 or e-mail at: *rgagne@fs.fed.us.*

**SUPPLEMENTARY INFORMATION:** The Davy Crockett National Forest RAC proposes projects and funding to the Secretary of Agriculture under section 203 of the Secure Rural Schools and Community Self Determination Act of 2000. The purpose of the June 24, 2004 meeting is to introduce the RAC members, discuss the operational requirements of the RAC, and elect a chairperson. These meetings are open to the public. The public may present written comments to the RAC. Each formal RAC meeting will also have time, as identified above, allocated for hearing public comments. Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited.

Dated: May 20, 2004.

**Raoul W. Gagne,**

*Designated Federal Official, Davy Crockett National Forest RAC.*

[FR Doc. 04–11808 Filed 5–24–04; 8:45 am]

BILLING CODE 3410–11–M

## DEPARTMENT OF AGRICULTURE

### Forest Service

**RIN 0596–AC19**

### Tribal Watershed Forestry Assistance Program

**AGENCY:** Forest Service, USDA.

**ACTION:** Advanced notice of interim final guideline; request for comment.

**SUMMARY:** The Forest Service is announcing its intent to prepare an interim final guideline, in cooperation with Indian tribes, for the Tribal Watershed Forestry Assistance Program, as authorized by Title III, Section 303, of the Healthy Forests Restoration Act of 2003 (Pub. L. 108–148). The Tribal Watershed Forestry Assistance Program (TWFAP) is administered by the Forest Service and implemented by participating Indian tribes. The purpose of the TWFAP is to build and strengthen watershed partnerships that focus on forested landscapes at the State, regional, tribal, and local levels; to provide tribal forestry best-management practices and water quality technical assistance directly to Indian tribes; to provide technical guidance to tribal land managers and policy makers for water quality protection through forest management; to complement tribal efforts to protect water quality and provide enhanced opportunities for consultation and cooperation among Federal agencies and tribal entities charged with responsibility for water and watershed management; and to provide enhanced forest resource data and support for improved implementation and monitoring of tribal forestry best-management practices. In accordance with Forest Service policy, formal consultation is ongoing with Indian tribes on development of this new program. This notice supplements the consultation process. Comments are invited and will be considered in the development of the interim final guideline. Additional direction on the implementation of TWFAP will be issued to the Forest Service Manual Chapter 3500, Cooperative Watershed Management.

**DATES:** Comments must be received by July 26, 2004.

**ADDRESSES:** Send written comments to Karen Solari, USDA Forest Service, Cooperative Forestry, Mail Stop Code 1123, 1400 Independence Avenue, SW., Washington, DC 20250–0003; via electronic mail to *ksolari@fs.fed.us*; or via facsimile to (202) 205–1271. Comments also may be submitted via the World Wide Web/Internet at *http://www.regulations.gov*. The agency cannot confirm receipt of comments. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments during regular business hours at the office of the Cooperative Forestry Staff, 4th Floor SE., Yates Building, 201 14th Street, SW., Washington, DC. Visitors are encouraged to call ahead to (202) 205–1389 to facilitate entry into the building.

**FOR FURTHER INFORMATION CONTACT:** Karen Solari, USDA Forest Service, Cooperative Forestry, (202) 205–1274, or Susan Johnson, USDA Forest Service, Office of Tribal Relations, *sjohnson08@fs.fed.us*, (303)275–5760.

**SUPPLEMENTARY INFORMATION:** The Tribal Watershed Forestry Assistance Program (TWFAP) is established in the Healthy Forests Restoration Act of 2003 to provide technical, financial, and related assistance to Indian tribes for the purpose of expanding tribal stewardship capacities and activities through tribal forestry best-management practices and other means at the tribal level to address watershed issues on land under the jurisdiction of or administered by the Indian tribes. A copy of the Healthy Forests Restoration Act of 2003, Title III, and other information on the watershed forestry program can be found at: *http://www.fs.fed.us/cooperativeforestry/programs/wfa/*. The TWFAP provides for (1) Development a program of technical assistance; (2) Annual awards to participating tribes for watershed forestry projects; (3) Selection of priority watersheds to target watershed forestry projects for funding; and (4) An opportunity to create tribal watershed forester positions. At a minimum, the TWFAP interim final guideline will address these provisions.

In addition, the TWFAP interim final guideline will establish the criteria that Indian tribes should follow in implementing the TWFAP. These will include criteria for priority watershed selection, acceptable watershed forest projects, and best management practice programs. The guideline also will establish monitoring and accomplishment reporting requirements. The guideline will, to the extent consistent with Federal accountability and oversight responsibility, allow flexibility to the

tribes to implement the program in a manner consistent with local needs and opportunities. Comments are solicited on these provisions and other issues that should be included in the interim final guideline.

The interim final guideline and additional direction issued to Forest Service Manual 3500 will be developed by a workgroup of representatives from Indian tribes, and regional and national Forest Service State and Private Forestry.

The agency goal is to publish a notice of issuance of the interim final guideline with request for further comment in the **Federal Register** by October, 2004. A separate advance notice of an interim final guideline for the Watershed Forestry Assistance Program, to be developed in cooperation with State Foresters, has been published in today's **Federal Register**.

Dated: May 6, 2004.

**Sally D. Collins,**

*Associate Chief.*

[FR Doc. 04–11735 Filed 5–24–04; 8:45 am]

BILLING CODE 3410–11–P

## DEPARTMENT OF AGRICULTURE

### Forest Service

**RIN 0596–AC18**

### Watershed Forestry Assistance Program

**AGENCY:** Forest Service, USDA.

**ACTION:** Advanced notice of interim final guideline; request for comment.

**SUMMARY:** The Forest Service is announcing its intent to prepare an interim final guideline, in cooperation with the State Foresters and with involvement of the public, for the implementation of the Watershed Forestry Assistance Program, as authorized by Title III, section 302, of the Healthy Forests Restoration Act of 2003 (Pub. L. 108–148). The Watershed Forestry Assistance Program (WFAP) is administered by the Forest Service and implemented by the State Foresters, or an equivalent State official. The purpose of the WFAP is to improve public understanding of the connection between forest management and watershed health; encourage property owners to maintain tree cover and use tree plantings and vegetative treatments as creative solutions to watershed problems; enhance forest management and riparian buffer use in watersheds, with an emphasis on community watersheds; and establish partnerships and collaborative watershed approaches to forest management, protection, and conservation. Public comment is invited and will be considered in the development of the interim final guideline. Additional direction on the implementation of WFAP will be issued to the Forest Service Manual Chapter 3500, Cooperative Watershed Management.

**DATES:** Comments must be received by July 26, 2004.

**ADDRESSES:** Send written comments to Karen Solari, USDA Forest Service, Cooperative Forestry, Mail Stop Code 1123, 1400 Independence Avenue, SW., Washington, DC 20250–0003; via electronic mail to *ksolari@fs.fed.us*; or via facsimile to (202) 205–1271. Comments also may be submitted via the World Wide Web/Internet at *http://www.regulations.gov*. The agency cannot confirm receipt of comments. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments during regular business hours at the office of the Cooperative Forestry Staff, 4th Floor SE., Yates Building, 201 14th Street, SW., Washington, DC. Visitors are encouraged to call ahead to (202) 205–1389 to facilitate entry into the building.

**FOR FURTHER INFORMATION CONTACT:** Karen Solari, USDA Forest Service, Cooperative Forestry, (202) 205–1274.

**SUPPLEMENTARY INFORMATION:** The Watershed Forestry Assistance Program (WFAP) is established in the Healthy Forests Restoration Act of 2003 to address watershed issues on nonfederal forested and potentially forested land. A copy of the Healthy Forests Restoration Act of 2003, Title III, and other information on the watershed forestry program can be found at: *http://www.fs.fed.us/cooperativeforestry/programs/wfa/*. The WFAP provides for (1) development of a program of technical assistance; (2) establishment of a watershed forestry cost-share program; (3) creation of State watershed forester positions; and (4) selection of priority watersheds by the state forest stewardship coordinating committees. At a minimum, the WFAP interim final guideline will address these provisions.

In addition, the WFAP interim final guideline will establish the criteria that State Foresters and communities, nonprofit groups, and owners of nonindustrial private forest land should follow in implementing the WFAP. These will include criteria for priority watershed selection, acceptable watershed forest projects, and best management practice programs. The guideline also will establish budget allocation procedures and monitoring and accomplishment reporting requirements. The guideline will, to the extent consistent with Federal accountability and oversight responsibility, allow flexibility to the States to implement the program in a manner consistent with local needs and opportunities. Comments are solicited on these provisions and other issues that should be included in the interim final guideline.

The interim final guideline and additional direction issued to Forest Service Manual 3500 will be developed by a workgroup of representatives from State forestry agencies and regional and national Forest Service State and Private Forestry offices and USDA Cooperative State Research Education and Extension Service.

The agency goal is to publish a notice of issuance of the interim final guideline with request for further comment in the **Federal Register** by October 2004. A separate notice of an interim final guideline for the Tribal Watershed Forestry Assistance Program, to be developed in cooperation with Indian tribes, has been published in today's **Federal Register**.

Dated: May 6, 2004.

**Sally Collins,**

*Associate Chief.*

[FR Doc. 04–11734 Filed 5–24–04; 8:45 am]

BILLING CODE 3410–11–P

## COMMISSION ON CIVIL RIGHTS

### Agenda and Notice of Public Meeting of the Pennsylvania Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights that a conference call of the Pennsylvania Advisory Committee will convene at 1 p.m. and adjourn at 2 p.m. on May 26, 2004. The purpose of the conference call is to discuss future projects.

This conference call is available to the public through the following call-in number: 1–800–659–1088, access code: 23863133. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls not initiated using the supplied call-in number or over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls using the call-in number over land-line connections. Persons with hearing impairments may also follow the proceedings by first calling the Federal

Relay Service at 1–800–977–8339 and providing the Service with the conference call number and access code number.

To ensure that the Commission secures an appropriate number of lines for the public, persons are asked to register by contacting Barbara de La Viez of the Eastern Regional Office, 202–376–7533 (TTY 202–375–8116), by 4 p.m. on Monday May 24, 2004.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, May 14, 2004.

**Ivy L. Davis,**

*Chief, Regional Programs Coordination Unit.*

[FR Doc. 04–11712 Filed 5–24–04; 8:45 am]

BILLING CODE 6335–01–P

## COMMISSION ON CIVIL RIGHTS

### Agenda and Notice of Public Meeting of the Rhode Island Advisory Committee

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a conference call of the Rhode Island Advisory Committee will convene at 1 p.m. and adjourn at 2 p.m. on Thursday, June 3, 2004. The purpose of the conference call is to discuss and plan future projects.

This conference call is available to the public through the following call-in number: 1–800–659–1081, access code number: 23626539. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls not initiated using the supplied call-in number or over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls using the call-in number over land-line connections. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and access code number.

To ensure that the Commission secures an appropriate number of lines for the public, persons are asked to register by contacting Barbara de La Viez of the Eastern Regional Office, 202–376–7533 (TTY 202–375–8116), by 4 p.m. on Wednesday, June 2, 2004.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, May 14, 2004.

**Ivy L. Davis,**

*Chief, Regional Programs Coordination Unit.*

[FR Doc. 04–11713 Filed 5–24–04; 8:45 am]

BILLING CODE 6335–01–P

## COMMISSION ON CIVIL RIGHTS

### Agenda and Notice of Public Meeting of the Alabama, Arkansas, Louisiana and Mississippi Advisory Committees

Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights, that a conference call of the Alabama, Arkansas, Louisiana and Mississippi Advisory Committees will convene at 1:30 p.m. and adjourn at 3 p.m. (CDT) on Thursday, June 10, 2004. The purpose of the conference call is to discuss and plan future SAC activities and conduct a public briefing meeting.

This conference call is available to the public through the following call-in number: 1–888–777–0937, access code #23714062. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls not initiated using the supplied call-in number or over wireless lines and the Commission will not refund any incurred charges. Callers will incur no charge for calls using the call-in number over land-line connections. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and access code.

To ensure that the Commission secures an appropriate number of lines for the public, persons are asked to register by contacting Corrine Sanders of the Central Regional Office 913–551–1400 (TDD 913–551–1414), by 3 p.m. on Friday, June 4, 2004.

The meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, DC, May 14, 2004.

**Ivy L. Davis,**

*Chief, Regional Programs Coordination Unit.*

[FR Doc. 04–11711 Filed 5–24–04; 8:45 am]

BILLING CODE 6335–01–P

## DEPARTMENT OF COMMERCE

### Bureau of the Census

**[Docket Number 040510146–4146–01]**

### Annual Survey of Manufacturers

**AGENCY:** Bureau of the Census, Commerce.

**ACTION:** Notice of consideration and request for comments.

**SUMMARY:** The Bureau of the Census (Census Bureau) plans to reduce the number of individual 6-digit North American Industry Classification System (NAICS) industries for which the Annual Survey of Manufacturers (ASM) estimates are published. We will continue to publish estimates for all manufacturing industries at higher levels of industry aggregation. By doing this, we hope to improve the timeliness of the estimates we produce as well as enhance the reliability and relevance of variables we collect.

We are replacing the current 473 6-digit NAICS industries with a new list of 318 ASM industries, which will include selected 6-digit NAICS industries and other industries defined as groups of the 6-digit NAICS industries. Six-digit industries are the most detailed defined by the NAICS. The lists of present and proposed industries along with the concordance are available on our Web site at *http://www.census.gov/mcd/asmchange/.*

**DATES:** Written comments on this notice must be submitted on or before June 24, 2004.

**ADDRESSES:** Direct all written comments to the Director, U.S. Census Bureau, Room 2049, Federal Building 3, Washington, DC 20233.

**FOR FURTHER INFORMATION CONTACT:** Judy M. Dodds, Assistant Division Chief, Census and Related Programs, Manufacturing and Construction Division, on (301) 763–4587 or by e-mail at *judy.m.dodds@census.gov.*

**SUPPLEMENTARY INFORMATION:** The Census Bureau is authorized to conduct surveys necessary to furnish current data on subjects covered by the major censuses authorized by title 13, United States Code (U.S.C.), sections 182, 224, and 225. Reporting by ASM establishments will continue to be mandatory and provide continuing and timely national statistical data on the manufacturing sector. Data collected in this survey will be within the general scope, type, and character of those inquiries covered in the Economic Census.

The ASM collects industry statistics, such as total value of shipments, employment, payroll, workers' hours, capital expenditures, cost of materials consumed, supplemental labor costs, and so forth. This survey, conducted on a sample basis, covers all manufacturing industries, including data on plants under construction, but not yet in operation.

Beginning with the survey year 2003, the Census Bureau plans to reduce the number of detailed industries for which the ASM estimates are published. Reducing the level of detail for which characteristics are estimated will allow the Census Bureau to focus resources on improving other aspects of the ASM program. We believe that this reduction in ASM detail will not have a substantial adverse impact upon the public. While some industry detail will be lost for ASM, similar data for some of the variables are available from other sources, such as County Business Patterns or programs of the Bureau of Labor Statistics. The ASM is conducted as a mail-out/mail-back survey. No changes in the collection of information are planned as a result of this proposal.

Published estimates from the ASM are used by a variety of private business and trade associations. They provide various governmental agencies with a tool to evaluate economic policy and to measure progress toward established goals. For example, Bureau of Economic Analysis staff use data to develop nonresidential fixed investment components of gross private domestic investment in the gross domestic product. The Federal Reserve Board uses the data to estimate indexes of production, which are presented to the Board of Governors and have an impact on monetary policy.

**Paperwork Reduction Act**

Notwithstanding any other provision of law, no person is required to respond to, nor shall a person be subject to a penalty for failure to comply with, a collection of information subject to requirements of the Paperwork Reduction Act (PRA), unless that collection of information displays a current valid Office of Management and Budget (OMB) control number. In accordance with the PRA, 44 U.S.C. chapter 35, the OMB approved the current ASM under OMB Control Number 0607–0449. The total burden hours associated with OMB Control Number 0607–0449 are 187,000 hours. We will provide copies of each form upon written request to the Director, U.S. Census Bureau, Washington, DC 20233–0001.

Dated: May 19, 2004.

**Charles Louis Kincannon,**

*Director, Bureau of the Census.*

[FR Doc. 04–11763 Filed 5–24–04; 8:45 am]

BILLING CODE 3510–07–P

## DEPARTMENT OF COMMERCE

### International Trade Administration

### Case Western Reserve University, et al.; Notice of Consolidated Decision on Applications for Duty-Free Entry of Scientific Instruments

This is a decision consolidated pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 a.m. and 5 p.m. in Suite 4100W, Franklin Court Building, U.S. Department of Commerce, 1099 14th Street, NW., Washington, DC.

*Comments:* None received. *Decision:* Approved. No instrument of equivalent scientific value to the foreign instruments described below, for such purposes as each is intended to be used, is being manufactured in the United States.

*Docket Number:* 03–053. *Applicant:* Case Western Reserve University, Cleveland, OH 44106. *Instrument:* Scanning Near-Field Optical Microscope, Model ALPHASNOM. *Manufacturer:* WITEC, Germany. *Intended Use:* See notice at 69 FR 26074, May 11, 2004. *Reasons:* The foreign instrument provides: (1) The ability to perform tapping mode AFM imaging simultaneously with near field imaging, (2) > 200 nm bandwidth in the illuminating light source without having to change the near-field aperture and (3) performance of reflection mode confocal microscopy using a range of upper objectives. Advice received from: The National Institutes of Health, May 12, 2004.

*Docket Number:* 04–007. *Applicant:* Argonne National Laboratory, Argonne, IL 60439. *Instrument:* UHV STM Microscope with cryostat. *Manufacturer:* Unisoku Scientific Instruments, Japan. *Intended Use:* See notice at 69 FR 26074, May 11, 2004. *Reasons:* The foreign instrument provides: (1) An operating temperature of 1.8 °K, (2) *in situ* surface cleaving, (3) double stage mechanical damping and (4) a magnetic field to 7.0 Tesla. Advice received from: The National Institute of Standards and Technology, May 17, 2004.

*Docket Number:* 04–008. *Applicant:* California Institute of Technology, Pasadena, CA 91125. *Instrument:* Dual Beam SEM/FIB System, Model Nova 600 Nanolab. *Manufacturer:* FEI Company, the Netherlands. *Intended Use:* See notice at 69 FR 26074, May 11, 2004. *Reasons:* The foreign instrument provides: (1) Operation in high and low vacuum, with high and low energy electrons, (2) ability to work with both thick and thin samples and (3) laser interferometer capability. Advice received from: Sandia National Laboratories, February 12, 2004 (comparable case).

*Docket Number:* 04–009. *Applicant:* University of Colorado, Boulder, CO 80303. *Instrument:* Cryogenic Fabry-Perot Etalon Controller (accessory). *Manufacturer:* IC Optical Systems Ltd., United Kingdom. *Reasons:* This is a compatible accessory for an existing instrument purchased for use by the applicant. It is pertinent to the intended uses and we know of no domestic accessory which can be readily adapted to the previously imported foreign instrument.

The capabilities of each of the foreign instruments described above are pertinent to each applicant's intended purposes and we know of no other instrument or apparatus being manufactured in the United States which is of equivalent scientific value to any of the foreign instruments.

**Gerald A. Zerdy,**

*Program Manager, Statutory Import Programs Staff.*

[FR Doc. 04–11806 Filed 5–24–04; 8:45 am]

BILLING CODE 3510–DS–P

## DEPARTMENT OF COMMERCE

### International Trade Administration

### The Jackson Laboratory; Notice of Decision on Application for Duty-Free Entry of Electron Microscope

This decision is made pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 a.m. and 5 p.m. in Suite 4100W, Franklin Court Building, U.S. Department of Commerce, 1099 14th Street, NW., Washington, DC.

*Docket Number*: 04–006. *Applicant*: The Jackson Laboratory, Bar Harbor, ME 04609. *Instrument*: Electron Microscope, Model JEM–1230 (HC). *Manufacturer*: JEOL Ltd., Japan. *Intended use*: See notice at 69 FR 26074, May 11, 2004. *Order Date*: December 30, 2003.

*Comments*: None received. *Decision*: Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as the instrument is intended to be used, was being manufactured in the United States at the time the instrument was ordered. *Reasons*: The foreign instrument is a conventional transmission electron

microscope (CTEM) and is intended for research or scientific educational uses requiring a CTEM. We know of no CTEM, or any other instrument suited to these purposes, which was being manufactured in the United States either at the time of order of the instrument or at the time of receipt of the application by U.S. Customs and Border Protection.

**Gerald A. Zerdy,**

*Program Manager, Statutory Import Programs Staff.*

[FR Doc. 04–11807 Filed 5–24–04; 8:45 am]

BILLING CODE 3510–DS–M

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

### Environmental Impact Statement for the Monterey Bay Aquarium Institute Application To Install a Cabled Observatory Within the Monterey Bay National Marine Sanctuary and Notice of Scoping Meeting

**AGENCY:** National Marine Sanctuary Program (NMSP), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

**ACTION:** Notice of Intent to prepare an EIS; notice of public scoping meeting; request for public comments.

**SUMMARY:** NOAA announces its intention to prepare an environmental impact statement (EIS) in accordance with the National Environmental Policy Act of 1969 (NEPA) for the proposed Monterey Bay Aquarium Research Institute (MBARI) installation of an advanced cabled observatory on the seafloor within the Monterey Bay National Marine Sanctuary (MBNMS). The proposed scientific research project, known as the Monterey Accelerated Research System (MARS), is comprised of one science node on 51 kilometers (km) of submarine cable. The Federal action at issue would be the NMSP's issuance of a MBNMS permit to authorize the conduct of this activity.

The EIS will be prepared in cooperation with the California State Lands Commission, which issued a Notice of Preparation on May 21, 2004, regarding its internet to prepare an Environmental Impact Report (EIR) pursuant to the California Environmental Quality Act (CEQA). The EIS prepared under this notice will be combined with the EIR and a joint EIR/EIS will be published.

**DATES:** Written comments on the scope of the EIS, suggested alternatives and potential impacts must be received on or before June 24, 2004. Two public scoping meetings to inform interested parties of the proposed action and to receive public comments on the scope of the EIS are scheduled as follows:

Wednesday, June 9, 2004—4 p.m.

Wednesday, June 9, 2004—6:30 p.m.

**ADDRESSES:** Submit written comments to Deirdre Hall, Monterey Bay National Marine Sanctuary, 299 Foam Street, Monterey, CA 93940. Comments may be submitted by fax at (831) 647–4250 or by e-mail at: *deirdre.hall@noaa.gov*. Comments received will be available for public inspection at the above address.

Copies of the application materials may be obtained by writing to the above address, or by contacting Deirdre Hall at (831) 647–4207. For directions to the public scoping meeting, contact the MBNMS office at (831) 647–4201.

The public meetings will be held at the Moss Landing Marine Laboratory, 8272 Moss Landing Road, Moss Landing, California.

**FOR FURTHER INFORMATION CONTACT:** William J. Douros, MBNMS Superintendent at (831) 647–4201 or by e-mail at *William.Douros@noaa.gov*.

**SUPPLEMENTARY INFORMATION:**

#### I. Proposed Action

The proposed action is MBARI's installation of approximately 51 kilometers of 28 mm wide submarine cable and a science node at the end of the cable, all within the boundaries of the MBNMS. The Federal action at issue would be the NMSP's issuance of a MBNMS permit to authorize the conduct of this activity. The cable route extends from Moss Landing (Monterey Bay, California) towards the northwest, to the north of the Monterey Canyon, and along the continental margin to the southeastern part of the Smooth Ridge. The applicant, Monterey Aquarium Research Institute (MBARI), proposes this scientific research project under the title of Monterey Accelerated Research System (MARS) cabled observatory.

*Project Objectives*

The purpose of the MARS project is to design and install an advanced-technology cabled observatory that will provide power and high-bandwidth communications to instruments sited at critical areas of science interest in State and federal waters of Monterey Bay. The site chosen in Monterey Bay's Smooth Ridge will enable important science experiments and science observations to be undertaken, as well as serve as the test bed for a state-of-the-art regional scale cabled observatory (NEPTUNE), currently one component of the National Science Foundation Ocean Observatories Initiative. NEPTUNE is a regional scale cabled observatory that the NSF plans to construct in 2006 off the coast of Washington. MARS will provide an advance opportunity to look at the operations, management, outreach activities, and costs involved with NEPTUNE on a smaller scale, and allow adjustments where necessary.

Specific Project Objectives are to:

- Test aspects of the regional cabled observatory (NEPTUNE) technology, both for the initial design of the system and during the lifetime of the project.
- Test methods for education and outreach in partnership with the Monterey Bay Aquarium, which enjoys a world-class reputation for its innovative programs in public education.
- Test deep-water remotely operated vehicle (ROV) procedures that will later be used for installing and servicing instruments on NEPTUNE.
- Serve as an instrument test bed to verify the performance of new instrumentation under development prior to being deployed on NEPTUNE.
- Provide power and high bandwidth real time communications to a broadband seismic observatory located on the west side of the San Gregorio fault line.
- Provide power and high bandwidth communications to instrumentation that will (a) allow long term in situ studies of chemosynthetic biological communities on Smooth Ridge, (b) be located in the active upper canyon enabling better understanding of canyon mass wasting events, (c) enable long term monitoring of spatial and temporal variability in parameters such as temperature and chlorophyll associated with phenomena such as El Niño that can significantly affect fishery stocks, and (d) enable studies of carbon transport from the region of primary production in the upper ocean to benthic communities.

*Need for Project Location*

MARS would be located in Monterey Bay offshore the MBARI facilities at Moss Landing, Monterey County, California. MBARI has indicated that Monterey Bay is needed because:

- Moss Landing is within easy year round access to deep water due to its location at the head of Monterey Canyon, and its mild climate. The MARS observatory must be located in deep water to test both the NEPTUNE technology and to develop the ROV procedures needed to operate deep-water cabled observatories.
- MBARI has two ships equipped with ROVs berthed at Moss Landing,

one of which is nearly always deployed as a day boat. These ROVs are the only ones located on the west coast of the U.S. operated by an oceanographic institute.

- One of MBARI's joint projects with the Monterey Bay Aquarium, Education, and Research: Testing Hypothesis (EARTH) provides wide public and educational benefits.
- Smooth Ridge is located on the west side of the San Gregorio fault line, critical for seismic studies, and is close to several well established chemosynthetic biological communities. It is also provides a location that is within easy reach of the active upper section on Monterey Canyon.

*Project Installation*

The proposed science node, located approximately 891 meters below the ocean surface, will provide eight science ports for oceanographic instruments. Extension cable can be plugged into any science port to provide power and communications up to 3.5 km away from the original node. By supplying both data links and electrical power, the network will allow real-time, continuous, and long-term monitoring of conditions beneath the surface of the bay.

The applicant proposes to bury the cable along most of the route to a depth of one meter, where feasible, using a hydraulically operated plow that is towed by a cable installation vessel. The plow would cut a narrow trench for the cable and bury the cable. In areas where the cable cannot be buried with this method, the cable would be laid on the sea bottom and would be post lay buried by jetting, where feasible. Some portions of the cable would remain unburied due to potentially hard seafloor substrate and exposed rocks. In the nearshore area, the cable would be installed in an existing pipeline that extends from 153 meters offshore to the proposed landing site located in Moss Landing and owned by Duke Energy.

The applicant anticipates the cable would operate for a minimum of 25 years. The scope of the EIS will address the offshore area from shore to the end of the cable.

**II. Summary of Environmental Issues**

MBNMS has made a determination that the issuance of a permit for this activity would require the preparation of an EIS pursuant to NEPA, the Council on Environmental Quality (CEQ) implementing regulations (40 CFR Parts 1500 through 1508), and NOAA's implementing guidelines on NEPA codified in NOAA Administrative Order 216–6.

The installation, maintenance, and eventual decommissioning and removal of the cable pose potentially significant impacts upon Sanctuary resources and qualities. The EIR/EIS will address onshore and offshore environmental effects of cable construction, operation, maintenance, repair and removal.

A preliminary listing of issues to be discussed in the EIS is provided below. Additional issues may be identified at the public scoping meeting and in written comments.

- Air Quality—short-term air quality effects from construction equipment, vehicle, and vessel emissions.
- Biological Resources—effects on benthic communities, rocky hard-bottom communities, plankton, fish, marine birds, marine mammals, and marine turtles from construction disturbances (e.g., cable laying, boat anchoring, increased turbidity), release of contaminants, or entanglement; direct or indirect effects on sensitive species and habitats.
- Commercial and Recreational Fishing—effects on fisheries and fisheries operations, including construction interference with fishing activities, potential loss of catch, potential accidents (e.g., fishing net entanglement), and long-term preemption of fishing grounds.
- Cultural Resources—potential for impacts on cultural resources that may be buried along the proposed cable route.
- Environmental Justice—potential to cause disproportionate effects on minority and/or low-income populations within the project impact area. Such populations may include, but not be limited to, those in the local fishing industry.
- Geology and Soils—geologic hazards and physical effects on the cable (e.g., submarine landslides and erosion).
- Marine Water Quality—trenching effects on the water column (e.g., sediment plume, benthic disruption, and siltation) or contamination from accidental spills.
- Noise—increased noise levels from construction and maintenance operations.
- Marine Vessel Traffic—cable installation vessel interference with commercial and recreational vessel navigation.
- Strumming—lateral movement of the cable along the seafloor, which may impact the marine environment.

**III. Alternatives**

In addition to the applicant's proposed action, the EIS will, at a minimum, consider the following project alternatives:

- *No Project/No-Action Alternative:* The EIS will examine the impacts of not approving the proposed action.
- *Alternative Offshore Locations:* The EIS will consider alternative routing and landing locations in the vicinity of the project within Monterey Bay and in proximity to the MBARI facilities.
- *Alternative Means of Obtaining Data:* The EIS will examine the feasibility of utilizing buoys and other means to accomplish the project objectives.

**IV. Comments**

MBNMS would like public comments on the following:

1. Comments about the scope of issues that should be evaluated in the EIS concerning this proposal;
2. Comments regarding the expected impacts of this project on the environment of the NBNMS and the overall significance of those impacts;
3. Recommendations on mitigation measures and permit conditions that would eliminate or minimize the impacts of this project on the MBNMS or the environment generally should the permit be issued;
4. Recommendations for specific monitoring programs or plans that would allow the MBNMS Superintendent to know the effectiveness of mitigation measures and conditions; and
5. Comments on other alternatives or technologies that meet the research objectives.

**V. Future Public Involvement**

Additional opportunities for public review will be provided when the Draft EIR/EIS is completed. A notice of availability (NOA) of the Draft EIR/EIS will be published in the **Federal Register**.

**VI. Special Accommodations**

The scoping meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Deirdre Hall, at the MBNMS, (831) 647–4207, at least five (5) days prior to the meeting date.

**Richard W. Spinrad,**

*Assistant Administrator, Ocean Services and Coastal Zone Management, National Oceanic and Atmospheric Administration.*

[FR Doc. 04–11738 Filed 5–24–04; 8:45 am]

BILLING CODE 3510–NK–M

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

[I.D. 051304A]

### Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Final Environmental Impact Statement Addressing Essential Fish Habitat Requirements of the Fishery Management Plans of the U.S. Caribbean

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

**ACTION:** Notice of availability of a Record of Decision.

**SUMMARY:** In compliance with the National Environmental Policy Act of 1969, NMFS announces the availability of a Record of Decision (ROD) regarding a final environmental impact statement (FEIS) that was prepared to determine whether to amend the fishery management plans of the Caribbean Fishery Management Council to address essential fish habitat (EFH) requirements of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). This ROD documents the decision by NMFS to proceed with such an amendment to: describe and identify EFH for each fishery; identify other actions to encourage the conservation and enhancement of such EFH; and identify measures to prevent, mitigate or minimize to the extent practicable the adverse effects of fishing on such EFH.

**ADDRESSES:** Copies of the ROD and the FEIS can be obtained from NMFS, Southeast Regional Office, 9721 Executive Center Drive North, St. Petersburg, FL 33702; telephone: 727–570–5317.

**FOR FURTHER INFORMATION CONTACT:** David Dale, Fishery Biologist, 727–570–5317, fax: 727–570–5300; email: *david.dale@noaa.gov*.

**SUPPLEMENTARY INFORMATION:** NMFS Southeast Region was the lead agency responsible for preparing, under third party contract, an FEIS for the Generic Essential Fish Habitat Amendment (EFH Amendment) for the spiny lobster, queen conch, reef fish, and coral fishery management plans for the U.S. Caribbean. The FEIS evaluates alternatives for bringing the EFH Amendment into compliance with the EFH mandates of the Magnuson-Stevens Act. For each of the four Caribbean fisheries, the FEIS analyzes a range of potential alternatives to: (1) describe and identify EFH for the fishery; (2) identify other actions to encourage the conservation and enhancement of such EFH; and (3) identify measures to minimize, to the extent practicable, the adverse effects of fishing on such EFH. The FEIS contains the methods and data used in the analyses, background information on the physical, biological, human, and administrative environments, and a description of the fishing and non-fishing threats to EFH. The notice of availability of the FEIS was published on April 23, 2004 (69 FR 22025).

The ROD documents NMFS' decision to proceed, in cooperation with the Caribbean Fishery Management Council (Council), with amending the spiny lobster, queen conch, reef fish, and coral fishery management plans for the U.S. Caribbean to implement the Council's preferred alternatives for identifying EFH, identifying habitat areas of particular concern, and preventing, mitigating, or minimizing the adverse effects of fishing on EFH. The ROD identifies all alternatives considered in reaching the decision, specifies the alternatives which were considered to be environmentally preferable, and identifies and discusses relevant factors which were balanced by NMFS in making its decision. A copy of the ROD will be mailed to individuals, agencies, or companies that commented on the draft and final EISs. In addition, copies of the ROD and FEIS are available from NMFS (see **ADDRESSES**).

**Authority:** 16 U.S.C. 1801 *et seq.*

Dated: May 20, 2004.

**John Oliver,**

*Deputy Assistant Administrator for Operations, National Marine Fisheries Service.*

[FR Doc. 04–11802 Filed 5–24–04; 8:45 am]

BILLING CODE 3510–22–S

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

[I.D. 031604B]

### Taking Marine Mammals Incidental to Specified Activities; Alafia River Navigation Channel, Tampa, FL

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

**ACTION:** Notice of receipt of application and proposed authorization for an incidental take authorization; request for comments.

**SUMMARY:** NMFS has received a request from the U.S. Army Corps of Engineers-Jacksonville District (Corps) for authorizations to take marine mammals, by harassment, incidental to expanding and deepening the Alafia River Navigation Channel in Tampa Harbor, FL (Alafia River project). Under the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue a 1–year Incidental Harassment Authorization (IHA) to the Corps to incidentally take, by harassment, bottlenose dolphins (*Tursiops truncatus*) as a result of conducting this activity and the Corps' application for regulations.

**DATES:** Comments and information must be received no later than June 24, 2004.

**ADDRESSES:** Comments on the application should be addressed to Michael Payne, Chief, Marine Mammal Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Silver Spring, MD 20910–3225. The mailbox address for providing e-mail comments on this action is *PR2.Tampa1@noaa.gov* Include in the subject line of the e-mail comment the following document identifier: ID#031604B. Comments sent via email, including all attachments, must not exceed a 10–megabyte file size. A copy of the application containing a list of references used in this document may be obtained by writing to the address provided or by telephoning the contact listed under the heading **FOR FURTHER INFORMATION CONTACT**. Publications referenced in this document are available for viewing, by appointment during regular business hours, at the address provided here during this comment period.

**FOR FURTHER INFORMATION CONTACT:** Kenneth R. Hollingshead, NMFS, (301) 713–2322, ext 128.

**SUPPLEMENTARY INFORMATION:**

#### Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

Permission may be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an

unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses and that the permissible methods of taking and requirements pertaining to the monitoring and reporting of such takings are set forth. NMFS has defined "negligible impact" in 50 CFR 216.103 as "an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival."

Subsection 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the United States can apply for an authorization to incidentally take small numbers of marine mammals by harassment. The MMPA defines "harassment" as:

> any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].

Subsection 101(a)(5)(D) establishes a 45–day time limit for NMFS review of an application followed by a 30–day public notice and comment period on any proposed authorizations for the incidental harassment of small numbers of marine mammals. Within 45 days of the close of the comment period, NMFS must either issue or deny issuance of the authorization.

**Summary of Request**

On February 26, 2004, NMFS received a request from the Corps for an authorization to take bottlenose dolphins incidental to using blasting during expansion of the Alafia River Navigation Channel by widening the channel to 250 ft (76.2 m) and deepening the channel to 42 ft (12.8 m) at mean low low water (mllw). The existing turning basin would be enlarged to a diameter of 1200 ft (365.8 m) with a depth of 42 ft (12.8 m) at mllw. The specific geographic area of the construction will be within the boundaries of the Alafia River Navigation Channel, part of the Tampa harbor navigation project. The Alafia River is located in northern Tampa Bay, Hillsborough County, Florida.

Completion of the dredging project may employ a clamshell dredge, cutterhead dredge and/or blasting. The dredging will remove 5.5 million cubic yards of material from the existing navigation channel and turning basin. Material removed from the dredging will be placed in the Tampa Ocean Dredged Material Disposal Site and at two "beneficial use of dredged material" sites located near the project area. The project is proposed to start in February 2005 and is estimated to last for 24 months.

The Corps expects the contractor to employ underwater confined blasting and dredging to construct the project. Blasting may have adverse impacts on bottlenose dolphins and manatees (*Trichechus manatus latirostris*) inhabiting near or utilizing the Alafia River channel in the northern portion of Tampa Bay. Dolphins and other marine mammals have not been documented as being directly affected by dredging activities other than blasting.

While the Corps does not presently have a blasting plan from the contractor, which will specifically identify the number of holes that will be drilled, the amount of explosives that will be used for each hole, the number of blasts per day (usually no more than 3/day), or the number of days the construction is anticipated to take to complete, the Corps submitted a description of a completed project in San Juan Harbor, Puerto Rico as an example. For that project, the maximum weight of the explosives used for each event was 375 lbs (170 kg) and the contractors detonated explosives once or twice daily from July 16 to September 9, for a total of 38 individual detonations. Normal practice is for each charge to be placed approximately 5 - 10 ft (1.5 - 3 m) deep within the rock substrate, depending on how much rock needs to be broken and how deep a channel depth is authorized. The charges are placed in the holes and tamped with rock. Therefore, if the total explosive weight needed is 375 lbs (170 kg) and they have 10 holes, they would average 37.5 lbs (17.0 kgs)/hole. However, a more likely weight for this project may be only 90 lbs (41 kgs) and, therefore, 9 lbs (4.1 kg)/hole. Charge weight and other determinations are expected to be made by the Corps and the contractor approximately 30–60 days prior to commencement of the construction project. Because the charge weight and other information is not presently available, NMFS will require the Corps to provide this information to NMFS, including calculations for impact/mitigation zones (for the protection of marine mammals from injury), prior to commencing work. However, as described later in this document, mitigation measures will require the Corps to limit detonations to the minimum level necessary to accomplish the task and the larger the charge weight, the greater the safety zone that will be required to protect marine mammals.

**Summary of Request for Regulations**

While the Corps was coordinating with NMFS on the application and issuance of an IHA for the Miami Turning Basin in early 2003 (see 68 FR 32016, May 29, 2003 and 69 FR 2899, January 21, 2004), the Corps identified at least 6 additional Federal navigation projects that might need similar MMPA authorizations within the next few years, if confined blasting is used as a construction technique. To ensure consistency across MMPA authorizations for these dredging projects, and efficiency for both agencies, NMFS recommended that the Corps apply for these authorizations under section 101(a)(5)(A) of the MMPA, instead of individually under section 101(a)(5)(D) of the MMPA. This request was received on December 1, 2003. At this time only the Miami Turning Basin and this Alafia River project are proposed to be covered by the section 101(a)(5)(A) rulemaking. This rule, if implemented, and Letters of Authorization (LOA) issued under that rule, would replace the IHA process for these activities in the Jacksonville District. Each application for an LOA for additional projects within the Jacksonville District for confined blasting within the District would require separate public review and comment, prior to issuance of an LOA. NMFS expects to start this rulemaking shortly.

**Description of the Marine Mammals Affected by the Activity**

General information on marine mammal species found off the east coast of the United States can be found in Waring et al. (2001, 2002). These reports are available on the Internet at the following location: *http://www.nmfs.noaa.gov/prot_res/PR2/Stock_Assessment_Program/sars.html*

Bottlenose dolphins and West Indian manatees are the only marine mammal species expected in the activity area. However, take authorizations for manatees are issued by the U.S. Fish and Wildlife Service (USFWS) and are not covered by this proposed IHA or any future rulemaking for LOAs issued by NMFS. Wang et al. (2002) provides the following minimum population estimates for the Gulf of Mexico bottlenose dolphin stocks: outer shelf, 43,233; shelf and slope, 4,530; western Gulf, 2,938; northern Gulf, 3,518; eastern Gulf, 8,953; and Bay, Sound & Estuarine waters, 3,933.

The best estimate is that the Tampa Bay bottlenose dolphin population

(which includes any dolphins within the Alafia River) consists of 559 individuals (Wang *et al.*, 2002). Previous population estimates for Tampa Bay include Wells *et al.* (1996), Weigle (1990), Scott *et al.* (1989) Wells (1986), Thompson (1981), and O'Dell and Reynolds (1980). A monitoring study of bottlenose dolphins in Tampa Bay was conducted from 1988–1993. The results of that study were published in Wells et al. (1996). It is the most recent study of those animals currently available (R. Wells, pers. comm. to T. Jordan, Corps, 2004). The study identified a population size ranging between 437 and 728 individuals utilizing three different survey and population estimation techniques. Some of these animals have been shown to be in the vicinity of the Alafia River channel. In a subsequent examination of the data, Urian (2002) identified five populations of bottlenose dolphins in Tampa Bay. Two of these populations utilize the area adjacent to the Alafia River channel. Specific population levels for these two groups were not provided in the study.

**Potential Effects on Marine Mammals**

According to the Corps, bottlenose dolphins and other marine mammals have not been documented as being directly affected by dredging activities and therefore the Corps does not anticipate any incidental harassment of bottlenose dolphins by dredging.

Potential impacts to marine mammals from explosive detonations include both lethal and non-lethal injury, as well as Level B harassment. Marine mammals may be killed or injured as a result of an explosive detonation due to the response of air cavities in the body, such as the lungs and bubbles in the intestines. Effects are likely to be most severe in near-surface waters where the reflected shock wave creates a region of negative pressure called "cavitation." This is a region of near total physical trauma within which no animals would be expected to survive. A second possible cause of mortality or lethal injury is the onset of extensive lung hemorrhage. Extensive lung hemorrhage is considered debilitating and potentially fatal. Suffocation caused by lung hemorrhage is likely to be the major cause of marine mammal death from underwater shock waves. The onset of extensive lung hemorrhage for marine mammals will vary depending upon the animal's weight, with the smallest mammals having the greatest potential hazard range.

NMFS has also established criteria for determining non-lethal injury (Level A harassment) and non-injurious (Level B harassment) harassment from underwater explosions (see 66 FR 22450, May 4, 2001). For non-lethal injury from explosives the criteria are established as the peak pressure that will result in: (1) the onset of slight lung hemorrhage, or (2) a 50–percent probability level for a rupture of the tympanic membrane. These are injuries from which animals would be expected to recover on their own.

Although each of the tamped charges are fairly small (probably less than the 37 lbs (16.8 kg) per drilled hole used in Puerto Rico) and detonation staggered to reduce total pressure, the maximum horizontal extent for mortality/lethal injury and non-lethal injury (Level A harassment), estimated based on the total charge weight (375 lbs in the case of Puerto Rico) would be less than 1875 ft (571 m) and 3750 ft (1143 m) respectively. As these distances are based on an open-water charge calculation, and as stemmed/confined blasts result in a significant decrease in the strength of the pressure wave released as compared to an open water blast, the zones for mortality and non-serious injury would be significantly less than these distances. As a result of these small impact zones, the relatively shallow waters for blasting, and the nature of bottlenose dolphins to remain in surface waters, the biological monitoring (aerial- and vessel-based) is expected to be effective in locating all marine mammals prior to them entering an area where injury or mortality might result and thereby preventing any takes by injury or mortality.

NMFS has also established dual criteria for what constitutes Level B acoustic harassment for all marine mammals: (1) an energy-based temporary threshold shift (TTS) from received sound levels of 182 dB re 1 microPa2–sec cumulative energy flux in any 1/3 octave band above 100 Hz for odontocetes (derived from experiments with bottlenose dolphins (Ridgway et al., 1997; Schlundt et al., 2000); and (2) 12 psi peak pressure (cited by Ketten (1995) as associated with a safe outer limit for minimal, recoverable auditory trauma (i.e., TTS)).

**Mitigation**

The Corps proposes to implement mitigation measures that will establish both caution- and safety-zone radii to ensure that bottlenose dolphins will not be injured or killed during blasting and that impacts will be at the lowest level practicable. In the absence of acoustic measurements of the shock and pressure waves emanating from the detonations (due to the high cost and complex instrumentation needed), the following equations have been proposed by the Corps for blasting projects to determine zones for injury or mortality from an open water explosion and to assist the Corps in establishing mitigation to reduce impacts to the lowest level practicable. These equations are conservative because they are based on humans, which are more sensitive to the effects from the pressure wave of the detonation than are dolphins and because they are based on unconfined charges while the proposed blasts in the Alafia River will be confined or stemmed charges (i.e., placed in a hole drilled in rock and tamped with rock). Studies (e.g., Nedwell and Thandavamoorthy 1992) have shown that stemmed/confined blasts have a greater than 90 percent decrease in the strength of the pressure wave released as compared to an open water blast.

The equations, based on Young (1991), are:

Caution Zone radius = 260 (lbs/delay)$^{1/3}$

Safety Zone radius = 520 (lbs/delay)$^{1/3}$

with R = 260 times or 520 times the cube root of the weight of the explosive charge in pounds where R = radius of the safety zone in ft and W = weight of the explosive charge in lbs. The Caution Zone represents the radius from the point of detonation beyond which mortality would not be expected from an open-water blast. The Safety Zone is the approximate distance beyond which non-serious injury (Level A harassment) would be unlikely from an open-water explosion. These zones will be used for implementing mitigation measures to protect both marine mammals and sea turtles, although the activity area is apparently not good habitat for sea turtles.

In the area where explosives are required to obtain channel design depth for each explosive charge, the Corps proposes that detonation will not occur if a marine mammal is sighted within the Safety Zone by a member of the marine mammal observer program.

Although the Caution Zone is considered to be an area for potential mortality, the Corps and NMFS believe that because all explosive charges will be stemmed, the true areas for potential mortality and injury will be significantly smaller than this area and, therefore, for reasons mentioned previously, it is unlikely that even non-serious injury will occur. This is particularly true in this case, since bottlenose dolphins are commonly found on the surface of the water and implementation of a mitigation/monitoring program is unlikely to miss bottlenose dolphins in such a small area.

Additional mitigation measures that will significantly lower potential impacts to marine mammals (and sea turtles) include: (1) confining the explosives in a hole with drill patterns restricted to a minimum of 8 ft (2.44 m) separation from any other loaded hole; (2) restricting the hours of detonation from 2 hours after sunrise to 1 hour before sunset to ensure adequate observation of marine mammals in the safety zone; (3) staggering the detonation for each explosive hole in order to spread the explosive's total overpressure over time, which in turn will reduce the radius of the caution zone; (4) capping the hole containing explosives with rock in order to reduce the outward potential of the blast, thereby reducing the chance of injuring a dolphin or manatee; (5) matching, to the extent possible, the energy needed in the "work effort" of the borehole to the rock mass to minimize excess energy vented into the water column; and (6) conducting a marine mammal watch with no less than two qualified observers from a small water craft and/or an elevated platform on the explosives barge, at least 30 minutes before and continue for 30 minutes after each detonation to ensure that there are no dolphins, manatees or sea turtles in the area at the time of detonation.

*Monitoring Program*

The Corps proposes to implement a aerial and vessel-based observer monitoring programs. The vessel-based observer program will take place in a circular area at least three times the radius of the above described Caution Zone (called the watch zone). Detonation will not occur if a marine mammal or sea turtle is sighted within the safety zone and will be delayed until the animal(s) move(s) out of the safety zone on its own volition. The aerial and vessel-based marine mammal watch is proposed to be conducted for at least a half hour before and after the time of each detonation.

**Reporting**

NMFS proposes to require the Corps to submit a report of activities 120 days before the expiration of the proposed IHA if the proposed work has started. This report will include the status of the work being undertaken, marine mammals sighted during the monitoring period, any behavioral observations made on bottlenose dolphins and any delays in detonation due to marine mammals being within the safety zone.

In the unlikely event a marine mammal or sea turtle is injured or killed during blasting, the Contractor shall immediately notify the NMFS Regional Office.

**Endangered Species Act**

Under section 7 of the ESA, the Corps completed consultation with the USFWS on December 14, 1998 for this project. The USFWS concluded that the work would not likely jeopardize the continued existence of the manatee, if standard manatee protection conditions were implemented. The Corps reinitiated consultation with the USFWS by letter dated July 5, 2000, because blasting was identified as a component of the project. On July 24, 2000 and September 5, 2000, the USFWS provided the Corps with recommendations for protecting manatees while conducting blasting operations. These recommendations have been incorporated into the project. Because the proposed issuance of this IHA to the Corps is a federal action under section 7 of the ESA that might affect sea turtles (a listed species under NMFS' jurisdiction), NMFS has begun consultation on the proposed issuance of an IHA under section 101(a)(5)(D) of the MMPA for this activity. Consultation will be concluded prior to a determination on whether or not to issue an IHA.

**National Environmental Policy Act**

The Corps prepared an Environmental Assessment (EA) on the Navigation Study for Tampa Harbor-Alafia River, Florida in September 2000 and made a finding of no significant impact on October 11, 2000. A copy of this document is available for viewing (see **ADDRESSES**). NMFS is reviewing this EA in relation to the Corps' application and will determine the appropriate action to take under NEPA prior to making a determination on the issuance of an IHA.

**Preliminary Conclusions**

NMFS has preliminarily determined that the Corps' proposed action, including mitigation measures to protect marine mammals, should result, at worst, in the temporary modification in behavior by bottlenose dolphins resulting from temporary hearing impairment (TTS), but may also include temporarily vacating the Alafia River area to avoid the blasting activity and the potential for minor visual and acoustic disturbance from dredging and detonations. Because this project will affect at most a few dolphins due to its local impact, short time duration, and implementation of effective vessel-based and aerial monitoring programs, NMFS believes that only a small number of dolphins may be taken by Level B harassment and this is expected to have only a negligible impact on the affected species or stocks of bottlenose dolphins. In addition, no take by injury and/or death is anticipated, and harassment takes will be at the lowest level practicable due to incorporation of the mitigation measures described in this document.

**Proposed Authorization**

NMFS proposes to issue an IHA to the Corps for the harassment of small numbers of bottlenose dolphins incidental to expanding and deepening the Alafia River Navigation Channel in Tampa Harbor, FL, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. NMFS has preliminarily determined that the proposed activity would result in the harassment of only small numbers of bottlenose dolphins and will have no more than a negligible impact on this marine mammal stock.

**Information Solicited**

NMFS requests interested persons to submit comments and information concerning this proposed IHA and the application for regulations request (see **ADDRESSES**).

Dated: May 18, 2004.

**Laurie K. Allen,**

*Director, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 04–11800 Filed 5–24–04; 8:45 am]

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**[I.D. 032904C]**

### Small Takes of Marine Mammals Incidental to Specified Activities; Harbor Activities at Vandenberg Air Force Base, CA

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

**ACTION:** Notice of issuance of an incidental take authorization.

**SUMMARY:** In accordance with provisions of the Marine Mammal Protection Act (MMPA) as amended. notification is hereby given that NMFS has issued an Incidental Harassment Authorization (IHA) to The Boeing Company (Boeing) to take marine mammals by harassment incidental to harbor activities related to the Delta IV/Evolved Expendable

Launch Vehicle (EELV) at south Vandenberg Air Force Base, CA (VAFB).

**DATES:** Effective from May 20, 2004, through May 19, 2005.

**ADDRESSES:** A copy of the IHA and the application are available by writing to Mr. P. Michael Payne, Chief, Marine Mammal Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Silver Spring, MD 20910–3225, or by telephoning the contact listed here. A copy of the application containing a list of the references used in this document may be obtained by writing to this address or by telephoning the contact listed here and is also available at: *http://www.nmfs.noaa.gov/prot_res/PR2/Small_Take/smalltake_info.htm#applications.*

**FOR FURTHER INFORMATION CONTACT:** Kimberly Skrupky, (301) 713–2322, ext. 163 or Monica DeAngelis, (562) 980–3232.

**SUPPLEMENTARY INFORMATION:**

## Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, notice of a proposed authorization is provided to the public for review.

Permission for incidental takings may be granted if NMFS finds that the taking will have no more than a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses and that the permissible methods of taking and requirements pertaining to the monitoring and reporting of such taking are set forth.

NMFS has defined "negligible impact" in 50 CFR 216.103 as:

> an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

Subsection 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the United States can apply for an authorization to incidentally take small numbers of marine mammals by harassment. The MMPA defines "harassment" as:

> any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild ["Level A harassment"]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering ["Level B harassment"].

Subsection 101(a)(5)(D) establishes a 45–day time limit for NMFS review of an application followed by a 30–day public notice and comment period on any proposed authorizations for the incidental harassment of small numbers of marine mammals. Within 45 days of the close of the comment period, NMFS must either issue or deny issuance of the authorization.

## Summary of Request

On December 12, 2003, NMFS received an application from Boeing requesting an authorization for the harassment of small numbers of Pacific harbor seals (*Phoca vitulina richardsi*) and California sea lions (*Zalophus californianus*) incidental to harbor activities related to the Delta IV/EELV, including: transport vessel operations, cargo movement activities, harbor maintenance dredging, and kelp habitat mitigation operations. In addition, northern elephant seals (*Mirounga angustirostris*)and northern fur seals (*Callorhinus ursinus*) may also be incidentally harassed but in even smaller numbers. Incidental Harassment Authorizations (IHAs) were issued to Boeing on May 15, 2002 (67 FR 36151, May 23, 2002) and on May 20, 2003 (68 FR 36540, June 18, 2003) each for a one-year period. The harbor where activities will take place is on south VAFB approximately 2.5 mi (4.02 km) south of Point Arguello, CA and approximately 1 mi (1.61 km) north of the nearest marine mammal pupping site (i.e., Rocky Point).

## Comments and Responses

A notice of receipt of the Boeing application and proposed IHA was published in the **Federal Register** on April 7, 2004 (69 FR 18353). During the comment period, NMFS received comments from the Marine Mammal Commission (Commission) and from one individual.

*Comment 1:* The Commission states that NMFS' preliminary determinations are reasonable provided that all reasonable measures will be taken to ensure the least practicable impact on the subject species and the require mitigation and monitoring activities be carried out as described in the April 7, 2004 **Federal Register** notice and the subject application.

*Response:* NMFS appreciates the Commission's comment and is requiring all mitigation and monitoring activities described in Boeing's application. NMFS is also requiring Boeing to take all reasonable measures to ensure the least practicable impact on the species, such as turning on lighting before dusk and initiating activities before dusk if Boeing will be conducting harbor activities at night.

*Comment 2:* An individual stated that they oppose the proposal for harbor activities on Vandenberg Air Force Base because there is no explanation of reef enhancement in the **Federal Register** notice.

*Response:* To mitigate the unavoidable removal of kelp habitat within the dredge footprint, Boeing, the U.S. Air Force, and regulatory agencies have agreed that 150 tons (136.08) metric tons) of rocky substrate will be placed in a sandy area between the breakwater and the mooring dolphins to enhance an existing artificial reef. This type of mitigation was implemented by the U.S. Army Corps of Engineers following the 1984 and 1989 dredgings and has resulted in the growth of a lush kept bed adjacent to this sandy area. The location is outside of the dredge footprint and navigation channel in a protected environment. The breakwater will help protect the kept from storms and surges that might tear young kelp plants from the substrate. The substrate will be in the form of approximately 150 sharp-faced boulders, each with a diameter of approximately 2 ft (0.61 m) and a weight of approximately 1 ton (0.91 metric ton). The boulders will be brought in by truck from an off-site quarry, loaded by crane onto a small barge at the wharf, and pushed by tugboat to a location along the mooring dolphins from which a small barge-mounted crane can place them randomly into the sandy area. This information is also contained in the Boeing application, which could be found at:*http://www.nmfs.noaa.gov/prot_res/PR2/Small_Take/smalltake_info.htm#applications*

*Comment 3:* The individual also states that many population estimates are unreliable and untruthful and are political estimates made to support something that humans want to do.

*Response:* Monitoring is conducted by biologically trained, on-site individuals, approved by the NMFS Southwest Regional Office. Baseline observations are made prior to each day's activities, recording the species present, numbers, location(s), and behavior of the marine mammals in the area. Observations are also conducted during and after each day's activities. NMFS does not believe

that past data reporting the species and numbers have ever been doctored to justify conducting any activities.

**Specified Activities**

*Delta Mariner* off-loading operations and associated cargo movements will occur a maximum of three times per year. The *Delta Mariner* is a 95.1–m (312–ft) long, 25.6–m (84–ft) wide steel hull ocean-going vessel capable of operating at a 2.4–m (8–ft) draft. For the first few visits to the south VAFB harbor, tug boats will accompany the *Delta Mariner*. Sources of noise from the *Delta Mariner* include ventilating propellers used for maneuvering into position and the cargo bay door when it becomes disengaged. Removal of the common booster core (CBC) from the *Delta Mariner* requires use of an elevating platform transporter. An additional source of noise with sound levels measured at a maximum of 82 dB A-weighted (re 20 microPascals at 1 m) 6.1 m (20 ft) comes from the engine exhaust (Acentech, 1998). Procedures require two short (approximately 1/3 second) beeps of the horn prior to starting the ignition. At 60.9 m (200 ft) away, the sound level of the EPT horn ranged from 62–70 dB A-weighted. Containers containing flight hardware items will be towed off the *Delta Mariner* by a tractor tug that generates a sound level of approximately 87 dB A-weighted at 15.2 m (50 ft) while in operational mode. Total time of *Delta Mariner* docking and cargo movement activities is estimated at between 14 and 18 hours in good weather.

To accommodate the *Delta Mariner*, the harbor will need to be dredged, removing up to 5,000 cubic yards of sediment per dredging. Dredging will involve the use of heavy equipment, including a clamshell dredge, dredging crane, a small tug, dredging barge, dump trucks, and a skip loader. Measured sound levels from this equipment are roughly equivalent to those estimated for the wharf modification equipment: 43 to 81 dB A-weighted at 76.2 m (250 ft). Dredge operations, from set-up to tear-down, would continue 24 hours a day for 3 to 5 weeks. Sedimentation surveys have shown that initial dredging indicates that maintenance dredging should be required annually or twice per year, depending on the hardware delivery schedule.A more detailed description of the work proposed for 2004 is contained in the application which is available upon request (see **ADDRESSES**) and in the Final US Air Force Environmental Assessment for Harbor Activities Associated with the Delta IV Program at Vandenberg Air Force Base (ENSR International, 2001).

**Habitat and Marine Mammals Affected by the Activity**

*Pacific Harbor Seals*

The marine mammal species most likely to be harassed incidental to harbor activities at south VAFB are the Pacific harbor seal and the California sea lion. The most recent estimate of the Pacific harbor seal population in California is 30,293 seals (Forney et al., 2000). From 1979 to 1995, the California population increased at an estimated annual rate of 5.6 percent. The total population of harbor seals on VAFB is now estimated to be 1,118 (500 hauled-out on south VAFB) based on sighting surveys and telemetry data (SRS Technologies, 2001).

The daily haul-out behavior of harbor seals along the south VAFB coastline is primarily dependent on time of day. The highest number of seals haul-out at south VAFB between 1100 through 1700 hours. In addition, haul-out behavior at all sites seems to be influenced by environmental factors such as high swell, tide height, and wind. The combination of all three may prevent seals from hauling out at most sites. The number of seals hauled out at any site can vary greatly from day to day based on environmental conditions. Harbor seals occasionally haul out at a beach 76.2 m (250 ft) west of the south VAFB harbor and on rocks outside the harbor breakwater where Boeing will be conducting *Delta Mariner* operations, cargo loading, dredging activities, and reef enhancement activities. The maximum number of seals present during past dredging of the harbor was 23, with an average of seven seals sighted per observation. The harbor seal pupping site closest to south VAFB harbor is at Rocky Point, approximately 1.6 km (1 mi) north of the harbor.

Several factors affect the seasonal haul-out behavior of harbor seals including environmental conditions, reproduction, and molting. Harbor seal numbers at VAFB begin to increase in March during the pupping season (March to June) as females spend more time on shore nursing pups. The number of hauled-out seals is at its highest during the molt which occurs from May through July. During the molting season, tagged harbor seals at VAFB increased their time spent on shore by 22.4 percent; however, all seals continued to make daily trips to sea to forage. Molting harbor seals entering the water because of a disturbance are not adversely affected in their ability to molt and do not endure thermoregulatory stress. During pupping and molting season, harbor seals at the south VAFB sites expand into haul-out areas that are not used the rest of the year. The number of seals hauled out begins to decrease in August after the molt is complete and reaches the lowest number in late fall and early winter.

*California Sea Lions*

During the wharf modification activity in June-July 2002, California sea lions were observed hauling out in small numbers. Although this is considered to be an unusual occurrence and is possibly related to fish schooling in the area, Boeing has included sea lions in their IHA request.

California sea lions range from British Columbia to Mexico. The minimum U.S. population estimate for California sea lions is 109,854 individuals. Since 1983, the population has grown at a rate of 6.2 percent annually. A 1985–1987 population survey indicated that most individuals on the Northern Channel Islands were on San Miguel Island, with the population ranging from 2,235 to over 17,000. The largest numbers of California sea lions in the VAFB vicinity occur at Lion Rock, 0.4 mi (0.64 km) southeast of Point Sal. This area is approximately 1.5 mi (2.41 km) north of the VAFB boundary. At least 100 sea lions can be observed during any season at this site. The Point Arguello beaches and the rocky ledges of South Rocky Point on south VAFB are haulout areas that may be used by California sea lions. In 2003, at least 145 sea lions were observed at Rocky Point, including five pups that did not survive due to abandonment shortly after birth. This was thought to be an El Nino effect, as there have never been any reported sea lion births at VAB previously (Thomson, 2003). Each year, small groups of sea lions have been observed heading south along the VAFB coastline in April and May (Tetra Tech, 1997). Starting in August, large groups of sea lions can be seen moving north, in groups varying in size from 25 to more than 300 (Roest, 1995). This concurs with established migration patterns (Reeves *et al.*, 1992; Roest, 1995). Juvenile sea lions can be observed hauled-out with harbor seals along the South Base sites from July through September (Tetra Tech, 1997). Starving and exhausted subadult sea lions are fairly common on central California beaches during the months of July and August (Roest, 1995).

During the breeding season, most of California sea lions inhabit southern California and Mexico. Rookery sites in southern California are limited to San Miguel Island and to the southerly

Channel Islands of San Nicolas, Santa Barbara, and San Clemente. Breeding season begins in mid-May, occurring within 10 days of arrival at the rookeries. Molting occurs gradually over several months in the late summer and fall. Because the molt is not catastrophic, the sea lions can enter the water to feed.

Male California sea lions migrate annually. In the spring they migrate southward to breeding rookeries in the Channel Islands and Mexico, then migrate northward in the late summer following breeding season. Females appear to remain near the breeding rookeries. The greatest population on land occurs in September and October during the post-breeding dispersal and although many of the sea lions, particularly juveniles and sub-adult and adult males, may move north away from the Channel Islands.

*Other Marine Mammals*

Other marine mammal species are rare to infrequent along the south VAFB coast during certain times of the year and, therefore, are unlikely to be harassed by Boeing's activities. These two species are: the Guadalupe fur seal (*Arctocephalus townsendi*), and Steller sea lions (*Eumetopias jubatus*). Northern elephant seals and northern fur seals may occur on VAFB but do not haul out in the harbor area. Guadalupe fur seals, and Steller sea lions occur along the California coast and Northern Channel Islands but are not likely to be found on VAFB. Descriptions of the biology and local distribution of these species can be found in the application as well as other sources such as Stewart and Yochem (1994, 1984), Forney *et al.* (2000), Koski *et al.* (1998), Barlow *et al.* (1993), Stewart and DeLong (1995), and Lowry *et al.* (1992). NMFS Stock Assessments can be viewed at: *http://www.NMFS.noaa.gov/pr/PR2/Stock_Assessment_Program/sars.html*. Please refer to those documents for information on these species.

**Potential Effects of Activities on Marine Mammals**

Acoustic and visual stimuli generated by the use of heavy equipment during the *Delta Mariner* off-loading operations, dredging, and kelp habitat mitigation, as well as the increased presence of personnel, may cause short-term disturbance to harbor seals and California sea lions hauled out along the beach and rocks in the vicinity of the south VAFB harbor. This disturbance from acoustic and visual stimuli is the principal means of marine mammal taking associated with these activities. Based on the measured sounds of construction equipment, such as might be used during Boeing's activities, sound level intensity decreases proportional to the square root of the distance from the source. A dredging crane at the end of the dock producing 88 dBA of noise would still be noisy (approximately 72 dBA) at the nearest beach or the end of the breakwater, roughly 250 ft (76.2 m) away. The Elevating Platform Transporter (EPT) produces approximately 85 dBA, measured less than 20 ft (6 m) from the engine exhaust, when the engine is running at mid speed. The EPT operation procedure requires two short beeps of the horn (approximately 1/3 of a second each) prior to starting the ignition. Sound level measurements for the horn ranged from 84 to 112 dBA at 25 ft (7.6 m) away and 62 to 70 dBA at 200 ft (61 m) away. The highest measurement was taken from the side of the vehicle where the horn is mounted.

Pinnipeds sometimes show startle reactions when exposed to sudden brief sounds. An acoustic stimulus with sudden onset (such as a sonic boom) may be analogous to a "looming" visual stimulus (Hayes and Saif, 1967), which may elicit flight away from the source (Berrens *et al.*, 1988). The onset of operations by a loud sound source, such as the elevating platform transporter during CBC off-loading procedures, may elicit such a reaction. In addition, the movements of cranes and dredges may represent a "looming" visual stimulus to seals hauled out in close proximity. Seals and sea lions exposed to such acoustic and visual stimuli may either exhibit a startle response and/or leave the haul-out site.

Under the MMPA, if harbor activities disrupt the behavioral patterns of harbor seals, these activities would take marine mammals by Level B harassment. In general, if the received level of the noise stimulus exceeds both the background (ambient) noise level and the auditory threshold of the animals, and especially if the stimulus is novel to them, there may be a behavioral response. The probability and degree of response will also depend on the season, the group composition of the pinnipeds, and the type of activity in which they are engaged. Minor and brief responses, such as short-duration startle or alert reactions, are not likely to result in disruption of behavioral patterns, such as migration, nursing, breeding, feeding, or sheltering (i.e., Level B harassment) and would not cause serious injury or mortality to marine mammals.

On the other hand, startle and alert reactions accompanied by large-scale movements, such as stampedes into the water, may rise to the level of level B harassment and could even result in injury of individuals. In addition, such large-scale movements by dense aggregations of marine mammals or on pupping sites could potentially lead to takes by serious injury or death. However, there is no potential for large-scale movements leading to serious injury or mortality near the south VAFB harbor, because on average the number of harbor seals hauled out near the site is less than 30 and there is no pupping at nearby sites. The effects of the harbor activities are expected to be limited to short-term startle responses and localized behavioral changes.

According to the June 2002 dock modification construction report (ENSR 2002), the maximum number of harbor seals hauled out each day ranged from 23 to 25 animals. There were 15 occasions in which construction noise, vehicle noise, or noise from a fishing boat caused the seals to lift their heads. Flushing only occurred due to fishing activities which were unrelated to the construction activities. The sea lions were less reactive to the construction noise than the harbor seals. None of the construction activities caused any of the sea lions to leave the jetty rocks and there was only one incident of a head alert reaction.

The report from the December 2002 dredging activities show that the number of Pacific harbor seals ranged from 0 to 19 and that California sea lions did not haul out during the monitoring period. On 10 occasions, harbor seals showed head alerts although two of the alerts were for disturbances that were not related to the project. No harbor seals flushed during the activities on the dock.

For a further discussion of the anticipated effects of the planned activities on harbor seals in the area, please refer to the application and Final Environmental Assessment. Information in the application and referenced sources is adopted by NMFS as the best information available on this subject.

**Mitigation**

To reduce the potential for disturbance from visual and acoustic stimuli associated with the activities Boeing will undertake the following marine mammal mitigating measures:

(1) If activities occur during nighttime hours, lighting will be turned on before dusk and left on the entire night to avoid startling harbor seals at night.

(2) Activities will be initiated before dusk.

(3) Construction noises must be kept constant (i.e., not interrupted by periods

of quiet in excess of 30 minutes) while harbor seals are present.

(4) If activities cease for longer than 30 minutes and harbor seals are in the area, start-up of activities will include a gradual increase in noise levels.

(5) A NMFS-approved marine mammal observer will visually monitor the harbor seals on the beach adjacent to the harbor and on rocks for any flushing or other behaviors as a result of Boeing's activities (see Monitoring).

(6) The *Delta Mariner* and accompanying vessels will enter the harbor only when the tide is too high for harbor seals to haul-out on the rocks and the vessel will reduce speed 1.5 to 2 knots (1.5–2.0 nm/hr; 2.8–3.7 km/hr) once the vessel is within 3 mi (4.83 km) of the harbor. The vessel will enter the harbor stern first, approaching the wharf and dolphins at less than 0.75 knot (1.4 km/hr).

(7) As alternate dredge methods are explored, the dredge contractor may introduce quieter techniques and equipment.

**Monitoring**

As part of its 2002 application, Boeing provided a proposed monitoring plan for assessing impacts to harbor seals from the activities at south VAFB harbor and for determining when mitigation measures should be employed. NMFS adopts the same plan for this IHA.

A NMFS-approved and VAFB-designated biologically trained observer will monitor the area for pinnipeds during all harbor activities. During nighttime activities, the harbor area will be illuminated, and the monitor will use a night vision scope. Monitoring activities will consist of:

(1) Conducting baseline observation of pinnipeds in the project area prior to initiating project activities.

(2) Conducting and recording observations on pinnipeds in the vicinity of the harbor for the duration of the activity occurring when tides are low enough for pinnipeds to haul out (2 ft (0.61 m) or less).

(3) Conducting post-construction observations of pinniped haul-outs in the project area to determine whether animals disturbed by the project activities return to the haul-out.

**Reporting**

Boeing will notify NMFS 2 weeks prior to initiation of each activity. After each activity is completed, Boeing will provide a report to NMFS within 90 days. This report will provide dates and locations of specific activities, details of seal behavioral observations, and estimates of the amount and nature of all takes of seals by harassment or in other ways. In addition, the report will include information on the weather, the tidal state, the horizontal visibility, and the composition (species, gender, and age class) and locations of haul-out group(s). In the unanticipated event that any cases of pinniped injury or mortality are judged to result from these activities, this will be reported to NMFS immediately.

**Numbers of Marine Mammals Expected to Be Harassed**

Boeing estimates that a maximum of 43 harbor seals per day may be hauled out near the south VAFB harbor, with a daily average of 21 seals sighted when tidal conditions were favorable during previous dredging operations in the harbor. Considering the maximum and average number of seals hauled out per day, assuming that the seals may be seen more than once, and using a maximum total of 83 operating days in 2004–2005, NMFS estimates that 145 to 623 Pacific harbor seals may be subject to Level B harassment.

During wharf modification activities, a maximum of 6 California sea lions were seen hauling out in a single day, averaging between 1 and 6 sea lions each day. Based on its own calculations, NMFS believes that a total of 100 California sea lions, 10 northern elephant seals, and 5 northern fur seals may be subject to Level B harassment, because they may be in nearby waters.

**Possible Effects of Activities on Marine Mammal Habitat**

Boeing anticipates no loss or modification to the habitat used by Pacific harbor seals or California sea lions that haul out near the south VAFB harbor. The harbor seal and sea lion haul-out sites near south VAFB harbor are not used as breeding, molting, or mating sites; therefore, it is not expected that the activities in the harbor will have any impact on the ability of Pacific harbor seals or California sea lions in the area to reproduce.

Boeing does anticipate unavoidable kelp removal during dredging. This habitat modification will not affect the marine mammal habitat. However, Boeing will mitigate for the removal of kelp habitat by placing 150 tons (136.08 metric tons) of rocky substrate in a sandy area between the breakwater and the mooring dolphins to enhance an existing artificial reef. This type of mitigation was implemented by the Army Corps of Engineers following the 1984 and 1989 dredging. A lush kelp bed adjacent to the sandy area has developed from the efforts. The substrate will consist of approximately 150 sharp-faced boulders, each with a diameter of about 2 ft (0.61 m) and each weighing about 1 ton (907 kg). The boulders will be brought in by truck from an off-site quarry and loaded by crane onto a small barge at the wharf. The barge is towed by a tugboat to a location along the mooring dolphins from which a small barge-mounted crane can place them into the sandy area. Boeing plans to perform the reef enhancement in conjunction with the next maintenance dredging event in order to minimize cost and disturbances to animals. Noise will be generated by the trucks delivering the boulders to the harbor and during the operation of unloading the boulders onto the barges and into the water.

**Possible Effects of Activities on Subsistence Needs**

There are no subsistence uses for Pacific harbor seals in California waters, and, thus, there are no anticipated effects on subsistence needs.

**Conclusions**

NMFS has determined that the impact of conducting harbor activities related to the Delta IV/EELV at VAFB, including transport vessel operations, cargo movement activities, harbor maintenance dredging, and kelp habitat mitigation will result in the harassment of small numbers of Pacific harbor seals, California sea lions, northern elephant seals, and northern fur seals; would have a negligible impact on these marine mammal stocks; and would not have an unmitigable adverse impact on the availability of marine mammal stocks for subsistence uses. Guadalupe fur seals and Steller sea lions are unlikely to be found in the area and, therefore, will not be affected. While behavioral modifications may be made by the affected species to avoid the resultant acoustic and visual stimuli, there is no potential for large-scale movements, such as stampedes, since harbor seals and California sea lions haul out in small numbers near the site and northern elephant seals and northern fur seals do not haul out in the harbor area. The effects of Boeing's harbor activities are expected to be limited to short-term and localized behavioral changes.

Due to the localized nature of these activities, the number of marine mammals potentially taken by harassment are estimated to be small. In addition, no take by injury and/or death is anticipated, and the potential for temporary or permanent hearing impairment is unlikely given the low noise levels expected at the site. No rookeries, mating grounds, areas of concentrated feeding, or other areas of

special significance for marine mammals occur within or near south VAFB harbor. This activity is expected to result in no more than a negligible impact on the affected species or stocks.

**Endangered Species Act (ESA)**

This action will not affect species listed under the Endangered Species Act (ESA) that are under the jurisdiction of NMFS. VAFB formally consulted with U.S. Fish and Wildlife Service (FWS) in 1998 on the possible take of southern sea otters during Boeing's harbor activities at south VAFB. A Biological Opinion was issued in August 2001. FWS recognized that Boeing will restore sea otter habitat (i.e., kelp beds) in the vicinity of the harbor to replace kelp destroyed during dredging and stated that there would not be takes of southern sea otters. In addition, the FWS noting that VAFB has committed to a southern sea otter monitoring program designed to detect the presence and possible disturbance at the VAFB harbor area during dredging activities (see 68 FR 36540, June 18, 2003).

**National Environmental Protection Act (NEPA)**

ENSR International (ENSRI) made a Finding of No Significant Impact (FONSI) determination on August 15, 2001, based on information contained within its Environmental Assessment (EA), that implementation of the subject action is not a major Federal action having significant effects on the environment within the meaning of Executive Order 12114. ENSRI determined therefore, that an environmental impact statement would not be prepared. On April 7, 2004 (69 FR 18353), NMFS noted that ENSRI had prepared an EA for the VAFB harbor activities and made this EA available upon request. In accordance with NOAA Administrative Order 216–6 (Environmental Review Procedures for Implementing the National Environmental Policy Act, May 20, 1999), NMFS has reviewed the information contained in ENSRI's EA and determined that the ENSRI EA accurately and completely describes the proposed action alternative, reasonable additional alternatives, and the potential impacts on marine mammals, endangered species, and other marine life that could be impacted by the preferred alternative and the other alternatives. Therefore, it is not necessary to issue a new EA, supplemental EA or an environmental impact statement for the issuance of an IHA to Boeing for this activity. Based on this review and analysis, NMFS is adopting the ENSRI EA under 40 CFR 1506.3 and has made its own FONSI. A copy of the ENSRI EA and the NMFS FONSI for this activity is available upon request (see **ADDRESSES**).

**Authorization**

NMFS has issued an IHA to take marine mammals, by harassment, incidental to conducting harbor activities at VAFB to Boeing for a 1–year period, provided the mitigation, monitoring, and reporting requirements are undertaken.

Dated: May 19, 2004.

**Stephen L. Leathery,**

*Acting Director, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 04–11801 Filed 5–24–04; 8:45 am]

BILLING CODE 3510–22–S

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**[I.D. 051904A]**

### Pacific Fishery Management Council; Public Meeting

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

**ACTION:** Notice of public meeting.

**SUMMARY:** The Pacific Fishery Management Council's (Council) Ad Hoc Groundfish Trawl Individual Quota Analytical Team (TIQ Analytical Team) will hold a working meeting, which is open to the public.

**DATES:** The TIQ Analytical Team working meeting will begin Tuesday, June 8, 2004 at 8:30 a.m. and may go into the evening until business for the day is completed. The meeting will reconvene from 8 a.m. and continue until business for the day is complete on Wednesday, June 9, 2004.

**ADDRESSES:** The meeting will be held at The University Inn, Orcus Room, 4140 Roosevelt Way NE, Seattle, WA 98105; telephone: (206) 632–5055.

*Council address*: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 200, Portland, OR 97220–1384.

**FOR FURTHER INFORMATION CONTACT:** Mr. Jim Seger, Staff Officer (Economist); telephone: (503) 820–2280.

**SUPPLEMENTARY INFORMATION:** The purpose of the TIQ Analytical Team meeting is to conduct preliminary scoping on the types impacts to be considered and analytical methods used in a groundfish trawl dedicated access privilege Environmental Impact Statement. Related data collection issues will also be discussed. A panel of independent advisors has been invited to work with the TIQ Analytical Team on these issues during the meeting.

Although non-emergency issues not contained in the TIQ Analytical Team meeting agenda may come before the group for discussion, those issues may not be the subject of formal committee action during these meetings. TIQ Analytical Team action will be restricted to those issues specifically listed in this notice and to any issues arising after publication of this notice requiring emergency action under Section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the group's intent to take final action to address the emergency.

**Special Accommodations**

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Ms. Carolyn Porter at (503) 820–2280 at least 5 days prior to the meeting date.

Dated: May 20, 2004.

**Matteo J. Milazzo,**

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

[FR Doc. 04–11803 Filed 5–24–04; 8:45 am]

BILLING CODE 3510–22–S

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**[I. D. 052004C]**

### Fisheries of the Exclusive Economic Zone Off Alaska; Application for an Exempted Fishing Permit

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

**ACTION:** Notice of receipt of an application for an exempted fishing permit.

**SUMMARY:** NMFS has received an application for an exempted fishing permit (EFP) from the Washington Sea Grant Program (WSGP). If granted, this EFP would authorize the applicant to conduct an experiment to evaluate the integrated weight groundline as a potential seabird avoidance measure in the fall 2004 Pacific cod hook-and-line fishery in the Bering Sea and Aleutian Islands Management Area (BSAI). The project is intended to promote the objectives of the Fishery Management Plan for the Groundfish Fishery of the

Bering Sea and Aleutian Islands Area (FMP) by reducing fishery interactions with the endangered short-tailed albatross (*Phoebastria albatrus*) and other seabird species.

**ADDRESSES:** Copies of the EFP application may be requested from Sue Salveson, Assistant Regional Administrator for Sustainable Fisheries, Alaska Region, NMFS, Attn: Lori Durall by: mail to P. O. Box 21668, Juneau, AK 99802; fax to 907–586–7557; or email to *Lori.Durall@noaa.gov*.

**FOR FURTHER INFORMATION CONTACT:** Kim Rivera, 907–586–7424 or *Kim.Rivera@noaa.gov*.

**SUPPLEMENTARY INFORMATION:** NMFS manages the domestic groundfish fisheries in the BSAI under the FMP. The North Pacific Fishery Management Council (Council) prepared the FMP under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). Regulations governing the groundfish fisheries of the BSAI appear at 50 CFR parts 600 and 679. The FMP and the implementing regulations at §§ 679.6 and 600.745(b) authorize the issuance of EFPs to allow fishing that would otherwise be prohibited. Procedures for issuing EFPs are contained in the implementing regulations.

NMFS received an application for an EFP from the WSGP. The purpose of this EFP is to authorize experimental fishing using integrated weight groundline to evaluate its effectiveness as a potential new seabird avoidance measure. The application calls for testing integrated weight groundlines against unweighted groundlines, with and without paired streamer lines. This proposed effort follows up on work that was completed in Alaska in 2002, and compliments efforts taking place in other fisheries. Information from this experiment could ultimately result in better and more effective seabird avoidance measures. The hook-and-line fishing industry appears especially interested in this experiment, because it may provide them a better tool with which to avoid the incidental catch of the endangered short-tailed albatross and other seabird species. In addition, potential exists for improved fishing efficiency with better gear handling characteristics and increased target catch rates resulting from getting baited hooks down more quickly. The U.S. Fish and Wildlife Service issued a Biological Opinion (September 2003) that includes a conservation recommendation for NMFS to support research efforts to develop new and novel deterrent technologies such as integrated weight groundlines. This experiment would fulfill such a recommendation.

The goal of the experiment is to reduce the incidental catch of the endangered short-tailed albatross and other seabird species in ways that are consistent with Magnuson-Stevens Act National Standard 9 which requires conservation and management measures to minimize bycatch and bycatch mortality and that the effects on birds should be considered when selecting these measures. A preliminary WSGP investigation in 2002 evaluated four weightings of integrated weight groundline (25, 50, 75, and 100 g/m). The four weighting treatments were compared to a control of unweighted groundline in the sablefish fishery in the Aleutian Islands and the Pacific cod fishery in the Gulf of Alaska. Preliminary results strongly suggest that 50 g/m line was the optimal weighting. It was the most practical gear in terms of operational performance in mechanical baiting (auto-bait) longline systems and it sank quickly beyond the range of seabirds.

Based on these initial results, WSGP proposes to continue this work by comparing the catch rates of all species, the abundance and behavior of seabirds, and the sink rate of groundlines under three scenarios: 50 g/m integrated weight groundline, and un-weighted groundlines with and without paired streamer lines. Regulations at 50 CFR § 679.24(e)(4)(ii)(c) require the use of paired streamer lines by vessels greater than 55 ft (16.8 m) length overall. Thus, an EFP is necessary to conduct the experimental control treatments that call for the experimental gear to be deployed in the absence of paired streamer lines, to allow fishing in a way that would otherwise be prohibited. Work will take place on two freezer-longliner vessels using auto-bait systems in the Pacific cod fishery in the BSAI during the fall of 2004, and during 2005, if unforeseen circumstances prohibit completion of the work in 2004.

In accordance with § 679.6, NMFS has determined that the application warrants further consideration and has initiated consultation with the Council by forwarding the application to the Council for consultation. The Council will consider the application during its June 9–15, 2004, meeting which will be held at the Benson Hotel in Portland, Oregon. While the applicant has been invited to appear in support of the application, all interested parties may comment on the application at the meeting during public testimony.

The vessels that would conduct the experimental fishing were not identified on the application, but will be identified on the EFP, once they have been selected for the project. The NMFS Regional Administrator may consider and attach additional terms and conditions to the EFP that are consistent with the purpose of the experiment. Public comment may help determine such conditions.

A copy of the application is available for review from NMFS (see **ADDRESSES**).

**Authority:** 16 U.S.C. 1801 *et seq.*

Dated: May 20, 2004.

**Tracey L. Thompson,**

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

[FR Doc. E4–1208 Filed 5–24–04; 8:45 am]

**BILLING CODE 3510–22–S**

## DEPARTMENT OF DEFENSE

### Department of the Army

### Notice of Availability (NOA) for the Final Environmental Impact Statement (EIS) for the Transformation of the 2nd Brigade, 25th Infantry Division (Light) to a Stryker Brigade Combat Team (SBCT) in Hawaii

**AGENCY:** Department of the Army, DoD.

**ACTION:** Notice of Availability.

**SUMMARY:** The Proposed Action includes training to be conducted at Schofield Barracks Military Reservation (SBMR), Dillingham Military Reservation, Kahuku Training Area and Kawailoa Training Area on the island of Oahu and at Pōhakuloa Training Area on the island of Hawaii. Twenty-eight projects are proposed that would improve the existing support structure and facilities to provide the necessary field training required for an SBCT. These projects include construction of ranges, airfield upgrades, land acquisition, and new equipment such as new and modernized vehicles (namely the Stryker, an eight-wheeled, 20-ton combat vehicle) and weapons systems (105mm cannon, 155 mm howitzer, and 120mm mortar). The number of soldiers and vehicles stationed at SBMR also would increase. The Army would acquire land on the island of Oahu (approximately 1,400 acres) and on the island of Hawaii. (approximately 23,000 acres) for training areas and road construction.

**DATES:** The waiting period for the Final EIS will end 30 days after publication of the NOA in the **Federal Register** by the U.S. Environmental Protection Agency.

**ADDRESSES:** Direct questions and/or written comments regarding the Final EIS to, or a request for a copy of the document from, Ms. Cindy Barger, U.S. Army Corps of Engineers, Honolulu

Engineer District, Program and Project Management, Attention: CEPOH–PP–E (Barger), Building 230, Room 306, Fort Shafter, Hawaii 96858–5540.

**FOR FURTHER INFORMATION CONTACT:** Ms. Cindy Barger at (808) 438–4812; by facsimile at (808) 438–7801; or by e-mail at *SBCT_EIS@poh01.usace.army.mil.*

**SUPPLEMENTARY INFORMATION:** The SBCT Final EIS analyzes three alternative courses of action with respect to the transformation of the 2nd Brigade, 25th Infantry Division in Hawaii: (1) The transformation of the 2nd Brigade, 25th Infantry Division (Light) to an SBCT with a range of supporting activities including new, additional, or modified ranges, facilities and infrastructure and acquisition of approximately 1,400 acres of additional training lands on the island of Oahu and 23,000 acres on the island of Hawaii (preferred alternative); (2) the transformation of the 2nd Brigade, 25th Infantry Division (Light) to an SBCT with a range of supporting activities including new, additional, or modified ranges, facilities and infrastructure, and acquisition of approximately 100 acres of additional training lands on the island of Oahu and 23,000 acres on the island of Hawaii; (3) the no action alternative, under which no transformation would occur in the near term and training would continue as currently exists.

Copies of the SBCT Final EIS are available for review at the following libraries: Hilo Public Library, 300 Waianuenue Avenue, Hilo; Kailua-Kona Public Library, 75–138 Hualalai Road, Kailua-Kona; Thelma Parker Memorial Public and School Library, 96767–1209 Mamalahoa Highway, Kamuela; Kahuku Public and School Library, 56–490 Kamehameha Highway, Kahuku; Mililani Public Library, 95–450 Makaimoimo Street, Mililani; Hawaii State Library, 478 South King Street, Honolulu; Wahiawa Public Library, 820 California Avenue, Wahiawa; Waianae Public Library, 85–625 Farrington Highway., Waianae; Waialua Public Library, 67–068 Kealohanui Street, Waialua; UH Environmental Center, Krauss Annex 19, 2500 Dole Road, Honolulu.

The Final EIS also may be reviewed at the SBCT Web Site *http://www.SBCTEIS.com.*

Dated: May 18, 2004.

**Raymond J. Fatz,**

*Deputy Assistant Secretary of the Army, (Environment, Safety and Occupational Health), OASA(I&E).*

[FR Doc. 04–11752 Filed 5–24–04; 8:45 am]

BILLING CODE 3710–08–M

## DEPARTMENT OF DEFENSE

### Department of the Navy

### Privacy Act of 1974; System of Records

**AGENCY:** Department of the Navy

**ACTION:** Notice to add systems of records.

**SUMMARY:** The Department of the Navy proposes to add two systems of records notices to its inventory of record systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended.

**DATES:** This action will be effective on June 24, 2004, unless comments are received that would result in a contrary determination.

**ADDRESSES:** Send comments to the Department of the Navy, PA/FOIA Policy Branch, Chief of Naval Operations (DNS–36), 2000 Navy Pentagon, Washington, DC 20350–2000.

**FOR FURTHER INFORMATION CONTACT:** Mrs. Doris Lama at (202) 685–6545 or DSN 325–6545.

**SUPPLEMENTARY INFORMATION:** The Department of the Navy's record system notices for records systems subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The proposed system reports, as required by 5 U.S.C. 552a(r) of the Privacy Act, were submitted on May 17, 2004, to the House Committee on Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, Federal Agency Responsibilities for Maintaining Records About Individuals, dated February 8, 1996, (61 FR 6427, February 20, 1996).

Dated: May 18, 2004.

**L.M. Bynum,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

**NM03760–3**

**SYSTEM NAME:**

NATOPS Flight Personnel Training/ Qualification Jacket.

**SYSTEM LOCATION:**

The NATOPS Flight Personnel Training and Qualification Jacket accompanies the individual aircrew member throughout his career in the Navy or U.S. Marine Corps. Upon completion of service, the jacket will be given to the individual. For a deceased, missing, or captured air crewman, the jacket will be treated as personal effects.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

All aeronautically designated commissioned Navy and U.S. Marine Corps officers and enlisted members assigned as aircrew members in the operation of an aircraft.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

OPNAV Forms 3710/2, 3710/7, 3760/32–32I, and NAVMED 6410/1 or 6410/2; containing name and Social Security Number of aircrew member; general flight-related information, including jacket review and certification record; a copy of the most recent PCS orders; recent aero-medical clearance or grounding notice; and the flight equipment issue record. Flight qualifications and achievements information, including a flight personnel designation record and a mission qualification record. Flight training information, including schools and courses attendance records, operational physiology and survival training record, NATOPS examinations record, NATOPS evaluation reports, and instrument rating reports. Flight records, including copies of Monthly Individual flight Activity Reports and aircrft mishap/violation record.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

10 U.S.C. 5013, Secretary of the Navy; 10 U.S.C. 5041, Headquarters, Marine Corps; OPNAVINST 3710.7, NATOPS General Flight and Operating Instructions; and E.O. 9397 (SSN)..

**PURPOSE(S):**

To provide a consolidated record of the training status and readiness of an air crewman and serve as a repository for certain aviation records accumulated during active aviation tours, and to prove commanding officers with pertinent data to assist in assignment, utilization, and training of an air crewman.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

In addition to those disclosures generally permitted under 5 U.S.C. 552(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552(b)(3) as follows:

The DoD 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems and records notices apply to the system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper and automated records.

RETRIEVABILITY:

Name and Social Security Number.

SAFEGUARDS:

Physical access in restricted to the individual and those who maintain training records, or those who are directly involved with individual's training or evaluation. The aviation unit's file cabinets containing the jackets are in command areas under normal military 24-hour security measures. May also be resident in a password controlled system with file and element access based on predefined need-to-know. Physical access to terminals, terminal rooms, buildings and activities' grounds are controlled by locked terminals and room, guards, personnel screening and visitor registers.

RETENTION AND DISPOSAL:

Upon detachment from a squadron/command or from active duty service, the jacket will be reviewed, certified by the commanding officer or designated representative, and given to the individual. For a deceased, missing, or captured air crewman, the jacket will be treated as personal effects.

SYSTEM MANAGER AND ADDRESS:

Commander Naval Air Force, U.S. Pacific Fleet, Code N32, NAS North Island, P.O. Box 357051, San Diego, CA 92135–7051.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to Commander Naval Air Force, U.S. Pacific Fleet, Code N32, NAS North Island, P.O. Box 357051, San Diego, CA 92135–7051.

The request should contain the full name and Social Security Number of the individual, the squadron assigned and dates assigned, and be signed by the requester.

RECORD ACCESS PROCEDURE:

Individuals seeking access to information about themselves contained in this system should address written inquiries to the Commander Naval Air Force, U.S. Pacific Fleet, Code N32, NAS North Island, P.O. Box 357051, San Diego, CA 92135–7051.

The request should contain the full name and Social Security Number of the individual, the squadron assigned and dates assigned, and be signed by the requester.

CONTESTING RECORD PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in the Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individual aeronautically designated Navy and Marine Corps officer or enlisted aircrew member; aviation unit personnel; academic tests support flight training, flight performance evaluations, check flight evaluations, aviation physiology training and Individual Flight Activity Reporting System data extracts.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

**NM03760–4**

SYSTEM NAME:

Aviator's Flight Log Book System.

SYSTEM LOCATION:

Aviation unit to which the individual aircrew member is assigned. When not assigned to an aviation unit, the individual maintains custody of the log book.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All aeronautically designated commissioned Navy and U.S. Marine Corps officers and enlisted members assigned as aircrew members in the operation of an aircraft. Possession and maintenance of the log book is mandatory for all Naval Aviators, Student Naval Aviators, Naval Flight Officer, and Student Naval Flight Officers. Possession and maintenance of the log book is optional for other personnel on duty involving flying.

CATEGORIES OF RECORDS IN THE SYSTEM:

OPNAV Form 3760/31 (Aviators Flight Log Book), containing name and Social Security Number of aircrew member, contains sections for the aviator's qualifications and achievements, personal changes, summary of total flight record, flight record summary, summary of pilot time, record of individual flights, flight clothing record, accident and flight rule violation record, and mishap record.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 5013, Secretary of the Navy; 10 U.S.C. 5041, Headquarters, Marine Corps; OPNAVINST 3710.7, NATOPS General Flight and Operating Instructions; and E.O. 9397 (SSN).

PURPOSE(S):

To provide a personal flight record for the individual aircrew member, to serve as a record of certain aviation information developed during active aviation tours, and to provide commanding officers with pertinent data to assist in assignment, utilization, and training of the air crewman.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552(b) of the Privacy Act, these records of information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552(b)(3) as follows:

The DoD 'Blanket Routine Uses' that appears at the beginning of the Navy's compilation of systems and records notices apply to this system.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper and automated records.

RETRIEVABILITY:

Name and Social Security Number.

SAFEGUARDS:

Access is restricted to the individual and those who maintain training records, or those who are directly involved with the individual's training or evaluation. The file cabinets or bookshelves containing the log books are in command areas under normal military 24-hour security measures. Automated systems are password protected and accessible only by individuals having an official need to know.

RETENTION AND DISPOSAL:

Upon detachment from squadron/command or from active duty service, the log book will be given to the individual. For a deceased, missing, or captured air crewman, the log book will be treated as personal effects.

SYSTEM MANAGER AND ADDRESS:

Commander Naval Air Forces (N32), NAS North Island, P.O. Box 357051, San Diego, CA 92135–7051.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether information about themselves is contained in this system should

address written inquiries to the Commander Naval Air Forces (N32), NAS North Island, P.O. Box 357051, San Diego, CA 92135–7051.

The request should contain the full name and Social Security Number of the individual, the squadron assigned and dates assigned, and be signed by the requester.

**RECORD ACCESS PROCEDURE:**

Individuals seeking access to information about themselves contained in this system should address written inquiries to the Commander Naval Air Forces (N32), NAS North Island, P.O. Box 357051, San Diego, CA 92135–7051.

The request should contain the full name and Social Security Number of the individual, the squadron assigned and dates assigned, and be signed by the requester.

**CONTESTING RECORD PROCEDURES:**

The Navy's rules for accessing records, and for contesting contents and appealing initial agency determinations are published in the Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

**RECORD SOURCE CATEGORIES:**

Individual aeronautically designated Navy or Marine Corps officer or enlisted crewmember, academic tests supporting flight training, flight performance evaluations, flight check evaluations, aviation physiology training, and transcribed Individual Flight Activity Reporting System data.

**EXEMPTIONS CLAIMED FOR THE SYSTEM:**

None.

[FR Doc. 04–11688 Filed 5–24–04; 8:45 am]

**BILLING CODE 5001–06–M**

## DEPARTMENT OF DEFENSE

### Department of the Navy

### Privacy Act of 1974; System of Records

**AGENCY:** Department of the Navy, DoD.

**ACTION:** Notice to amend a system of records.

**SUMMARY:** The Department of the Navy is amending a system of records notice in its existing inventory of records systems subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended.

**DATES:** This proposed action will be effective without further notice on June 24, 2004, unless comments are received which result in a contrary determination.

**ADDRESSES:** Send comments to Department of the Navy, PA/FOIA Policy Branch, Chief of Naval Operations, (DNS–36), 2000 Navy Pentagon, Washington, DC 20350–2000.

**FOR FURTHER INFORMATION CONTACT:** Mrs. Doris Lama at (202) 685–6545 or DSN 325–6545.

**SUPPLEMENTARY INFORMATION:** The Department of the Navy systems of records notices subject to the Privacy Act of 1974, (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address above.

The specific changes to the records systems being amended are set forth below followed by the notices, as amended, published in their entirety. The proposed amendments are not within the purview of subsection (r) of the Privacy Act of 1974, (5 U.S.C. 552a), as amended, which requires the submission of a new or altered system report.

Dated: May 18,2004.

**L.M. Bynum,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

**N12610–1**

**SYSTEM NAME:**

Hours of Duty Records (May 9, 2003, 68 FR 24959).

**CHANGES:**

**SYSTEM IDENTIFIER:**

Replace entry with 'NM12610' 1.

* * * * *

**SYSTEM LOCATION:**

Delete first paragraph and replace with 'Organizational elements of the Department of the Navy. Official mailing addresses are published in the Standard Navy Distribution List that is available at *http://neds.nebt.daps.mil/sndl.htm.*'

* * * * *

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Delete entry and replace with '10 U.S.C. 5013, Secretary of the Navy; 10 U.S.C. 5041, Headquarters, Marine Corps; and E.O. 9397 (SSN).'

* * * * *

**NM12610–1**

**SYSTEM NAME:**

Hours of Duty Records

**SYSTEM LOCATION:**

Organizational elements of the Department of the Navy. Official mailing addresses are published in the Standard Navy Distribution List that is available at *http://neds.nebt.daps.mil/sndl.htm.*

Commander, U.S. Joint Forces Command, 1562 Mitscher Avenue, Suite 200, Norfolk, VA 23551–2488.

Commander, U.S. Pacific Command, P.O. Box 64028, Camp H.M. Smith, HI 96861–4028.

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Military and civilian personnel.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

Record contains such information as name, grade/rate, Social Security Number, organizational code, work center code, grade code, pay rate, labor code, type transaction, hours assigned. Database includes scheduling and assignment of work; skill level; tools issued; leave; temporary assignments to other areas.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

10 U.S.C. 5013, Secretary of the Navy; 10 U.S.C. 5041, Headquarters, Marine Corps; and E.O. 9397 (SSN).

**PURPOSE(S):**

To effectively manage the work force.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The DoD 'Blanket Routine Uses' that appear at the beginning of the Navy's compilation of systems of records notices apply to this system.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Paper and computerized records.

**RETRIEVABILITY:**

Name, organization code, Social Security Number, and work center.

**SAFEGUARDS:**

Access is provided on need-to-know basis only. Manual records are maintained in file cabinets under the control of authorized personnel during working hours. The office space in which the file cabinets are located is locked outside of official working hours. Computer terminals are located in supervised areas. Access to computerized data is controlled by password or other user code system.

**RETENTION AND DISPOSAL:**

Records are destroyed when three years old.

SYSTEM MANGER(S) AND ADDRESS:

The commanding officer of the activity in question. Official mailing addresses are published in the Standard Navy Distribution List that is available at *http://neds.nebt.daps.mil/sndl.htm.*

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to the commanding officer of the naval activity where currently employed. Official mailing addresses are published in the Standard Navy Distribution List that is available at *http://neds.nebt.daps.mil/sndl.htm.*

RECORD ACCESS PROCEDURES:

Individuals seeking access to records about themselves contained in this system of records should address written inquiries to the commanding officer of the naval activity where currently employed. Official mailing addresses are published in the Standard Navy Distribution List that is available at *http://neds.nebt.daps.mil/sndl.htm.*

CONTESTING RECORDS PROCEDURES:

The Navy's rules for accessing records, and for contesting contents and appealing determinations are published in Secretary of the Navy Instruction 5211.5; 32 CFR part 701; or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Individual, correspondence, and personnel records.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 04–11689 Filed 5–24–04; 8:45 am]

BILLING CODE 5001–06–M

## DELAWARE RIVER BASIN COMMISSION

### Notice of Commission Meeting and Public Hearing

Notice is hereby given that the Delaware River Basin Commission will hold an informal conference followed by a public hearing on Wednesday, June 2, 2004. The hearing will be part of the Commission's regular business meeting. Both the conference session and business meeting are open to the public and will be held at the Delaware River Basin Commission, 25 State Police Drive, West Trenton, New Jersey.

The conference among the commissioners and staff will begin at 10 a.m. Topics of discussion will include: An update on the development and completion of the Water Resources Plan for the Delaware River Basin; a proposed resolution amending the *Water Quality Regulations, Water Code,* and *Comprehensive Plan* by authorizing the Commission to require waste minimization plans for point and non-point dischargers; and a proposed resolution amending the *Water Code* and *Comprehensive Plan* relating to basin reservoir operations during drought.

The subjects of the public hearing to be held during the 1 p.m. business meeting include the dockets listed below:

1. *Borough of Catasauqua D–87–60 CP RENEWAL 2.* An application for the renewal of a ground water withdrawal project to continue withdrawal of 40mg/30 days to supply the applicant's public water supply distribution system from existing Wells Nos. 1, 2, 4, and 5 in the Epler formation. The project is located in Catasauqua Borough, Lehigh County, Pennsylvania.

2. *Northampton Borough Municipal Authority D–2004–6 CP.* An application to increase the surface water withdrawal from 6 million gallons per day (mgd) to 8 mgd from the applicant's existing intakes on the Lehigh River, which are located at the northern tip of Whitehall Township, Lehigh County, Pennsylvania. The water will continue to supply the applicant's distribution system which serves the Boroughs of Northampton and North Catasauqua in Northampton County; and the Borough of Coplay plus a portion of Whitehall Township in Lehigh County. The project requires only the upgrade of two raw water pumping stations with new pumping facilities.

3. *Stony Creek Anglers, Inc. D–2004–12.* An application for approval of a ground water withdrawal project to supply up to 5.2 million gallons (mg)/30 days of water to the applicant's trout nursery from Well No. 2 in the Stockton Formation, and to retain the existing withdrawal from all wells to 5.2 mg/30 days. The project well is located in the Stony Creek Watershed in West Norriton Township, Montgomery County, Pennsylvania and is located in the Southeastern Pennsylvania Ground Water Protected Area.

4. *Warminster Municipal Authority D–2004–21 CP.* An application to construct a 1.2 million gallon per day (mgd) Sewage Treatment Plant (STP) to provide tertiary treatment of wastewater from the proposed commercial redevelopment of the Naval Air Warfare Center (NAWC) Site. The project is located on Jacksonville Road, near the intersection of Street Road at the NAWC in Warminster Township, Bucks County, Pennsylvania. Following tertiary treatment, the effluent will be discharged to an unnamed tributary of the Little Neshaminy Creek in the Neshaminy Creek Watershed.

The Commission's 1 p.m. business meeting also will include consideration of a resolution to initiate a notice and comment rulemaking process to amend the *Water Quality Regulations, Water Code,* and *Comprehensive Plan* by authorizing the Commission to require waste minimization plans for point and non-point dischargers; a resolution to initiate a notice and comment rulemaking process to amend the *Water Code* and *Comprehensive Plan* relating to basin reservoir operations during drought, for purposes of clarification; a resolution authorizing the executive director to enter into agreements with the U.S. Army Corps of Engineers, PPL Holtwood, LLC and others as appropriate to fund a study to determine flow needs of the dwarf wedgemussel in the upper basin; a resolution authorizing the executive director to enter into a contract for analytical services to support the Lower Delaware monitoring program; a resolution providing for election of the Commission Chair, Vice Chair and Second Vice Chair for the year 2004–2005, commencing July 1, 2004. In addition, the meeting will include: adoption of the Minutes of the April 21, 2004, business meeting; announcements; a report on Basin hydrologic conditions; a report by the executive director; and a report by the Commission's general counsel.

Draft dockets scheduled for public hearing on June 2, 2004, are posted on the Commission's Web site, *http://www.drbc.net,* where they can be accessed through the Notice of Commission Meeting and Public Hearing. Additional documents relating to the dockets and other items may be examined at the Commission's offices. Please contact William Muszynski at 609–883–9500 ext. 221 with any docket-related questions.

Individuals in need of an accommodation as provided for in the Americans with Disabilities Act who wish to attend the informational meeting, conference session or hearings should contact the Commission secretary directly at 609–883–9500 ext. 203 or through the Telecommunications Relay Services (TRS) at 711, to discuss how the Commission may accommodate your needs.

Dated: May 18, 2004.

**Pamela M. Bush,**

*Commission Secretary.*

[FR Doc. 04–11695 Filed 5–24–04; 8:45 am]

BILLING CODE 6360–01–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 July 19, 2004.

**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: May 18, 2004.

**Angela C. Arrington,**

*Leader, Regulatory Information Management, Office of the Chief Information Officer.*

**Office of Postsecondary Education**

*Type of Review:* Revision.
*Title:* Student Aid Report (SAR).
*Frequency:* Annually.
*Affected Public:* Individuals or households.
*Reporting and Recordkeeping Hour Burden:*
*Responses:* 24,521,978.
*Burden Hours:* 5,402,415.
*Abstract:* The Student Aid Report (SAR) is used to notify all applicants of their eligibility to receive Federal student aid for postsecondary education.

Requests for copies of the proposed information collection request may be accessed from *http://edicsweb.ed.gov*, or should be addressed to Department of Education, 400 Maryland Avenue, SW., Potomac Center, 9th Floor, Washington, DC 20202–4700. Requests may also be electronically mailed to the Internet address *OCIO_IMG_Issues@ed.gov* or faxed to 202–245–6623. 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 Joseph Schubart at (202) 245–6566, or via his Internet address *Joe.Schubart@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. 04–11605 Filed 5–24–04; 8:45 am]

BILLING CODE 4000–01–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 July 26, 2004.

**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: May 19, 2004.

**Angela C. Arrington,**

*Leader, Regulatory Information Management Group, Office of the Chief Information Officer.*

**Institute of Education Sciences**

*Type of Review:* New.
*Title:* Reading First Impact Study.
*Frequency:* Annually.
*Affected Public:* State, Local, or Tribal Gov't, SEAs or LEAs; Individuals or household.
*Reporting and Recordkeeping Hour Burden:*
Responses: 75,347
Burden Hours: 110,320.
*Abstract:* The Reading First Impact Study is a five-year evaluation of the effectiveness of the Reading First Program. This study will estimate the impact of the program on student reading achievement through the use of a regression discontinuity design that compares Reading First schools with non-Reading First schools.

Requests for copies of the proposed information collection request may be

accessed from *http://edicsweb.ed.gov*, by selecting the "Browse Pending Collections" link and by clicking on link number 2556. When you access the information collection, click on "Download Attachments" to view. Written requests for information should be addressed to Department of Education, 400 Maryland Avenue, SW., Potomac Center, 9th Floor, Washington, DC 20202–4700. Requests may also be electronically mailed to the Internet address *OCIO_RIMG@ed.gov* or faxed to 202–245–6623. 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 e-mail 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. 04–11748 Filed 5–24–04; 8:45 am]

BILLING CODE 4000–01–P

## DEPARTMENT OF ENERGY

### Office of Energy Efficiency and Renewable Energy

### Federal Energy Management Advisory Committee

**AGENCY:** Department of Energy.

**ACTION:** Notice of open meeting.

**SUMMARY:** This notice announces an open meeting of the Federal Energy Management Advisory Committee (FEMAC). The Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770) requires that these meetings be announced in the **Federal Register** to allow for public participation. This notice announces the eighth meeting of FEMAC, an advisory committee established under Executive Order 13123—Greening the Government through Efficient Energy Management."

**DATES:** Wednesday, June 9, 2004; 9 a.m. to 12 p.m.

**ADDRESSES:** U.S. Department of Energy, 1000 Independence Avenue, SW., Room Number 8E–089, Washington, DC 20585–0121.

**FOR FURTHER INFORMATION CONTACT:** Rick Klimkos, Designated Federal Officer, Office of Federal Energy Management Programs, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585; (202) 586–8287.

**SUPPLEMENTARY INFORMATION:** *Purpose of the Meeting:* To provide advice and guidance on a range of issues critical to meeting mandated Federal energy management goals.

*Tentative Agenda:* Agenda will include discussions on the following topics:

- Review of FEMP activities.
- Report on FEMAC Working Groups.
- Discussion on FEMAC priorities.
- Votes on Working Group reports and recommendations.

*Public Participation:* In keeping with procedures, members of the public are welcome to observe the business of the Federal Energy Management Advisory Committee. If you would like to file a written statement with the committee, you may do so either before or after the meeting. If you would like to make oral statements regarding any of these items on the agenda, you should contact Rick Klimkos at (202) 586–8287 or *rick.klimkos@ee.doe.gov* (e-mail). You must make your request for an oral statement at least 5 business days before the meeting. Members of the public will be heard in the order in which they sign up at the beginning of the meeting. Reasonable provision will be made to include the scheduled oral statements on the agenda. The chair of the committee will make every effort to hear the views of all interested parties. The chair will conduct the meeting to facilitate the orderly conduct of business.

*Minutes:* The minutes of the meeting will be available for public review and copying within 30 days at the Freedom of Information Public Reading Room, Room 1E–190, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC on May 20, 2004.

**Rachel M. Samuel,**

*Deputy Committee Management Officer.*

[FR Doc. 04–11783 Filed 5–24–04; 8:45 am]

BILLING CODE 6450–01–P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

**[Docket No. ER02–1406–001, et al.]**

### Acadia Power Partners, LLC, et al.; Order Implementing New Generation Market Power Analysis and Mitigation Procedures

Issued May 13, 2004.

Before Commissioners: Pat Wood, III, Chairman; Nora Mead Brownell, and Joseph T. Kelliher

1. In this order, the Commission addresses the procedures for implementing the new interim generation market power analysis and mitigation policy announced in the Commission's April 14, 2004 Order in *AEP Power Marketing, Inc., et al.*, 107 FERC ¶ 61,018 (2004), *reh'g pending* (SMA Rehearing Order). This order benefits customers by implementing the policies adopted in the SMA Rehearing Order, which improve the assessment and mitigation of generation market power in wholesale markets, thus better ensuring that prices charged for jurisdictional sales are just and reasonable.

**Background**

2. In an order issued on November 20, 2001,[1] the Commission announced a new generation market power test, the Supply Margin Assessment (SMA), to be applied to market-based rate applications on an interim basis pending a generic review of new methods for analyzing market power. It also established mitigation measures applicable to entities that fail the interim generation market power test.

3. In the SMA Rehearing Order, the Commission granted rehearing of the SMA Order to the extent that it replaced the SMA generation market power test with two "indicative screens" for assessing generation market power and modified the mitigation announced in the SMA Order. Concurrently with the SMA Rehearing Order, the Commission issued a notice establishing a generic rulemaking docket to initiate a comprehensive review of the appropriate analysis for granting market-based rate authority, in particular, the analysis of generation market power, transmission market power, other barriers to entry, and affiliate abuse and reciprocal dealing.[2] In the interim, the Commission indicated that the policies it was adopting in the SMA Rehearing Order (which deal with the generation market power part of the analysis) would apply to all pending and future market-based rate applications, including three-year market-based rate reviews, pending the completion of the market-based rate rulemaking. The Commission stated that it intended to issue a subsequent order addressing the implementation process for pending three-year market-based rate reviews as well as pending applications for initial market-based rate authority.

4. In the SMA Rehearing Order, the Commission stated it was not making

[1] *See* AEP Power Marketing, Inc., *et al.*, 97 FERC ¶ 61,219 (2001) (SMA Order).

[2] *See* Initiation of Rulemaking Proceeding on Market-Based Rates and Notice of Technical Conference, Docket No. RM04–7–000, 107 FERC ¶ 61,109 (2004).

any findings at that time in connection with the three-year market-based rate review filings of the three applicants that were the subject of the rehearing, nor was it imposing in that order mitigation on those applicants. Instead, each applicant was directed, within 60 days from the date of issuance of the SMA Rehearing Order, to make a filing with the Commission submitting revised generation market power analyses pursuant to the two indicative screens (pivotal supplier and market share) adopted in the order. As the Commission explained, each of these revised filings will be noticed in the **Federal Register**, with an opportunity for comment by interested parties. The Commission stated that, following its review of these analyses, it would issue an order addressing the filings on the indicative screens. We further stated that applicants that do not pass the two indicative screens (and thus are rebuttably presumed to possess generation market power) will have the option of presenting a more thorough analysis using the Delivered Price Test. In the alternative, the applicants may proceed directly to mitigation. Should they choose this route, we explained that each company will have the option of proposing specific mitigation tailored to its particular circumstances sufficient to alleviate any market power concerns, or adopting default rates, as set forth in the SMA Rehearing Order.[3]

**Discussion**

5. The purpose of this order is to provide a framework for applying the substantive and procedural requirements of the SMA Rehearing Order to other applicants with: (1) Pending three-year market-based rate reviews; (2) pending filings for initial market-based rate authority; or (3) future applications for initial market-based rate authority or future three-year market-based rate reviews.

6. Because the Commission has adopted a new interim approach for analyzing generation market power, we will require that the generation market power portion of all pending and future three-year reviews, as well as all pending and future initial applications for market-based rate authority, address the indicative screens (pivotal supplier and market share) adopted in the SMA Rehearing Order.[4]

**Pending Three-Year Market-Based Rate Reviews**

7. Consistent with the procedures set forth in the SMA Rehearing Order, all applicants with three-year market-based rate reviews pending before the Commission on or before the date of issuance of this order are directed to make a filing with the Commission to revise the generation market power portion of their three-year reviews to address the two interim indicative generation market power screens adopted in the SMA Rehearing Order.[5] The revised filings will be treated as amendments to the pending filings, and all pleadings on the pending filings will remain in the record.

8. In order to facilitate the processing of the pending three-year market-based rate reviews, however, we have decided to stagger the time periods within which such revised filings must be made. In doing so, we have attempted to take into consideration resource issues from the standpoint of both the industry and the Commission. A schedule listing the time period within which each applicant's revised three-year market-based rate review filing must be made is set forth in Appendix A. Each applicant's revised filing will be noticed in the **Federal Register**, with an opportunity for comment by interested parties.

9. We believe it is appropriate to start with transmission-providing utilities because these utilities are required by the SMA Rehearing Order to undertake simultaneous import capability studies for their home control areas and for each of their interconnected first-tier control areas. As other utilities may need such simultaneous import capability information in order to perform their own generation market power analyses, as a practical matter it is necessary to require that the public utilities with the access to such simultaneous import information (the transmission-providing public utilities) be among the first directed to revise their pending three-year market-based rate reviews consistent with the interim screens adopted in the SMA Rehearing Order.

10. Similarly, because of the importance of information accessibility, we will address early on the three-year market-based rate reviews of public utilities located in ISO/RTOs with a single energy market under the control of the ISO/RTO (*e.g.*, PJM, ISO NE, NYISO, and CAISO). Acting on these types of filings will provide other applicants seeking to obtain or retain market-based rate authority with needed market information that will facilitate the completion of their studies.

11. The timing for processing of the remaining filings is generally based on the age of the filings. We will consider the revised applications directed herein to be the next required three-year market-based rate review for the applicants listed in Appendix A. In the event that a public utility with a three-year market-based rate review *pending before the Commission* is not listed in Appendix A (and, accordingly, has not been assigned a date for submitting its revised generation market power analysis pursuant to the two indicative screens), such omission is inadvertent. Any such omitted public utility is directed, within 30 days of the date of issuance of this order, to identify itself and the pending docket number.

12. We remind applicants that they may provide streamlined applications, where appropriate, to show that they pass both screens.[6] For example, if an applicant would pass both screens without considering competing supplies imported from adjacent control areas, the applicant need not include such imports. Likewise, an applicant need only account for the minimum amount of capacity that would result in the applicant passing both screens. Accordingly, an applicant may not need to consider the capacity of all competitors within the relevant market. For example, if there are seven competitors in the relevant market and the applicant passes both screens when considering only three of those competitors, the applicant need not account for the other four competitors, nor consider competing supplies imported from adjacent control areas. Further, utilities meeting the criteria of section 35.27 of our regulations,[7] as clarified in LG&E Capital Trimble County LLC, 98 FERC ¶ 61,261 at 62,034–35 (2002) (dealing with sales for resale from capacity for which construction commenced on or after July 9, 1996), may provide evidence demonstrating that they satisfy our regulations rather than submit a generation market power analysis.[8]

[3] SMA Rehearing Order, 107 FERC ¶ 61,018 at P 206, 207.

[4] As we stated in the SMA Rehearing Order, we will apply this approach on an interim basis, pending a comprehensive generic review of the appropriate analysis for granting market-based rate authority in the market-based rate rulemaking proceeding. *Id.* at P 2.

[5] Moreover, to the extent that the factual circumstances have changed from those described in the pending filing regarding the other three parts of our four-part analysis (*i.e.*, transmission market power, barriers to entry, and affiliate abuse and/or reciprocal dealing), such applicants should provide updated information regarding those parts of the test.

[6] *See* SMA Rehearing Order, 107 FERC ¶ 61,018 at P 38, 113–117.

[7] 18 CFR 35.27 (2003).

[8] As we explained in the SMA Rehearing Order, however, if an applicant sites generation in an area where it or its affiliates own or control other generation assets, the applicant must address whether its new capacity, when added to existing capacity, raises generation market power concerns. 107 FERC ¶ 61,018 at P 38, 116.

13. In addition, consistent with the procedures set forth in the SMA Rehearing Order, applicants may forgo submitting a generation market power analysis and go directly to mitigation by proposing case-specific mitigation that eliminates the ability to exercise market power, or agreeing to the default rates.[9]

14. Finally, we understand that there may be a number of utilities whose three-year market-based rate reviews are due to be filed with the Commission within the next 60 days. In order to provide such utilities an opportunity to incorporate the two indicative screens adopted in the SMA Rehearing Order into the generation market power portion of their three-year reviews, we will grant these utilities an extension of time of 60 days from the date of issuance of this order to submit their three-year market-based rate reviews.

**Pending Applications for Initial Market-Based Rate Authority**

15. A number of utilities have applications for *initial* market-based rate authority pending before the Commission, which were filed on or before the date of issuance of this order. These utilities are listed in Appendix B. In light of the Commission's decision to analyze generation market power based on the two indicative screens adopted in the SMA Rehearing Order, the generation market power studies submitted in connection with these pending applications have been rendered deficient. Accordingly, the utilities listed in Appendix B are directed to revise their filings within 60 days from the date of issuance of this order to reflect the new interim generation market power screens. In the alternative, these utilities can revise their filings to indicate that they will forgo submitting a generation market power analysis and go directly to mitigation by proposing case-specific mitigation that eliminates the ability to exercise market power, or agreeing to the default rates.

**Future Initial Market-Based Rate Applications and Future Three-Year Reviews**

16. All future applications for initial market-based rate authority and future three-year market-based rate reviews (*i.e.*, those not currently pending and that are filed after the date of issuance of this order) should include generation market power analyses pursuant to the two indicative screens (pivotal supplier and market share) described in the SMA Rehearing Order, as well as the other three parts of our four-part analysis. In the alternative, new applicants for market-based rate authority, as well as applicants filing three-year market-based rate reviews, can forgo submitting a generation market power analysis and go directly to mitigation by proposing case-specific mitigation that eliminates the ability to exercise market power, or agreeing to the default rates.

*The Commission orders:*

(A) The applicants listed in Appendix A are directed to file, within the time period set forth in Appendix A, revised applications, as discussed in the body of this order.

(B) The applicants listed in Appendix B are directed to revise their applications for initial market-based rate authority, as discussed in the body of this order.

(C) Applicants with three-year market-based rate reviews due to be filed within the next 60 days are hereby granted an extension of time of 60 days from the date of issuance of this order, as discussed in the body of this order.

(D) The Secretary is hereby directed to promptly publish this order in the **Federal Register**.

By the Commission. Commissioner Kelly not participating.

**Linda Mitry,**

*Acting Secretary.*

**Appendix A**

**Group I (due within 90 days of the date of this order)**

| | |
|---|---|
| Alliant Energy Corporate Services | ER99–230–002 |
| APS Energy Services, Inc | ER99–4122–004 |
| Arizona Public Service Company | ER99–4124–001 |
| Pinnacle West Capital Corporation | ER00–2268–003 |
| Pinnacle West Energy Corporation | ER00–3312–002 |
| CMS Generation Michigan Power LLC | ER99–3677–001 |
| Consumers Energy Company | ER98–4421–002 |
| Consolidated Water Power Company | ER98–4512–002 |
| El Paso Electric Company | ER99–2416–001 |
| Dayton Power & Light Company | ER96–2602–004 |
| DPL Energy LLC | ER96–2601–015 |
| Duke Energy Morro Bay, LLC | ER98–2681–002 |
| Duke Energy Moss Landing, LLC | ER98–2680–002 |
| Duke Energy Oakland, LLC | ER98–2682–002 |
| Duke Energy South Bay, LLC | ER99–1785–001 |
| Duke Power Co. | ER96–110–007 |
| Duke Solutions, Inc | ER98–3813–007 |
| Kansas City Power & Light Company | ER99–1005–001 |
| Public Service Company of New Mexico | ER96–1551–006 |
| | ER01–615–003 |
| Puget Sound Energy, Inc | ER99–845–003 |

**Group II (due within 135 days of the date of this order)**

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|---|---|
| Avista Energy Inc | ER96–2408–018 |
| Empire District Electric Company | ER99–1757–002 |
| | ER99–1757–003 |
| | ER99–1757–004 |
| AG-Energy, LP | ER98–2782–002 |
| Amergen Energy Company, LLC | ER99–754–008 |
| Commonwealth Edison Company | ER98–1734–006 |
| Exelon Edgar LLC | ER01–513–005 |
| Exelon Energy Company | ER97–3954–016 |

[9] *Id.* at P 39, 148.

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|---|---|
| Exelon Fore River Development, LLC | ER01–41–004 |
| Exelon Framingham LLC | ER01–513–005 |
| Exelon Generation Company, LLC | ER00–3251–005 |
| Exelon New Boston LLC | ER01–513–005 |
| Exelon New England Power Marketing, L.P | ER99–2404–001 |
| | ER99–2404–004 |
| Exelon Mystic Development, LLC | ER01–42–005 |
| Exelon West Medway LLC | ER01–513–005 |
| Exelon Wyman LLC | ER01–513–005 |
| PECO Energy Company | ER99–1872–005 |
| Power City Partners, L.P | ER98–2782–002 |
| Seneca Power Partners, L.P | ER98–2782–002 |
| Sithe Edgar LLC | ER98–1943–002 |
| Sithe New Boston LLC | ER98–1943–002 |
| Sithe Framingham LLC | ER98–1943–002 |
| Sithe West Medway LLC | ER98–1943–002 |
| Sithe Wyman LLC | ER98–1943–002 |
| Sithe Mystic LLC | ER98–1943–002 |
| Sithe Power Marketing, L.P | ER98–107–011 |
| Unicom Power Marketing, Inc | ER01–1919–002 |
| Sterling Power Partners, L.P | ER98–2782–002 |
| Idaho Power Company | ER97–1481–003 |
| Northeast Generation Company | ER99–4463–001 |
| Northeast Utilities Service Company | ER96–496–010 |
| Select Energy, Inc | ER99–14–007 |
| Athens Generating Company, L.P | ER99–4282–002 |
| Attala Generating Company, LLC | ER01–747–002 |
| Badger Generating Company, LLC | ER00–3457–001 |
| Covert Generating Company, LLC | ER01–520–002 |
| Harquahala Generating Company, LLC | ER01–748–002 |
| La Paloma Generating Company, LLC | ER00–107–001 |
| Lake Road Generating Company, L.P | ER99–1714–002 |
| Liberty Generating Company, LLC | ER00–1792–001 |
| Logan Generating Company, L.P | ER95–1007–014 |
| Madison Windpower LLC | ER00–1742–001 |
| Mantua Creek Generating Company, L.P | ER99–4162–002 |
| Millennium Power Partners, L.P | ER98–830–006 |
| Mountain View Power Partners, LLC | ER01–751–001 |
| | ER01–751–005 |
| Mountain View Power Partners II, LLC | ER01–1336–002 |
| Okeechobee Generating Company, LLC | ER99–3643–001 |
| PG&E Dispersed Generating Company, LLC | ER00–2134–001 |
| PG&E Energy Trading Power, L.P | ER95–1625–024 |
| Pittsfield Generating Company, L.P | ER98–4400–003 |
| Plains End, LLC | ER01–2741–002 |
| USGen New England, Inc | ER98–6–008 |
| Western Resources, Inc | ER98–2157–002 |
| Griffin Energy Marketing, LLC | ER97–4168–012 |
| Wisconsin Electric Power Company | ER98–855–002 |
| | ER98–855–003 |
| Wisconsin Public Service Corporation | ER95–1528–006 |
| WPS Energy Services, Inc | ER96–1088–031 |
| WPS Power Development, Inc | ER96–1088–031 |

**Group III (due within 180 days of the date of this order)**

| | |
|---|---|
| AES Alamitos, LLC | ER98–2185–006 |
| AES Huntington Beach, LLC | ER98–2184–006 |
| AES Placerita, Inc | ER00–33–003 |
| AES Redondo Beach, LLC | ER98–2186–006 |
| Indianapolis Power & Light Company | ER00–1026–006 |
| Citizens Power Sales | ER94–1685–031 |
| CPL Power Sales One, LLC | ER95–892–055 |
| CPL Power Sales Two, LLC | ER95–892–055 |
| CPL Power Sales Five, LLC | ER95–892–055 |
| CPL Power Sales Six, LLC | ER96–2652–049 |
| CPL Power Sales Seven, LLC | ER96–2652–049 |
| CPL Power Sales Eight, LLC | ER96–2652–049 |
| CPL Power Sales Nine, LLC | ER96–2652–049 |
| CPL Power Sales Ten, LLC | ER96–2652–049 |
| CPL Power Sales Twelve, LLC | ER99–893–007 |
| CPL Power Sales Thirteen, LLC | ER99–892–008 |
| CPL Power Sales Fourteen, LLC | ER99–891–008 |
| CPL Power Sales Fifteen, LLC | ER99–890–008 |
| CPL Power Sales Seventeen, LLC | ER99–4229–005 |
| CPL Power Sales Eighteen, LLC | ER99–4230–004 |

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| CPL Power Sales Nineteen, LLC | ER99–4228–005 |
| CPL Power Sales Twenty, LLC | ER99–4231–004 |
| Edison Mission Marketing & Trading, Inc | ER99–852–006 |
| EME Homer City Generation, L.P | ER99–666–002 |
| Midwest Generation, LLC | ER99–3693–001 |
| Sunrise Power Co | ER01–2217–002 |
| LG&E Energy Marketing, Inc | ER94–1188–033 |
| Louisville Gas & Electric Company | ER98–4540–002 |
| Kentucky Utilities Company | ER99–1623–001 |
| WKE Station 2, Inc | ER98–1278–008 |
| Western Kentucky Energy Corporation | ER98–1279–004 |
| Madison Gas & Electric Company | ER00–586–002 |
| Mirant Americas Energy Marketing, LP | ER01–1265–002 |
| Mirant Bowline, LLC | ER01–1266–002 |
| Mirant California, LLC | ER01–1267–002 |
| | ER01–1267–003 |
| Mirant Canal, LLC | ER01–1268–003 |
| Mirant Chalk Point, LLC | ER01–1269–002 |
| Mirant Delta, LLC | ER01–1270–002 |
| | ER01–1270–003 |
| Mirant Energy Trading, LLC | ER02–1213–001 |
| Mirant Kendall, LLC | ER01–1271–003 |
| Mirant Las Vegas, LLC | ER03–160–001 |
| Mirant Lovett, LLC | ER01–1272–002 |
| Mirant Mid-Atlantic, LLC | ER01–1273–002 |
| Mirant NY-Gen, LLC | ER01–1275–002 |
| Mirant New England, LLC | ER01–1274–003 |
| Mirant Oregon, LLC | ER02–1331–002 |
| Mirant Peaker, LLC | ER01–1276–002 |
| Mirant Potomac River, LLC | ER01–1277–002 |
| Mirant Potrero, LLC | ER01–1278–002 |
| | ER01–1278–003 |
| Mirant Sugar Creek, LLC | ER02–900–001 |
| Mirant Zeeland, LLC | ER01–1263–002 |
| Shady Hills Power Company, LLC | ER02–537–002 |
| West Georgia Generating Company, LLC | ER02–1052–001 |
| Wrightsville Power Facility, LLC | ER02–1028–001 |
| Minnesota Power | ER01–2636–001 |
| Split Rock Energy, LLC | ER00–1857–002 |
| PPL Brunner Island, LLC | ER00–744–001 |
| PPL Colstrip I, LLC | ER99–3491–002 |
| PPL Colstrip II, LLC | ER99–3491–002 |
| PPL Electric Utilities Corp | ER00–1712–003 |
| PPL EnergyPlus, LLC | ER98–4608–005 |
| PPL Holtwood, LLC | ER00–744–001 |
| PPL Martins Creek, LLC | ER00–744–001 |
| PPL Montana, LLC | ER99–3491–002 |
| PPL Montour, LLC | ER00–744–001 |
| PPL Susquehanna, LLC | ER00–744–001 |
| Reliant Energy Coolwater, LLC | ER99–2082–002 |
| Reliant Energy Ellwood, LLC | ER99–2081–002 |
| Reliant Energy Etiwanda, LLC | ER99–2083–002 |
| Reliant Energy Mandalay, LLC | ER99–2080–002 |
| Reliant Energy Ormond Beach, LLC | ER99–2079–002 |
| Reliant Energy Services, Inc | ER99–1801–005 |
| Sempra Energy Solutions | ER00–3444–002 |
| Hardee Power Partners Limited | ER99–2341–001 |
| Panda Gila River, L.P | ER01–931–004 |
| Tampa Electric Company | ER99–2342–001 |
| TECO Energy Source, Inc | ER96–1563–017 |
| Union Power Partners, L.P | ER01–930–004 |

**Group IV (due within 225 days of the date of this order)**

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|---|---|
| Ameren Energy Development Co | ER01–294–002 |
| Ameren Energy Generating Co | ER00–3412–003 |
| Ameren Energy Marketing Co | ER00–816–001 |
| AmerenEnergy Medina Valley Cogen, LLC | ER04–8–002 |
| | ER98–2440–003 |
| AmerenEnergy Resources Generating Co | ER04–53–002 |
| Central Illinois Light Co | ER98–2440–002 |
| Union Electric Co | ER00–2687–002 |
| Aquila, Inc | ER03–1079–002 |
| Aquila Merchant Services, Inc | ER94–216–001 |
| MEP Investments, LLC | ER99–2322–001 |
| MEP Pleasant Hill, LLC | ER99–2858–002 |

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| MEP Pleasant Hill Operating, LLC | ER01–905–001 |
| Pleasant Hill Marketing, LLC | ER00–1851–001 |
| Adirondack Hydro Development Corporation | ER00–3109–001 |
| Adirondack Hydro Fourth Branch, LLC | ER00–3774–001 |
| Black Hills Colorado, LLC | ER00–1952–001 |
| Black Hills Generation, Inc | ER01–1844–001 |
| Black Hills Pepperell Power Associates, Inc. | ER96–1635–008 |
| Black Hills Power, Inc | ER99–2287–001 |
| Fountain Valley Power, LLC | ER01–1784–004 |
| Harbor Cogeneration Company | ER99–1248–002 |
| | ER99–1248–003 |
| NYSD LP | ER00–3109–001 |
| Sissonville LP | ER00–3109–001 |
| Warrensburg Hydro Power LP | ER00–3109–001 |
| Acadia Power Partners, LLC | ER02–1406–001 |
| Cleco Evangeline, LLC | ER99–2928–001 |
| Cleco Marketing & Trading, LLC | ER99–2300–004 |
| Cleco Power, LLC | ER99–3855–002 |
| Perryville Energy Partners, LLC | ER01–1397–002 |
| Delmarva Power & Light Company | ER99–2781–002 |
| Crete Energy Venture, LLC | ER02–963–002 |
| The Detroit Edison Company | ER97–324–004 |
| DTE Edison America, Inc | ER98–3026–007 |
| DTE Energy Marketing, Inc | ER99–3368–003 |
| DTE Energy Trading, Inc | ER97–3834–010 |
| DTE Georgetown, LLC | ER00–1746–001 |
| DTE River Rouge No. 1, LLC | ER00–1816–002 |
| Armstrong Limited Energy Partnership, LLP | ER02–24–002 |
| Dominion Energy Marketing, Inc | ER01–468–001 |
| Dominion Nuclear Connecticut, Inc | ER00–3621–002 |
| Dominion Nuclear Marketing I, Inc | ER00–3620–002 |
| Dominion Nuclear Marketing II, Inc | ER00–3619–002 |
| Dominion Nuclear Marketing III, Inc | ER00–3746–003 |
| Dresden Energy, LLC | ER02–22–002 |
| Elwood Energy, LLC | ER99–1695–002 |
| Fairless Energy, LLC | ER02–23–002 |
| Kincaid Generation, LLC | ER99–1432–002 |
| Pleasants Energy, LLC | ER02–26–002 |
| State Line Energy, LLC | ER96–2869–005 |
| Troy Energy, LLC | ER02–25–002 |
| Virginia Electric & Power Company | ER00–1737–004 |
| Backbone Windpower Holdings, LLC | ER02–2559–001 |
| Badger Windpower, LLC | ER01–1071–002 |
| Bayswater Peaking Facility, LLC | ER02–669–002 |
| Blythe Energy, LLC | ER02–2018–002 |
| Calhoun Power Company I, LLC | ER01–2074–002 |
| Doswell Limited Partnership | ER90–80–001 |
| ESI Vansycle Partners, L.P | ER98–2494–004 |
| Florida Power & Light Company | ER97–3359–005 |
| FPL Energy Cape, LLC | ER00–3068–002 |
| FPL Energy Hancock County Wind, LLC | ER03–34–001 |
| FPL Energy Maine Hydro, Inc | ER98–3511–006 |
| FPL Energy Marcus Hook, L.P | ER02–1903–001 |
| FPL Energy Mason, LLC | ER98–3562–006 |
| FPL Energy MH 50, L.P | ER99–2917–003 |
| FPL Energy New Mexico Wind, LLC | ER03–179–002 |
| FPL Energy Pennsylvania Wind, LLC | ER02–2166–001 |
| FPL Energy Power Marketing, Inc | ER98–3566–009 |
| FPL Energy Rhode Island Energy, L.P | ER02–2120–001 |
| FPL Energy Seabrook, LLC | ER02–1838–001 |
| FPL Energy Vansycle, LLC | ER01–838–002 |
| FPL Energy Wyman, LLC | ER98–3563–006 |
| FPL Energy Wyman IV, LLC | ER98–3564–006 |
| Gray County Wind Energy, LLC | ER01–1972–002 |
| Hawkeye Power Partners, LLC | ER98–2076–005 |
| High Winds, LLC | ER03–155–001 |
| Jamaica Bay Peaking Facility, LLC | ER03–623–002 |
| Lake Benton Power Partners II, LLC | ER98–4222–001 |
| Mill Run Windpower, LLC | ER01–1710–002 |
| Somerset Windpower, LLC | ER01–2139–003 |
| West Texas Wind Energy Partners, LP | ER98–1965–002 |
| Florida Power Corporation | ER97–2846–003 |

**Group V (due within 270 days of the date of this order)**

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|---|---|
| The Cleveland Electric Illuminating Company | ER99–2330–001 |

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|---|---|
| FirstEnergy Generation Corp | ER01–845–001 |
| FirstEnergy Solutions Corp | ER01–2968–002 |
| Jersey Central Power & Light Company | ER99–2330–001 |
| Metropolitan Edison Company | ER99–2330–001 |
| Ohio Edison Company | ER99–2330–001 |
| Pennsylvania Electric Company | ER99–2330–001 |
| Pennsylvania Power Company | ER99–2330–001 |
| The Toledo Edison Company | ER99–2330–001 |
| Bluegrass Generation Company, LLC | ER02–506–002 |
| Cabrillo Power I LLC | ER99–1115–005 |
| Cabrillo Power II LLC | ER99–1116–005 |
| Calcasieu Power, LLC | ER00–1049–003 |
| Dynegy Danskammer, LLC | ER01–140–002 |
| Dynegy Midwest Generation, Inc | ER00–1895–002 |
| Dynegy Power Marketing, Inc | ER99–4160–003 |
| Dynegy Power Services, Inc | ER94–1612–026 |
| Dynegy Roseton, LLC | ER01–141–002 |
| El Segundo Power, LLC | ER98–1127–005 |
| Foothills Generating, LLC | ER02–554–001 |
| Heard County Power, LLC | ER01–943–002 |
| Illinova Energy Partners, Inc | ER94–1475–021 |
| Long Beach Generation LLC | ER98–1796–004 |
| Nicor Energy, LLC | ER01–1169–002 |
| Renaissance Power, LLC | ER01–3109–002 |
| Riverside Generating Company, LLC | ER01–1044–002 |
| Rockingham Power, LLC | ER99–1567–002 |
| Rocky Road Power, LLC | ER99–2157–002 |
| Rolling Hills Generating, LLC | ER02–553–001 |
| Energy USA–TPC Corp | ER01–1300–003 |
| Northern Indiana Public Service Company | ER00–2173–002 |
| Whiting Clean Energy, Inc | ER00–3219–002 |
| OGE Energy Resources, Inc | ER98–511–002 |
| Oklahoma Gas and Electric Company | ER97–4345–014 |
| Pepco Energy Services, Inc | ER98–3096–008 |
| Potomac Power Resources, LLC | ER01–202–001 |
| Portland General Electric Company | ER98–1643–006 |
| South Carolina Electric & Gas Company | ER96–1085–006 |
| Tucson Electric Power Company | ER98–1150–002 |
| Northern States Power Company | ER98–2640–004 |
| Northern States Power Company (Wisconsin) | ER98–2640–004 |
| Public Service Company of Colorado | ER98–4590–002 |
| Southwestern Public Service Company | ER99–1610–008 |
| Xcel Energy Services Inc | ER01–205–004 |

**Group VI (due within 315 days of the date of this order)**

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|---|---|
| Astoria Gas Turbine Power LLC | ER99–3000–001 |
| CPN Pleasant Hill, LLC | ER01–915–002 |
| CPN Pleasant Hill Operating, LLC | ER01–915–002 |
| De Pere Energy LLC | ER97–1432–011 |
| Mobile Energy LLC | ER01–480–003 |
| Elkem Metals Company—Alloy L.P | ER00–2093–001 |
| Fresno Cogeneration Partners, L.P | ER00–2392–001 |
| HQ Energy Services (US) Inc | ER97–851–012 |
| | ER97–851–013 |
| Morgan Stanley Capital Group Inc | ER94–1384–030 |
| MS Retail Development Corp | ER03–1315–001 |
| Power Contract Finance, LLC | ER02–1485–003 |
| Power Contract Financing II, LLC | ER03–1108–002 |
| Power Contract Financing II, Inc | ER03–1109–002 |
| South Eastern Electric Development Corporation | ER99–2329–002 |
| South Eastern Generating Corporation | ER00–1803–001 |
| Louisiana Generating, LLC | ER00–1259–001 |
| NRG Energy Center Dover LLC | ER00–3160–001 |
| NRG Energy Center Paxton LLC | ER00–2313–001 |
| Onondaga Cogeneration Limited Partnership | ER00–895–001 |
| Otter Tail Corporation | ER00–3080–001 |
| Redbud Energy, LP | ER01–1011–002 |
| South Jersey Energy Company | ER97–1397–010 |
| WFEC GENCO, LLC | ER01–388–002 |
| Williams Energy Marketing & Trading Company | ER99–1722–004 |
| Williams Flexible Generation, LLC | ER00–2469–001 |
| Williams Generation Company—Hazelton | ER97–4587–004 |
| Williams Power Company, Inc | ER03–1331–003 |

**Appendix B**

| | |
|---|---|
| Duquesne Power, L.P | ER04–268–000 |
| Hartford Steam Company | ER04–582–000 |
| | ER04–582–001 |
| | ER04–582–002 |
| PPL Distributed Generation, LLC | ER04–671–000 |
| Tor Power, Inc | ER04–698–000 |

[FR Doc. 04–11744 Filed 5–24–04; 8:45 am]
BILLING CODE 6717–01–P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### Sunshine Act Meeting

May 19, 2004.

The following notice of meeting is published pursuant to section 3(a) of the Government in the Sunshine Act (Pub. L. 94–409), 5 U.S.C 552b:

**AGENCY HOLDING MEETING:** Federal Energy Regulatory Commission.

**DATE AND TIME:** May 26, 2004, 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.

**FOR FURTHER INFORMATION CONTACT:** Magalie R. Salas, Secretary, Telephone (202) 502–8400. For a recording listing items stricken from or added to the meeting, call (202) 502–8627.

This is a list of matters to be considerd 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.

**860th—Meeting May 26, 2004, Regular Meeting, 10 a.m.**

**Administrative Agenda**

A–1.
DOCKET# AD02–1, 000, Agency Administrative Matters
A–2.
DOCKET# AD02–7, 000, Customer Matters, Reliability, Security and Market Operations

**Markets, Tariffs and Rates—Electric**

E–1.
DOCKET# ER03–563, 030, Devon Power LLC, Middletown Power LLC, Montville Power LLC, Norwalk Power LLC and NRG Power Marketing Inc.
OTHER#S EL04–102,000, Devon Power LLC, Middletown Power LLC, Montville Power LLC, Norwalk Power LLC and NRG Power Marketing Inc.
E–2.
OMITTED
E–3.
DOCKET# ER04–691, 000, Midwest Independent Transmission System Operator, Inc.
E–4.
OMITTED
E–5.
DOCKET# ER04–714, 000, Florida Power & Light Company-New England Division
E–6.
DOCKET# ER04–697, 000, New England Power Pool
E–7.
DOCKET# ER04–677, 000, New England Power Pool
E–8.
DOCKET# ER04–641, 000, Duke Energy Lee, LLC
OTHER#S ER04–641, 001, Duke Energy Lee, LLC
E–9.
DOCKET# ER04–658, 000, Southwest Power Pool, Inc.
E–10.
DOCKET# ER04–589, 000, Commonwealth Edison Company
OTHER#S ER04–589, 001 Commonwealth Edison Company
ER04–594, 000, Commonwealth Edison Company
E–11.
OMITTED
E–12.
OMITTED
E–13.
DOCKET# ER04–742, 000, PJM Interconnection, L.L.C.
E–14.
OMITTED
E–15.
OMITTED
E–16.
DOCKET# ER03–861, 000, Entergy Services, Inc.
E–17.
DOCKET# ER03–1396. 000, Troy Energy, LLC
E–18.
OMITTED
E–19.
DOCKET# ER04–680, 000, Tenaska Virginia Partners, LP
OTHER#S ER04–680, 001, Tenaska Virginia Partners, LP
E–20.
DOCKET# OA96–194, 010, Niagara Mohawk Power Corporation
E–21.
DOCKET# ER03–552, 006, New York Independent System Operator, Inc.
OTHER#S ER03–552, 007, New York Independent System Operator, Inc.
ER03–552, 008, New York Independent System Operator, Inc.
ER03–984, 004, New York Independent System Operator, Inc.
ER03–984, 005, New York Independent System Operator, Inc.
ER03–984, 006, New York Independent System Operator, Inc.
E–22.
DOCKET# ER02–320, 007, Michigan Electric Transmission Company, LLC
E–23.
DOCKET# EL99–14, 005, Southwestern Electric Cooperative, Inc. v. Soyland Power Cooperative, Inc.
E–24.
DOCKET# EL01–50, 003, New York Independent System Operator, Inc.
E–25.
DOCKET# ER97–1523, 065, Central Hudson Gas & Electric Corporation, Consolidated Edison Company of New York, Inc., Long Island Lighting Company, New York State Electric & Gas Corporation, Niagara Mohawk Power Corporation, Orange and Rockland Utilities, Inc., Rochester Gas and Electric Corporation and New York Power Pool
OTHER#S OA97–470, 060, Central Hudson Gas & Electric Corporation, Consolidated Edison Company of New York, Inc., Long Island Lighting Company, New York State Electric & Gas Corporation, Niagara Mohawk Power Corporation, Orange and Rockland Utilities, Inc., Rochester Gas and Electric Corporation and New York Power Pool
OA97–470, 062, Central Hudson Gas & Electric Corporation, Consolidated Edison Company of New York, Inc., Long Island Lighting Company, New York State Electric & Gas Corporation, Niagara Mohawk Power Corporation, Orange and Rockland Utilities, Inc., Rochester Gas and Electric Corporation and New York Power Pool
ER97–1523, 067, Central Hudson Gas & Electric Corporation, Consolidated Edison Company of New York, Inc., Long Island Lighting Company, New York State Electric & Gas Corporation, Niagara Mohawk Power Corporation, Orange and Rockland Utilities, Inc., Rochester Gas and Electric Corporation and New York Power Pool
ER97–4234, 058, Central Hudson Gas & Electric Corporation, Consolidated Edison Company of New York, Inc., Long Island Lighting Company, New York State Electric & Gas Corporation, Niagara Mohawk Power Corporation, Orange and Rockland Utilities, Inc., Rochester Gas and Electric Corporation and New York Power Pool
ER97–4234, 060, Central Hudson Gas & Electric Corporation, Consolidated Edison Company of New York, Inc., Long

Island Lighting Company, New York State Electric & Gas Corporation, Niagara Mohawk Power Corporation, Orange and Rockland Utilities, Inc., Rochester Gas and Electric Corporation and New York Power Pool

E–26.
DOCKET# QF86–159, 001, Zond Windsystem Partners, Ltd., Series 85–C
OTHER#S EL03–47, 001, Investigation of Certain Enron-Affiliated QF's

E–27.
DOCKET# EC04–88, 000, American Electric Power Service Corporation, Oklaunion Electric Generating Cooperative, Inc., and Golden Spread Electric Cooperative, Inc.

E–28.
DOCKET# EC04–66, 000, Entergy Asset Management, Inc., Entergy Power Ventures, L.P., Warren Power, LLC, and East Texas Electric Cooperative, Inc.

E–29.
DOCKET# ER01–2905, 002, Xcel Energy Services, Inc.
OTHER#S ER01–2905, 000, Xcel Energy Services, Inc.
ER01–2905,001, Xcel Energy Services, Inc.

E–30.
OMITTED

E–31.
DOCKET# ER04–23, 001, ISO New England Inc.
OTHER#S ER04–23, 004, ISO New England Inc.

E–32.
OMITTED

E–33.
DOCKET# ER04–35, 001, Entergy Services, Inc.
OTHER#S ER04–35, 002, Entergy Services, Inc.

E–34.
DOCKET# EL04–2, 001, *Sacramento Municipal Utility District* v. *Pacific Gas and Electric Company, Southern California Edison Company and San Diego Gas & Electric Company*

E–35.
DOCKET# EL04–11, 001, *Californians for Renewable Energy, Inc.* v. *Calpine Energy Services, L.P. and the California Department of Water Resource*

E–36.
OMITTED

E–37.
DOCKET# ER04–77, 003, Dayton Power and Light Company
OTHER#S ER04–77, 002, Dayton Power and Light Company

E–38.
OMITTED

E–39.
DOCKET# ER04–335, 001, New England Power Pool
OTHER#S ER04–335, 002, New England Power Pool

E–40.
DOCKET# EL04–43, 001, *Tenaska Power Services Company* v. *Midwest Independent Transmission System Operator, Inc.*
OTHER#S EL04–46, 001, *Cargill Power Markets, LLC* v. *Midwest Independent Transmission System Operator, Inc.*

E–41.
OMITTED

E–42.
OMITTED

E–43.
DOCKET# ER03–766, 003, New York Independent System Operator, Inc.

E–44.
DOCKET# EL04–92, 000, Northeast Utilities Service Company

E–45.
DOCKET# EL04–91, 000, *Patrick C. Lynch, Attorney General of the State of Rhode Island* v. *ISO New England, Inc.*

E–46.
OMITTED

E–47.
OMITTED

E–48.
OMITTED

E–49.
DOCKET# EL04–82, 000, *NRG Power Marketing, Inc., Connecticut Jet Power LLC, Middletown Power LLC, Montville Power LLC, and Norwalk Power, LLC* v. *ISO New England, Inc.*

E–50.
DOCKET# ER98–1438, 020 Midwest Independent Transmission System Operator, Inc.
OTHER#S EC98–24, 012, Midwest Independent Transmission System Operator, Inc.

E–51.
DOCKET# ER03–1206, 000, DTE East China, LLC and DTE Energy Trading, Inc.

E–52.
DOCKET# EL03–47, 001, Investigation of Certain Enron-Affiliated QF's
OTHER#S QF84–422, 002, Zond-PanAero Windsystem Partners I (ZP I)
QF85–263,002, Zond-PanAero Windsystem Partners II (ZP II)

E–53.
DOCKET# EL02–123, 002, Boston Edison Company

E–54.
DOCKET# ER03–1091, 000, Pacific Gas and Electric Company
OTHER#S ER03–1091, 001, Pacific Gas and Electric Company
ER03–1091,004, Pacific Gas and Electric Company

E–55.
DOCKET# ER04–717, 000, Orion Power MidWest, L.P.

**Miscellaneous Agenda**

M–1.
DOCKET# RM03–8, 001, Quarterly Financial Reporting and Revisions to the Annual Reports

**Markets, Tariffs and Rates—Gas**

G–1.
DOCKET# RP00–463, 006, Williston Basin Interstate Pipeline Company

G–2.
OMITTED

G–3.
OMITTED

G–4.
DOCKET# RP04–264, 000, ANR Pipeline Company

G–5.
DOCKET# PR04–7, 000, Raptor Natural Pipeline, LLC
PR04–7,001, Raptor Natural Pipeline, LLC

G–6.
DOCKET# RP03–292, 001, Viking Gas Transmission Company

G–7.
DOCKET# RP04–76, 000, Southern Star Central Gas Pipeline, Inc.

G–8.
OMITTED

G–9.
DOCKET# RP98–40, 000, Panhandle Eastern Pipe Line Company

G–10.
DOCKET# RP03–542, 001, Texas Eastern Transmission, LP

G–11.
DOCKET# RP03–492, 001, Columbia Gulf Transmission Company

G–12.
DOCKET# RP03–552, 001, Dominion Cove Point LNG, LP

G–13.
DOCKET# RP04–36, 000, Enbridge Pipelines (KPC)

G–14.
DOCKET# RP03–491, 001, Columbia Gas Transmission Corporation

G–15.
DOCKET# RP03–123, 002, Southern Natural Gas Company
OTHER#S RP02–86, 002, Southern Natural Gas Company
RP04–79, 001, Southern Natural Gas Company

G–16.
DOCKET# RP04–155, 002, Northern Natural Gas Company
OTHER#S RP03–398, 007, Northern Natural Gas Company

G–17.
OMITTED

G–18.
DOCKET# RP93–109, 020, Southern Star Central Gas Pipeline, Inc.

G–19.
DOCKET# RP03–398, 005, Northern Natural Gas Company
OTHER#S RP03–398, 004, Northern Natural Gas Company

G–20.
DOCKET# RP02–361, 025 Gulfstream Natural Gas System, L.L.C.

G–21.
DOCKET# RP04–267, 000, Transcontinental Gas Pipe Line Corporation

**Energy Projects—Hydro**

H–1.
DOCKET# P–77, 120, Pacific Gas and Electric Company

H–2.
DOCKET# P–2009, 031, Virginia Electric and Power Company, dba Dominion Virginia Power/Dominion North Carolina Power

H–3.
DOCKET# P–516, 380, South Carolina Electric & Gas Company

H–4.
OMITTED

H–5.
DOCKET# P–1494, 244, Grand River Dam Authority

**Energy Projects—Certificates**

C–1.

DOCKET# CP04–1, 000, ANR Pipeline Company

C–2.

DOCKET# CP04–67, 000, Algonquin Gas Transmission Company

C–3.

DOCKET# CP01–49, 004, Northwest Pipeline Corporation

The Capitol Connection offers the opportunity for remote listening and viewing of the meeting. It is available for a fee, live over the Internet, via C-Band Satellite. Persons interested in receiving the broadcast, or who need information on making arrangements should contact David Reininger or Julia Morelli at the Capitol Connection (703–993–3100) as soon as possible or visit the Capitol Connection Web site at *http://www.capitolconnection.gmu.edu* and click on "FERC".

**Magalie R. Salas,**

*Secretary.*

[FR Doc. 04–11885 Filed 5–21–04; 11:16 am]

BILLING CODE 6717–01–P

## ENVIRONMENTAL PROTECTION AGENCY

**[RCRA–2000–0066; FRL–7666–8]**

### Agency Information Collection Activities; Submission to OMB for Review and Approval; Comment Request; Reporting and Recordkeeping Requirements Under EPA's WasteWise Program (Renewal), EPA ICR Number 1698.05, OMB Control Number 2050–0139

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

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that an Information Collection Request (ICR) has been forwarded to the Office of Management and Budget (OMB) for review and approval. This is a request to renew an existing approved collection. This ICR is scheduled to expire on May 31, 2004. Under OMB regulations, the Agency may continue to conduct or sponsor the collection of information while this submission is pending at OMB. This ICR describes the nature of the information collection and its estimated burden and cost.

**DATES:** Additional comments may be submitted on or before June 24, 2004.

**ADDRESSES:** Submit your comments, referencing docket ID number RCRA–2000–0066, to (1) EPA online using EDOCKET (our preferred method), by e-mail to *rcra-docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mailcode 5305T, 1200 Pennsylvania Ave., NW., Washington, DC 20460, and (2) OMB at: Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attention: Desk Officer for EPA, 725 17th Street, NW., Washington, DC 20503.

**FOR FURTHER INFORMATION CONTACT:** Charles Heizenroth, Office of Solid Waste, 5306W, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–0154; fax number: (703) 308–8686; e-mail address: *heizenroth.charles@epa.gov.*

**SUPPLEMENTARY INFORMATION:** EPA has submitted the following ICR to OMB for review and approval according to the procedures prescribed in 5 CFR 1320.12. On January 13, 2004 (69 *FR* 1977), EPA sought comments on this ICR pursuant to 5 CFR 1320.8(d). EPA received no comments.

EPA has established a public docket for this ICR under Docket ID No. RCRA–2000–0066, which is available for public viewing at the RCRA Docket in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the RCRA Docket is (202) 566–0270. An electronic version of the public docket is available through EPA Dockets (EDOCKET) at *http://www.epa.gov/edocket.* Use EDOCKET to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the docket ID number identified above.

Any comments related to this ICR should be submitted to EPA and OMB within 30 days of this notice. EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EDOCKET as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose public disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EDOCKET. The entire printed comment, including the copyrighted material, will be available in the public docket. Although identified as an item in the official docket, information claimed as CBI, or whose disclosure is otherwise restricted by statute, is not included in the official public docket, and will not be available for public viewing in EDOCKET. For further information about the electronic docket, see EPA's **Federal Register** notice describing the electronic docket at 67 *FR* 38102 (May 31, 2002), or go to *http://www.epa.gov/edocket.*

*Title:* Reporting and Recordkeeping Requirements Under EPA's WasteWise Program (Renewal).

*Abstract:* EPA's voluntary WasteWise program encourages businesses and other organizations to reduce solid waste through waste prevention, recycling, and the purchase or manufacture of recycled-content products. WasteWise participants include partners, which commit to implementing waste reduction activities of their choice, and endorsers which promote the WasteWise program and waste reduction to their members.

The Partner Registration Form identifies an organization and its facilities registering to participate in WasteWise, and requires the signature of a senior official that can commit the organization to the program. (This form can be submitted either electronically or in hard copy.) Within six months of registering, each partner is asked to conduct a waste assessment and submit baseline data and waste reduction goals to EPA via the Annual Assessment Form. (This form can also be submitted either electronically or in hard copy.) On an annual basis partners are asked to report, via the Annual Assessment Form, on their progress toward achieving their waste reduction goals by estimating amounts of waste prevented and recyclables collected, and describing buying or manufacturing recycled-content products. They can also provide WasteWise with information on total waste prevention revenue, total recycling revenue, total avoided purchasing costs due to waste prevention, and total avoided disposal costs due to recycling and waste prevention. Additionally, they are asked to submit new waste reduction goals.

Endorsers, which are typically trade associations or state/local governments, submit the Endorser Registration Form once during their endorser relationship with WasteWise. (This form can be submitted either electronically or in hard copy.) The Endorser Registration Form identifies the organization, the principal contact, and the activities to which the Endorser commits.

EPA's WasteWise program uses the submitted information to (1) identify and recognize outstanding waste

reduction achievements by individual organizations, (2) compile aggregate results that indicate overall accomplishments of WasteWise partners, (3) identify cost-effective waste reduction strategies to share with other organizations, and (4) identify topics on which to develop assistance and information efforts.

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 numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9 and are identified on the form and/or instrument, if applicable.

*Burden Statement:* The respondent burden for this collection is estimated to average 1 hour per response for the Partner Registration Form, 40 hours per response for the Annual Assessment Form, and 10 hours per response for the Endorser Registration Form. This results in an estimated annual partner respondent burden of 41 hours for new partners, 40 hours for established partners, and a one-time respondent burden of 10 hours for endorsers.

The estimated number of respondents is 1,325 in Year 1; 1,425 in Year 2; and 1,525 in Year 3. Estimated total annual burden on all respondents is 52,350 hours in Year 1; 56,350 hours in Year 2; and 60,350 hours in Year 3. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: The WasteWise program was initially targeted to the Fortune 500 manufacturing companies and the Fortune 500 service companies. During the period covered by this ICR, however, WasteWise will continue to focus its marketing efforts on a broader audience, including medium to large size businesses, universities, and federal/state/local/tribal governments. While WasteWise actively promotes the program to a smaller subset of these groups, the program is open to all companies, trade associations, nonprofit organizations, schools, colleges, universities, and federal/state/local/tribal governments. Due to the broad universe of eligible WasteWise partners, a relevant list of NAICS codes would include virtually every business area contained in the NAICS code manual. Therefore, it is not practical to include such a comprehensive list of affected organizations. The WasteWise Endorser Program initially targeted more than 100 trade associations across numerous industry sectors. The program is, however, open to all trade associations, membership organizations, and federal/state/local/tribal organizations.

*Estimated Number of Respondents:* 1,425.

*Frequency of Response:* Once when registering for the program, then yearly to report progress.

*Estimated Total Annual Hour Burden:* 56,350.

*Estimated Total Annual Cost:* $3,527,000, includes $0 annual capital/startup costs, $0 annual O&M and $3,527,000 annual labor costs.

*Changes in the Estimates:* There is a decrease of 7,910 hours in the total estimated burden currently identified in the OMB Inventory of Approved ICR Burdens. This decrease is due to a change in program requirements. The goals identification form was eliminated and the new annual assessment form is easier for respondents to complete.

Dated: May 18, 2004.

**Oscar Morales,**

*Director, Collection Strategies Division.*

[FR Doc. 04–11776 Filed 5–24–04; 8:45 am]

BILLING CODE 6560–50–P

## ENVIRONMENTAL PROTECTION AGENCY

**[Docket ID Numbers OECA–2004–0004 to 0016, OECA–2004–0018 to 0022, FRL–7667–4]**

## Agency Information Collection Activities: Request for Comments on Eighteen Proposed Information Collection Requests (ICRs)

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

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this document announces that EPA is planning to submit the following eighteen existing, approved, continuing Information Collection Requests (ICR) to the Office of Management and Budget (OMB) for the purpose of renewing the ICRs. Before submitting the ICRs to OMB for review and approval, EPA is soliciting comments on specific aspects of the information collections as described at the beginning of **SUPPLEMENTARY INFORMATION.**

**DATES:** Comments must be submitted on or before July 26, 2004.

**ADDRESSES:** Comments may be submitted electronically, by mail, or through hand delivery/courier service. Follow the detailed instructions as provided under **SUPPLEMENTARY INFORMATION**, Section I.B.

**FOR FURTHER INFORMATION CONTACT:** The contact individuals for each ICR are listed under **SUPPLEMENTARY INFORMATION**, section II. C.

**SUPPLEMENTARY INFORMATION:**

### I. General Information

*A. How Can I Get Copies of the ICR Supporting Statement and Other Related Information?*

1. Docket. EPA has established official public dockets for these ICRs as follows:

(1) NSPS for Incinerators (40 CFR part 50, subpart E), Docket ID Number OECA–2004–0009.

(2) NSPS for Small Industrial-Commercial-Industrial Steam Generating Units (40 CFR part 60, subpart Dc), Docket ID Number OECA–2004–0010.

(3) NSPS for Rubber Tire Manufacturing (40 CFR part 60, subpart BBB), Docket ID Number OECA–2004–0014.

(4) NSPS for the Graphic Arts Industry (40 CFR part 60, subpart QQ), Docket ID Number OECA–2004–0012.

(5) NSPS for Onshore Natural Gas Processing Plants (40 CFR part 60, subparts KKK and LLL), Docket ID Number OECA–2004–0005.

(6) NSPS for Phosphate Rock Plants (40 CFR part 60, subpart NN); Docket ID Number OECA–2004–0021.

(7) NESHAP for Pesticide Active Ingredient Production (40 CFR part 63, subpart MMM), Docket ID Number OECA–2004–0007.

(8) NSPS for Hospital/Medical/Infectious Waste Incinerators (40 CFR part 60, subpart Ec), Docket ID Number OECA–2004–0015.

(9) NESHAP for Vinyl Chloride (40 CFR part 61, subpart F), Docket ID Number OECA–2004–0011.

(10) NSPS for Portland Cement Plants (40 CFR Part 60, Subpart F), Docket ID Number OECA–2004–0022.

(11) NSPS for Asphalt Processing and Roofing Manufacture (40 CFR Part 60, Subpart UU), Docket ID Number OECA–2004–0013.

(12) NESHAP for Pulp and Paper Production (40 CFR part 63, subpart S), Docket ID Number OECA–2004–0019.

(13) NESHAP for Beryllium Rocket Motor Fuel Firing (40 CFR part 61, subpart D), Docket ID Number OECA–2004–0006.

(14) NESHAP for Petroleum Refineries (40 CFR part 63, subpart CC), Docket ID Number OECA–2004–0016.

(15) NESHAP for Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semichemical Pulp Mills (40 CFR part 63, subpart MM), Docket ID Number OECA–2004–0020.

(16) NESHAP for Ferroalloys Production: Ferromaganese and Silconmaganese (40 CFR part 63, subpart XXX), Docket ID Number OECA–2004–0004.

(17) NSPS for Polymeric Coating of Supporting Substrates Facilities (40 CFR part 60, subpart VVV), Docket ID Number OECA–2004–0018.

(18) NESHAP for Solvent Extraction for Vegetable Oil Production (40 CFR part 63, subpart GGGG), Docket ID Number OECA–2004–0008.

The official public docket for each ICR consists of the documents specifically referenced in the ICR, any public comments received, and other information related to each ICR. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket for each ICR is the collection of materials that is available for public viewing at the Enforcement and Compliance Docket and Information Center in the EPA Docket Center (EPA/DC), EPA West, Room B102, 1301 Constitution Avenue, NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566–1744, and the telephone number for the Enforcement and Compliance Docket and Information Center Docket is (202) 566–1514.

2. Electronic Access. You may access this document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr.* You may use EPA Dockets at *http://www.epa.gov/edocket* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. After entering the system, select "search," then key in the docket identification number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI, and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in section I.A.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the Docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

For additional information about EPA's electronic public docket, visit EPA Dockets online or see 67 FR 38102, May 31, 2002.

*B. How and to Whom Do I Submit Comments?*

You may submit comments electronically, by mail, or through hand delivery/courier service. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider late comments in formulating a final decision. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in section I.C. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. Electronically. If you submit an electronic comment as prescribed below, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. EPA Dockets. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket*, and follow the online instructions for submitting comments. To access EPA's electronic public docket from the EPA Internet Home Page, select "Information Sources," "Dockets," and "EPA Dockets." After entering the system, select "search," and then key in Docket ID Number. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. E-mail. Comments may be sent by electronic mail (e-mail) to *docket.oeca@epa.gov*. Provide the Docket ID Number when submitting your comments. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the Docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. Disk or CD ROM. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in section I.A.1. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. By Mail. Send your comments to the EPA Docket Center using the address provided in section I.A.1.; Attention: Docket ID Number (provide number).

3. By Hand Delivery or Courier Service. Deliver your comments to the address provided in section I.A.1.; Attention: Docket ID Number (provide number). Such deliveries are only accepted during the Docket's normal hours of operation as identified in section I.A.1.

*C. How Should I Submit CBI to the Agency?*

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. Send or deliver information identified as CBI only to the contact individuals listed in section II.C.; Attention: Docket ID Number (provide number). You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI. If you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI, and then identify within the disk or CD ROM the specific information that is CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under the section titled **FOR FURTHER INFORMATION CONTACT**.

*D. What Should I Consider as I Prepare My Comments for EPA?*

You may find the following suggestions helpful for preparing your comments:

(1) Explain your views as clearly as possible.

(2) Describe any assumptions that you used.

(3) Provide any technical information and/or data you used that support your views.

(4) If you estimate potential burden or costs, explain how you arrived at your estimate.

(5) Provide specific examples to illustrate your concerns.

(6) Offer alternatives.

(7) Make sure to submit your comments by the comment period deadline identified.

(8) To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

*E. In What Information Is EPA Particularly Interested?*

Pursuant to section 3506(c)(2)(A) of the PRA, EPA specifically solicits comments and information to enable it to:

(1) Evaluate whether the proposed collections of information are necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the Agency's estimates of the burdens of the proposed collections of information;

(3) Enhance the quality, utility, and clarity of the information to be collected;

(4) Minimize the burden of the collections of information on those who are to respond, including through the use of appropriate automated or electronic collection technologies or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

**II. ICRs To Be Renewed**

*A. For All ICRs*

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 numbers for EPA's standards are displayed in 40 CFR Part 9.

These information collection requirements are mandatory. Furthermore, the records required by New Source Performance Standards (NSPS) must be retained by the owner or operator for at least two years and records required by the National Emission Standards for Hazardous Air Pollutants (NESHAP) must be retained by the owner or operator for at least five years. In general, the required information consists of emissions data and other information deemed not to be private.

In the absence of such information collection requirements, enforcement personnel would be unable to determine whether the standards are being met on a continuous basis, as required by the Clean Air Act.

The Agency computed the burden for each of the recordkeeping and reporting requirements applicable to the industry for the currently approved Information Collection Requests (ICRs) listed in this notice. Where applicable, the Agency identified specific tasks and made assumptions, while being consistent with the concept of the Paperwork Reduction Act.

*B. List of ICRs Planned To Be Submitted*

In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), this notice announces that EPA is planning to submit the following eighteen Information Collection Requests (ICR) to the Office of Management and Budget (OMB):

(1) NSPS for Incinerators (40 CFR part 50, subpart E), Docket ID Number

OECA–2004–0009; EPA Preliminary ICR Number 1058.08; OMB Control Number 2060–0040; expiration date October 31, 2004.

(2) NSPS for Small Industrial-Commercial-Industrial Steam Generating Units (40 CFR part 60, subpart Dc), Docket ID Number OECA–2004–0010; EPA Preliminary ICR Number 1564.06; OMB Control Number 2060–0202; expiration date October 31, 2004.

(3) NSPS for Rubber Tire Manufacturing (40 CFR part 60, subpart BBB); Docket ID Number OECA–2004–0014; EPA ICR Number 1158.08; OMB Control Number 2060–0156; expiration date is October 31, 2004.

(4) NSPS for the Graphic Arts Industry (40 CFR part 60, subpart QQ), Docket ID Number OECA–2004–0012; EPA Preliminary ICR Number 0657.08; OMB Control Number 2060–0105; expiration date October 31, 2004.

(5) NSPS for Onshore Natural Gas Processing Plants (40 CFR part 60, subparts KKK and LLL); Docket ID Number OECA–2004–0005; EPA Preliminary ICR Number 1086.07; OMB Control Number 2060–0120; expiration date October 31, 2004.

(6) NSPS for Phosphate Rock Plants (40 CFR Part 60, Subpart NN); Docket ID Number OECA–2004–0021; EPA Preliminary ICR Number 1078.07; OMB Control Number 2060–0111; expiration date October 31, 2004.

(7) NESHAP for Pesticide Active Ingredient Production (40 CFR part 63, subpart MMM), Docket ID Number OECA–2004–0007; EPA Preliminary ICR Number 1807.03; OMB Control Number 2060–0370; expiration date October 31, 2004.

(8) NSPS for Hospital/Medical/Infectious Waste Incinerators (40 CFR part 60, subpart Ec), Docket ID Number OECA–2004–0015; EPA Preliminary ICR Number 1730.04; OMB Control Number 2060–0363; expiration date November 30, 2004.

(9) NESHAP for Vinyl Chloride (40 CFR part 61, subpart F), Docket ID Number OECA–2004–0011; EPA Preliminary ICR Number 0186.10; OMB Control Number 2060–0071; expiration date November 30, 2004.

(10) NSPS for Portland Cement Plants (40 CFR part 60, subpart F); Docket ID Number OECA–2004–0022; EPA Preliminary ICR Number 1051.09; OMB Control Number 2060–0025; expiration date November 30, 2004.

(11) NSPS for Asphalt Processing and Roofing Manufacture (40 CFR part 60, subpart UU); Docket ID Number OECA–2004–0013; EPA Preliminary ICR Number 0661.08; OMB Control Number 2060–0002; expiration date November 30, 2004.

(12) NESHAP for Pulp and Paper Production (40 CFR part 63, subpart S); Docket ID Number OECA–2004–0019; EPA Preliminary ICR Number 1657.05; OMB Control Number 2060–0387; expiration date November 30, 2004.

(13) NESHAP for Beryllium Rocket Motor Fuel Firing (40 CFR part 61, subpart D); Docket ID Number OECA–2004–0006; EPA Preliminary ICR Number 1125.04; OMB Control Number 2060–0394; expiration date November 30, 2004.

(14) NESHAP for Petroleum Refineries (40 CFR part 63, subpart CC); Docket ID Number OECA; EPA ICR Number 1692.05, OMB Control Number 2060–0340; expiration date is December 31, 2004.

(15) NESHAP for Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semichemical Pulp Mills (40 CFR part 63, subpart MM); Docket ID Number OECA–2004–0020; EPA Preliminary ICR Number 1805.04; OMB Control Number 2060–0377; expiration date December 31, 2004.

(16) NESHAP for Ferroalloys Production: Ferromaganese and Silconmaganese (40 CFR part 63, subpart XXX); Docket ID Number OECA–2004–0004; EPA ICR Number 1831.03; OMB Control Number 2060–0391; expiration date is December 31, 2004.

(17) NSPS for Polymeric Coating of Supporting Substrates Facilities (40 CFR part 60. subpart VVV); Docket ID Number OECA–2004–0018; EPA Preliminary ICR Number 1284.07; OMB Control Number 2060–0181; expiration date January 31, 2005.

(18) NESHAP for Solvent Extraction for Vegetable Oil Production (40 CFR part 63, Subpart GGGG), Docket ID Number OECA–2004–0008; EPA Preliminary ICR Number 1947.03; OMB Control Number 2060–0471; expiration date January 31, 2005.

*C. Contact Individuals for ICRs*

(1) NSPS for Incinerators (40 CFR part 50, subpart E); Learia Williams of the Office of Compliance at (202) 564–4113 or via e-mail at *williams.learia@epa.gov*; EPA ICR Number 1058.08; OMB Control Number 2060–0040; expiration date October 31, 2004.

(2) NSPS for Small Industrial-Commercial-Industrial Steam Generating Units (40 CFR part 60, subpart Dc); Dan Chadwick of the Office of Compliance at (202) 564–7054, or via e-mail at *chadwick.dan@epa.gov*; EPA ICR Number 1564.06; OMB Control Number 2060–0202; expiration date October 31, 2004.

(3) NSPS for Rubber Tire Manufacturing (40 CFR part 60, subpart BBB); María Malavé of the Office of Compliance at (202) 564–7027 or via e-mail at *malave.maria@epa.gov*; EPA ICR Number 1158.08; OMB Control Number 2060–0156; expiration date is October 31, 2004.

(4) NSPS for the Graphic Arts Industry (40 CFR part 60, subpart QQ); Learia Williams of the Office of Compliance at (202) 564–4113 or via e-mail at *williams.learia@epa.gov*; EPA ICR Number 0657.08; OMB Control Number 2060–0105; expiration date October 31, 2004.

(5) NSPS for Onshore Natural Gas Processing Plants (40 CFR part 60, subparts KKK and LLL); Dan Chadwick of the Office of Compliance at (202) 564–7054, or via e-mail at *chadwick.dan@epa.gov;* EPA ICR Number 1086.07; OMB Control Number 2060–0120; expiration date October 31, 2004.

(6) NSPS for Phosphate Rock Plants (40 CFR part 60, subpart NN); Gregory Fried of the Office of Compliance at (202) 564–7016 or via e-mail at *fried.gregory@epa.gov;* EPA ICR Number 1078.07; OMB Control Number 2060–0111; expiration date October 31, 2004.

(7) NESHAP for Pesticide Active Ingredient Production (40 CFR part 63, subpart MMM); Learia Williams of the Office of Compliance at (202) 564–4113 or via e-mail at *williams.learia@epa.gov;* EPA ICR Number 1807.03; OMB Control Number 2060–0370; expiration date October 31, 2004.

(8) NSPS for Hospital/Medical/Infectious Waste Incinerators (40 CFR part 60, subpart Ec); Learia Williams of the Office of Compliance at (202) 564–4113 or via e-mail at *williams.learia@epa.gov;* EPA ICR Number 1730.04; OMB Control Number 2060–0363; expiration date November 30, 2004.

(9) NESHAP for Vinyl Chloride (40 CFR part 61, subpart F); Learia Williams of the Office of Compliance at (202) 564–4113 or via e-mail at *williams.learia@epa.gov;* EPA ICR Number 0186.10; OMB Control Number 2060–0071; expiration date November 30, 2004.

(10) NSPS for Portland Cement Plants (40 CFR part 60, subpart F); Gregory Fried of the Office of Compliance at (202) 564–7016 or via e-mail at *fried.gregory@epa.gov;* EPA ICR Number 1051.09; OMB Control Number 2060–0025; expiration date November 30, 2004.

(11) NSPS for Asphalt Processing and Roofing (40 CFR part 60, subpart UU);

Gregory Fried of the Office of Compliance at (202) 564–7016 or via e-mail at *fried.gregory@epa.gov;* EPA ICR Number 0661.08; OMB Control Number 2060–0002; expiration date November 30, 2004.

(12) NESHAP for Pulp and Paper Production (40 CFR part 63, subpart S); Leonard Lazarus of the Office of Compliance at (202) 564–6369 or via e-mail at *lazarus.leonard@epa.gov;* EPA Preliminary ICR Number 1657.05; OMB Control Number 2060–0387; expiration date November 30, 2004.

(13) NESHAP for Beryllium Rocket Motor Fuel Firing (40 CFR part 61, subpart D); Dan Chadwick of the Office of Compliance at (202) 564–7054, or via e-mail at *chadwick.dan@epa.gov;* EPA Preliminary ICR Number 1125.04; OMB Control Number 2060–0394; expiration date November 30, 2004.

(14) NESHAP for Petroleum Refineries (40 CFR part 63, subpart CC); Docket ID Number OECA–2003–0016; Dan Chadwick of the Office of Compliance at (202) 564–7054, or via e-mail at *chadwick.dan@epa.gov;* EPA ICR Number 1692.05; OMB Control Number 2060–0340; expiration date is December 31, 2004.

(15) NESHAP for Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semichemical Pulp Mills (40 CFR part 63, subpart MM); Leonard Lazarus of the Office of Compliance at (202) 564–6369 or via e-mail at *lazarus.leonard@epa.gov;* EPA Preliminary ICR Number 1805.04; OMB Control Number 2060–0377; expiration date December 31, 2004.

(16) NESHAP for Ferroalloys Production: Ferromaganese and Silconmaganese (40 CFR part 63, subpart XXX); Maria Malavé of the Office of Compliance at (202) 564–7027 or via e-mail at *malave.maria@epa.gov;* EPA ICR Number 1831.03; OMB Control Number 2060–0391; expiration date is December 31, 2004.

(17) NSPS for Polymeric Coating of Supporting Substrates Facilities (40 CFR part 60, subpart VVV); Leonard Lazarus of the Office of Compliance at (202) 564–6369 or via e-mail at *lazarus.leonard@epa.gov;* EPA Preliminary ICR Number 1284.07; OMB Control Number 2060–0181; expiration date January 31, 2005.

(18) NESHAP for Solvent Extraction for Vegetable Oil Production (40 CFR part 63, subpart GGGG); Learia Williams of the Office of Compliance at (202) 564–4113 or via e-mail at *williams.learia@epa.gov;* EPA ICR Number 1947.03; OMB Control Number 2060–0471; expiration date January 31, 2005.

*D. Information for Individual ICRs*

(1) NSPS for Incinerators (40 CFR part 60, subpart E); EPA Preliminary ICR Number 1058.08; OMB Control Number 2060–0040; expiration date October 31, 2004.

*Affected Entities:* Sources potentially affected by this action are incinerators that charge more than 45 megagrams per day (50 tons per day) of solid waste.

*Abstract:* The New Source Performance Standard (NSPS) for incinerators was promulgated on December 23, 1971.

The affected sources are subject to the General Provisions of the NSPS at 40 CFR part 60, subpart A and any changes or additions to the General Provisions specified at 40 CFR part 60, subpart E. Owners/operators of the affected sources described must make one-time-only notifications including: (1) Notification of any physical or operational change to an existing facility which may increase the regulated pollutant emission rate; (2) notification of the initial performance test, including information necessary to determine the conditions of the performance test; and (3) performance test measurements and results. Owners or operators are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring system is inoperative. Monitoring requirements specific to the standard provide information on daily charging rates and hours of operation.

*Burden Statement:* In the previously approved ICR, the estimated number of respondents for this information collection was 96 with 96 responses per year. The annual industry reporting and recordkeeping burden for this collection of information was 8,544 hours. On average, each respondent reported one time per year, and 89 hours were spent preparing each response. The total annualized costs associated with the continuous monitoring equipment in the previous ICR were $240,000. There were no capital/startup costs. However, there were operation and maintenance costs in the previous ICR of $240,000.

(2) NSPS for Small Industrial-Commercial-Industrial Steam Generating Units (40 CFR part 60, subpart Dc); EPA Preliminary ICR Number 1564.06; OMB Control Number 2060–0202; expiration date October 31, 2004.

*Affected Entities:* Sources potentially affected by this action are small industrial-commercial-institutional steam generating units having a maximum design heat input capacity of less than 29 megawatt (MW) (100 million Btu/hr), but greater than or equal to 2.9 MW (10 million Btu/hr).

*Abstract:* The New Source Performance Standard (NSPS) for small industrial-commercial-institutional steam generation units was promulgated on September 12, 1990.

The affected sources are subject to the General Provisions of the NSPS at 40 CFR part 60, subpart A and any changes or additions to the General Provisions specified at 40 CFR part 60, subpart Dc. Owners/operators must make one-time-only notifications of construction, reconstruction, or startup, the initial performance test, and physical or operational changes. They must also demonstrate a continuous monitoring system that meets the requirements of the standard, and submit reports on the performance test results, monitoring results and excess emissions.

*Burden Statement:* In the previously approved ICR, the estimated number of respondents for this information collection was 708 with 1,696 responses per year. The annual industry reporting and recordkeeping burden for this collection of information was 432,767 hours. On average, each respondent reported 2.4 times per year, and 255 hours were spent preparing each response. The total annualized cost for this ICR is $13,185,000 which is comprised of capital/startup costs of $8,400,000 and operation and maintenance costs of $4,785,000.

(3) NSPS for Rubber Tire Manufacturing (40 CFR part 60, subpart BBB); EPA ICR Number 1158.08; OMB Control Number 2060–0156; expiration date is October 31, 2004.

*Affected Entities:* Sources potentially affected by this action are rubber tire manufacturing plants.

*Abstract:* The New Source Performance Standard (NSPS) for rubber tire manufacturing at 40 CFR part 60, subpart BBB was promulgated on September 15, 1987, and revised most recently on September 19, 1989.

The affected sources are subject to the General Provisions of the NSPS at 40 CFR part 60, subpart A and any changes or additions to the General Provisions specified at 40 CFR part 60, subpart BBB. The standards require the submission of notifications when conducting performance tests and during periods of excess emissions. Owners/operators are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction, or any period during which the monitoring system is inoperative. Additional monitoring requirements specific to rubber tire manufacturing plants provide

information on the operation of the emissions control device and compliance with the volatile organic compounds emission limitation. Semiannual reports are also required.

*Burden Statement:* In the previously approved ICR, the estimated number of respondents for this information collection was 43 with 79 responses per year. The annual industry reporting and recordkeeping burden for this collection of information was 13,151 hours. On average, each respondent reported 1.8 times per year and 167 hours were spent preparing each response. There were no capital/startup costs since no new sources were expected over the three-year period of the ICR. The total annual operations and maintenance (O&M) cost for this ICR is estimated to be $17,200 dollars. This estimate was based on the assumption that 10 percent of the existing plants have a temperature monitor with a continuous recorder per combustion control device for volatile organic compound (VOC) emission reduction (*e.g.*, an incinerator).

(4) NSPS for the Graphic Arts Industry (40 CFR part 60, subpart QQ); EPA Preliminary ICR Number 0657.08; OMB Control Number 2060–0105; expiration date October 31, 2004.

*Affected Entities:* Sources potentially affected by this action are publication rotogravure printing presses.

*Abstract:* The New Source Performance Standard (NSPS) for the graphic arts industry was promulgated on November 8, 1982.

The affect sources are subject to the General Provisions of the NSPS at 40 CFR part 60, subpart A and any changes, or additions to the General Provisions specified at 40 CFR part 60, subpart QQ. The General Provisions are comprised of notification, reporting, and recordkeeping requirements including a one-time-only notifications of the startup date, a report on the initial performance test, semiannual reports and reports of excess emissions. In addition, certain weekly and monthly records are needed for this industry in order to ensure continuous compliance.

*Burden Statement:* In the previously approved ICR, the estimated number of respondents for this information collection was 31 with 60 responses per year. The annual industry reporting and recordkeeping burden for this collection of information was 3,871 hours. On average, each respondent reported twice per year and 65 hours were spent preparing each response.There were no capital/startup costs or operation and maintenance costs associated with the previous ICR.

(5) NSPS for Onshore Natural Gas Processing Plants (40 CFR part 60, subparts KKK and LLL), EPA ICR Number 1086.07; OMB Control Number 2060–0120; expiration date October 31, 2004.

*Affected Entities:* Sources potentially affected by this action are onshore natural gas processing plants.

*Abstract:* The New Source Performance Standards (NSPS) for onshore natural gas processing plants were promulgated on June 24, 1985 (subpart KKK) and October 1, 1985 (subpart LLL).

The affected sources are subject to the General Provisions of the NSPS at 40 CFR part 60, subpart A and any changes, or additions to the General Provisions specified at 40 CFR part 60, subparts KKK and LLL. The standards require performance tests, notifications, reports, recordkeeping, and monitoring of emissions. The standards also require that the owners/operators of onshore natural gas processing plants must notify EPA of construction, modification, startup, shutdowns, malfunctions, and the results of the initial performance test.

Owners/operators of onshore natural gas processing plants that are potential volatile organic compound emitters must also keep records of leaks from pressure relief devices, the date of leak detection, repair method used, and other pertinent details.

*Burden Statement:* In the previously approved ICR, the estimated number of respondents for this information collection was 558 with 1,116 responses per year. The annual industry reporting and recordkeeping burden for this collection of information was 114,036 hours. On average, each respondent reported two times per year, and 102 hours were spent preparing each response. There were no annualized capital/startup costs in the previous ICR, and the total operation and maintenance costs associated with continuous emission monitoring were estimated to be $74,000 per year.

(6) NSPS for Phosphate Rock Plants (40 CFR part 60, subpart NN); EPA ICR Number 1078.07; OMB Control Number 2060–0111; expiration date October 31, 2004.

*Affected Entities:* Entities potentially affected by this action are phosphate rock plants.

*Abstract:* The New Source Performance Standards (NSPS) for phosphate rock plants were promulgated on April 16, 1982.

The affected entities are subject to the General Provisions of the NSPS at 40 CFR part 60, subpart A and any changes or additions to the General Provisions specified at 40 CFR part 60, subpart NN. Owners/operators of the affected sources described must make the following one-time-only reports: Notification of the date of construction or reconstruction; notification of the actual dates of startup; notification of any physical or operational change to an existing facility which may increase the regulated pollutant emission rate; notification of demonstration of the continuous monitoring system (CMS); notification of the date of the initial performance test; and the results of the initial performance test.

Owners or operators are also required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility, or any period during which the monitoring is inoperative.

*Burden Statement:* In the previously approved ICR, the estimated number of respondents for this information collection was 31. In addition, it is estimated that each respondent will submit one response per year for a total of 31 responses. The annual industry reporting and recordkeeping burden in the previous ICR was 3,002 hours or approximately 97 hours per response. The annualized capital/startup costs for installation of compliance monitors is estimated to be $74,000 based on two new plants per year at $37,000 per plant. The annualized operation and maintenance costs for the monitoring systems is estimated to be $253,000. Therefore, the total annualized cost on the industry is estimated to be $327,000.

(7) NESHAP for Pesticide Active Ingredient Production (40 CFR part 63, subpart MMM); EPA Preliminary ICR Number 1807.03; OMB Control Number 2060–0370; expiration date October 31, 2004.

*Affected Entities:* Sources potentially affected by this action are pesticide active ingredient manufacturing processing units.

*Abstract:* The National Emission Standards for Hazardous Air Pollutants for pesticide active ingredient production were promulgated on June 23, 1999.

The affected sources are subject to the General Provisions of the NESHAP at 40 CFR part 63, subpart A and any changes or additions to the General Provisions specified at 40 CFR part 63, subpart MMM. These reporting requirements include: A notification by the source (*i.e.*, self-reporting) that the facility is subject to the rule; a notification of emission testing (control device performance test and continuous monitoring system (CMS) performance evaluation); submission of the results of performance testing and CMS performance evaluations; startup, shutdown, and malfunction reports;

semiannual/quarterly reports; and CMS performance reports. In addition to the requirements of subpart A, respondents are required to submit a precompliance plan, and plants that wish to implement the emission averaging provisions in the standard must submit an emissions averaging plan.

Respondents electing to comply with the emission limit or emission reduction requirements for process vents, storage tanks, or wastewater must also record certain equipment operating parameters. If the owner/operator identifies any deviation resulting from a known cause for which no exemption from an emission limitation or standard applies, the compliance report will also include all records that the affected source is required to maintain that pertain to the periods during which such deviation occurred, as well as the following: The magnitude of each deviation; the reason for each deviation; a description of the corrective action taken for each deviation, including action taken to minimize each deviation and action taken to prevent recurrence; and a copy of all quality assurance activities performed on any element of the monitoring protocol.

Since many of the facilities potentially affected by the NESHAP standard are also subject to a similar new source performance standard (NSPS), the standard includes an exemption from the NSPS for such sources. The exemption eliminates a duplication of information collection requirements.

*Burden Statement:* In the previously approved ICR, the estimated number of respondents for this information collection was 84 with 375 responses per year. The annual industry reporting and recordkeeping burden for this collection of information was 53,752 hours. On average, each respondent reported 4.5 times per year, and 143 hours were spent preparing each response. The total annualized costs of this ICR are estimated to be $2,268,000 of which the capital/startup costs are $2,210,000, and the operation and maintenance costs are $58,000.

(8) NSPS for Hospital/Medical/Infectious Waste Incinerators (40 CFR part 60, subpart Ec); EPA Preliminary ICR Number 1730.04; OMB Control Number 2060–0363; expiration date November 30, 2004.

*Affected Entities:* Sources potentially affected by this action are hospital/medical/infectious waste incinerators.

*Abstract:* The New Source Performance Standards (NSPS) for Hospital/Medical/Infectious Waste Incinerators (HMIWI), 40 CFR part 60, subpart Ec were promulgated on September 15, 1997.The standards apply to HMIWIs for which construction commenced after June 20, 1996 or for which modification commenced after the date of promulgation.

The source are subject to the General Provisions of the NSPS at 40 CFR part 60, subpart A and any changes or additions to the General Provisions specified at 40 CFR part 60, subpart Ec. As such, the reporting and recordkeeping requirements differ somewhat for incinerators burning hospital waste or medical/infectious waste and for co-fired combustors incinerators burning only pathological, low-level radioactive, and/or chemotherapeutic waste. Notification reports are required for all sources constructing, reconstructing, or modifying an HMIWI. Also, required are one-time-only reports related to initial performance tests and continuous measurements of site-specific operating parameters. Annual compliance reports are required for site-specific operating parameters, including exceedance of applicable limits. Semiannual reports are also required.

Co-fired combustors and incinerators burning only pathological, low-level radioactive, and/or chemotherapeutic waste are required to submit notification of any exemption claim, and an estimate of the relative amounts of waste and fuels to be combusted. These co-fired combustors and incinerators are also required to maintain records on a calendar quarter basis of the weight of hospital waste combusted, the weight of medical/infectious waste combusted, and the weight of fuels combusted.

Owners/operators are required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction, or any period during which the monitoring system is inoperative. These notifications, reports, and records are essential in determining compliance and are required of all sources subject to NSPS.

*Burden Statement:* In the previously approved ICR, the estimated number of respondents was six with 2,349 responses per year. The annual industry reporting and recordkeeping burden for this collection of information was 4,541 hours. On average, each respondent reported 391.5 times per year,and 1.9 hours were spent preparing each response. The total annualized costs for this ICR are estimated to be $19,000 which is comprised of capital/startup costs of $2,000 and operation and maintenance costs of $17,000.

(9) NESHAP for Vinyl Chloride (40 CFR part 61, subpart F); EPA Preliminary ICR Number 0186.10; OMB Control Number 2060–0071; expiration date November 30, 2004.

*Affected Entities:* Sources potentially affected by this action are ethylene dichloride plants, vinyl chloride monomer plants, and polyvinyl chloride plants.

*Abstract:* The National Emissions Standard for Hazardous Air Pollutants (NESHAP) from Vinyl Chloride (VC) was promulgated on October 21, 1976, and amended on June 7, 1977, September 30, 1986, September 23, 1988 and December 23, 1992.

The affected sources are subject to the General Provisions of the NESHAP at 40 CFR part 61, subpart A and any changes, or additions to the General Provisions specified at 40 CFR part 63, subpart F. The standard applies to exhaust gases and oxychlorination vents at ethylene dichloride plants; exhaust gases at vinyl chloride monomer plants; and exhaust gases, reactors opening losses, manual vent valves, and stripping residuals at polyvinyl chloride plants. The standards also apply to relief valves and fugitive emission sources at all three types of plants.

In order to ensure compliance with the standard, the owner/operator must make the following one-time-only reports; application for approval of construction or modification; notification of startup; application of a waiver of testing (if desired by source); and an initial compliance report. The initial compliance report includes a list of the control equipment installed, a description of the physical and functional characteristics of each piece of equipment, a description of the methods which have been incorporated into the standard operation procedures at the source to measure and calculate emissions, and a statement that the equipment and procedures are in-place and are being used. Initial reports also include an application for approval of construction or modification, and notification of startup. The standards require quarterly reporting of vinyl chloride emissions from stripping, reactor openings, and exhausts. Reports must be submitted within 10 days of each valve discharge and manual vent valve discharge. Semiannual and excess emission reports are also required.

*Burden Statement:* In the previously approved ICR, the estimated number of respondents for this information collection was 44 with 308 responses per year. The annual industry reporting and recordkeeping burden for this collection of information was 16,159 hours. On average, each respondent reported seven times per year, and 52 hours were spent preparing each response. The total annualized cost of

this ICR is estimated to be $1,980,000. In the previous ICR, there were no capital/startup costs and the annualized operation and maintenance costs were $1,980,000.

(10) NSPS for Portland Cement Plants (40 CFR part 60, subpart F); EPA ICR Number 1051.09; OMB Control Number 2060–0025; expiration date November 30, 2004.

*Affected Entities:* Entities potentially affected by this action are portland cement plants.

*Abstract:* The New Source Performance Standards (NSPS) for portland cement plants were promulgated on July 25, 1977.

The affected entities are subject to the General Provisions of the NSPS at 40 CFR part 60, subpart A and any changes or additions to the General Provisions specified at 40 CFR part 60, subpart F. Owners/operators of portland cement plants must notify EPA of construction, modification, startups, shut downs, date and results of initial performance test and excess emissions.

*Burden Statement:* In the previously approved ICR, the estimated number of respondents for this information collection was 113. In addition, it is estimated that each existing respondent will submit approximately four responses per year, or a total of 448 responses per year. The annual industry reporting and recordkeeping burden in the previous ICR was 7,968 hours or approximately 18 hours per response. The capital/startup for installation of continuous monitoring systems was estimated to be $139,200 based on four new plants per year at $34,800 per plant. The operation and maintenance costs for the monitoring systems was estimated at $848,000. Therefore, the total annualized cost to the industry in the previous ICR was $987,200.

(11) NSPS for Asphalt Processing and Roofing (40 CFR part 60, subpart UU); EPA ICR Number 0661.08; OMB Control Number 2060–0002; expiration date November 30, 2004.

*Affected Entities:* Entities potentially affected by this action are asphalt storage facilities, asphalt processing plants and petroleum refineries.

*Abstract:* The New Source Performance Standards (NSPS) for asphalt processing and roofing were promulgated on August 6, 1982.

The affected sources are subject to the General Provisions of the NSPS at 40 CFR part 60, subpart A and any changes or additions to the General Provisions specified at 40 CFR part 60, subpart UU. Owners/operators of the regulated sources must notify EPA of construction, modification, startups, shut downs, date and results of initial performance test. Excess emission reports are also required.

*Burden Statement:* In the previously approved ICR, the estimated number of respondents for this information collection was 83 with ten responses per year. The annual industry reporting and recordkeeping burden for this collection of information was 15,089 hours or approximately 1,509 hours per response. The total annualized capital/startup for installation of temperature monitors is estimated to be approximately $200,000 based on two new plants annually at $100,000 per plant. The total annualized operation and maintenance costs for the monitoring systems is estimated at $2,905,000. Therefore, the total annualized cost to the industry is estimated to be $3,105,000.

(12) NESHAP for Pulp and Paper Production (40 CFR part 63, subpart S); EPA Preliminary ICR Number 1657.05; OMB Control Number 2060–0387; expiration date November 31, 2004.

*Affected Entities:* Sources potentially affected by this action are pulp and paper mills.

*Abstract:* The National Emission Standards for Hazardous Air Pollutants (NESHAP) for pulp and paper production was promulgated on April 15, 1998.

The affected sources are subject to the General Provisions of the NESHAP at 40 CFR part 63, subpart A and any changes or additions to the General Provisions specified at 40 CFR part 63, subpart S.

Pulp mill owners/operators are required to submit initial notifications, maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected source, or any period during which the emission monitoring system is inoperative. Respondents are required to monitor and keep records of specific operating parameters for each control device and to perform and document periodic inspections of the closed vent and wastewater conveyance systems. All respondents must submit semiannual reports of the monitored parameters, and they must submit an additional monitoring report during each quarter in which monitored parameters were outside the ranges established in the standard or during initial performance tests.

*Burden Statement:* In the previously approved ICR, the estimated number of respondents for this information collection was 162 with 500 responses per year. The annual industry reporting and recordkeeping burden for this collection of information was 50,232 hours. On average, each respondent reported three times per year, and 100 hours were spent preparing each response. The annual reporting and recordkeeping cost burden was estimated to be $370,000 in the previous ICR. The capital/startup cost was $370,000 with no expected operation and maintenance cost.

(13) NESHAP for Beryllium Rocket Motor Fuel Firing (40 CFR part 61, subpart D), EPA ICR Number 1125.04; OMB Control Number 2060–0394; expiration date November 31, 2004.

*Affected Entities:* Sources potentially affected by this action are beryllium rocket motor testing facilities.

*Abstract:* The National Emission Standards for Hazardous Air Pollutants (NESHAP) for beryllium rocket motor firing were promulgated on April 6, 1973.

The affected sources are subject to the General Provisions of the NESHAP at 40 CFR part 61, subpart A and any changes or additions to the General Provisions specified at 40 CFR part 63, subpart D. The standard requires source to test the ambient air for beryllium during and after firing of a rocket motor. Sampling techniques are approved by the Administrator. Samples are analyzed within 30 days and results are reported to the EPA Region by registered letter by the business day following the compliance determination (see 40 CFR 61.43). In addition, stack sampling required at 40 CFR 61.41, requires continuous sampling of beryllium combustion products, analysis and reporting within 30 days. The results are reported to EPA the day following the compliance determination.

*Burden Statement:* In the previously approved ICR, the estimated number of respondents for this information collection was 1 with ⅓ response per year (Once per test firing, one test firing in three years). The annual industry reporting and recordkeeping burden for this collection of information was eight hours. On average, each respondent reported one time every two years and 8 hours were spent preparing each response. The responses were prepared biannually. In the previously approved ICR, there were no capital/startup costs and the total operation and maintenance costs associated with continuous emission monitoring in the previous ICR were estimated to be $453 per year.

(14) NESHAP for Petroleum Refineries (40 CFR part 63, subpart CC); EPA ICR Number 1692.05; OMB Control Number 2060–0340; expiration date December 31, 2004.

*Affected Entities:* Sources potentially affected by this action are petroleum refineries.

*Abstract:* The National Emission Standards for Hazardous Air Pollutants

(NESHAP) for petroleum refineries (40 CFR part 63, subpart CC) were promulgated on August 18, 1995, and technically corrected and amended several times with the most recent correction made on May 25, 2001, and the most recent revision made on August 18, 1998.

The affected sources are subject to the General Provisions of the NESHAP at 40 CFR part 63, subpart A and any changes or additions to the General Provisions specified at 40 CFR part 63, subpart CC. This standard requires sources to comply with the recordkeeping and reporting requirements contained in either 40 CFR part 61 subpart VV or 40 CFR part 63, subpart H for equipment leaks (which include an initial report and semiannual summaries of leak detection and repair) and 40 CFR part 61, subpart FF or 40 CFR part 63, subpart H for wastewater operations.

This rule also requires sources to submit initial notifications, conduct performance tests, and submit periodic reports. In addition, sources are required to: Maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility; any period during which the monitoring system is inoperative; bag leak detection system alarms and corrective actions; parametric monitoring data; and system maintenance and calibration data.

*Burden Statement:* In the previously approved ICR, the estimated number of respondents for this information collection was 157 with 314 responses per year. The annual industry reporting and recordkeeping burden for this collection of information was 469,430 hours. On the average each respondent reported twice per year and 1,495 hours were spent preparing each response. The annualized capital/startup costs for this ICR was estimated to be $542,173. This estimate was based on the assumptions that all refineries ("respondents") will hire a contractor to provide sampling and analytical services during the initial performance tests. There are no operation and maintenance costs since this rule does not require any additional monitoring equipment and any related costs are assumed to be negligible.

(15) NESHAP for Chemical Recovery Combustion Sources at Kraft, Soda, Sulfite, and Stand-Alone Semichemical Pulp Mills (40 CFR part 63, subpart MM); EPA Preliminary ICR Number 1805.04; OMB Control Number 2060–0377; expiration date December 31, 2004.

*Affected Entities:* Sources potentially affected by this action are owners and operators of chemical recovery combustion sources at kraft, soda, sulfite, and stand-alone semichemical pulp mills.

*Abstract:* The National Emission Standards for Hazardous Air Pollutants (NESHAP) for chemical recovery combustion sources at kraft, soda, sulfite, and stand-alone semichemical pulp mills at 40 CFR part 63, subpart MM were promulgated on January 12, 2001.

The subject sources are subject to the General Provisions of the NESHAP at 40 CFR part 63, subpart A and any changes or additions to the General Provisions specified at 40 CFR part 63, subpart MM. These requirements include initial notifications; notifications of performance tests; notifications of performance evaluations; notifications of compliance status, including the results of performance tests; startup, shutdown, and malfunction reports; and semiannual compliance reports.

*Burden Statement:* In the previously approved ICR, the estimated number of respondents for this information collection was 136 with 125 responses per year. The annual industry reporting and recordkeeping burden for this collection of information was 21,528 hours. On average, each respondent reported 0.9 times per year, and 172 hours were spent preparing each response. The annual reporting and recordkeeping cost burden in the previous ICR was $5,000. The total annualized capital/startup costs were $2,000, and the total operation and maintenance costs were $3,000.

(16) NESHAP for Ferroalloys Production: Ferromaganese and Silconmaganese (40 CFR part 63, subpart XXX); EPA ICR Number 1831.03; OMB Control Number 2060–0391; expiration date is December 31, 2004.

*Affected Entities:* Sources potentially affected by this action are affected facilities at ferromanganese and silicomanganese production facilities that are major sources or are co-located at major sources.

*Abstract:* The National Emission Standards for Hazardous Air Pollutants (NESHAP) for ferroalloys production: ferromaganese and silconmaganese at 40 CFR part 63, subpart XXX were promulgated on May 20, 1999, and amended most recently on March 22, 2001.

The affected sources are subject to the General Provisions of the NESHAP at 40 CFR part 63, subpart A and any changes or additions to the General Provisions specified at 40 CFR part 63, subpart XXX. This rule requires sources to submit initial notifications, conduct performance tests, and submit periodic reports. In addition, sources are required to maintain records of the occurrence and duration of any startup, shutdown, or malfunction in the operation of an affected facility; any period during which the monitoring system is inoperative; bag leak detection system alarms, including corrective actions; parametric monitoring data; system maintenance and calibration; and opacity and visible emissions observations to demonstrate initial and on-going compliance with the regulation.

*Burden Statement:* In the previously approved ICR, the estimated number of respondents for this information collection was one with 31 responses per year. The annual industry reporting and recordkeeping burden for this collection of information was 746 hours. On average, the respondent spent 24 hours preparing each response. There were no capital/startup costs or operation and maintenance costs associated with continuous emission monitoring in the previous ICR.

(17) NSPS for Polymeric Coating of Supporting Substrates Facilities (40 CFR part 60, subpart VVV); EPA Preliminary ICR Number 1284.07; OMB Control Number 2060–0181; expiration date January 31, 2005.

*Affected Entities:* Sources potentially affected by this action are of polymeric coating plants.

*Abstract:* The New Source Performance Standard (NSPS) polymeric coating of supporting substrates facilities at 40 CFR part 60, subpart VVV were promulgated on September 15, 1987, and revised most recently on September 19, 1989.

The affected sources are subject to the General Provisions of the NSPS at 40 CFR part 60, subpart A and any changes, or additions to the General Provisions specified at 40 CFR part 60, subpart VVV. Sources must: maintain records of startups, shutdowns, malfunctions; periods where the continuous monitoring system is inoperative; all measurements including performance tests; operating parameters of monitoring device results for catalytic or thermal incinerators, carbon adsorption system, condensation system, vapor capture system and/or total enclosure; monitor the annual use of volatile organic compounds (VOC); and make semiannual estimates of projected VOC use, if affected facility uses less than 95 Mg/year of volatile organic compounds or is subject to provisions specified at § 60.742(c)(3).

*Burden Statement:* In the previously approved ICR, the estimated number of respondents for this information collection was 56 with 173 responses

per year. The annual industry reporting and recordkeeping burden for this collection of information was 14,366 hours. On average, each respondent reported 3.1 times per year, and 83 hours were spent preparing each response. The annual reporting and recordkeeping cost burden in the previous ICR was $564,000, which was comprised of capital/startup costs of $43,000 and operation and maintenance costs of $521,000.

(18) NESHAP for Solvent Extraction for Vegetable Oil Production (40 CFR part 63, subpart GGGG); EPA Preliminary ICR Number 1947.03; OMB Control Number 2060–0471; expiration date January 31, 2005.

*Affected Entities:* Sources potentially affected by this action are vegetable oil production plants.

*Abstract:* The National Emission Standards for Hazardous Air Pollutants (NESHAP) for vegetable oil production at 40 CFR part 63, subpart GGGG for vegetable oil production were promulgated on April 12, 2001.

This standard applies to any reconstructed, or new vegetable oil production process, which is defined as a group of continuous process equipment used to remove an oil from oilseeds through direct contact with an organic solvent such as n-hexane. The term oilseed refers to the following agricultural products: corn germ, cottonseed, flax, peanut, rapeseed (for example, canola), safflower, soybean, and sunflower. A vegetable oil production process is only subject to the regulation if it is a major source of hazardous air pollutant (HAP) emissions, or is collocated with other sources that are individually or collectively a major source of HAP emissions.

The source are subject to the General Provisions of the NESHAP at 40 CFR part 63, subpart A and any changes, or additions to the General Provisions specified at 40 CFR part 63, subpart GGGG. The solvent extraction for vegetable oil production standard requires each source to develop a plan for demonstrating compliance. On a monthly basis, sources must measure/record extraction solvent, and record the HAP content of the extraction solvent and oilseed inventories. Sources also develop a startup, shutdown, and malfunction plan to be followed during noncompliance events. Each source must submit initial and startup notifications. Sources must submit a compliance status notification 12 months after the compliance date and an annual compliance certification every subsequent 12 months.

*Burden Statement:* In the previously approved ICR, the estimated number of respondents for this information collection was 75 with 75 responses per year. The annual industry reporting and recordkeeping burden for this collection of information was 10,092 hours. On average, each respondent reported once per year and 135 hours per spent preparing each response. There were no capital/startup costs or operation and maintenance costs associated with continuous emission monitoring in the previous ICR.

Dated: May 18, 2004.

**Michael M. Stahl,**

*Director, Office of Compliance.*

[FR Doc. 04–11777 Filed 5–24–04; 8:45 am]

BILLING CODE 6560–50–P

## ENVIRONMENTAL PROTECTION AGENCY

**[FRL–7667–2]**

## EPA Region III Comprehensive Environmental Response, Compensation and Liability Act Program; Transfer of Information to Contractors and Subcontractors

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

**ACTION:** Notice.

**SUMMARY:** EPA Region III intends to authorize certain contractors and subcontractors access to information submitted to EPA under the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA"). Some of this information may be claimed or determined to be confidential business information (CBI).

**DATES:** Contractor access to this information will occur June 24, 2004. Comments concerning CBI access will be accepted for thirty days from May 25, 2004.

**FOR FURTHER INFORMATION CONTACT:** Ben Mykijewycz (3HS42), Chief Contracts, ADP and State Support Section, EPA Region III (215) 814–3351.

**SUPPLEMENTARY INFORMATION:** The contractor and subcontractors listed below will provide certain services to EPA Region III, including; (1) information management support services for the operation of a file room and an administrative records room in Philadelphia, Pennsylvania; (2) compilation and organization of documents and information; and (3) review and analysis of documents and information. In performing these tasks, employees of the contractors and subcontractors listed below will have access to Agency documents for purposes of document processing, filing, abstracting, analyzing, inventorying, retrieving, tracking, etc. The documents to which these contractors and subcontractors will have access potentially include all document submitted under the CERCLA. Some of these documents may contain information claimed as CBI.

Pursuant to EPA regulations at 40 CFR part 2, subpart B, EPA has determined that these contractors and subcontractors require access to CBI to perform the work required under the contracts and subcontracts. These regulations provide for five days notice before contractors are given CBI. This notice is intended to provide notice of all disclosures of such information by EPA Region III to the contractors and subcontractors listed below.

All of the listed contractors and subcontractors are required by contract to protect confidential information. When the contractors' and subcontractors' need for the documents is completed, the contractors and subcontractors will return them to EPA. The contractors and subcontractors to which this notice applies are as follows:

**List of Contractors That May Review Your Response**

Chenega Technical Products

- Contract # EP–S3–04–01
- Tetra Tech EM, Inc.—
- Contract #68S3–0002

Subcontractor to Tetra Tech EM, Inc. is:
Eagle Instruments, Inc.

- Ecology and Environment, Inc.—
- Contract #68–S3–001

Subcontractor to Ecology and Environment, Inc. is:
S & S Engineers, Inc.

- IT Corporation—
- Contract #68–S3–00–06

Subcontracts to IT Corporation are:
Weavertown Environmental Group
Environmental Restoration Company

- Earth Tech, Inc.—
- Contract #68–S3–00–07

Subcontractors to Earth Tech, Inc. are:
Industrial Marine Services, Inc.
Cline Oil
Hertz Equipment Rental

- Tetra Tech NUS Inc.—

Contract #68–S6–3003

Subcontractors to Tetra Tech NUS Inc. are:
Gannett Fleming, Inc.
Dynamic Corporation
C.C. Johnson & Malhotra, P.C.

- CDM—Federal Programs Corporation—

Contract #68–S7–3003

Subcontractors to CDM—Federal Programs Corporation are:
Tetra Tech EM, Inc.
Robert Kimball & Associates
PMA & Associates
Horne Engineering
Pacific Environmental Services

- Black and Veatch Waste Science and Technology Corporation/Tetra Tech, Inc.—

Contract #68–S7–3002
Subcontractor:
Enviro Consultants Group

- Tech Law, Inc.—

Contract #68–W–00–108

- WRS Infrastructure & Environment, Inc.—

Contract #68–S3–03–02

- Kemron Environmental Services—

Contract #68–S3–03–05

- ASRC Aerospace Corp.—

Contract #68–W–01–02

- Industrial Marine Services, Inc.

Contract #68–S3–03–03

- Guardian Environmental Services, Inc.

68–S3–03–04

**List of Inter-Agency Agreements**

- General Services Administration
  CERCLA File Room
  Contractor: Booz-Allen & Hamilton
- General Services Administration
  Spectron Superfund Site
  Contractor: Booz-Allen & Hamilton
- General Services Administration
  Breslube Penn Superfund Site
  Contractor: Booz-Allen & Hamilton

**List of Cooperative Agreements**

- National Association of Hispanic Elderly (Senior Environmental Employment)–#CQ–822511
- AARP Foundation (Senior Environmental Employment)—#823052

Dated: May 14, 2004.

**Peter W. Schaul,**

*Acting Division Director, Hazardous Site Cleanup Division.*

[FR Doc. 04–11774 Filed 5–24–04; 8:45 am]

**BILLING CODE 6560–50–M**

## ENVIRONMENTAL PROTECTION AGENCY

**[FRL–7666–7]**

## Notice Concerning Certain Issues Pertaining to the July 2002 Spill Prevention, Control, and Countermeasure (SPCC) Rule

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA) has partially settled litigation over the Spill Prevention, Control, and Countermeasure (SPCC) rule. This notice provides clarifications developed by the Agency during the course of settlement proceedings. It also announces the availability of a letter issued by EPA's Office of Solid Waste and Emergency Response (OSWER) to the Petroleum Marketers Association of America (PMAA) on our website, *i.e., epa.gov/oilspill,* or by contacting the docket as described below under **ADDRESSES.**

**ADDRESSES:** EPA has established a docket for this action under Docket: OPA–2004–0002. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the EPA Docket Center EPA West, Room B102, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. and 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket is (202) 566–0276.

**FOR FURTHER INFORMATION CONTACT:** Hugo Paul Fleischman, Oil Program Staff, U.S. EPA, at 703–603–8769 (*fleischman.hugo@epa.gov*); or the RCRA/Superfund Hotline at 800–424–9346 (in the Washington, DC metropolitan area, 703–412–9810) (*epahotline@bah.com*). The Telecommunications Device for the Deaf (TDD) Hotline number is 800–553–7672 (in the Washington, DC metropolitan area, 703–412–3323). You may wish to visit the Oil Program's Internet site at *http://www.epa.gov/oilspill.*

**SUPPLEMENTARY INFORMATION:**

### I. General

*How Can I Get Copies of the Background Materials Supporting Today's Notice or Other Related Information?*

EPA will publish this document, as well as the letter from OSWER to PMAA described more fully below, on its Web site, *http://epa.gov/oilspill,* and has already posted the settlement agreement on that Web site. Alternatively, contact the docket as described above under **ADDRESSES.** You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr.*

### II. Background

**Authority:** 33 U.S.C. 1251 *et seq.*; 33 U.S.C. 2720; E.O. 12777 (October 18, 1991), 3 CFR, 1991 Comp., p. 351.

*Litigation*

On July 17, 2002, EPA published a final rule (67 FR 47042), amending the SPCC regulation. Several members of the regulated community filed legal challenges to certain aspects of the rule. *See American Petroleum Institute* v. *Leavitt* et al., No. 1;102CV02247 PLF and consolidated cases (D.D.C. filed November 14, 2002).[1]

Settlement discussions between EPA and the plaintiffs have led to an agreement on all issues except one. In this notice, we are publishing clarifications developed by the Agency during the course of settlement proceedings (and which provided the basis for the settlement agreement) regarding the SPCC regulation to the regulated community and other interested parties. We are also notifying the public of the availability of OSWER's letter to PMAA referenced above, on our Web site, *http://epa.gov/oilspill,* and through the docket, as described above.

### III. Clarifications

*"Loading Racks"*

Plaintiffs challenged certain statements made in the preamble to the July 2002 SPCC amendments (and the response-to-comment document) concerning the "loading/unloading rack" requirements under 40 CFR 112.7(h). That provision addresses specific SPCC requirements for tank car and tank truck loading and unloading racks, including requirements for secondary containment. The preamble language at issue, which appears at 67 FR 47110 (July 17, 2002), stated the following:

> *This section is applicable to any non-transportation-related or terminal facility where oil is loaded or unloaded from or to a tank car or tank truck.* It applies to containers which are aboveground (including partially buried tanks, bunkered tanks, or vaulted tanks) or completely buried (except those exempted by this rule), and to all facilities, large or small. All of these facilities have a risk of discharge from transfers. (Emphasis added.)

The Agency did not intend with the emphasized language to interpret the term "loading/unloading rack." Instead, the Agency was responding generally to a variety of comments each asking that their specific situation not be subject to the 40 CFR 112.7(h) requirements. The reasoning of these commenters did not focus specifically on the contours of what might be considered a loading/unloading rack, but instead focused on

[1] Lead plaintiffs in the cases were the American Petroleum Institute, Marathon Oil Co., and the Petroleum Marketers Association of America.

a variety of other factors relevant to their facilities. See, *e.g.*, 67 FR 47110 (July 17, 2002) ("Another commenter asked that we clarify that only facilities routinely used for loading or unloading of tanker trucks from or into aboveground bulk storage tanks are subject to this provision.") Thus, the emphasized language above was meant to be a rejection of pleas for exclusions of specific facilities, not an interpretation of the term "loading/unloading rack."

In the response-to-comments document for the rule, EPA stated that "[w]e intend § 112.7(h) to apply to all facilities, including production facilities." As discussed more fully below, we interpret § 112.7(h) only to apply to loading and unloading "racks." Under this interpretation, if a facility does not have a loading or unloading "rack," § 112.7(h) does not apply. Thus, in stating that section 112.7(h) applies to "all facilities, including production facilities," the Agency only meant that the provision applies if a "facility" happens to have a loading or unloading rack present. The Agency did not mean to imply that any particular category of facilities, such as production facilities, are likely to have loading or unloading racks present.

Plaintiffs also challenged a change in the language of § 112.7(h) (formerly codified as § 112.7(e)(4)). Specifically, EPA substituted the phrase "loading/unloading area drainage" for the phrase "rack area drainage" in paragraph § 112.7(h)(1). The Agency does not interpret this change as expanding the requirements of that section beyond activities associated with tank car and tank truck loading/unloading racks. After all, the title of § 112.7(h) remains "facility tank car and tank truck loading/unloading rack." In addition, the record for the rulemaking reflects that the Agency specifically rejected the idea of enlarging the scope of that section to apply beyond "racks." (See response-to-comment document, p. 212, rejecting a comment on the proposed rule suggesting that we change the title of § 112.7(h) from "loading/unloading rack" to "loading/unloading area" because the Agency had not proposed such a change.)

Like other editorial changes to the rule, many of which were not accompanied by specific explanations, the Agency believes the change simply serves to make the rule easier to understand. *See,* 67 FR 47051 (describing the Agency's use of a "plain language" approach in the rule). In this case, the change in language made the terminology used in the sentence uniform (a basic principle of plain language approaches to rule writing). Previously, the rule stated that a facility must compensate for lack of specified drainage systems at the "rack area" with "a quick drainage system for tank car or tank truck loading and unloading areas." Obviously, the scope of these two emphasized terms was always meant to be identical, and the challenged language change only makes that clearer.

*"Impracticability"*

Plaintiffs challenged statements made in the preamble to the SPCC amendments concerning the meaning of "impracticability" under 40 CFR 112.7(d). As you know, that section provides that where secondary containment is "not practicable," a facility may use a contingency plan instead. The preamble language at issue, which appears at 67 FR 47104 (July 17, 2002), stated the following:

> We believe that it may be appropriate for an owner or operator to consider costs or economic impacts in determining whether he can meet a specific requirement that falls within the general deviation provision of § 112.7(a)(2). We believe so because under this section, the owner or operator will still have to utilize good engineering practices and come up with an alternative that provides "equivalent environmental protection." However, we believe that the secondary containment requirement in § 112.7(d) is an important component in preventing discharges as described in § 112.1(b) and is environmentally preferable to a contingency plan prepared under 40 CFR part 109. *Thus, we do not believe it is appropriate to allow an owner or operator to consider costs or economic impacts in any determination as to whether he can satisfy the secondary containment requirement. Instead, the owner or operator may only provide a contingency Plan in his SPCC Plan and otherwise comply with § 112.7(d). Therefore, the purpose of a determination of impracticability is to examine whether space or other geographic limitations of the facility would accommodate secondary containment; or, if local zoning ordinances or fire prevention standards or safety considerations would not allow secondary containment; or, if installing secondary containment would defeat the overall goal of the regulation to prevent discharges as described in § 112.1(b).* (Emphasis added.)

The Agency did not intend with the language emphasized above to opine broadly on the role of costs in determinations of impracticability. Instead, the Agency intended to make the narrower point that secondary containment may not be considered impracticable solely because a contingency plan is cheaper. (This was the concern that was presented by the commenter to whom the Agency was responding.) As discussed above, this conclusion is different than that reached with respect to purely economic considerations in determining whether to meet other rule requirements subject to deviation under § 112.7(a)(2). Under that section, as stated above, facilities may choose environmentally equivalent approaches (selected in accordance with good engineering practices) for any reason, including because they are cheaper.

In addition, with respect to the emphasized language enumerating considerations for determinations of impracticability, the Agency did not intend to foreclose the consideration of other pertinent factors. In fact, in the response-to-comment document for the SPCC amendments rulemaking, the "Agency stated that "* * * for certain facilities, secondary containment may not be practicable because of geographic limitations, local zoning ordinances, fire prevention standards, *or other good engineering practice reasons.*" For more examples of situations that may rise to the level of impracticability, *see, e.g.* 67 FR 47102 (July 17, 2002) and 67 FR 47078 (July 17, 2002) (pertaining to flow and gathering lines).

*Produced Water*

The Agency has been asked whether produced water tanks at dry gas facilities are eligible for the SPCC rule's wastewater treatment exemption at 40 CFR 112.7(d)(6). A dry gas production facility is a facility that produces natural gas from a well (or wells) from which it does not also produce condensate or crude oil that can be drawn off the tanks, containers or other production equipment at the facility.

The SPCC rule's wastewater treatment exemption excludes from 40 CFR part 112 "any facility or part thereof used exclusively for wastewater treatment and not used to satisfy any requirement of this part." However, for the purposes of the exemption, the "production, recovery, or recycling of oil is not wastewater treatment." In interpreting this provision, the preamble to the final rule states that the Agency does "not consider wastewater treatment facilities or parts thereof at an oil production, oil recovery, or oil recycling facility to be wastewater treatment for purposes of this paragraph."

It is our view that a dry gas production facility (as described above) would not be excluded from the wastewater treatment exemption based on the view that it constitutes an "oil production, oil recovery, or oil recycling facility." As discussed in the preamble to the July 2002 rulemaking, "the goal of an oil production, oil recovery, or oil recycling facility is to maximize the

production or recovery of oil. * * *'' 67 FR 47068. A dry gas facility does not meet this description.

In verifying that a particular gas facility is not an "oil production, oil recovery, or oil recycling facility," the Agency plans to consider, as appropriate, evidence at the facility pertaining to the presence or absence of condensate or crude oil that can be drawn off the tanks, containers or other production equipment at the facility, as well as pertinent facility test data and reports (*e.g.*, flow tests, daily gauge reports, royalty reports or other production reports required by state or federal regulatory bodies).

*"Facility"*

In the July 2002 SPCC amendments, the Agency promulgated definitions of "facility" and "production facility." These definitions, which appear in 40 CFR 112.2, apply "for the purposes of" part 112. The Agency has been asked which of these definitions governs the term "facility" as it is used in 40 CFR 112.20(f)(1) when applied to oil production facilities. 40 CFR 112.20(f)(1) sets criteria for determining whether a "*facility* could, because of its location, reasonably be expected to cause substantial harm to the environment" (emphasis added). It is the Agency's view that, because, among other things, that section consistently uses the term "facility," not "production facility," it is the definition of "facility" in 40 CFR 112.2 that governs the meaning of "facility" as it is used in 40 CFR 112.20(f)(1), regardless of the specific type of facility at issue.

**Notice of Availability**

With this notice, EPA is announcing the availability of a letter issued by the Assistant Administrator for OSWER to PMAA addressing certain matters pertaining to the SPCC rule's requirements for integrity testing, security, and loading racks. This letter is available on EPA's website at *epa.gov/oilspill* or by contacting the docket as described above.

Dated: May 17, 2004.

**Marianne Lamont Horinko,**

*Assistant Administrator, Office of Solid Waste and Emergency Response.*

[FR Doc. 04–11775 Filed 5–24–04; 8:45 am]

BILLING CODE 6560–50–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

**[Program Announcement 04130]**

### National Organizations for Nutrition and Physical Activity Programs; Notice of Intent To Fund Single Eligibility Award

**A. Purpose**

The Centers for Disease Control and Prevention (CDC) announces the intent to fund fiscal year (FY) 2004 funds for a cooperative agreement program to enhance nutrition, 5 a day, and physical activity efforts by:

- Providing annual training opportunities and professional development.
- Coordinating training activities and programs between health departments that have nutrition and physical activity components and the State Nutrition and Physical Activity Programs to Prevent Obesity and Chronic Diseases.
- Establishing a National 5 A Day Council to provide leadership on policies and programs to increase fruit and vegetable consumption.
- Conducting State or community-based special projects. The Catalog of Federal Domestic Assistance number for this program is 93.945.

**B. Eligible Applicant**

Assistance will be provided only to the Association of State and Territorial Public Health Nutrition Directors (ASTPHND). No other applications are solicited.

ASTPHND is the only organization with State nutrition directors or designees and nutrition-related staff uniquely positioned in State health departments to provide statewide leadership for nutrition, 5 A Day, physical activity, and obesity and chronic disease prevention efforts. ASTPHND's members direct the nutrition and 5 A Day programs in the State health departments or public health agencies of fifty States, the District of Columbia, and five Territories. ASTPHND has established a unique network of public health nutritionists working to improve the health of the American population through statewide and local community efforts. The group is committed to addressing nutrition and physical activity related to the prevention of obesity. ASTPHND has experience conducting training and professional development related to nutrition, 5 A Day, and physical activity.

ASTPHND the only national organization representing 5 A Day Coordinators from each State, district, and territory. ASTPHND is the only organization positioned to provide training and promote the translation of public health nutrition research to practice that is critical to CDC efforts to build State capacity to implement effective nutrition programs. All State nutrition directors and 5 A Day coordinators are members of ASTPHND, therefore it is the only national organization with a membership representing State nutrition directors and 5 A Day coordinators from all 50 States, the District of Columbia, and five territories.

**C. Funding**

Approximately $200,000 is available in FY 2004 to fund this award. It is expected that the award will begin on or before September 1, 2004, and will be made for a 12-month budget period within a project period of up to 5 years. Funding estimates may change.

**D. Where To Obtain Additional Information**

For general comments or questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146. Telephone: 770–488–2700.

For technical questions about this program, contact: Diane Thompson, M.P.H., RD, Project Officer, Division of Nutrition and Physical Activity, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway, NE., MS K–25, Atlanta, GA 30341.

Dated: May 19, 2004.

**William P. Nichols,**

*Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.*

[FR Doc. 04–11754 Filed 5–24–04; 8:45 am]

BILLING CODE 4163–18–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

**[Program Announcement 04145]**

### Enhancing State Capacity To Address Child and Adolescent Health Through Violence Prevention; Notice of Availability of Funds—Amendment

A notice announcing the availability of fiscal year (FY) 2004 funds for a cooperative agreement entitled,

"Enhancing State Capacity to Address Child and Adolescent Health Through Violence Prevention" was published in the **Federal Register** Friday, May 14, 2004, Volume 69, Number 94, pages 26829–26833. The notice is amended as follows:

- Page 26829, first column, change Application Deadline Date to June 23, 2004.
- Page 26830, second column, change Anticipated Award Date to September 1, 2004.
- Page 26831, first column, section, "IV.3. Submission Dates and Times," change Application Deadline Date to June 23, 2004.

Dated: May 19, 2004.

**William P. Nichols,**

*Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.*

[FR Doc. 04–11751 Filed 5–24–04; 8:45 am]

BILLING CODE 4163–18–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Proposed Information Collection Activity; Comment Request

### Proposed Projects

*Title:* Financial Institution Data Match.

*OMB No.* 0970–0196.

*Description:* Section 466(a)(17) of the Social Security Act (the Act), requires states to establish procedures under which the state child support enforcement (IV–D) agency shall enter into agreements with financial institutions doing business in the state for the purpose of securing information leading to the enforcement of child support orders. Under 452(1) of the Act, financial institutions doing business in multiple states may comply by centrally matching through the Federal Parent Locator Service rather than matching in each state in which the financial institution conducts business.

*Respondents:* Financial institutions doing business in two or more states.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|---|---|---|---|
| Financial Data Match Tape | 4501 | 4 | .5 | 9002 |
| Election Form | 333 | 1 | .5 | 166.5 |

*Estimated Total Annual Burden Hours:* 9168.5.

In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *grjohnson@acf.hhs.gov.*

The Department specifically requests comments on: (a) Whether the proposed 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 proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: May 19, 2004.

**Bob Sargis,**

*Reports Clearance Officer.*

[FR Doc. 04–11814 Filed 5–24–04; 8:45 am]

BILLING CODE 4184–01–M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Submission for OMB Review; Comment Request

*Title:* National Extranet Optimized Runaway and Homeless Youth Management Information System (NEORHYMIS)

*OMB No.:* 0970–0123.

*Description:* The Runaway and Homeless Youth Act (RHYA), as amended by Public Law 106–71 (42 U.S.C. 5701 *et seq.*), mandates that the Department of Health and Human Services (HHS) report regularly to Congress on the status of HHS-funded programs serving runaway and homeless youth. Organizations funded under the Runaway and Homeless Youth (RHY) program are required by section 312(b)(7) of the statute to meet several data collection and reporting requirements. These requirements include maintenance of client statistical records and submission of annual program reports profiling the characteristics of the youth and families served and the services provided to them. The October 2003 reauthorization of the Act maintained the requirements as described in the standing legislation.

Data from the National Extranet Optimized Runaway and Homeless Youth Management Information System (NEORHYMIS) support grantee organizations as they carry out a variety of integrated, ongoing responsibilities and projects. These include meeting statutory and regulatory reporting requirements, maintaining program service and management information for internal uses, tracking youth in their programs, accountability monitoring, management improvement, research, and evaluation.

*Respondents:* Recipients of grants from the HHS/ACF/Family and Youth Services Bureau to operate emergency shelters for runaway youth, transitional programs for homeless youth, and street outreach programs.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|---|---|---|---|
| Youth Profile | 535 | 153 | 0.25 | 20,464 |
| Street Outreach Report | 147 | 4211 | 0.02 | 12,380 |
| Brief Contacts | 535 | 305 | 0.15 | 24,476 |
| Turnaways | 535 | 13 | 0.1 | 696 |
| Data Transfer | 535 | 2 | 0.5 | 535 |

*Estimated Total Annual Burden Hours:*

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *grjohnson@acf.hhs.gov.*

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Officer for ACF, E-mail address: *katherine_t._astrich@omb.eop.gov.*

Dated: May 19, 2004.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 04–11815 Filed 5–24–04; 8:45 am]

BILLING CODE 4184–01–M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Field Initiated Child Care Research Projects

**AGENCY:** Administration for Children and Families (ACF), Administration on Children, Youth, and Families (ACYF), Child Care Bureau (CCB).

*Funding Opportunity Title:* Field Initiated Child Care Research Projects.

*Announcement Type:* Competitive Grant-Initial.

*Funding Opportunity Number:* HHS–2004–ACF–ACYF–YE–0020.

*CFDA Number:* 93.575.

**DATES:** *Due Date for Applications:* The due date for receipt of applications is July 26, 2004.

*Due Date for Letters of Intent:* If you intend to submit an application, please e-mail the ACYF Operations Center and include the following information: the number and title of this announcement, your organization's name and address, and your contact person's name, title, phone number, fax number, and e-mail address. This notice is not required but is strongly encouraged. The information will be used to determine the number of expert reviewers needed to evaluate applications and to update the mailing list for future program announcements.

**I. Funding Opportunity Description**

*1. Child Care Bureau*

Since its establishment in 1995, the Child Care Bureau (CCB) has been dedicated to enhancing the quality, affordability, and supply of child care available for all families. The Child Care Bureau administers the Child Care and Development Fund (CCDF), a $4.8 billion child care program that includes funding for child care subsidies and activities to improve child care quality and availability. Combined with related State and Federal funding, CCDF provides more than $11 billion a year to States, territories, and tribes. Most of these funds are used to assist low-income, working families in paying for child care.

The Bureau works closely with ACF Regions, States, territories, and tribes to facilitate, oversee, and document the implementation of policies and programs that support State, local, and private sector administration of child care services and systems. In addition, the Bureau collaborates extensively with other offices throughout the Federal government to promote integrated approaches, family-focused services, and coordinated child care delivery systems. In all of these activities, the Bureau strives to support children's healthy growth and development, family self-sufficiency, parental choice and involvement, and linkage of child care with other community services.

*2. Child Care Bureau's Research Agenda*

Since 2000, Congress has appropriated approximately $10 million per year to be used for child care research and evaluation. The Child Care Bureau's research agenda supports activities likely to help decision makers in crafting effective child care policies and practices that promote positive outcomes for children and families. It is also intended to increase the capacity for child care research at the national, State, and local levels and to promote better linkages among research, policy, and practice.

The Bureau's capacity to further child care-related research is enhanced by the Child Care Policy Research Consortium, which is an alliance of research projects sponsored by the CCB. The consortium is comprised of researchers and their partners in States, local communities and other organizations who join in linking research, policy, and practice. The research projects of consortium members cover a broad range of issues. For example, some projects describe State and local child care populations, services, and programs, while others focus on child care subsidy policies and market dynamics. In addition, some projects examine issues that deal with the professional development and training of child care providers. The consortium meets annually in Washington, DC.

In order to synthesize the broad array of child care information being generated, the Bureau has created the Child Care and Early Education Research Collaboration and Archive (CCEERCA), which serves as the Child Care Bureau's national research knowledge management system for the child care field. The CCEERCA consists of an interactive Web site, an archive of data sets and reports, and a technical assistance support system to assist researchers and facilitate collaboration.

*3. Purpose and Goals*

The purpose of these grants is to support researchers in investigating child care issues that are consistent with the Child Care Bureau's research agenda and to improve the overall quality of

child care research. They are funded under the authority of the Child Care and Development Block Grant Act of 1990, as amended.

The goals of this program area are as follows:

*To address issues of current relevance to decision makers at the local, State, and national levels.* Research and evaluation are critical to understanding child care issues and their implications for children and families. In fiscal year 2004 (FY 2004), the Bureau is particularly concerned with outcomes that relate to alternative child care subsidy policies and practices, investments in child care quality including provider training and professional development, the school readiness of young children cared for in a variety of care settings, and coordination across child care and other programs that serve children and families.

*To increase the capacity for child care research at the national, State, and local levels.* Once completed and released, studies funded through this announcement must be prepared and archived according to the specifications supplied by the Child Care and Early Education Research Collaboration and Archive. These public-use data files will be the property of the Federal government and will remain in the public domain for secondary analysis by other researchers.

*To encourage the active communication, networking, and collaboration among prominent child care researchers, and policy makers.* In order to facilitate networking with policy makers, researchers are required to participate in the Child Care Bureau's Annual Meeting of the Child Care Policy Research Consortium and invited to attend the State Administrators' Meeting.

*4. Fiscal Year 2004 Field Initiated Child Care Research Priorities*

In FY 2004, the Child Care Bureau is seeking to fund Field Initiated Child Care Research Projects that address questions that are highly relevant to the issues faced by Federal, State, and local community policy makers. These include: The effects of alternative child care subsidy policies and practices; the relative effectiveness of child care quality investments; issues and outcomes related to the professional development and training of caregivers; the school readiness of young children in a range of care settings; and issues and approaches in coordinating between child care and other services for children and families. The following describes each of these areas in detail and provides examples of research questions under each area.

A. *Child Care Subsidy Policies.* Under the Child Care and Development Fund, States have the flexibility to establish child care policies and practices that respond to State and local needs. Existing research demonstrates that significant variations exist across jurisdictions. Relatively little is known about how these variations influence which families and children are being served, the types and amounts of child care being used, continuity of care for children, and employment and school readiness outcomes. For example:

- What family and child outcomes are associated with receipt of subsidies? How do outcomes differ for different population groups and types of care?
- How do child care policies and administrative practices affect the child care decisions parents make, including the selection of faith-based providers?
- How do alternatives to on-site application and eligibility re-determination processes, and the frequency of these activities, relate to characteristics of families served, the duration of arrangements, continuity of care, and outcomes for families and children?
- How do alternative approaches to parental co-payments influence the number of families that can be served, the types of care parents use, the affordability of care, continuity of care, and the willingness of providers to serve subsidized families?
- How well do market rate surveys assess the price of care in various types of communities? What methods can be used to validate the findings from market rate surveys?
- What are the effects of child care subsidies on the larger child care market (*e.g.*, does an infusion of public funding result in higher community child care prices or is there displacement between subsidized and non-subsidized children)?
- How do child care subsidy policies, financing strategies, and delivery systems affect the role of child care in community economic development?

B. *Quality Investments.* In FY 02, States spent 11 percent of the funds they received through the Child Care and Development Fund on activities to improve child care quality. The Child Care Bureau seeks projects that will provide sound information about the cost-effectiveness of alternative investments in improving child care quality. For example:

- Does giving informal caregivers, such as relatives, friends and neighbors, access to USDA adult and child nutrition programs result in improved child care quality? Do partnerships among child care and nutrition programs result in an effective system for the delivery of training for informal caregivers? How does participation in other types of support relate to the quality of care provided by this group of caregivers?
- What proportion of child care providers take advantage of State and community systems of tiered reimbursement? Does tiered reimbursement result in increased participation in accreditation, certification, or other mechanisms through which providers can demonstrate that they offer higher quality care? How do variations across systems of tiered reimbursement, including incentive amounts, influence provider participation? Are there differences in participation in tiered reimbursement and responses to licensing incentives among types of providers (including faith-based organizations)? Is it possible to demonstrate improvements in the quality of care? Do such systems influence the child care choices parents make?
- Do strategies such as putting licensing information on the web or monitoring child care facilities based on risk factors improve the health, safety and quality of child care facilities? Do such strategies result in better informed consumers?

C. *Professional Development and Training.* In connection with the administration's early learning initiative, Good Start, Grow Smart, the Child Care Bureau has been working with States on the development of voluntary guidelines for early learning. States are being encouraged to link their professional development and provider training strategies to the outcomes they hope to achieve for children. In support of these efforts, the Bureau is interested in research projects that can provide greater insight into the effectiveness of alternative approaches to professional development and training in improving the quality of care and outcomes for children across the range of child care settings. For example:

- What characteristics of caregivers are associated with choosing child care as a long-term profession and staying in the field?
- What levels of compensation and benefits are necessary to motivate caregivers to participate in quality improvement initiatives such as incentives for earning professional credentials or degrees and specialized training?
- Are States implementing policies (such as tax incentives, loan programs

and training) that encourage individuals to work in child care or establish child care businesses? How effective are these strategies?

• What characteristics of professional development systems provide an effective vehicle for the pursuit of career paths in child care and early childhood education? How well do articulation agreements and systems of training approval and registry work for individual caregivers?

• Do professional development systems support the workforce in all sectors and levels of development including caregivers working in family child care and informal settings as well as center-based programs (including faith-based)?

• How effective are alternative training strategies such as distance learning, mentoring, and coaching in improving the skills of caregivers with limited education and access to the formal system?

D. *School Readiness.* Young children are spending increasing numbers of hours in child care and other early education settings. More needs to be known about how the school readiness of young children is influenced across types of child care as well as how school readiness can be promoted across settings. For example:

• How do school readiness outcomes differ among early childhood education settings? What are the characteristics of settings that make a difference in school readiness outcomes for children? How does this vary by racial, ethnic, or language differences among children?

• How do hours in child care and early education relate to child outcomes?

• Does subsidy receipt impact the probability that low-income children will be in settings that support school readiness?

• What factors promote children's early learning and school readiness in child care centers, family child care homes, and in informal arrangements among families, friends and neighbors?

E. *Coordination.* With growth in child care subsidies, Head Start, State pre-kindergarten programs, services for children with special needs, and a range of other programs targeted toward low-income families and children, it is critical that services be coordinated. This is necessary to maximize the resources that are available and to ensure that services make sense and are effective in supporting positive outcomes for families and children. Examples of research questions include:

• What are States and communities doing to coordinate across early childhood and school-age programs, including health, assistance for children with special needs, TANF, child care, Head Start, pre-kindergarten, and K–12 services with respect to service delivery and funding? How well do these strategies work?

• What are the barriers and facilitators to collaboration and integration across programs?

• What are the effects of universal pre-kindergarten programs on the larger child care market?

Applicants should propose sound research methodologies and analyses that are appropriate to the study. Projects may also involve secondary analyses of completed data sets. Within the maximum funding level available ($400,000), applicants are expected to develop a budget that is reasonable given the nature and scope of the proposed study. Projects may include multiple sites, propose linkages with other studies, or otherwise leverage resources and knowledge.

Applicants are encouraged to form research partnerships if the result will be a more comprehensive, policy-relevant, and rigorous study than could be accomplished by a single organization. Funding partnerships to enhance the scope or quality of research activities are also encouraged.

## II. Award Information

*Funding Instrument Type:* Grant.

*Category of Funding Activity:* ISS Income Security and Social Services.

*Anticipated Total Program Funding:* $2 million in FY 2004.

*Anticipated Number of Awards:* Five to eight awards will be funded.

*Ceiling on Amount of Individual Awards:* $400,000 per budget period. Applications that exceed this ceiling will be considered non-responsive and will not be eligible for funding under this announcement.

*Floor on Amount of Individual Awards:* None.

*Average Anticipated Award:* $200,000–$400,000 per budget period.

*Project Period for Awards:* This announcement invites applications for project periods up to three years. Awards, on a competitive basis, will be for a one-year budget period, although project periods may be for three years. Applications for continuation of grants beyond the one-year budget period will be entertained in subsequent years on a non-competitive basis, subject to the availability of funds from future appropriations, satisfactory progress of the grantee, and a determination that continued funding is in the best interest of the government. Should additional funds be available in FY 2005 or 2006, ACF reserves the right to fund additional projects from among the applications received under this announcement.

## III. Eligibility Information

*1. Eligible Applicants*

Universities and colleges, public agencies, non-profit organizations, for-profit organizations agreeing to waive their fees are eligible applicants, faith-based and community organizations are also eligible to apply.

Institutions serving minority populations, including but not limited to Tribally Controlled Land Grant Colleges and Universities (TCUs) and Historically Black Colleges and Universities (HBCUs), are also eligible applicants.

• TCUs are those institutions cited in section 532 of the Equity in Educational Land Grant Status Act of 1994 (7 U.S.C. 301 *note*), any other institution that qualifies for funding under the Tribally Controlled Community College Assistance Act of 1978 (25 U.S.C. 1801 *et seq.*), and Navajo Community College, authorized in the Navajo Community College Assistance Act of 1978, Pub. L. 95–471, title II (25 U.S.C. 640a *note*). Those TCUs that are not accredited are not eligible to apply under this announcement.

• HBCUs are defined in the amended version of the Higher Education Act of 1965, codified at 20 U.S.C. 1061(2), as institutions established prior to 1964 whose principle mission was, and is, the education of Black Americans, and must satisfy section 322 of the Higher Education Act of 1965, as amended. Institutions which meet the definition of "Part B institution" in section 322 of the Higher Education Act of 1965, as amended, 20 U.S.C. 1061(2), shall be eligible for assistance under this announcement.

*Additional Information on Eligibility:* Non-profit organizations applying for funding are required to submit proof of their non-profit status. Proof of non-profit status is any one of the following:

(a) A reference to the applicant organization's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in the IRS code.

(b) A copy of a currently valid IRS tax exemption certificate.

(c) A statement from a State taxing body, State Attorney General, or other appropriate State official certifying that the applicant organization has a non-profit status and that none of the net earnings accrue to any private shareholders or individuals.

(d) A certified copy of the organization's certificate of

incorporation or similar document that clearly establishes non-profit status.

(e) Any of the items in the subparagraphs immediately above for a State or national parent organization and a statement signed by the parent organization that the applicant organization is a local non-profit affiliate.

*2. Cost-Sharing or Matching*

Grantees must provide at least 20 percent of the total approved cost of the project. The total approved cost of the project is the sum of the ACF share and the non-federal share. The non-federal share may be met by cash or in-kind contributions, although applicants are encouraged to meet their match requirements through cash contributions. For example, in order to meet the match requirements, a project with a total approved cost of $375,000, requesting $300,000 in ACF funds, must provide a non-federal share of at least $75,000 (20% of total approved project cost of $375,000). Grantees will be held accountable for commitments of non-federal resources even if over the amount of the required match. Failure to provide the amount will result in disallowance of Federal funds.

Applications that fail to include the required amount of cost-sharing will be considered non-responsive and will not be eligible for funding under this announcement.

*3. Other*

On June 27, 2003, the Office of Management and Budget published in the **Federal Register** a new Federal policy applicable to all Federal grant applicants. The policy requires all Federal grant applicants to provide a Dun and Bradstreet Data Universal Numbering System (DUNS) number when applying for Federal grants or cooperative agreements on or after October 1, 2003. The DUNS number will be required whether an applicant is submitting a paper application or using the government-wide electronic portal (*http://www.Grants.gov*). A DUNS number will be required for every application for a new award or renewal/continuation of an award, including applications or plans under formula, entitlement and block grant programs, submitted on or after October 1, 2003.

Please ensure that your organization has a DUNS number. You may acquire a DUNS number at no cost by calling the dedicated toll-free DUNS number request line at 1–866–705–5711 or you may request a number on-line at *http://www.dnb.com*.

Applications that fail to follow the required format described in Section IV.2 below will be considered non-responsive and will not be eligible for funding under this announcement.

Applications that exceed the funding ceiling will be considered non-responsive and will not be eligible for funding under this announcement.

Applications that fail to include the required amount of cost-sharing will be considered non-responsive and will not be eligible for funding under this announcement.

**IV. Application and Submission Information**

*1. Address To Request Application Package*

This full announcement can be obtained via the following link: *http://www.acf.hhs.gov/programs/ccb*.

If you are unable to download the complete announcement, requests for applications may be sent to: ACYF Operations Center, c/o The Dixon Group, Inc., Child Care Bureau, Field Initiated Child Care Research Grants, 118 Q Street, NE., Washington, DC 20002–2132, phone: 866–796–1591, e-mail: *CCB@dixongroup.com*.

*2. Content and Format of Application Submission*

*Electronic Submission*. You may submit your application to us in either electronic or paper format. To submit an application electronically, please use the *http://www.Grants.gov* apply site. If you use Grants.gov, you will be able to download a copy of the application package, complete it off-line, and then upload and submit the application via the Grants.gov site. You may not email an electronic copy of a grant application. Please note the following if you plan to submit your application electronically via Grants.gov:

- Electronic submission is voluntary.
- When you enter the Grants.gov site, you will find information about submitting an application electronically through the site, as well as the hours of operation. We strongly recommend that you do not wait until the application deadline date to begin the application process through Grants.gov.
- To use Grants.gov, you, as the applicant, must have a DUNS Number and register in the Central Contractor Registry (CCR). You should allow a minimum of five days to complete the CCR registration.
- You will not receive additional point value because you submit a grant application in electronic format, nor will we penalize you if you submit an application in paper format.
- You may submit all documents electronically, including all information typically included on the SF 424 and all necessary assurances and certifications.
- Your application must comply with any page limitation requirements described in this program announcement.
- After you electronically submit your application, you will receive an automatic acknowledgment from Grants.gov that contains a Grants.gov tracking number. The Administration for Children and Families will retrieve your application from Grants.gov and send you a second confirmation, which will include an ACF tracking number.
- We may request that you provide original signatures on forms at a later date.
- You may access the electronic application for this program on *http://www.Grants.gov*.

*Format and Organization*. An original and two copies of the application must be submitted. Applicants should limit their application to 100 pages, double-spaced, with standard one-inch margins and 12 point fonts. This page limit applies to both narrative text and supporting materials. In addition, applicants should number the pages of their application and include a table of contents.

Applicants are advised to include all required forms and materials and to organize these materials according to the format presented below:

a. Cover letter.

b. Required standard forms:

- Standard Application for Federal Assistance (forms 424 and 424A).
- Applicants requesting financial assistance for a non-construction project must sign and return Standard Form 424B, Assurances: Non-construction Programs, with their applications.
- Applicants must provide a Certification Regarding Lobbying. Prior to receiving an award in excess of $100,000, applicants shall furnish an executed copy of the lobbying certification. Applicants must sign and return the certification with their application.
- Applicants must make the appropriate certification of compliance with all Federal statues relation to nondiscrimination. By signing and submitting the application, applicants are providing the certification and need not mail back a certification form.
- Applicants must make the appropriate certification of their compliance with the requirements of the Pro-Children Act of 1994 as outlined in Certification Regarding Environment Tobacco Smoke.

c. Table of contents.

d. Project narrative statement.

e. Appendix:

Complete Contact Information for Principle Investigators;

Curriculum Vitae for Principle Investigators.

*Content of Project Narrative Statement:* The project narrative statement contains most of the information on which applications will be competitively reviewed. The project narrative should be carefully developed in accordance with the Bureau's research goals and agenda, the requirements listed in the Uniform Project Description and the evaluation criteria.

*Omission of Salary Rate:* Applicants have the option of omitting from the application copies (not the original) specific salary rates or amounts for individuals specified in the application budget.

*Applications from Non-profit Organizations:* Private, non-profit organizations are encouraged to submit with their applications the survey under "Grant Related Documents and Forms" titled "Survey for Private, Non-Profit Grant Applicants" at *http://www.acf.hhs.gov/programs/ofs/forms.htm.*

*3. Submission Dates and Times*

*Notice of Intent to Submit Application:* If you intend to submit an application, please e-mail the ACYF Operations Center and include the following information: the number and title of this announcement, your organization's name and address, and your contact person's name, title, phone number, fax number, and e-mail address. This notice is not required but is strongly encouraged. The information will be used to determine the number of expert reviewers needed to evaluate applications and to update the mailing list for future program announcements.

*Mailing and Delivery Instructions.* Applications may be sent through the U.S. Postal Service, delivered by private courier, or hand delivered to the ACYF Operations Center. Applications must be mailed or delivered to: ACYF Operations Center, The Dixon Group, Inc., Child Care Bureau, Field Initiated Child Care Research Program, 118 Q Street, NE., Washington, DC 20002–2132, phone: 866–796–1591, e-mail: *CCB@dixongroup.com.* Applications delivered by a private courier or by hand must be received no later than 4:30 p.m., eastern time (e.t.), on the closing date. ACYF cannot accept applications by fax or through other electronic media. Applicants will receive a confirmation postcard upon receipt of applications.

*Closing Date:* The closing date for receipt of applications is 4:30 p.m. eastern time (e.t.) on July 26, 2004. Mailed or handcarried applications received after 4:30 p.m. on the closing date will be classified as late.

*Late Applications:* Mailed applications will be considered as meeting the deadline if they are postmarked on or before the closing date and received by ACYF in time for the independent review. Applications hand carried by applicants, couriers, other representatives of the applicant, will be considered as meeting the deadline if they are received at the ACYF Operations Center on the closing date between the hours of 8 a.m. and 4:30 p.m., e.t., Monday through Friday (excluding Federal holidays). Applications that do not meet the criteria stated above will be considered late. The Administration for Children and Families (ACF) will notify each late applicant that his/her application will not be considered in the current competition.

*Extension of Deadline:* ACF may extend an application deadline for applicants affected by acts of God (such as floods and hurricanes), when there is widespread disruption of mail service, or for other disruption of services that affect the public at large (such as prolonged electrical blackout). Authority to waive or extend deadline requirements rests with the Chief Grants Management Officer.

The table below details when the materials need to be submitted and where these forms or formatting descriptions can be found.

| What to submit | Required content | Required form or format | When to submit |
|---|---|---|---|
| Standard Application for Federal Assistance (forms SF 424, 424A, and 424B). | Per required form | May be found at *http://acf.hhs.gov/programs/ofs/forms.htm.* | By application due date. |
| Certification regarding Lobbying and associated Disclosure of Lobbying Activities (SF LLL). | Per required form | May be found at *http://acf.hhs.gov/programs/ofs/forms.htm.* | By application due date. |
| Environmental Tobacco Smoke Certification. | Per required form | May be found at *http://acf.hhs.gov/programs/ofs/forms.htm.* | By application due date. |
| Protection of Human Subjects. | Per required form | May be found at *http://acf.hhs.gov/programs/ofs/forms.htm.* | By application due date. |
| Proof of Non-Profit Status | *See* Section III.1 | May be found at *http://acf.hhs.gov/programs/ofs/forms.htm.* | By application due date. |
| Project Narrative Statement | *See* Section IV.2 and Section V.1 and V.2. | Format described in Section V.1 and V.2 | By application due date. |
| Contact Information, Vita, Letter of Support, Transcript. | *See* Section and IV.2 | Format described in Section IV.2 | By Application due date. |

Additional Forms

Private, non-profit organizations are encouraged to submit with their applications the survey located under "Grant Related Documents and Forms" titled "Survey for Private, Non-Profit Grant Applicants" at *http://www.acf.hhs.gov/programs/ofs/forms.htm.*

| What to submit | Required content | Required form or format | When to submit |
|---|---|---|---|
| Survey for Private, Non-Profit Grant Applicants. | Per Required Form | *http://www.acf.hhs.gov/programs/ofs/form.htm* | By application due date. |

*4. Intergovernmental Review*

State Single Point of Contact (SPOC)

This program is covered under Executive Order 12372, "Intergovernmental Review of Federal Programs," and 45 CFR part 100, "Intergovernmental Review of Department of Health and Human Services Programs and Activities." Under the Order, States may design their own processes for reviewing and commenting on proposed Federal assistance under covered programs.

All States and territories except Alabama, Alaska, Arizona, Colorado, Connecticut, Hawaii, Idaho, Indiana, Kansas, Louisiana, Massachusetts, Minnesota, Montana, Nebraska, New Jersey, Ohio, Oklahoma, Oregon, Pennsylvania, South Dakota, Tennessee, Vermont, Virginia, Washington, Wyoming, and Palau have elected to participate in the Executive Order process and have established Single Points of Contact (SPOCs). Applicants from these twenty-six jurisdictions need take no action regarding E.O. 12372. Applicants for projects to be administered by federally-recognized Indian tribes are also exempt from the requirements of E.O. 12372. Otherwise, applicants should contact their SPOCs as soon as possible to alert them of the prospective applications and receive any necessary instructions. Applicants must submit any required material to the SPOCs as soon as possible so that the program office can obtain and review SPOC comments as part of the award process. It is imperative that the applicant submit all required materials, if any, to the SPOC and indicate the date of this submittal (or the date of contact if no submittal is required) on the Standard Form 424, item 16a. Under 45 CFR 100.8(a)(2), a SPOC has 60 days from the application deadline to comment on proposed new or competing continuation awards.

SPOCs are encouraged to eliminate the submission of routine endorsements as official recommendations. Additionally, SPOCs are requested to clearly differentiate between mere advisory comments and those official State process recommendations which may trigger the "accommodate or explain" rule.

When comments are submitted directly to ACF, they should be addressed to: Department of Health and Human Services, Administration for Children and Families, Division of Discretionary Grants, 370 L'Enfant Promenade, SW., Washington, DC 20447.

*5. Funding Restrictions*

Grants awarded as a result of this competition are not transferable to another institution. No individual institution will be funded for more than one award unless applications from different institutions do not qualify for support.

*6. Other Submission Requirements*

*Submission by Mail:* Mailed applications shall be considered as meeting an announced deadline if they are received on or before the deadline time and date at the ACYF Operations Center, The Dixon Group, Inc., Child Care Bureau, Field Initiated Child Care Research Grants, 118 Q Street, NE., Washington, DC 20002–2132. Applicants are responsible for mailing applications well in advance, when using all mail services, to ensure that the applications are received on or before the deadline time and date.

*Hand Delivery:* Applications handcarried by applicants, applicant couriers, other representatives of the applicant, or by overnight/express mail couriers shall be considered as meeting an announced deadline if they are received on or before the deadline date, between the hours of 8 a.m. and 4:30 p.m. eastern time at the ACYF Operations Center, c/o The Dixon Group, Inc., 118 Q Street, NE., Washington, DC 20002–2132, between Monday and Friday (excluding Federal holidays). This address must appear on the envelope/package containing the application with the note "Attention Field Initiated Child Care Research Grants." Applicants are cautioned that express/overnight courier services do not always deliver as agreed.

ACF cannot accommodate transmission of applications by fax.

**V. Application Review Information**

*1. Criteria*

*Paperwork Reduction Act of 1995 (Pub. L. 104–13):* Public reporting for this collection of information is estimated to average 15 hours for the Field Initiated Child Care Research Grants, including time for reviewing instructions, gathering and maintaining the data needed, and reviewing the collection of information.

The project description is approved under OMB Control No. 0970–0139.

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.

Instruction: ACF Uniform Project Description (UPD)

The following are instructions and guidelines on how to prepare the "Project Summary/Abstract" and "Full Project Description" sections of the application. The UPD was approved by the Office of Management and Budget (OMB) Control No. 0970–0139.

*The Project Description Overview.* The project description provides a major means by which an application is evaluated and ranked to compete with other applications for available assistance. The project description should be concise and complete and should address the activity for which Federal funds are being requested. Supporting documents should be included where they can present information clearly and succinctly. In preparing your project description, all information requested through each specific evaluation criteria should be provided. Awarding offices use this and other information in making their funding recommendations. It is important, therefore, that this information be included in the application.

*General Instructions.* ACF is particularly interested in specific factual information and statements of measurable goals in quantitative terms. Project descriptions are evaluated on the basis of substance, not length. Extensive exhibits are not required. Cross referencing should be used rather than repetition. Supporting information concerning activities that will not be directly funded by the grant or information that does not directly pertain to an integral part of the grant funded activity should be placed in an appendix. Pages should be numbered and a table of contents should be included for easy reference.

Instructions for Preparing a Full Project Description

*1. Project Summary Abstract*

Provide a summary of the project description (a page or less) with reference to the funding request.

*2. Objectives and Need for Assistance*

Clearly identify the physical, economic, social, financial, institutional, and/or other problem(s) requiring a solution. The need for assistance must be demonstrated and the principal and subordinate objectives of the project must be clearly stated; supporting documentation, such as letters of support and testimonials from concerned interests other than the applicant, may be included. Any relevant data based on planning studies

should be included or referred to in the endnotes/footnotes. Incorporate demographic data and participant/beneficiary information, as needed.

In developing the project description, the applicant may volunteer or be requested to provide information on the total range of projects currently being conducted and supported (or to be initiated), some of which may be outside the scope of the program announcement.

*3. Approach*

Outline a plan of action which describes the scope and detail of how the proposed work will be accomplished. Account for all functions or activities identified in the application. Cite factors which might accelerate or decelerate the work and state your reason for taking the proposed approach rather than others. Describe any unusual features of the project such as design or technological innovations, reductions in cost or time, or extraordinary social and community involvement.

Provide quantitative monthly or quarterly projections of the accomplishments to be achieved for each function or activity in such terms as the number of people to be served and the number of activities accomplished. When accomplishments cannot be quantified by activity or function, list them in chronological order to show the schedule of accomplishments and their target dates.

If any data is to be collected, maintained, and/or disseminated, clearance may be required from the U.S. Office of Management and Budget (OMB). This clearance pertains to any "collection of information that is conducted or sponsored by ACF."

List organizations, cooperating entities, consultants, or other key individuals who will work on the project, along with a short description of the nature of their effort or contribution.

*4. Additional Information*

Following are requests for additional information that need to be included in the application:

a. Staff and Position Data

Provide a biographical sketch for each key person appointed and a job description for each vacant key position. A biographical sketch will also be required for new key staff as appointed.

b. Budget and Budget Justification

Provide line item detail and detailed calculations for each budget object class identified on the Budget Information form. Detailed calculations must include estimation methods, quantities, unit costs, and other similar quantitative detail sufficient for the calculation to be duplicated. The detailed budget must also include a breakout by the funding sources identified in Block 15 of the SF–424.

Provide a narrative budget justification that describes how the categorical costs are derived. Discuss the necessity, reasonableness, and allocability of the proposed costs.

*5. General*

The following guidelines are for preparing the budget and budget justification. Both Federal and non-Federal resources shall be detailed and justified in the budget and narrative justification. For purposes of preparing the budget and budget justification, "Federal resources" refers only to the ACF grant for which you are applying. Non-Federal resources are all other Federal and non-Federal resources. It is suggested that budget amounts and computations be presented in a columnar format: First column, object class categories; second column, Federal budget; next column(s), non-Federal budget(s), and last column, total budget. The budget justification should be a narrative.

a. Personnel

*Description:* Costs of employee salaries and wages.

*Justification:* Identify the project director or principal investigator, if known. For each staff person, provide the title, time commitment to the project (in months), time commitment to the project (as a percentage or full-time equivalent), annual salary, grant salary, wage rates, etc. Do not include the costs of consultants or personnel costs of delegate agencies or of specific project(s) or businesses to be financed by the applicant.

b. Fringe Benefits

*Description:* Costs of employee fringe benefits unless treated as part of an approved indirect cost rate.

*Justification:* Provide a breakdown of the amounts and percentages that comprise fringe benefit costs such as health insurance, FICA, retirement insurance, taxes, etc.

c. Travel

*Description:* Costs of project-related travel by employees of the applicant organization (does not include costs of consultant travel).

*Justification:* For each trip, show the total number of traveler(s), travel destination, duration of trip, per diem, mileage allowances, if privately owned vehicles will be used, and other transportation costs and subsistence allowances. Travel costs for key staff to attend ACF-sponsored workshops should be detailed in the budget.

d. Equipment

*Description:* "Equipment" means an article of nonexpendable, tangible personal property having a useful life of more than one year and an acquisition cost which equals or exceeds the lesser of (a) the capitalization level established by the organization for the financial statement purposes, or (b) $5,000.

**Note:** Acquisition cost means the net invoice unit price of an item of equipment, including the cost of any modifications, attachments, accessories, or auxiliary apparatus necessary to make it usable for the purpose for which it is acquired. Ancillary charges, such as taxes, duty, protective in-transit insurance, freight, and installation shall be included in or excluded from acquisition cost in accordance with the organization's regular written accounting practices.

*Justification:* For each type of equipment requested, provide a description of the equipment, the cost per unit, the number of units, the total cost, and a plan for use on the project, as well as use or disposal of the equipment after the project ends. An applicant organization that uses its own definition for equipment should provide a copy of its policy or section of its policy which includes the equipment definition.

e. Supplies

*Description:* Costs of all tangible personal property other than that included under the Equipment category.

*Justification:* Specify general categories of supplies and their costs. Show computations and provide other information which supports the amount requested.

f. Other

*Description:* Enter the total of all other costs. Such costs, where applicable and appropriate, may include but are not limited to insurance, food, medical and dental costs (non-contractual), professional services costs, space and equipment rentals, printing and publication, computer use, training costs, such as tuition and stipends, staff development costs, and administrative costs.

*Justification:* Provide computations, a narrative description and a justification for each cost under this category.

g. Indirect Charges

*Description:* Total amount of indirect costs. This category should be used only

when the applicant currently has an indirect cost rate approved by the Department of Health and Human Services (HHS) or another cognizant Federal agency.

*Justification:* An applicant that will charge indirect costs to the grant must enclose a copy of the current rate agreement. If the applicant organization is in the process of initially developing or renegotiating a rate, it should immediately upon notification that an award will be made, develop a tentative indirect cost rate proposal based on its most recently completed fiscal year in accordance with the principles set forth in the cognizant agency's guidelines for establishing indirect cost rates, and submit it to the cognizant agency. Applicants awaiting approval of their indirect cost proposals may also request indirect costs. It should be noted that when an indirect cost rate is requested, those costs included in the indirect cost pool should not also be charged as direct costs to the grant. Also, if the applicant is requesting a rate which is less than what is allowed under the program, the authorized representative of the applicant organization must submit a signed acknowledgement that the applicant is accepting a lower rate than allowed.

*2. Evaluation Criteria*

Eligible applications will be scored competitively against the evaluation criteria. These criteria will be used in conjunction with the other expectations and requirements set forth in this announcement to evaluate how well each proposal addresses the bureau's research agenda and the program goals.

Criterion 1: Approach—Research Design and Methodology (30 Point Maximum)

The extent to which the application provides a theoretical framework and a review of empirical evidence supporting the proposed project:

The extent to which the proposed research design (a) appropriately links research issues, questions, variables, data sources, samples, and analyses; (b) provides a logic model that illustrates the expected linkages; and (c) employs technically sound and appropriate approaches, design elements and procedures, and sampling techniques.

The extent to which the application provides a detailed analysis plan that shows how the measures and analyses relate to the proposed hypotheses or research questions and demonstrates their appropriateness for the questions under consideration.

The extent to which the proposed design (a) reflects sensitivity to technical, logistical, cultural, and ethical issues that may arise and (b) and includes realistic strategies for the resolution of difficulties;

The extent to which the researchers assure adequate protection of human subjects, confidentiality of data, and consent procedures, as appropriate;

The extent to which the research design (a) specifies the measures to be used and their psychometric properties; (b) describes how these measures have been used to address the proposed research questions; and (c) describes how these measures have been used with the low-income, diverse population to be studied.

Criterion 2: Objectives and Need for Assistance (25 Point Maximum)

The extent to which the application responds to the Child Care Bureau's priorities and proposes research likely to yield findings that will help decision makers in crafting effective child care policies and strategies.

Identifies the results and benefits of the project and describes how these will inform child care policies and services, improve practice, and advance understanding of the contexts that promote healthy development and well-being in families and children.

The extent to which the application demonstrates a sound understanding of the critical issues and research needs in child care. This should include particular emphasis on the issues addressed by the proposed study.

The extent to which the application provides a literature review that is current and comprehensive, identifies other research that has addressed similar issues, and supports the need for the proposed study. Describes how the proposed study will help address gaps in the research literature and unanswered questions.

The extent to which the conceptual model, objectives and hypotheses are: (a) Well formulated and appropriately linked; (b) reflect the Bureau's research agenda and goals; and (c) will contribute new knowledge to the field.

The extent to which the application describes a project framework that is appropriate, feasible and contributes to the importance, comprehensiveness, and quality of the proposed research.

Criterion 3: Approach—Management Plan (25 Point Maximum)

The extent to which the application includes a management plan that (a) presents a sound framework for maintaining quality control over the implementation and ongoing operations of the study; (b) demonstrates how the applicant will gain access to necessary organizations, participants, and data sources; (c) provides evidence that the applicant and its partners, if any, have the expertise, resources and commitment to solve problems that may arise in carrying out the project; and (d) provides detailed project management charts showing tasks and sub tasks, milestones, staff allocation, and costs.

The extent to which (a) the scope of the project is reasonable for the funds available and feasible for the project time frame; (b) includes an effective plan for the dissemination and utilization of information by researchers, policy-makers, and practitioners in the field; and (c) includes assurances and plans for working with the Child Care Bureau's Child Care Research Collaboration and Archive to archive final data sets, reports, and other research products.

Criterion 4: Organizational Profile (10 Point Maximum)

The extent to which the application: (a) Demonstrates organizational competence and expertise in the areas addressed by the proposed research, including relevant background, experience, and training on related research or similar projects; (b) demonstrates expertise in research design, sampling, field work, data processing, statistical analysis, reporting, and information dissemination to academic and policy communities; (c) demonstrates an understanding of the child care subsidy system and the child care needs of low-income families.

The extent to which the application: (a) Provides evidence of an effective organizational structure and collaborative relationships, if appropriate; (b) provides evidence that the project will be effectively managed by the lead organization to ensure that all participants in the study operate as a cohesive research team; (c) includes a detailed organizational chart showing relationships and responsibilities of participating organizations; (d) demonstrates and documents specific organizational and staff experience in developing, implementing, and maintaining a research project of the nature and scope proposed; and (e) provides information on the skills, experience, and capabilities of the project director and key project staff including the principal investigators and other key staff at each site.

The extent to which the application describes the management plan for achieving the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and

milestones for accomplishing project tasks and ensuring quality.

Criterion 5: Budget (10 Points)

The extent to which the proposed project costs are reasonable and justified in terms of scope, approach, staff time commitment, and anticipated results. Refers to the budget information presented on Standard Forms 424 and 424 A and the applicant's budget justification.

The extent to which the application describes the fiscal control and accounting procedures that will be used to ensure prudent use, proper and timely disbursement, and accurate accounting of funds received under this announcement.

*3. Review and Selection Process*

Initial Screening for Eligibility and Conformance

*Review and Selection Process:* Each application will undergo an eligibility and conformance review by Federal Child Care Bureau staff. Applications that pass the eligibility and conformance review will be evaluated on a competitive basis according to the specified evaluation criteria.

Competitive Review Process

The competitive review will be conducted in the Washington, DC metropolitan area by panels of Federal and non-Federal experts knowledgeable in the areas of literacy, early learning, child care, early childhood education, and other relevant program areas.

Application review panels will assign a score to each application and identify its strengths and weaknesses.

Application Consideration and Selection

The Child Care Bureau will conduct an administrative review of the applications and results of the competitive review panels and make recommendations for funding to the Commissioner, ACYF.

Subject to the recommendation of the Child Care Bureau's Associate Commissioner, the Commissioner, ACYF, will make the final selection of the applications to be funded. Application may be funded in whole or in part depending on: (1) The ranked order of applicants resulting from the competitive review; (2) staff review and consultations; (3) the combination of projects that best meets the Bureau's objectives; (4) the funds available; and (6) other relevant considerations. The Commissioner may also elect not to fund any applicants with known management, fiscal, reporting, program, or other problems that make it unlikely they would be able to provide effective services.

Approved but Unfunded Applications

In cases where more applications are approved for funding than ACF can fund with the money available, the Grants Officer shall fund applications in their order of approval until funds run out. In this case, ACF has the option of carrying over the approved applications up to a year for funding consideration in a later competition of the same program. These applications need not be reviewed and scored again if the program's evaluation criteria have not changed. However, they must then be placed in rank order along with other applications in the later competition.

**VI. Award Administration Information**

*1. Award Notices*

Successful applicants will be notified through the issuance of a Financial Assistance Award document, which sets forth the amount of funds granted, the terms and conditions of the grant, the effective date of the grant, the budget period for which initial support will be given, the non-Federal share to be provided, and the total project period for which support is contemplated. The Financial Assistance Award will be signed by the Grants Officer and transmitted via postal mail.

Organizations whose applications will not be funded will be notified in writing.

*2. Administrative and National Policy Requirements*

Conference Attendance. The grantee must attend and present a poster at the Annual Meeting of the Child Care Policy Research Consortium each year of the grant. This conference is typically scheduled during the spring. In addition, the applicant may be asked to attend and present at the annual State Administrators' Meeting typically held each summer in Washington, DC. The budget should reflect travel funds for both conferences. Grantees with graduate students are encouraged to bring at least one student to these meetings.

Archiving and Publishing. The grantee must agree to archive final data sets, reports and other research products with the Child Care Research and Collaboration Archive (CCRCA).

45 CFR part 74 and 45 CFR part 92.

*3. Special Terms and Conditions of Award*

None.

*4. Reporting Requirements*

Programmatic Reports: Semi-annually and a final report is due 90 days after the end of the grant period.

Financial Reports: Semi-annually and a final report due 90 days after the end of the grant period.

**VII. Agency Contacts**

*Program Office Contacts:*

Dr. Ivelisse Martinez-Beck, Program Area Manager, 330 C Street, SW., Room 2046, Washington, DC 20447; (202) 690–7885, *imartinez-beck@acf.hhs.gov.*

Ms. Karen Tvedt, Director, Policy and Research Division, 330 C Street, SW., Room 2046, Washington, DC 20447; (202) 401–5130, *ktvedt@acf.hhs.gov.*

*Grants Management Office Contact:*

William Wilson, Grants Officer, 330 C Street, SW., Room 2070, Washington, DC 20447; (202) 205–8913, *wwilson@acf.hhs.gov.*

**VIII. Other Information**

None.

Dated: May 18, 2004.

**Joan E. Ohl,**

*Commissioner, Administration on Children, Youth and Families.*

[FR Doc. 04–11816 Filed 5–24–04; 8:45 am]

BILLING CODE 4184–01–P

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2001D–0357]**

### International Cooperation on Harmonisation of Technical Requirements for Approval of Veterinary Medicinal Products; Guidance for Industry on Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a final guidance for industry (#141) entitled "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing" (VICH GL28). This guidance has been adapted for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) from a guidance regarding pharmaceuticals for human use, which

was adopted by the International Conference on Harmonisation of Technical Requirements for Approval of Pharmaceuticals for Human Use (ICH). The objective of this VICH guidance document is to help ensure that the assessment of carcinogenic potential is appropriate to human exposure to residues of veterinary drugs in human food in the European Union, Japan, and the United States.

**DATES:** Submit written or electronic comments at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic or written comments at any time on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Comments should be identified with the full title of the guidance and the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Louis T. Mulligan, Center for Veterinary Medicine (HFV–153), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6984, e-mail: *lmulliga@cvm.fda.gov*.

**SUPPLEMENTARY INFORMATION:**

## I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the ICH for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission, European Medicines Evaluation Agency; European Federation of Animal Health; Committee on Veterinary Medicinal Products; the U.S. FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; the Japanese Association of Veterinary Biologics; and the Japanese Ministry of Agriculture, Forestry and Fisheries.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government in Canada, and one representative from the industry in Canada. The VICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH Steering Committee meetings.

## II. Guidance on Carcinogenicity Testing

In the **Federal Register** of August 28, 2001 (66 FR 45319), FDA published the notice of availability of the VICH draft guidance, giving interested persons until September 28, 2001 to submit comments. No comments were received. At a meeting held on October 10–11, 2002, the VICH Steering Committee endorsed the guidance for industry, VICH GL28.

This guidance is one of a series of VICH guidances developed to facilitate the mutual acceptance of safety data necessary for the establishment of acceptable daily intakes for veterinary drug residues in human food by the relevant regulatory authorities. The guidance on the overall strategy for the evaluation of veterinary drug residues in human food ("VICH Guidance on General Testing Approach") will be made available at a later time.

VICH developed this guidance after consideration of the existing ICH guidances for pharmaceuticals for human use: "Final Guideline on the Need for Long-Term Rodent Carcinogenicity Studies of Pharmaceuticals"; and "S1B Testing for Carcinogenicity of Pharmaceuticals." Notices of availability for these guidances published in the **Federal Register** of March 1, 1996, (61 FR 8153) and February 23, 1998, (63 FR 8983) respectively. The guidance has been adapted for veterinary use by the VICH from the aforementioned guidances regarding pharmaceuticals for human use. VICH also took into account the Organisation for Economic Cooperation and Development methodological guidances and the current practices for evaluating the safety of veterinary drug residues in human food in the European Union, Japan, the United States of America, Australia and New Zealand. (Information collection for new animal drug applications is covered under OMB control number 0910–0032.)

## III. Significance of Guidance

This document, developed under the VICH process, has been revised to conform to FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated "guidance" rather than "guideline." Because guidance documents are not binding unless specifically supported by statute or regulation, mandatory words such as "must," "shall," and "will" in the original VICH documents have been substituted with "should" or "it is recommended."

This guidance document represents the agency's current thinking on carcinogenicity testing for veterinary drug residues in human food. This guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative method may be used as long as it satisfies the requirements of applicable statutes and regulations.

## IV. Comments

As with all of FDA's guidances, the public is encouraged to submit written or electronic comments pertinent to this guidance. FDA will periodically review the comments in the docket and, where appropriate, will amend the guidance. The agency will notify the public of any such amendments through a notice in the **Federal Register**.

Interested persons may, at any time, submit written comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the

Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**V. Electronic Access**

Copies of the guidance document entitled "Studies to Evaluate the Safety of Residues of Veterinary Drugs in Human Food: Carcinogenicity Testing" (VICH GL28) may be obtained on the Internet from the CVM home page at *http://www.fda.gov/cvm.*

Dated: May 18, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–11781 Filed 5–24–04; 8:45 am]

BILLING CODE 4160–01–S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Proposed Collection: Comment Request; Revision of OMB No. 0925–0001 exp. 05/31/04, "Research and Research Training Grant Applications and Related Forms"

**SUMMARY:** In compliance with the requirement section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Director (OD), Office of Extramural Research (OER), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on February 19, 2004, Volume 69, No. 33, page 7763 and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

**Proposed Collection:**

*Title:* Research and Training Grant Applications and Related Forms. *Type of Information Collection Request:* Revision, OMB 0925–0001, Expiration Date 5/31/04. *Form Numbers:* PHS 398, 2590, 2271, 3734 and HHS 568. *Need and Use of Information Collection:* The application is used by applicants to request Federal assistance for research and research-related training. The other related forms are used for trainee appointment, final invention reporting, and to relinquish rights to a research grant. *Frequency of response:* Applicants may submit applications for published receipt dates. If awarded, annual progress is reported and trainees may be appointed or reappointed. *Affected Public:* Individuals or Households; Business or other for-profit, Not-for-profit institutions; Federal Government;l and State, Local or Tribal Government. *Type of Respondents:* Adult scientific professionals. The annual reporting burden is as follows: *Estimated Number of Respondents:* 122,000; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* 8.5; and *Estimates Total Annual Burden Hours Requested:* 1,032,439. The estimated operating cost to respondents is $500,000.

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) 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; (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 those who are to respond, including the use of appropriate automatted, electronic, mechanical, or other technological collection techniques or other forms of information technology.

*Direct Comments to OMB:* Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time should be directed to the Office of Management and Budget, Office of Regulatory Affairs, New executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the propose project or to obtain a copy of the data collection plans and instruments, contact Mr. Mikia Currie, Division of Grants Policy, Office the Policy for Extramural Research Administration, NIH, Rockledge 1 Building, Room 3505, 6705 Rockledge Drive, Bethesda, MD 20892–7974, or call non-toll-free number (301) 435–0941, or E-mail your request, including your address to: [*curriem@od.nih.gov*].

*Comments Due Date:* Comments regarding this informaiton collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: May 13, 2004.

**Dr. Charles Mackay,**

*Chief, Project Clearance Branch, OPERA, OER, National Institutes of Health.*

[FR Doc. 04–11708 Filed 5–24–04; 8:45 am]

BILLING CODE 4140–01–M

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[NV–025–1232–EA); Special Recreation Permit # NV–025–04–01]**

### Notice of Temporary Closure of Public Lands: Pershing, Washoe, & Humboldt Counties, NV

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice to the public of temporary closures on public lands administered by the Bureau of Land Management, Winnemucca Field Office, Nevada.

**SUMMARY:** Pursuant to 43 CFR 8364.1, notice is hereby given that certain public lands will be temporarily closed to all public use in and around the Paragon Astronautics rocket launch site, located in Pershing, Washoe and Humboldt counties, Nevada, from 0700 to 1200 hours, June 7th through June 11 and June 14 through June 18, 2004. These closures are being made in the interest of public safety at and around the location of an amateur high-altitude rocket launch site. This event is expected to attract approximately 50 participants. The public lands involved with the event are located northeast of Gerlach, Nevada in the Mount Diablo Meridian.

**DATES:** Closure to all public use from 0700–1200 hours, June 7 through June 11 and June 14 through June 18, 2004 with the exception of BLM personnel, law enforcement, emergency medical services, and Paragon Astronautics staff as designated by the BLM authorized officer.

**ADDRESSES:** A map showing these temporary closures, restrictions and prohibitions is available from the following BLM offices:

BLM-Winnemucca Field Office, 5100 East Winnemucca Blvd, Winnemucca, Nevada 89445–2921.

BLM-State Office, 1340 Financial Blvd., Reno, Nevada 89520–0006.

The map may also be viewed on the Winnemucca Field Office website at: *www.nv.blm.gov/winnemucca.* In

addition, notice of this closure will be posted at the primary access points within the area to which the closure applies.

**FOR FURTHER INFORMATION CONTACT:** Dave Lefevre, National Conservation Area Outdoor Recreation Planner, Bureau of Land Management, Winnemucca Field Office, 5100 E Winnemucca Blvd, Winnemucca, NV 89445, telephone: (775) 623–1500 or e-mail at *Dave_Lefevre@blm.gov*.

**SUPPLEMENTARY INFORMATION:** The following Public Lands are closed to public use: Public land areas north of the Union Pacific Railroad tracks, and east of State Highway 34 and County Road 200, and west of the Pahute Peak and Black Rock Desert wilderness boundaries within the following legally described areas are included in the closure:

T33.5N, R24E sec. 25–28, 32–36; T33N R24E secs., 1–5, 8–22, 23 ,27–30; T33N, R25E sec. 2,3,4,9; T34N, R24E sec. 1–3, 10–15, 21–27, 34–36; T34N, R25E sec.1–4, 9–16, 21–28, 33–36; T34N, R26E sec. 1–24, 28–33; T34N, R27E sec. 1–18; T35.5N, R25E sec. 27–34; T35.5N, R26E sec. 25–36; T35N, R24E sec. 6,13, 22–27, 34–36; T35N, R25E sec. 1–4,9–16, 21–28, 33–36; All of T35N, R26E; All of T35N R27E; T36N R23.5E sec. 1; T36N, R24E sec. 5, 6, 8, 17, 30; T36N, R25E sec. 1–5, 8–18, 21–36; All of T36N, R26E; T36N, R27E sec. 4–9, 16–21, 28–33; T37N, R23.5E sec. 36; T37N, R24E sec. 11, 14, 23, 24, 30; T37N, R25E sec. 7, 22–27, 34–36; T37N, R26E sec. 19–36; T37N, R27E sec. 19–21, 28–33; T38N, R23E sec. 22.

**Penalty**

Any person failing to comply with the closure orders may be subject to imprisonment for not more than 12 months, or a fine in accordance with the applicable provisions of 18 U.S.C. 3571, or both.

**Authority:** 43 CFR 8364.1.

**Terry A. Reed,**

*Field Manager.*

[FR Doc. 04–11718 Filed 5–24–04; 8:45 am]

BILLING CODE 4310–HC–P

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[NV–030–5700–BX; Closure Notice No. NV–030–04–002]**

### Notice of Temporary Closure of Public Lands: Washoe County, NV

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice to the public of temporary closure on public lands administered by the Bureau of Land Management, Carson City Field Office, Nevada.

**SUMMARY:** Pursuant to 43 CFR 8364.1 notice is hereby given that certain public lands will be temporarily closed to all public use located in Washoe County, Nevada. This action is being taken to provide for public safety during the 2004 Pylon Racing Seminar and 2004 Reno National Championship Air Races.

**DATES:** Closure to all public use from June 17 through June 20, 2004, and September 12 through September 19, 2004 (24 hrs. a day).

**ADDRESSES:** A map showing these temporary closures, restrictions, and prohibitions is available from the following BLM office:

Carson City Field Office, 5665 Morgan Mill Road, Carson City, Nevada 89701.

**FOR FURTHER INFORMATION CONTACT:** Charles P. Pope, Assistant Manager, Nonrenewable Resources, Carson City Field Office, 5665 Morgan Mill Road, Carson City, Nevada 89701. Telephone (775) 885–6000.

**SUPPLEMENTARY INFORMATION:** This closure applies to all public use, including pedestrian use and vehicles.

The public lands affected by this closure are described as follows:

**Mt. Diablo Meridian**

T. 21 N., R. 19 E.,
Sec. 8, N½NE¼, SE¼NE¼ and E½SE¼;
Sec. 16, N½ and SW¼.

Aggregating approximately 680 acres.

The above restrictions do not apply to emergency or law enforcement personnel or event officials. Persons who violate this closure order are subject to arrest and, upon conviction, may be fined not more than $1,000 and/or imprisoned for not more than 12 months.

**Authority:** 43 CFR 8364.1.

Dated: April 6, 2004.

**Bryant Smith,**

*Acting Assistant Manager, Nonrenewable Resources, Carson City Field Office.*

[FR Doc. 04–11728 Filed 5–24–04; 8:45 am]

BILLING CODE 4310–HC–P

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[CO–921–04–1320–EL; COC 67011]**

### Notice of Coal Lease Offering by Sealed Bid; COC 67011

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of competitive coal lease sale.

**SUMMARY:** Bureau of Land Management, Colorado State Office, Lakewood, Colorado, hereby gives notice that certain coal resources in the lands hereinafter described in Gunnison County, Colorado, will be offered for competitive lease by sealed bid in accordance with the provisions of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 181 *et seq.*).

**DATES:** The lease sale will be held at 11 a.m., Thursday, July 1, 2004. Sealed bids must be submitted no later than 10 a.m., Thursday, July 1, 2004.

**ADDRESSES:** The lease sale will be held in the Conference Room, Fourth Floor, Colorado State Office, 2850 Youngfield Street, Lakewood, Colorado. Sealed bids must be submitted to the Cashier, Colorado State Office, 2850 Youngfield Street, Lakewood, Colorado 80215.

**FOR FURTHER INFORMATION CONTACT:** Karen Purvis at 303–239–3795.

**SUPPLEMENTARY INFORMATION:** The tract will be leased to the qualified bidder submitting the highest offer, provided that the high bid meets the fair market value determination of the coal resource. The minimum bid for this tract is $100 per acre or fraction thereof. No bid less than $100 per acre or fraction thereof will be considered. The minimum bid is not intended to represent fair market value.

Sealed bids received after the time specified above will not be considered.

In the event identical high sealed bids are received, the tying high bidders will be requested to submit follow-up bids until a high bid is received. All tie-breaking sealed bids must be submitted within 15 minutes following the Sale Official's announcement at the sale that identical high bids have been received.

Fair market value will be determined by the authorized officer after the sale.

*Coal Offered:* The coal resource offered is limited to coal recoverable by underground mining methods in the B seam in the following lands:

T. 13 S., R. 90 W., 6th P.M.
Sec. 12, lots 8 to 10, inclusive;
Sec. 13, lots 2 to 7, inclusive, and lots 10 to 15, inclusive.
Sec. 24, lots 4 and 5.

Contains approximately 690.95 acres.

Total recoverable reserves are estimated to be 2.3 million tons. The underground minable coal in the B seam is ranked as high volatile B bituminous coal. The estimated coal quality on an as-received basis is as follows:

Btu—12,136 Btu/lb.
Moisture—5.52%
Sulfur Content—0.60%
Ash Content—12.20%

*Rental and Royalty:* The lease issued as a result of this offering will provide for payment of an annual rental of $3.00 per acre or fraction thereof and a royalty payable to the United States of 8 percent of the value of coal mined by underground methods. The value of the coal will be determined in accordance with 30 CFR 206.

*Notice of Availability:* Bidding instructions for the offered tract are included in the Detailed Statement of Coal Lease Sale. Copies of the statement and the proposed coal lease are available upon request in person or by mail from the Colorado State Office at the address given above. The case file is available for inspection in the Public Room, Colorado State Office, during normal business hours at the address given above.

Dated: March 24, 2004.

**Karen Purvis,**

*Solid Minerals Staff, Division of Energy, Lands and Minerals.*

[FR Doc. 04–11723 Filed 5–24–04; 8:45 am]

BILLING CODE 4310–JB–P

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[CO–921–04–1320–EL; COC 67664]**

### Notice of Invitation for Coal Exploration License Application, Colowyo Coal Company L.P. COC 67664; Colorado

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of invitation for coal exploration license application.

**SUMMARY:** Pursuant to the Mineral Leasing Act of February 25, 1920, as amended, and to Title 43, Code of Federal Regulations, Subpart 3410, members of the public are hereby invited to participate with Colowyo Coal Company L.P. in a program for the exploration of unleased coal deposits owned by the United States of America containing approximately 4,509.89 acres in Moffat County, Colorado.

**DATES:** Written Notice of Intent to Participate should be addressed to the attention of the following persons and must be received by June 24, 2004.

**ADDRESSES:** Karen Purvis, CO–921, Solid Minerals Staff, Division of Energy, Lands and Minerals, Colorado State Office, Bureau of Land Management, 2850 Youngfield Street, Lakewood, Colorado 80215; and Juan Garcia, Project Manager, Colowyo Coal Company L.P., 5731 State Highway 13, Meeker, Colorado 81641.

**SUPPLEMENTARY INFORMATION:** The application for coal exploration license is available for public inspection during normal business hours under serial number COC 67664 at the Bureau of Land Management, Colorado State Office, 2850 Youngfield Street, Lakewood, Colorado 80215, and at the Little Snake Field Office, 455 Emerson St., Craig, Colorado 81625. Any party electing to participate in this program must share all costs on a pro rata basis with Colowyo Coal Company L.P. and with any other party or parties who elect to participate.

Dated: April 14, 2004.

**Karen Purvis,**

*Solid Minerals Staff, Division of Energy, Lands and Minerals.*

[FR Doc. 04–11724 Filed 5–24–04; 8:45 am]

BILLING CODE 4310–JB–P

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[NV–910–04–1990–EX]**

### Notice of Intent To Prepare an Environmental Impact Statement on a Plan of Operations for the Newmont Mining Corporation Emigrant Mine Project in Elko County, NV; and Notice of Scoping Period and Public Meeting

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of Intent.

**SUMMARY:** In accordance with section 102(2)(c) of the National Environmental Policy Act of 1969 and 43 CFR part 3809, the Bureau of Land Management Elko Field Office will be directing the preparation of an EIS by a third-party contractor on the potential impacts of a proposed Plan of Operations for gold mining by Newmont Mining Corporation in Elko County, Nevada. The project encompasses approximately 1,172 acres of public land.

**DATES:** This Notice initiates the 30-day public scoping period. Within 30 days of the publication of this Notice, a public scoping meeting will be held at the BLM Elko Field Office, 3900 East Idaho Street, Elko, Nevada, to familiarize interested publics with the project and to identify issues and concerns to be addressed in the EIS. The scoping meeting will be announced through the local news media, newsletters, and the BLM Web site at *www.nv.blm.gov/Elko* at least 15 days prior to the event. Any additional public meetings, if necessary, will be announced similarly. Comments on issues can also be submitted in writing to the address listed below and for 30 days after publication of this Notice in the **Federal Register**. In addition to the ongoing public participation process, formal opportunities for public participation will be provided upon publication of the BLM Draft EIS.

**ADDRESSES:** You may submit comments by any of the following methods:

—E-mail: *tschmidt@nv.blm.gov.*
—Fax: (775) 753–0255.
—Mail: Send to the attention of the Emigrant Mine Project Manager, BLM Elko Field Office, 3900 East Idaho Street, Elko, NV 89801.

Comments, including names and street addresses of respondents, will be available for public review at the above address during regular business hours 7:30 a.m. to 4:30 p.m., Monday through Friday, except holidays, and may be published as part of the EIS. Individual respondents may request confidentiality. If you wish to withhold your name or street address from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your written comment. However, we will not consider anonymous comments. Such requests will be honored to the extent allowed by law. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be available for public inspection in their entirety.

**FOR FURTHER INFORMATION CONTACT:** Tom Schmidt, Project Manager at the Elko Field Office, 3900 E. Idaho Street, Elko, NV 89801. Telephone: (775) 753–0200. Email: *tschmidt@nv.blm.gov.*

**SUPPLEMENTARY INFORMATION:** The Newmont Mining Corporation has submitted a Plan of Operations to open the Emigrant Mine about ten miles south of Carlin, Nevada. The mine and associated facilities would be located in portions of Sections 24, 26, 34, 36 of T. 32 N., R. 53 E.; and Sections 1, 2, 3, 11, 12, T. 31 N., R 53 E. The proposed Emigrant Mine would include developing and operating an open pit mine; constructing a waste rock disposal facility, storing oxide waste in mined

out areas of the pit; developing an oxide heap leach pad; constructing ancillary facilities; temporarily rerouting intermittent stream and flows in the pit area; and concurrent reclamation. Proposed mining operations would last for approximately 9 years through the year 2013. Approximately 1172 acres of public land and 260 acres of private land would be disturbed.

The issues expected to be analyzed in the EIS include potential impacts to wildlife and cultural resources; the potential for waste rock, heap leach, and pit walls to produce acid rock drainage or heavy metals; and diversion of an unnamed drainage. Cumulative impacts will also be addressed. In addition, the following resources will be analyzed: geology and minerals, Native American religious concerns, air quality, paleontology, lands and realty, fisheries and aquatic resources, range management, vegetation, soils, visual resources, recreation and wilderness, weeds, social and economic values, environmental justice, and threatened, endangered, candidate, and sensitive resources.

A range of alternatives (including, but not limited to, alternative reclamation measures and the no-action alternative) will be developed to address the issues. Mitigating measures will be considered to minimize environmental impacts and to assure the proposed action does not result in undue or unnecessary degradation of public lands. Federal, state and local agencies and other individuals or organizations who may be interested in or affected by BLM's decision on Emigrant Mine Plan of Operations are invited to participate in the scoping process with respect to this EIS.

**Authority:** 43 CFR Part 3809.

Dated: March 9, 2004.

**Helen Hankins,**

*Field Office Manager.*

[FR Doc. 04–11720 Filed 5–24–04; 8:45 am]

BILLING CODE 4310–HC–P

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[MT–060–01–1020–PG]**

### Notice of Public Meeting; Central Montana Resource Advisory Council

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of Public Meeting.

**SUMMARY:** In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM) Central Montana Resource Advisory Council (RAC) will meet as indicated below.

**DATES:** The meeting will be held June 16 & 17, 2004, at the Great Northern Hotel in Malta, Montana. The June 16 meeting will begin at 1 p.m. with a 60-minute public comment period and will adjourn at 6 p.m. The June 17 meeting will begin at 8 a.m. with a 30-minute public comment period and will adjourn at 3 p.m.

**SUPPLEMENTARY INFORMATION:** This 15-member council advises the Secretary of the Interior on a variety of management issues associated with public lands in Montana. At this meeting the council will discuss:

The Blackleaf EIS scoping meetings;

The visitor use services category in the Monument RMP;

The definition of a road used in the Monument RMP;

The recent joint RAC meeting held in Phoenix;

The Region 6 prairie dog management guidelines; and

Field manager updates (time permitting).

All meetings are open to the public. The public may present written comments to the RAC. Each formal RAC meeting will also have time allocated for hearing public comments (as detailed above). Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited.

**FOR FURTHER INFORMATION CONTACT:** Dave Mari, Lewistown Field Manager, Lewistown Field Office, Airport Road, Lewistown, Montana 59457, 406/538–7461.

Dated: May 19, 2004.

**David L. Mari,**

*Lewistown Field Manager.*

[FR Doc. 04–11812 Filed 5–24–04; 8:45 am]

BILLING CODE 4310–$$–P

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[OR–056–04–1430–ES; GP4–0151]**

### Termination of Classification and Order Providing for Opening of Land, OR 40119

**AGENCY:** Bureau of Land Management (BLM), Interior.

**ACTION:** Notice.

**SUMMARY:** This notice terminates the existing classification in its entirety for public lands that were classified as suitable for lease/disposal pursuant to the Recreation and Public Purposes Act of June 14, 1926 (44 Stat. 741), as amended, and opens 20.00 acres of land to surface entry, and mining, subject to the existing laws, rules, and regulations applicable to public lands administered by the Bureau of Land Management. The land has been and will remain open to mineral leasing.

**DATES:** *Effective Date:* May 25, 2004.

**FOR FURTHER INFORMATION CONTACT:** Phyllis Gregory, BLM, Oregon/Washington State Office, P.O. Box 2965, Portland, OR 97208, 503–808–6188.

**SUPPLEMENTARY INFORMATION:** On April 23, 1987, 20.00 acres of public land under the jurisdiction of the Bureau of Land Management were classified as suitable for lease pursuant to the Recreation and Public Purposes Act of June 14, 1926 (44 Stat. 741), as amended, and the regulations at 43 CFR part 2400. Upon classification the land was leased to the LaPine Rodeo Association for the construction, operation, and maintenance of rodeo grounds and facilities for a term of 10 years under BLM Serial Number OR 40119. On June 25, 1997, this lease expired.

The formerly leased land is described as follows:

**Willamette Meridian, Oregon**

T. 23 S., R. 10 E.,

Sec. 3, SE¼ SE¼.

The area described contains 20.00 acres in Klamath County, Oregon.

At 8:30 a.m., on June 24, 2004, the land will be opened to operation of the public land laws generally, but not to location or entry, subject to valid existing rights, the provisions of existing withdrawals, and the requirements of applicable law. All valid existing applications received at or prior to 8:30 a.m., on June 24, 2004, will be considered as simultaneously filed at that time. Those received thereafter will be considered in the order of filing.

At 8:30 a.m., on July 9, 2004, the land will be opened to location and entry under the United States mining laws. Appropriation under the general mining laws prior to the date and time of restoration is unauthorized. Any such attempted appropriation, including attempted adverse possession under 30 U.S.C. Sec. 38, shall vest no rights against the United States. Acts required to establish a location and to initiate a right of possession are governed by State law where not in conflict with Federal law. The Bureau of Land Management will not intervene in disputes between rival locators over possessory rights

since Congress has provided for such determination in local courts.

Dated: April 9, 2004.

**Sherrie L. Reid,**

*Acting Chief, Branch of Realty and Records Services.*

[FR Doc. 04–11727 Filed 5–24–04; 8:45 am]

BILLING CODE 4310–33–P

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[WYW 88021]**

### Notice of Proposed Extension of Public Land Order No. 6581; Opportunity for Public Meeting; Wyoming

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice.

**SUMMARY:** As required by 43 CFR 2310.3–1, notice is hereby given that the Department of Housing and Urban Development (HUD) has filed an application to extend Public Land Order (PLO) No. 6581 for a 20-year period. This notice also gives an opportunity to comment on the proposed action and to request a public meeting. PLO No. 6581 will expire on January 5, 2005.

**DATES:** Comments and requests for a public meeting must be received by August 23, 2004.

**ADDRESSES:** Comments and meeting requests should be sent to the BLM Wyoming State Director, P.O. Box 1828, Cheyenne, Wyoming 82003–1828.

**FOR FURTHER INFORMATION CONTACT:** Janet Booth, BLM Wyoming State Office, 307–775–6124.

**SUPPLEMENTARY INFORMATION:** On April 14, 2004, HUD filed an application to extend PLO No. 6581. This order withdrew non-public land in which the United States may hereafter acquire interests from settlement, sale, location, or entry under the public land laws, but not the mining laws, for the purpose of protecting the equity of HUD in the development of public housing. The mineral estate of the land is owned by the State of Wyoming. The withdrawal comprises approximately 5.55 acres as described below:

**Sixth Principal Meridian**

A tract of land, being a portion of Parcel A, Township 50 and 51 North, Range 82 West, 6th P.M., Johnson County, Wyoming, being further described as follows: Commencing at an existing brass cap which marks the center of Section 34, Township 51 North, Range 82 West, 6th P.M., in Johnson County, Wyoming; thence S. 00°28′00″E. a distance of 79.03 feet to an aluminum capped rebar stamped LS 2335, said aluminum capped rebar being the true point of beginning; thence N. 89°58′15″E. a distance of 331.71 feet to an aluminum capped rebar stamped LS 2335; thence S. 18°59′05″E. a distance of 181.79 feet to an aluminum capped rebar stamped LS 2335; thence S. 79°29′04″E. a distance of 122.52 feet to an aluminum capped rebar stamped LS 2335; thence S. 00°28′00″E. a distance of 328.52 feet to an existing iron pipe; thence S. 89°01′06″W. a distance of 209.65 feet to an existing iron pipe; thence S. 89°04′17″W. a distance of 300.09 feet to an existing iron pipe; thence N. 00°28′00″W. a distance of 531.06 feet to the true point of beginning.

For a period of 90 days from the date of publication of this notice, all persons who wish to submit comments, suggestions, or objections in connection with the proposed extension may present their views in writing to the undersigned officer of the BLM.

Comments, including names and street addresses of respondents, will be available for public review at the BLM Wyoming State Office, 5353 Yellowstone Rd., Cheyenne, Wyoming, during regular business hours 9 a.m. to 4 p.m. Monday through Friday, except holidays. Individual respondents may request confidentiality. If you wish to withhold your name or address from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your comments. Such requests will be honored to the extent allowed by law. BLM will not consider anonymous comments. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public inspection in their entirety.

Notice is hereby given that an opportunity for a public meeting is afforded in connection with the proposed extension. All interested persons who desire a public meeting for the purpose of being heard on the proposed extension should submit a written request to the BLM Wyoming State Director within 90 days from the date of publication of this notice. If the authorized officer determines that a public meeting will be held, a notice of the time and place will be published in the **Federal Register** at least 30 days before the scheduled date of the meeting.

This extension will be processed in accordance with the regulations set forth in 43 CFR 2310.4.

Dated: April 22, 2004.

**Melvin Schlagel,**

*Realty Officer.*

[FR Doc. 04–11726 Filed 5–24–04; 8:45 am]

BILLING CODE 4210–33–P

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[NM–070–1430–ES; NMNM111110]**

### Notice of Realty Action—Recreation and Public Purpose (R&PP) Lease/Patent of Public Land in San Juan County, NM; Act Classification, New Mexico

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of realty action.

**SUMMARY:** The following described public land is determined suitable for classification for leasing and patenting to the City of Bloomfield, Bloomfield, New Mexico under the provisions of the R&PP Act, as amended (43 U.S.C. 869 et seq.). The City of Bloomfield proposes to use the land for a fire station/water loading facility and park facilities.

**New Mexico Principal Meridian**

T. 29 N., R. 11 W.,
Sec. 3: (S½S½NW¼NE¼, S½S½SW¼NE¼NE¼;) portion of lot 5;
Containing 12.5 acres, more or less.

*Comment Dates:* On or before July 9, 2004, interested parties may submit comments regarding the proposed leasing and conveyance, or classification of the lands to the Bureau of Land Management (BLM) at the following address. Any adverse comments will be reviewed by the BLM, Farmington Field Manager, 1235 La Plata Highway, Suite A, Farmington, NM 87401, who may sustain, vacate, or modify this realty action. In the absence of any adverse comments, this realty action becomes the final determination of the Department of the Interior and effective on July 26, 2004.

**FOR FURTHER INFORMATION CONTACT:** Information related to this action, including the environmental assessment, is available for review at the BLM, Farmington Field Office, 1235 La Plata Highway, Suite A, Farmington, NM 87401.

**SUPPLEMENTARY INFORMATION:** Publication of this notice segregates the public land described above from all other forms of appropriation under the public land laws, including the general mining laws, except for leasing and conveyance under the R&PP Act and leasing under the mineral leasing laws for a period of two (2) years from the

date of this publication in the **Federal Register**. The segregative affect will terminate upon issuance of the lease and patent to the City of Bloomfield, or two (2) years from the date of this publication, whichever occurs first. The lease, when issued, will be subject to the following terms:

1. Provisions of the R&PP Act and to all applicable regulations of the Secretary of the Interior.

2. Provisions of the Resource Conservation and Recovery Act of 1976 (RCAA) as amended, 42 U.S.C. 6901–6987 and the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA) as amended, 42 U.S.C. 9601 and all applicable regulations.

3. Provisions of Title VI of the Civil Rights Act of 1964.

4. Provisions that the lease be operated in compliance with the approved Development Plan.

The patent, when issued, will be subject to the following terms:

1. Reservation to the United States of a right-of-way for ditches and canals in accordance with 43 U.S.C. 945.

2. Reservation to the United States of all minerals.

3. All valid existing rights, e.g. rights-of-way and leases of record.

4. Provisions that if the patentee or its successor attempts to transfer title to or control over the land to another or the land is devoted to a use other than that for which the land was conveyed, without the consent of the Secretary of the Interior or his delegate, or prohibits or restricts, directly or indirectly, or permits its agents, employees, contractors, or subcontractors, including without limitation, lessees sub-lessees and permittees, to prohibit or restrict, directly or indirectly, the use of any part of the patented lands or any of the facilities whereon by any person because of such person's race, creed, color, or national origin, title shall revert to the United States.

The lands are not needed for Federal purposes. Leasing and later patenting is consistent with current Bureau of Land Management policies and land use planning. The estimated intended time of lease issuance is August 15, 2004, with the patent being issued upon substantial development taking place. The proposal serves the public interest since it would provide a fire station/water loading facility and park facilities.

Dated: May 11, 2004.

**Ray Sanchez,**

*Acting Assistant Field Manager.*

[FR Doc. 04–11721 Filed 5–24–04; 8:45 am]

BILLING CODE 4310–VB–P

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[OR–102–04–5870–EU; HAG4–0099]**

### Direct Sale of Public Lands, OR 59372

**AGENCY:** Bureau of Land Management (BLM), Roseburg District.

**ACTION:** Notice of realty action.

**SUMMARY:** A 0.08-acre parcel in Douglas County, Oregon, is being considered for direct sale to Douglas County as part of the road widening project for State Highway 99. The parcel is the minimum size possible which still ensures that the County has all the land it needs to complete its project. The parcel proposed for sale is identified as suitable for disposal in the Roseburg District Resource Management Plan, June 2, 1995.

**DATES:** Submit comments on or before July 9, 2004.

**ADDRESSES:** Address all written comments concerning this notice to Glenn W. Lahti, Acting Field Manager, Swiftwater Field Office, 777 NW. Garden Valley Blvd., Roseburg, Oregon 97470.

**FOR FURTHER INFORMATION CONTACT:** Mary Johnson, District Realty Specialist at (541) 464–3276.

**SUPPLEMENTARY INFORMATION:** The following described public land in Douglas 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). The parcel proposed for sale is identified as follows:

**Willamette Meridian, Oregon**

T. 25 S., R. 5 W.,
Parcel B, in DLC 52.

The area described contains 0.08 acre, more or less. Said legal description is subject to final approval and acceptance of a Cadastral Survey. This parcel will be sold at no less than the appraised market value, which has been determined to be $7,254.

In accordance with 43 CFR 2710.0–6(c)(3)(iii) direct sale procedures are appropriate since the land is needed for a public purpose.

Douglas County will be allowed 30 days from receipt of a written offer to submit a deposit of at least 20 percent of the appraised market value of the parcel, and within 180 days thereafter to submit the balance.

The following rights, reservations, and conditions will be included in the Deed conveying the land:

1. A reservation to the United States for a right-of-way for ditches and canals constructed by the authority of the United States. Act of August 30, 1890 (43 U.S.C. 945).

2. The Deed would also include a notice and indemnification statement under the Comprehensive Environmental Response, Compensation and Liability Act (42 U.S.C. 9620) holding the United States harmless from any release of hazardous materials that may have occurred as a result of the unauthorized use of the property by other parties.

The mineral interests being offered for conveyance have no known value. Acceptance of the direct sale offer constitutes an application for conveyance of the mineral interests also being offered under the authority of Section 209(b) of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1719). In addition to the full purchase price, a nonrefundable fee of $50 will be required for purchase of the mineral interests to be conveyed simultaneously with the sale of the land.

The land described is 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.

Detailed information concerning this land sale, including the reservations, sale procedures and conditions, planning and environmental documents, and mineral report is available for review at the Roseburg District Office, Bureau of Land Management, 777 NW. Garden Valley Blvd., Roseburg, Oregon 97470.

In the absence of any objections, this proposal will become the final determination of the Department of the Interior.

Comments, including names, street addresses, and other contact information of respondents, will be available for public review. Individual respondents may request confidentiality. If you wish to request that BLM consider withholding your name, street address and other contact information (such as: Internet address, fax or phone number) from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your written comment. BLM will honor requests for confidentiality on a case-by-case basis to the extent allowed by law. BLM will make available for public inspection in their entirety all submissions from organizations and businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses.

(Authority: 43 CFR 2711.1–2 (a)).

Dated: March 12, 2004.

**Glenn W. Lahti,**

*Acting Field Manager, Swiftwater Field Office.*

[FR Doc. 04–11732 Filed 5–24–04; 8:45 am]

BILLING CODE 4310–33–P

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[OR–014–01–1430–EU; GP–04–0066]**

### Realty Action: Modified Competitive Sale of Public Lands in Klamath County, OR

**AGENCY:** Bureau of Land Management (BLM), Interior.

**ACTION:** Notice of realty action.

**SUMMARY:** The following described public land in Klamath 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. The parcel proposed for sale is identified as suitable for disposal in the Klamath Falls Resource Area Resource Management Plan, June 2, 1995.

The parcel proposed for sale is identified as follows:

**Willamette Meridian,**

T. 41 S., R. 13 E.
Sec. 14, NE1/4NW1/4.
The area described contains 40 acres.

**DATES:** On or before July 9, 2004, interested persons may submit written comments. Objections will be reviewed by the Lakeview District Manager who may sustain, vacate, or modify this realty action. In the absence of any objections, this proposal will become the final determination of the Department of the Interior.

**ADDRESSES:** Written comments should be submitted to Jon Raby, Klamath Falls Resource Area Field Manager, Klamath Falls Field Office, 2795 Anderson Ave. Building 25, Klamath Falls, Oregon 97603. Electronic format submittal is not acceptable.

**FOR FURTHER INFORMATION CONTACT:** Detailed information concerning this land sale, including the reservations, sale procedures and conditions, appraisal, planning and environmental documents, is available from Linda Younger, Realty Specialist, at the above address, phone (541) 883–6916.

**SUPPLEMENTARY INFORMATION:** The area described contains 40 acres, more or less, in Klamath County, Oregon. The appraised market value for this parcel has been determined to be $3,600.00.

The land is being considered for a modified competitive sale. There is no legal access for BLM or members of the public. This land is difficult and uneconomic to manage as a part of the public lands and is not suitable for management by another Federal agency. No significant resource values will be affected by this disposal.

In accordance with 43 CFR 2711.3–2, Public lands may be offered for sale utilizing modified competitive bidding procedures when the authorized officer determines it is necessary in order to assure equitable distribution of land among purchasers or to recognize equitable considerations or public policies. Modified competitive bidding includes but is not limited to: Offering to designated bidder (Mr. Al Bruner of A.L. Bruner enterprises) the right to meet the highest bid. Mr. Bruner is the adjacent land owner and his land completely surrounds the 40-acre parcel on all four sides. Refusal or failure to meet the highest bid shall constitute a waiver of such bidding provisions.

The winning bidder will be allowed 30 days from receipt of a written offer to submit a deposit of at least 20 percent of the appraised market value of the parcel, and 180 days thereafter to submit the balance.

The following rights, reservations, and conditions will be included in the patent conveying the land:

1. A reservation to the United States for a right-of-way for ditches and canals constructed by the authority of the United States. Act of August 30, 1890 (43 U.S.C. 945).

2. A reservation to the United States for all oil, gas and geothermal resources in the land in accordance with Section 209 of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1719).

3. Patents will be issued subject to all valid existing rights and reservations of record.

4. The patent would also include a notice and indemnification statement under the Comprehensive Environmental Response, Compensation and Liability Act (42 U.S.C. 9620) holding the United States harmless from any release of hazardous materials that may have occurred as a result of the unauthorized use of the property by other parties.

The mineral interests being offered for conveyance have no known value. The successful bidder of modified competitive sale offer constitutes an application for conveyance of the mineral interest, with the exception of all leaseables, including oil, gas and geothermal interests, which will be reserved to the United States in accordance with Section 209 of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1719). In addition to the full purchase price, a nonrefundable fee of $50 will be required for purchase of the mineral interests to be conveyed simultaneously with the sale of the land.

The land described is segregated from appropriation under the public land laws, including the mining laws, with the exception of sales under the above cited statues, pending disposition of this action or 270 days from the date of publication of this notice, whichever occurs first.

Comments, including names, street addresses, and other contact information of respondents, will be available for public review. Individual respondents may request confidentiality. If you wish to request that BLM consider withholding your name, street address, and other contact information (such as: Internet address, FAX or phone number) from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your comment. BLM will honor requests for confidentiality on a case-by-case basis to the extent allowed by law. Anonymous comments will not be accepted. BLM will make available for public inspection in their entirety all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses.

Dated: February 4, 2004.

**Jon Raby,**

*Field Manager, Klamath Falls Resource Area.*

[FR Doc. 04–11733 Filed 5–24–04; 8:45 am]

BILLING CODE 4310–33–P

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[WY–100–22; WYW–158906]**

### Notice of Realty Action; Agricultural Lease of Public Lands, Wyoming

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of Realty Action, Agricultural Lease of Public Lands in Sublette County.

**SUMMARY:** The Bureau of Land Management has determined that the land described below is suitable for agricultural lease under Section 302 of the Federal Land Policy and

Management Act of 1976, 43 U.S.C. 1732.

**Sixth Principal Meridian**

T.30 N., R. 112 W., section 18, NE¼SE¼.

These lands contain 6.90 acres.

**FOR FURTHER INFORMATION CONTACT:** Priscilla Mecham, Field Manager, Bureau of Land Management, Pinedale Resource Area, P.O. Box 768, Pinedale, WY 82941, 307–367–5300. The casefile may be reviewed at the Pinedale Resource Area office.

**SUPPLEMENTARY INFORMATION:** The Bureau of Land Management proposes to lease the above described land for haying purposes for a 3-year period on a non-competitive land use permit.

Interested parties may submit comments to the Bureau of Land Management, Field Manager, Pinedale, P.O. Box 768, Pinedale, Wyoming 82941 until [*July 9, 2004.*] Any adverse comments will be evaluated by the State Director who may sustain, vacate, or modify this realty action. In the absence of any objections, this proposed realty action will become effective on *[July 26, 2004.]*

**Authority:** 43 U.S.C. 1712(f) and 43 CFR 2920.4(c)

Dated: February 4, 2004.

**Priscilla Mecham,**

*Field Manager.*

[FR Doc. 04–11722 Filed 5–24–04; 8:45 am]

**BILLING CODE 4310–22–M**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[ID–077–1220–MA]**

### Notice of Temporary Restriction of the Use of Public Lands in the Area Known as Castle Rocks State Park and Castle Rocks Inter-Agency Recreation Area Near Almo, ID

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of temporary restriction.

**SUMMARY:** The Bureau of Land Management announces temporary restriction of use of certain public lands in Cassia County. This closure will prohibit bolting and placement of fixed anchors to rocks, and overnight camping. The BLM intends to take this action to allow time for analysis of a fixed anchor management plan.

**DATES:** This closure will take effect on June 1, 2004 and shall remain in effect until June 1, 2005.

*The Legal Land Descriptions for the Closure are as Follows:* The public lands affected by this closure are all lands administered by the BLM within Section 08 of Township 15 South, Range 24 East, Boise Meridian. This area is known as Castle Rocks State Park and Castle Rocks Inter-Agency Recreation Area. The area covers approximately 320 acres of BLM land. A closure notice including time periods will be posted near the entry point at the Castle Rocks Ranch House.

*Exceptions To this Order are Granted To the Following:* No exceptions.

**EFFECTIVE DATE:** This closure is effective June 1, 2004 and shall remain effective until June 1, 2005.

**FOR FURTHER INFORMATION, CONTACT:** Dennis Thompson, Burley Field Office, 200 South 15 East, Burley, ID. 83318. Telephone (208) 677–6641. A Map of the closure area is available from the Burley BLM Office.

**SUPPLEMENTARY INFORMATION:** The authority for this closure is found under 43 CFR 8364.1. Any person who violates this closure may be subject to the penalties provided in Sec. 8360.0–7 of this title. Any person who violates this closure may be tried before a United States Magistrate and fined no more than $1,000 or imprisoned for no more than 12 months, or both. Such violations may also be subject to the enhanced fines provided for by 18 U.S.C. 3571.

Dated: April 5, 2004.

**Wendy Reynolds,**

*Burley Field Manager.*

[FR Doc. 04–11729 Filed 5–24–04; 8:45 am]

**BILLING CODE 4310–66–P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

## DEPARTMENT OF AGRICULTURE

### Forest Service

**[WO–230–04–1150–PG]**

### Joint Counterpart Endangered Species Act Section 7 Consultation Regulations; Bureau of Land Management and Forest Service Alternative Consultation Agreements With U.S. Fish and Wildlife Service and National Oceanic and Atmospheric Administration Fisheries

**AGENCY:** Bureau of Land Management, Interior. Forest Service, Agriculture.

**ACTION:** Notice of availability.

**SUMMARY:** The U.S. Fish and Wildlife Service (FWS) and National Oceanic and Atmospheric Administration Fisheries (NOAA Fisheries) (referred to as the Services), the Bureau of Land Management (BLM) and Forest Service (FS) have approved Alternative Consultation Agreements pursuant to the joint counterpart regulations for consultation under section 7 of the Endangered Species Act (ESA) to streamline consultation on proposed projects that support the National Fire Plan (NFP).

**DATES:** The BLM and FS Alternative Consultation Agreements with U.S. Fish and Wildlife Service and National Marine Fisheries Service are available on the BLM and FS Web sites.

**ADDRESSES:** Information on the Alternative Consultation Agreements is available electronically through the Internet sites (*http://www.blm.gov* or *http://www.fs.fed.us.* ), or from the BLM, 1849 C Street, NW., LSB–204, Washington, DC 20240 or from the FS, Mail Stop 1121, 1400 Independence Avenue, Washington, DC 20250.

**FOR FURTHER INFORMATION CONTACT:** Peggy Olwell, Bureau of Land Management, Endangered Species Program Lead, 202–452–7764, or *peggy_olwell@blm.gov* or Marc Bosch, U.S. Forest Service, Endangered Species Program Leader, 202–205–1220, or *mbosch@fs.fed.us.*

**SUPPLEMENTARY INFORMATION:** The counterpart regulations, authorized by 50 CFR 402.04, complement the consultation process by providing an alternative process for completing section 7 consultation for projects that authorize, fund, or carry out actions that support the NFP. The Counterpart Regulations eliminate the need to conduct informal consultations and obtain written concurrence from the Services for those NFP actions that the BLM or FS determines are "not likely to adversely affect" (NLAA) listed species or designated critical habitat.

The final rule for the counterpart regulations was published in the **Federal Register** on December 8, 2003, and became effective on January 7, 2004. Implementation of the counterpart regulations requires BLM and FS to develop and sign an Alternative Consultation Agreement (ACA) with the Services, and to jointly develop a training program, based on the needs of the agency. The BLM and the FS signed separate ACAs with the Services on March 3, 2004. The interagency training program is being developed by BLM, FS, FWS, and NOAA and will be available for agency staff by May, 2004.

The regulations require that the ACA and related oversight or monitoring reports be made available to the public through a **Federal Register** notice of availability. The ACA for the Bureau of

Land Management is available on BLM's Web site at: *http://www.blm.gov/nhp/text/index.html*. The Forest Service ACA is available on the Forest Service's Web site at *http://www.fs.fed.us*.

Dated: April 8, 2004.

**Jim Gladen,**

*Director, Watershed, Fisheries and Wildlife Staff, USDA Forest Service.*

Dated: April 21, 2004.

**Thomas H. Dyer,**

*Deputy Assistant Director, Renewable Resources and Planning, Bureau of Land Management.*

[FR Doc. 04–11730 Filed 5–24–04; 8:45 am]

BILLING CODE 4310–84–P

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[CA–170]**

### Notice of Intent To Prepare a Proposed Resource Management Plan Amendment and Associated Environmental Assessment for the Bureau of Land Management (BLM), Bishop Field Office, Located in Eastern California

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of intent.

**SUMMARY:** This document provides notice that the BLM intends to prepare a Proposed Resource Management Plan (RMP) Amendment and associated Environmental Assessment for the Bishop Field Office, located in eastern California. The Bishop Field Office manages approximately 750,000 acres of public lands, with its headquarters located in Bishop, California. An amendment to the existing 1993 RMP is needed to update Land Use Plan decisions to comply with new national direction for the National Fire Plan/Comprehensive Strategy and BLM directives.

The Proposed RMP Amendment and EA would fulfill the needs and obligations set forth by the National Environmental Policy Act (NEPA), the Federal Land Policy and Management Act (FLPMA), and BLM management policies. The BLM will work collaboratively with interested parties to identify management decisions that best address local, regional, and national needs and concerns. The public scoping process will identify wildland fire and hazardous fuels management planning issues and develop planning criteria.

**DATES:** This notice initiates the public scoping process. Public comments will be accepted throughout the entire planning process, but to be most beneficial comments on the preliminary issues and suggestions for potential planning criteria should be submitted in writing to the address listed below and will be accepted for 30 days following the publication of this notice in the **Federal Register**. Public meetings will be held throughout the plan scoping and preparation period. In order to ensure local community participation and input, public meetings will be held in locations most closely affiliated with the public lands in the planning area. Probable locations include Bridgeport and Bishop, California. These public meetings are scheduled to be held the month of May 2004. Specific dates and meeting locations will be announced by BLM through news releases, direct mailings or other applicable means of public notification within 15 days of the event.

**ADDRESSES:** Scoping comments should be sent to Bill Dunkelberger, Field Office Manager, BLM—Bishop Field Office, 351 Pacu Lane, Suite 100, Bishop, California 93514. Comments will also be received via Fax at (760) 872–5050 or e-mail at *caweb170@ca.blm.gov*.

The BLM will maintain a record of public documents related to the development of the RMP amendment at the Bishop Field Office at the address listed above. Comments, including names and street addresses of respondents will be available for public review at the Bishop Field Office in Bishop, California during regular business hours, 8 a.m. to 4 p.m., Monday through Friday, excluding Federal holidays, and may be published as part of the EA. Individual respondents may request confidentiality. Individuals who wish to withhold their name or street address from public review or from disclosure under the Freedom of Information Act must state this prominently at the beginning of their written comment. Such requests will be honored to the extent allowed by law. BLM will not consider anonymous comments. All submissions from organizations and businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be available for public inspection in their entirety.

**FOR FURTHER INFORMATION CONTACT:** Dale Johnson, Fuels Specialist, BLM—Bishop Field Office, 351 Pacu Lane, Suite 100, Bishop, California 93514, (760) 872–5055 or via e-mail at *dale_f_johnson@ca.blm.gov*.

**SUPPLEMENTARY INFORMATION:** Preliminary issues and management concerns have been identified by BLM personnel in consultation with other agencies, individuals and organizations, and include: Management of special areas, health and resilience of wetland, riparian and upland ecosystems, management and protection of sensitive, rare, threatened or endangered species, community protection, firefighter safety, invasive plants, visual resources management, Native American traditions and practices, and protection of cultural resource sites.

Disciplines involved in the planning process include specialists with expertise in wildlife and fisheries management, forestry, botany and vegetation community ecology, fire/fuels management and ecology, hydrology and watershed management, archeology, lands and realty, minerals and geology, grazing management and recreation management.

**Authority:** 43 CFR 1610.5–5.

Dated: April 2, 2004.

**Bill Dunkelberger,**

*Field Office Manager, Bishop Field Office.*

[FR Doc. 04–11731 Filed 5–24–04; 8:45 am]

BILLING CODE 4310–40–P

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

[UT 040–1150–CB, 1430–ES, 1220–BA]

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of intent and notice of realty action.

**SUMMARY:** This notice is to advise the public that the Bureau of Land Management (BLM) is proposing to amend the Cedar/Beaver/Garfield/Antimony (CBGA) Resource Management Plan (RMP) affecting public lands located in the Three Peaks Area of Iron County, Utah, to create a Special Recreation Management Area (SRMA) comprising 4,966 acres. The BLM also proposes to lease or convey under the provisions of the Recreation & Public Purposes (R&PP) Act forty-five (45) acres of public land described herein to Iron County, Utah, for recreational use purposes.

**DATES:** The comment period for the proposed plan amendment and R&PP classification/application will commence with publication of this notice. Comments must be submitted on or before July 9, 2004.

**ADDRESSES:** All comments addressing the actions proposed in this notice should be sent to Todd S. Christensen,

Field Office Manager, Cedar City Field Office, 176 East DL Sargent Drive, Cedar City, Utah, 84720.

**FOR FURTHER INFORMATION CONTACT:** Todd S. Christensen, Field Office Manager, Cedar City Field Office, 176 East DL Sargent Drive, Cedar City, Utah, 84720. Existing planning documents and information are available at the above address or telephone (435) 586–2401.

**SUPPLEMENTARY INFORMATION:** Interested parties may submit comments concerning the following actions: proposed plan amendment to the Cedar/Beaver/Garfield/Antimony RMP; specific proposed use in the R&PP application and plans of development and management, anticipated impacts of the proposal, and the BLM's administrative procedure used in reaching a decision on the lease or conveyance of the public lands; and suitability of the lands identified for R&PP lease or conveyance for the stated recreational purposes. Comments on the classification of lands are restricted to whether the lands are physically suited for the use, whether the use will maximize the use or future uses, whether the use is consistent with local planning and zoning, or whether the use is consistent with State or Federal programs. All comments submitted from organizations or businesses will be made available for public inspection in their entirety. Individuals may request confidentiality with respect to their name, address, and phone number. If you wish to have your name or street address withheld from public review, or from disclosure under the Freedom of Information Act, the first line of the comment should start with the words "CONFIDENTIALITY REQUESTED" in uppercase letters in order for BLM to comply with your request. Such requests will be honored to the extent allowed by law. Comment contents will not be kept confidential. BLM will not consider anonymous comments.

The proposed amendment to the CBGA RMP would designate land about nine miles northwest of Cedar City, Utah as the Greater Three Peaks Special Recreation Management Area (GTPSRMA). The current land use plan designates these lands for unstructured recreation, but increased use of the area has resulted in user conflicts and public safety concerns. The proposed recreation area would be designated and an associated recreation management plan implemented to mitigate these concerns and increase user satisfaction in the area. Actions being proposed which are not in conformance with the CBGA RMP are: designating the GTPSRMA, delineating certain trails in the GTPSRMA for non-motorized use only, limiting mechanized and equestrian use to designated roads and trails, and prohibiting of the use of firearms within the GTPSRMA, except in a designated shooting range. The CBGA RMP would be amended to allow for these changes.

The land being considered for inclusion in the GTPSRMA includes public, state, county and any acquired private land within the established boundaries of the GTPSRMA. The public land being considered comprises 4,966 acres described as follows: Salt Lake Meridian, Utah, Township 35 South, Range 12 West, Section 1, All except the SE¼NE¼; Section 2, Lot 3, N½; Sections 3 and 10, All except patented mining claims; Sections 4 and 9, All except the Iron County Shooting Range; Sections 11 and 12, All; Section 14, NW¼, N½SW¼, N½S½SW¼; Section 15, All except the S½S½SE¼ and patented mining claims; and Section 16, Lots 2, 3, and 8 except for patented mining claims.

State and private lands located in the sections mentioned above would be incorporated into the recreation area should they be acquired in the future by the BLM or Iron County, in accordance with the SRMA objectives. All existing federal land and any land acquired by the federal government within the GTPSRMA would be retained in federal ownership, except for the R&PP lease noted above and described below. These lands would be managed in accordance with the SRMA goals and objectives and the proposed management plan for the area.

This action also constitutes a Notice of Realty Action for the Classification and Lease or Conveyance (Patent) of Public Lands for Recreation Purposes (EA# UT–040–04–24). BLM proposes to lease or convey the following public lands in Iron County under the provision of the R&PP Act, as amended, (43 U.S.C. 869 *et. seq.*) to Iron County for public recreational purposes (UTU–54574). The R&PP area would be used for a motocross track and supporting amenities and would support the recreation objectives of the area. The land to be leased and or conveyed is described as follows:

Salt Lake Meridian, Utah, Township 35 South, Range 12 West, Section 11, S½ SE¼ SW¼ SW¼; and Section 14, NE¼ NW¼ NW¼, S½ NW¼ NW¼, N½ N½ SW¼ NW¼, containing 45 acres. Following completion of an environmental assessment and upon signature of a decision record, the classification of the public lands, if found suitable for lease or conveyance, will be effective, and the process to lease or convey the public lands may be completed. Iron County proposes to use the land for the development of a motocross track, an ATV trail head, parking lots, and camping and picnicking facilities. The patent, when issued, would be subject to the following terms, conditions, and reservations: (1) Provisions of the R&PP Act and applicable regulations of the Secretary of the Interior. (2) A right-of-way for ditches and canals constructed by the authority of the United States. (3) All valid existing rights documented on the official public land records at the time of patent issuance. (4) All minerals shall be reserved to the United States, together with the right to prospect for, mine, and remove the minerals. Upon publication of this Notice in the **Federal Register**, the public lands described above are segregated from all forms of appropriation under the public land laws, including the mining laws, except for conveyance under the R&PP Act and leasing under the Mineral Leasing Act.

**Gene R. Terland,**

*Associate State Director.*

[FR Doc. 04–11719 Filed 5–24–04; 8:45 am]

**BILLING CODE 4310–DQ–P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[ES–960–1420–BJ–TRST; ES–052303, Group No. 16, Maine]**

### Eastern States: Filing of Plat of Survey

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of filing of plat of survey; Maine.

**SUMMARY:** The Bureau of Land Management (BLM) will file the plat of survey of the lands described below in the BLM-Eastern States, Springfield, Virginia, 30 calender days from the date of publication in the **Federal Register.**

**FOR FURTHER INFORMATION CONTACT:** Bureau of Land Management, 7450 Boston Boulevard, Springfield, Virginia 22153. Attn: Cadastral Survey.

**SUPPLEMENTARY INFORMATION:** This survey was requested by the Bureau of Indian Affairs.

The lands we surveyed are:

**North of Bingham's Kennebec Purchase, Somerset County, Maine**

T. 2, R. 3 (Soldiertown) and T. 2, R. 4 (Pittston Academy Grant)

The plat of survey represents the dependent resurvey and survey of lands held in trust for the Passamaquoddy

Tribe in Township 2, Range 3 (Soldiertown) and Township 2, Range 4 (Pittston Academy Grant), North of Bingham's Kennebec Purchase, Somerset County, in the state of Maine, and was accepted May 18, 2004.

We will place a copy of the plat we described in the open files. It will be available to the public as a matter of information.

If BLM receives a protest against this survey, as shown on the plat, prior to the date of the official filing, we will stay the filing pending our consideration of the protest.

We will not officially file the plat until the day after we have accepted or dismissed all protests and they have become final, including decisions on appeals.

Dated: May 18, 2004.

**Stephen D. Douglas,**

*Chief Cadastral Surveyor.*

[FR Doc. 04–11749 Filed 5–24–04; 8:45 am]

BILLING CODE 4310–GJ–P

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[ES–960–1420–BJ–TRST; ES–052302, Group No. 15, Maine]**

### Eastern States: Filing of Plat of Survey

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of filing of plat of survey; Maine.

**SUMMARY:** The Bureau of Land Management (BLM) will file the plat of survey of the lands described below in the BLM-Eastern States, Springfield, Virginia, 30 calender days from the date of publication in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Bureau of Land Management, 7450 Boston Boulevard, Springfield, Virginia 22153. Attn: Cadastral Survey.

**SUPPLEMENTARY INFORMATION:** This survey was requested by the Bureau of Indian Affairs.

The lands we surveyed are:

**North of Bingham's Kennebec Purchase, Somerset County, Maine**

T. 3, R. 3 (Alder Brook)

The plat of survey represents the dependent resurvey and survey of lands held in trust for the Passamaquoddy Tribe in Township 3, Range 3 (Alder Brook), North of Bingham's Kennebec Purchase, Somerset County, in the state of Maine, and was accepted May 18, 2004.

We will place a copy of the plat we described in the open files. It will be available to the public as a matter of information.

If BLM receives a protest against this survey, as shown on the plat, prior to the date of the official filing, we will stay the filing pending our consideration of the protest.

We will not officially file the plat until the day after we have accepted or dismissed all protests and they have become final, including decisions on appeals.

Dated: May 18, 2004.

**Stephen D. Douglas,**

*Chief Cadastral Surveyor.*

[FR Doc. 04–11750 Filed 5–24–04; 8:45 am]

BILLING CODE 4310–GJ–P

## DEPARTMENT OF THE INTERIOR

### National Park Service

### Acadia National Park, Bar Harbor, ME, Acadia National Park Advisory Commission; Notice of Meeting

Notice is hereby given in accordance with the Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770, 5 U.S.C. App. 1, Sec. 10), that the Acadia National Park Advisory Commission will hold a meeting on Monday, June 7, 2004.

The Commission was established pursuant to Public Law 99–420, Sec. 103. The purpose of the commission is to consult with the Secretary of the Interior, or his designee, on matters relating to the management and development of the park, including but not limited to the acquisition of lands and interests in lands (including conservation easements on islands) and termination of rights of use and occupancy.

The meeting will convene at Acadia National Park, Schoodic Education and Research Center, Winter Harbor, Maine, at 1 p.m. to consider the following agenda:

1. Review and approval of minutes from the meeting held February 2, 2004
2. Committee reports:
   —Lands Conservation
   —Park Use
   —Science
3. Old business
4. Superintendent's report
5. Public comments
6. Proposed agenda for next Commission meeting, September 13, 2004.

The meeting is open to the public. Interested persons may make oral/written presentations to the Commission or file written statements. Such requests should be made to the Superintendent at least seven days prior to the meeting.

Further information concerning this meeting may be obtained from the Superintendent, Acadia National Park, P.O. Box 177, Bar Harbor, Maine 04609, tel: (207) 288–3338.

Dated: April 8, 2004.

**Len Bobinchock,**

*Acting Superintendent, Acadia National Park.*

[FR Doc. 04–11716 Filed 5–24–04; 8:45 am]

BILLING CODE 4312–52–M

## DEPARTMENT OF THE INTERIOR

### National Park Service

### Cape Cod National Seashore, South Wellfleet, MA, Cape Cod National Seashore Advisory Commission Two Hundred Forty-eighth; Notice of Meeting

Notice is hereby given in accordance with the Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770, 5 U.S.C. App 1, section 10), that a meeting of the Cape Cod National Seashore Advisory Commission will be held on June 21, 2004.

The Commission was reestablished pursuant to Public Law 87–126 as amended by Public Law 105–280. The purpose of the Commission is to consult with the Secretary of the Interior, or his designee, with respect to matters relating to the development of Cape Cod National Seashore, and with respect to carrying out the provisions of sections 4 and 5 of the Act establishing the Seashore.

The Commission members will meet at 1 p.m. at Headquarters, Marconi Station, Wellfleet, Massachusetts for the regular business meeting to discuss the following:

1. Adoption of Agenda
2. Approval of Minutes of Previous Meeting (May 3, 2004)
3. Reports of Officers
4. Reports of Subcommittees
5. Superintendent's Report
   News from Washington
6. Old Business
7. New Business
   Surf Side Colony, Commercial Certificate of Suspension of Condemnation
8. Date and agenda for next meeting
9. Public comment and
10. Adjournment

The meeting is open to the public. It is expected that 15 persons will be able to attend the meeting in addition to Commission members.

Interested persons may make oral/written presentations to the Commission during the business meeting or file written statements. Such requests

should be made to the park superintendent at least seven days prior to the meeting. Further information concerning the meeting may be obtained from the Superintendent, Cape Cod National Seashore, 99 Marconi Site Road, Wellfleet, MA 02667.

Dated: May 6, 2004.

**Michael B. Murray,**

*Deputy Superintendent.*

[FR Doc. 04–11714 Filed 5–24–04; 8:45 am]

BILLING CODE 4312–52–P

## DEPARTMENT OF THE INTERIOR

### National Park Service

### Gettysburg National Military Park Advisory Commission

**AGENCY:** National Park Service, Interior.

**ACTION:** Notice of two meetings to be held on June 17, 2004 and October 21, 2004.

**SUMMARY:** This notices sets forth the dates of June 17, 2004 and October 21, 2004 of the Gettysburg National Military Park Advisory Commission.

**DATES:** The public meetings will be held on June 17, 2004 and October 21, 2004 from 7 p.m. to 9 p.m.

**LOCATION:** The meeting will be held at the Cyclorama Auditorium, 125 Taneytown Road, Gettysburg, Pennsylvania 17325.

**AGENDA:** The June 19, 2004 and October 21, 2004 meetings will consist of The Sub-Committee Reports from the Historical, Executive, and Interpretive Committees; Federal Consistency Reports Within the Gettysburg Battlefield Historic District; Operational Updates on Park Activities, which consists of an update on the Gettysburg National Battlefield Museum Foundation and National Park Service activities related to the new Visitor Center/Museum Complex, updates on the Wills House and the Train Station; Transportation which consists of the National Park Service and the Gettysburg Borough working on the Shuttle System; Update on Land Acquisition within the park boundary or in the historic District; and the Citizens Open Forum where the public can make Comments and ask questions on any park activity.

**FOR FURTHER INFORMATION CONTACT:** John A. Latschar, Superintendent, Gettysburg National Military Park, 97 Taneytown Road, Gettysburg, Pennsylvania 17325.

**SUPPLEMENTARY INFORMATION:** The meeting will be open to the public. Any member of the public may file with the Commission a written statement concerning agenda items. The statement should be Addressed to the Gettysburg National Military Park Advisory Commission, 97 Taneytown Road, Gettysburg, Pennsylvania 17325.

Dated: April 26, 2004.

**John A. Latschar,**

*Superintendent, Gettysburg NMP/Eisenhower NHS.*

[FR Doc. 04–11715 Filed 5–24–04; 8:45 am]

BILLING CODE 4312–52–P

## DEPARTMENT OF THE INTERIOR

### National Park Service

### National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before May 8, 2004.

Pursuant to § 60.13 of 36 CFR Part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded by United States Postal Service, to the National Register of Historic Places, National Park Service, 1849 C St. NW., 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye St. NW., 8th floor, Washington, DC 20005; or by fax, 202–371–6447. Written or faxed comments should be submitted by June 9, 2004.

**Beth M. Boland,**

*Acting Keeper of the National Register of Historic Places.*

**ALASKA**

**Kodiak Island Borough-Census Area**

SS ALEUTIAN (Shipwreck), Address Restricted, Larsen Bay, 04000593

**CALIFORNIA**

**Alameda County**

Green Shutter Hotel, 22650 Main St., Hayward, 04000594

**Madera County**

Young's Market Company Building, 1610 W. Seventh St., Los Angeles, 04000595

**COLORADO**

**Morgan County**

Fort Morgan State Armory, 528 State St., Fort Morgan, 04000596

**IOWA**

**Bremer County**

Sumner High School, 300 West 4th, Sumner, 04000597

**MICHIGAN**

**Kent County**

Grand Rapids Cycle Company Factory, 514 Butterworth St. SW., Grand Rapids, 04000600

**Tuscola County**

Hart, Jr., Lovira and Esther Maria Parker, Farm, 9491 W. Frankenmuth Rd., Tuscola, 04000599

**Wayne County**

Jeffferson—Chalmers Historic Business District, E. Jefferson bet. Eastlawn and Alter, Detroit, 04000598

**Piquette Avenue Industrial Historic District,**

Roughly bounded by Woodward, Harper, Hastings and the Grand Trunk Western Railroad Line, Detroit, 04000601

**MISSOURI**

**Montgomery County**

Farmers Mercantile Co. Building, 872 Boone's Lick Rd., High Hill, 04000604

**Reynolds County**

Buford—Carty Farmstead, 0.75 mi. S of Hwy J on Cty Rd. 814, Black, 04000603

**St. Louis Independent City**

Weisert, John, Tobacco Company, 1120 S. Sitxth St., St. Louis (Independent City), 04000602

**NORTH CAROLINA**

**Northampton County**

Jackson Historic District, Roughly bounded by Atherton St., Picard St., Buxton St.; and northern town limit line, Jackson, 04000606

**Yancey County**

Chase—Coletta House, 108 Town Sq., Burnsville, 04000605

**OHIO**

**Cuyahoga County**

Van Rooy Coffee Company Building, 2900 Detroit Ave., Cleveland, 04000608

**Franklin County**

Zion's Evangelical Lutheran Church, 4501 Groveport Rd., Obetz, 04000609

**Greene County**

Carnegie Library (Old Wilberforce University Campus), 1400 Brush Row Rd., Wilberforce, 04000610

**Lake County**

Foster, Claud, House, 30333 Lake Shore Blvd., Willowick, 04000611

**Warren County**

Hunt—Forman Farm, 2945 N OH 741, Franklin, 04000607

**OREGON**

**Benton County**

Crystal Lake Cemetery, 1945 SE., Crystal Lake Dr., Corvallis, 04000613

**Deschutes County**

Nerdrum—Conrad House, 979 S. Fifth St., Coos Bay, 04000616

**Jackson County**

Medford Plaza Apartments, 235 S. Oakdale Ave., Medford, 04000614

**Multnomah County**

Sweeney, Straub and Dimm Printing Plant, 535 NW., 16th Ave., Portland, 04000615

**PENNSYLVANIA**

**Bradford County**

Athens Historic District, Roughly bounded by Elm and Locust Sts., 772 S. Main St., and the Chemung and Susquehanna River, Athens, 04000612

**SOUTH CAROLINA**

**Newberry County**

Newberry Historic District (Boundary Increase), (Newberry MRA) Along sections of Main, Lindsay and Wilson Sts., Newberry, 04000617

**Oconee County**

Oconee State Park Historic District, (South Carolina State Parks MPS) 624 State Park Rd., Mountain Rest, 04000618

**Sumter County**

Sumter County Courthouse, (Courthouses in South Carolina Designed by William Augustus Edwards TR) 141 N. Main St., Sumter, 04000619

A request for a Move has been made for the following resource:

**NORTH DAKOTA**

**Grand Forks County**

Campbell, Thomas D., House 2405 Belmont Rd. Grand Forks, 87002010

[FR Doc. 04–11717 Filed 5–24–04; 8:45 am]

BILLING CODE 4312–51–P

## DEPARTMENT OF THE INTERIOR

### Bureau of Reclamation

**[INT–FES–04–09]**

### Banks Lake Drawdown, Columbia Basin Project, Washington

**AGENCY:** Bureau of Reclamation, Interior.

**ACTION:** Notice of availability of the Banks Lake Drawdown final environmental impact statement.

**SUMMARY:** Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, as amended, the Department of the Interior, Bureau of Reclamation (Reclamation), has prepared a final environmental impact statement (Final EIS) that examines the impacts of annually lowering the water surface elevation of Banks Lake in August.

The Final EIS evaluates two alternatives. The Action Alternative describes the resource conditions that would occur with Banks Lake water surface elevations between 1570 feet and 1560 feet, while the No Action Alternative describes the conditions that would occur without the action, with surface elevation between 1570 feet and 1565 feet. Both the No Action and Action Alternatives include four possible operational scenarios that could occur within their respective ranges, depending upon the hydrology of each year. The Action Alternative refills the reservoir to elevation 1565 by September 10 and to 1570 feet by September 22. The No Action Alternative also refills to 1570 feet elevation by September 22.

The Final EIS includes the comment letters received on the Draft EIS and Reclamation's responses to those comments, as well as a summary of comments from the public hearings. Changes from the Draft EIS include minor revisions and additions to the analysis as a result of review comments. The No Action Alternative is identified as the preferred alternative in the Final EIS.

A Record of Decision (ROD) identifying the alternative chosen for implementation, and discussing factors for its selection, is anticipated by June, 2004.

**ADDRESSES:** Copies of the Final EIS are available for public review and inspection at the locations listed in the Supplementary Information Section.

**FOR FURTHER INFORMATION CONTACT:** Mr. Jim Blanchard, Special Projects Officer, at (509) 754–0226 (relay users may dial 711). Those wishing to obtain a copy of the Final EIS in the form of a printed document or a compact disk (CD–ROM with reader included), or a summary of the Final EIS may contact Mr. Blanchard.

**SUPPLEMENTARY INFORMATION:** Since its creation in the early 1950s, Banks Lake has been operated and maintained for the storage and delivery of irrigation water drawn from the Columbia River to Columbia Basin Project (CBP) lands. Reclamation operates the reservoir within established constraints on water surface elevation to meet contractual obligations, ensure public safety, and protect property. Reclamation considers other resource needs as feasible within existing operational constraints.

In December of 2000, the National Marine Fisheries Service issued a Biological Opinion (BiOp) to the Bureau of Reclamation, Bonneville Power Administration and the U.S. Army Corps of Engineers for the operation of the Federal Columbia River Power System. The BiOp's Reasonable and Prudent Alternative (RPA) included Action 31 that advised Reclamation to "assess the likely environmental effects of operation of Banks Lake up to 10 feet down from full pool during August." Reclamation has completed RPA Action 31 by preparing the Banks Lake Drawdown Environmental Impact Statement which describes and analyzes the environmental effects of lowering the August surface elevation of Banks Lake annually to elevation 1560 feet, which is 10 feet below full pool.

Copies of the Final EIS are available for public review and inspection at the following locations:

- Bureau of Reclamation, U.S. Department of the Interior, Room 7455, 18th and C Streets, NW., Washington, DC 20240.
- Bureau of Reclamation, Denver Office Library, Denver Federal Center, Building 67, Room 167, Denver, Colorado 80225.
- Bureau of Reclamation, Pacific Northwest Regional Office, 1150 North Curtis Road, Suite 100, Boise, Idaho 83706–1234.
- Bureau of Reclamation, Upper Columbia Area Office, 1917 Marsh Road, Yakima, Washington 98901.
- Bureau of Reclamation, Ephrata Field Office, 32 C Street, Ephrata, Washington 98823.

**Libraries**

- Bridgeport Community Library, Douglas County, 1206 Columbia St., Bridgeport, WA (509) 686–7281.
- Coulee City Community Library, 405 W. Main St., Coulee City, WA (509) 674–2313.
- Des Moines Library, 21620 11th Ave. S, Des Moines, WA (206) 824–6066.
- East Wenatchee Community Library, Douglas County, 271 9th St, NE., East Wenatchee, WA (509) 886–7404.
- Ephrata Public Library, 45 Alder NW., Ephrata, WA (509) 754–3971.
- Grand Coulee Community Library, 225 Federal, Grand Coulee, WA (509) 633–0972.
- Moses Lake Public Library, 418 E. 5th Ave., Moses Lake, WA (509) 765–3489.
- Quincy Community Library, 108 B St., SW., Quincy, WA (509) 787–2359.
- Royal City Community Library, 356 Camelia, Royal City, WA (509) 346–9281.
- Seattle Public Library, 800 Pike St., Seattle, WA (206) 386–4636.
- Soap Lake Community Library, 32 E. Main, Soap Lake, WA (509) 246–1313.

• Warden Community Library, 305 S. Main, Warden, WA (509) 349–2226.

• Wenatchee Public Library, Chelan County, 310 Douglas St., Wenatchee, WA (509) 662–5021.

**Internet**

The DEIS is also available on the Internet at *www.usbr.gov/pn*.

Dated: March 11, 2004.

**J. William McDonald,**

*Regional Director, Pacific Northwest Region.*

[FR Doc. 04–11797 Filed 5–24–04; 8:45 am]

BILLING CODE 4310–MN–P

## DEPARTMENT OF JUSTICE

### Bureau of Alcohol, Tobacco, Firearms and Explosives

### Agency Information Collection Activities: Proposed Collection; Comments Requested

**ACTION:** 60-day notice of information collection under review: Application for Tax-Exempt Transfer of Firearm and Registration to Special (Occupational) Taxpayer

The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for "sixty days" until July 26, 2004. This process is conducted in accordance with 5 CFR 1320.10.

If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Gary Schaible, National Firearms Act Branch, Room 5100, 650 Massachusetts Avenue, NW., Washington, DC 20226.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—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 agencies 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.

Overview of this information collection:

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Application for Tax-Exempt Transfer of Firearm and Registration to Special (Occupational) Taxpayer.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: ATF F 3 (5320.3). Bureau of Alcohol, Tobacco, Firearms and Explosives.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit. Other: None. The form is submitted and approved by ATF prior to the transfer of a National Firearms Act weapon from one Special Occupational Tax paying Federal firearms licensee to another special taxpaying licensee. The form is required whenever such a transfer is to be made.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 2,521 respondents will complete a 30 minute form.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 11,144 annual total burden hours associated with this collection.

If additional information is required contact: Brenda E. Dyer, Deputy Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Dated: May 19, 2004.

**Brenda E. Dyer,**

*Department Deputy Clearance Officer, PRA, Department of Justice.*

[FR Doc. 04–11766 Filed 5–24–04; 8:45 am]

BILLING CODE 4410–FY–P

## DEPARTMENT OF JUSTICE

### Antitrust Division

### Notice Pursuant to The National Cooperative Research and Production Act of 1993—National Electronics Manufacturing Initiative, Inc. ("NEMI")

Notice is hereby given that, on April 23, 2004, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), National Electronics Manufacturing Initiative, Inc. ("NEMI") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership status. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Centor Software, Irvine, CA; Cisco Systems Inc., San Jose, CA; Dell, Inc., Round Rock, TX; Endicott Interconnect Technologies (E.I.T.), Endicott, NY; Foxconn, Houston TX; Massachusetts Institute of Technology (M.I.T.), Cambridge, MA; MatrixOne, Inc., Westford, MA; Microsoft, Redmond, WA; Senju Comtek Corporation, San Jose, CA; Speedline Technologies, Foxboro, MA; and Tyco Corporation, Middletown, PA have been added as parties to this venture.

Also, 3SAE Technologies, Inc., Nashville, TN; Aerotech World Trade; Ltd., Westlake Village, CA; ChipPAC, Fremont, CA; Cimetrix, Inc., Salt Lake City, UT; CTS Corporation, Elkhart, IN; GSI Lumonics, Northville, MI; iManage, Inc., San Mateo, CA; IONA Technologies, Santa Clara, CA; Kasaria Corporation, Wilmington, MA; KIC Thermal Profiling, San Diego, CA; Henkel Loctite Corporation, Rocky Hill, CT; Peregrine Systems, Inc., Belmont, CA; and Tecnomatrix Unicam, Inc., Portsmouth, NH have been dropped as parties to this venture. The following members have changed their names: Delphi Corporation to Delphi Electronics & Safety, Kokomo, IN; and Shipley Company to Rohm and Haas Electronics Materials, Freeport, NY.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and National Electronics Manufacturing Initiatives, Inc. ("NEMI") intends to file additional written notification disclosing all changes in membership.

On June 6, 1996, National Electronics Manufacturing Initiative, Inc. ("MENI") filed its original notification pursuant to

Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on June 28, 1996 (61 FR 33774).

The last notification was filed with the Department on December 30, 2002. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on January 23, 2003 (68 FR 3273).

**Dorothy B. Fountain,**

*Deputy Director of Operations Antitrust Division.*

[FR Doc. 04–11804 Filed 5–24–04; 8:45 am]

BILLING CODE 4410–11–M

## DEPARTMENT OF JUSTICE

### Antitrust Division

### Notice Pursuant to the National Cooperative Research and Production Act of 1993—Petrotechnical Open Standards Consortium, Inc. ("POSC")

Notice is hereby given that, on April 13, 2004, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), Petrotechnical Open Standards Consortium, Inc. ("POSC") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership status. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Anadarko Petroleum Corporation, The Woodlands, TX; U.S. Department of the Interior, Washington, DC; OpenSpirit Corporation, Sugar Land, TX; MetaCarta, Inc., Cambridge, MA; and Fugro-Jason, Rotterdam, Netherlands have been added as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Petrotechnical Open Standards Consortium, Inc. ("POSC") intends to file additional written notification disclosing all changes in membership.

On January 14, 1991, Petrotechnical Open Standards Consortium, Inc. ("POSC") filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on February 7, 1991 (56 FR 5021).

The last notification was filed with the Department on July 17, 2003. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on August 15, 2003 (68 FR 48942).

**Dorothy B. Fountain,**

*Deputy Director of Operations Antitrust Division.*

[FR Doc. 04–11805 Filed 5–24–04; 8:45 am]

BILLING CODE 4410–11–M

## DEPARTMENT OF LABOR

### Employee Benefits and Security Administration

### Proposed Extension of Information Collection Request; Comment Request; 29 CFR 2550.408b–1

**AGENCY:** Employee Benefits Security Administration, Labor.

**ACTION:** Notice.

**SUMMARY:** The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, provides 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 (PRA 95) 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 requirements on respondents can be properly assessed. Currently, the Employee Benefits Security Administration is soliciting comments concerning the proposed extension of the information collection provisions of the regulation relating to loans to plan participants and beneficiaries that are parties in interest with respect to the plan (29 CFR 2550.408b–1).

A copy of the proposed information collection request (ICR) can be obtained by contacting the individual listed in the **ADDRESSES** section of this notice.

**DATES:** Written comments must be submitted to the office shown in the **ADDRESSES** section on or before July 26, 2004.

**ADDRESSES:** Gerald B. Lindrew, Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue, NW., Washington, DC 20210, (202) 693–8410, FAX (202) 219–5333. (These are not toll-free numbers.)

**SUPPLEMENTARY INFORMATION:**

#### I. Background

The Employee Retirement Income Security Act of 1974 (ERISA) prohibits a fiduciary with respect to a plan from causing the plan to engage in the direct or indirect lending of money or other extension of credit between the plan and a party in interest. ERISA section 408(b)(1) exempts loans made by a plan to parties in interest who are participants and beneficiaries of the plan from this prohibition provided that certain requirements are satisfied. In final regulations published in the **Federal Register** on July 20, 1989 (54 FR 30520), the Department of Labor provided additional guidance on section 408(b)(1)(C), which requires that loans must be made in accordance with specific provisions set forth in the plan. This ICR relates to the specific provisions that must be included in plan documents for those plans that permit loans to participants.

#### II. Review Focus

The Department of Labor is particularly interested in comments that:

- 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 clarify 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.

#### III. Current Actions

This notice requests comments on the extension of the ICR included in 29 CFR 2550.408b–1. The ICR ensures that participants and beneficiaries are provided with adequate information with respect to matters affecting their benefits. The Department is not proposing or implementing changes to the existing ICR at this time.

*Type of Review:* Extension.

*Agency:* Employee Benefits Security Administration, Department of Labor.

*Title:* Regulation Relating to Loans to Plan Participants and Beneficiaries who are Parties in Interest with Respect to the Plan.

*OMB Number:* 1210–0076.

*Affected Public:* Business or other for-profit, not-for-profit institutions, individuals.

*Total Respondents:* 1,400.

*Frequency:* On occasion.

*Total Responses:* 1,400.

*Average Time Per Response:* 3 hours.

*Estimated Total Burden Hours:* 0.

*Total Burden Cost (operating/maintenance):* $348,600.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: May 19, 2004.

**Gerald B. Lindrew,**

*Deputy Director, Office of Policy and Research, Employee Benefits Security Administration.*

[FR Doc. 04–11795 Filed 5–24–04; 8:45 am]

BILLING CODE 4910–29–P

## NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**AGENCY:** National Archives and Records Administration (NARA).

**ACTION:** Notice.

**SUMMARY:** NARA is giving public notice that the agency has submitted to OMB for approval the information collection described in this notice. The public is invited to comment on the proposed information collection pursuant to the Paperwork Reduction Act of 1995.

**DATES:** Written comments must be submitted to OMB at the address below on or before June 24, 2004 to be assured of consideration.

**ADDRESSES:** Comments should be electronically mailed to: *Jonathan_P._Womer@omb.eop.gov;* or faxed to 202–395–5806, Attn: Mr. Jonathan Womer, Desk Officer for NARA.

**FOR FURTHER INFORMATION CONTACT:** Requests for additional information or copies of the proposed information collection and supporting statement should be directed to Tamee Fechhelm at telephone number 301–837–1694 or fax number 301–837–3213.

**SUPPLEMENTARY INFORMATION:** Pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13), NARA invites the general public and other Federal agencies to comment on proposed information collections. NARA published a notice of proposed collection for this information collection on March 2, 2004 (69 FR 9854 and 9855). No comments were received. NARA has submitted the described information collection to OMB for approval.

In response to this notice, comments and suggestions should address one or more of the following points: (a) Whether the proposed information collection is necessary for the proper performance of the functions of NARA; (b) the accuracy of NARA's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of information technology. In this notice, NARA is soliciting comments concerning the following information collection:

*Title:* Microfilm Rental Order Form.

*OMB number:* 3095–NEW.

*Agency form number:* NA Form 14127.

*Type of review:* Regular.

*Affected public:* Individuals or households.

*Estimated number of respondents:* 5,200.

*Estimated time per response:* 10 minutes.

*Frequency of response:* On occasion.

*Estimated total annual burden hours:* 867 hours.

*Abstract:* The NARA microfilm publications provides ready access to records for research in a variety of fields including history, economics, political science, law, and genealogy. NARA emphasizes microfilming groups of records relating to the same general subject or to a specific geographic area. For example, the decennial population censuses from 1790 to 1930 and their related indexes are available on microfilm. Census records constitute the vast majority of microfilmed records available currently through the rental program.

Dated: May 17, 2004.

**L. Reynolds Cahoon,**

*Assistant Archivist for Human Resources and Information Services.*

[FR Doc. 04–11703 Filed 5–24–04; 8:45 am]

BILLING CODE 7515–01–P

## NATIONAL SCIENCE FOUNDATION

### Agency Information Collection Activities: Comment Request

**AGENCY:** National Science Foundation.

**ACTION:** Submission for OMB review; comment request.

**SUMMARY:** The National Science Foundation (NSF) has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. This is the second notice for public comment; the first was published in the **Federal Register** at 69 FR 9386, and no comments were received. NSF is forwarding the proposed renewal submission to the Office of Management and Budget (OMB) for clearance simultaneously with the publication of this second notice. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (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 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 should be addressed to: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for National Science Foundation, 725—17th Street, NW., Room 10235, Washington, DC 20503, and to Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 4201 Wilson Boulevard, Suite 295, Arlington, Virginia 22230 or send e-mail to *splimpto@nsf.gov.* Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling 703–292–7556.

NSF may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number. Under OMB regulations, NSF may continue to conduct or sponsor the collection of information while this submission is pending at OMB.

**SUPPLEMENTARY INFORMATION:** *Title:* Antarctic Conservation Act Application and Permit Form.

*OMB Control Number:* 3145–0034.

*Proposed Project:* The current Antarctic Conservation Act Application

Permit Form (NSF 1078) has been in use for several years. The form requests general information, such as name, affiliation, location, etc., and more specific information as to the type of object to be taken (plant, native mammal, or native bird).

*Use of the Information:* The purpose of the regulations (45 CFR part 670) is to conserve and protect the native mammals, birds, plants, and invertebrates of Antarctica and the ecosystem upon which they depend and to implement the Antarctic Conservation Act of 1978, Public Law 95–541, as amended by the Antarctic Science, Tourism, and Conservation Act of 1996, Public Law 104–227.

*Burden on the Public:* The Foundation estimates about 25 responses annually at ½ hour per response; this computes to approximately 12.5 hours annually.

Dated: May 19, 2004.

**Suzanne H. Plimpton,**

*Reports Clearance Officer, National Science Foundation.*

[FR Doc. 04–11747 Filed 5–24–04; 8:45 am]

BILLING CODE 7555–01–M

## NATIONAL SCIENCE FOUNDATION

### Notice of Permits Issued Under the Antarctic Conservation Act of 1978

**AGENCY:** National Science Foundation.

**ACTION:** Notice of permits issued under the Antarctic Conservation of 1978, Public Law 95–541.

**SUMMARY:** The National Science Foundation (NSF) is required to publish notice of permits issued under the Antarctic Conservation Act of 1978. This is the required notice.

**FOR FURTHER INFORMATION CONTACT:** Nadene G. Kennedy, Permit Office, Office of Polar Programs, Rm. 755, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230.

**SUPPLEMENTARY INFORMATION:** On March 26, 2004, the National Science Foundation published a notice in the **Federal Register** of a permit application received. A permit was issued on may 18, 2004 to: Stacy Kim Permit No. 2005–001.

**Nadene G. Kennedy,**

*Permit Officer.*

[FR Doc. 04–11701 Filed 5–24–04; 8:45 am]

BILLING CODE 7555–01–M

## NATIONAL SCIENCE FOUNDATION

### Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978 (Pub. L. 95–541)

**AGENCY:** National Science Foundation.

**ACTION:** Notice of Permit Applications Received under the Antarctic Conservation Act of 1978, Public Law 95–541.

**SUMMARY:** The National Science Foundation (NSF) is required to publish notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act at Title 45 Part 670 of the Code of Federal Regulations. This is the required notice of permit applications received.

**DATES:** Interested parties are invited to submit written data, comments, or views with respect to this permit application by June 24,2004. This application may be inspected by interested parties at the Permit Office, address below.

**ADDRESSES:** Comments should be addressed to Permit Office, Room 755, Office of Polar Programs, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230.

**FOR FURTHER INFORMATION CONTACT:** Nadene G. Kennedy at the above address or (703) 292–7405.

**SUPPLEMENTARY INFORMATION:** The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas a requiring special protection. The regulations establish such a permit system to designate Antarctic Specially Protected Areas.

The applications received are as follows:

1. Applicant

Michael Castellini, Director, Institute of Marine Science, University of Alaska, Fairbanks, Fairbanks, AK 99775.

**Permit Application No. 2005–002**

*Activity for Which Permit Is Requested*

Taking. The applicant proposes to study Weddell seals to quantify the dynamics of lipid uptake and utilization in a naturally foraging mammalian carnivore by examining freely diving Weddell seals in Antarctica. This species offers a unique opportunity to model the biochemistry and physiology of nutrient utilization in a large carnivore that may not be possible in any other system. The applicant plans to capture up to 8 adult female seals, attach diving recorders and blood sampling lines, then transport the seals to a diving hut where they will be observed for several days and blood samples taken. Blood samples will also be taken from about 6 pups less than 5 weeks old. All seals will be returned to the tide crack areas.

*Location*

McMurdo Sound, Antarctica.

*Dates*

October 5, 2004 to December 31, 2004.

2. Applicant

Arthur L. DeVries, Department of Animal Biology, 524 Burrill Hall, University of Illinois, Urbana, IL 61801.

**Permit Application No. 2005–003**

*Activity for Which Permit Is Requested*

Introduce non-indigenous species to Antarctica. The applicant plans to import algal cells (Nanochloropsis) to be fed to imported marine rotifers (Brachionus calyciflorus) after they hatch. After 5 days the rotifers will be harvested by filtering out the algae, and concentrating the rotifers into a thick slurry. The slurry will be flash-frozen and aliquots of the thawed rotifers will be fed daily to the larval stages of the naked dragon fish, Gymnodraco acuticeps. The naked dragon fish spawns in mid-October on rocks in the shallow waters of McMurdo Sound. Their eggs hatch some 10 months later, the full-terms eggs will be collected, the larva hatched in aquarium tanks, and reared in seawater tanks in the Crary Science and Engineering Center at McMurdo Station. The fish will be raised to juvenile stage to follow their elaboration of blood antifreeze glycoproteins. The rotifers and algae will be autoclaved and disposed of as dry biological waste.

*Location*

McMurdo Station, Ross Island Antarctica.

*Dates*

August 20, 2004 to February 15, 2005.

*Applicant*

Lawrence J. Conrad, 845 17th Street, Washougal, WA 98761.

**Permit Application No. 2005–004**

*Activity for Which Permit Is Requested*

Enter Antarctic Specially Protected Areas. The applicant proposes take photographs of named geographic features throughout the McMurdo Sound region. The photographs will illustrate a geographically arranged gazetteer or "field guide" to the features. The applicant proposes to enter the Barwick Valley, Victoria Land (ASPA #123) to fully document the Barwick Valley features which will benefit the scientific community in current and future work. Delineating data accompanying each photograph will include latitude, longitude, altitude, date, time, elevation, look direction, focal length and associated camera settings. The photographs and accompanying data will provide the potential for contemporary and future comparative studies of landscape change, thereby reducing need for access to the ASPA. The applicant proposes approximately 5-days work in the Barwick Valley and will fully comply with the designated management plan for the site. Furthermore, the applicant will visit Cape Crozier (ASPA #124) to film Wilson's Stone Igloo and The Knoll, avoiding the penguin and skua rookeries.

In addition, the applicant proposes to enter Discovery Hut (ASPA #157), Cape Evans Historic Site (ASPA #154), and Hut and Associated Artifacts, Backdoor Bay, Cape Royds (ASPA #156) for the purpose of reproducing historic photos of the area for use in the described gazetteer.

*Location*

ASPA #123—Barwick Valley, Victoria Land

ASPA #124—Cape Crozier, Ross Island

ASPA #154—Cape Evans Historic Site

ASPA #156—Hut and associated artifacts, Backdoor Bay, Cape Royds, Ross Island

ASPA #157—Discovery Hut, Hut Point, Ross Island

*Dates*

August 22, 2004 to February 15, 2006.

**Nadene G. Kennedy,**

*Permit Officer, Office of Polar Programs.*

[FR Doc. 04–11702 Filed 5–24–04; 8:45 am]

BILLING CODE 7555–01–M

## DEPARTMENT OF NATIONAL SCIENCE FOUNDATION

### Proposal Review; Notice of Meetings

In accordance with the Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation (NSF) announces its intent to hold proposal review meetings throughout the year. The purpose of these meetings is to provide advice and recommendations concerning proposals submitted to the NSF for financial support. The agenda for each of these meetings is to review and evaluate proposals as part of the selection process for awards. The review and evaluation may also include assessment of the progress of awarded proposals. The majority of these meetings will take place as NSF, 4201 Wilson, Blvd., Arlington, Virginia 22230.

These meetings will be closed to the public. The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act. NSF will continue to review the agenda and merits of each meeting for overall compliance of the Federal Advisory Committee Act.

These closed proposal review meetings will not be announced on an individual basis in the Federal Register. NSF intends to publish a notice similar to this on a quarterly basis. For an advance listing of the closed proposed review meetings that include the names of the proposal review panel and the time, date, place, and any information on changes, corrections, or cancellations, please visit the NSF Website: *http://www.nsf.gov/home/pubinfo/advisory.htm*. This information may also be requested by telephone (703) 292–8182.

Dated: May 19, 2004.

**Susanne Bolton,**

*Committee Management Officer.*

[FR Doc. 04–11700 Filed 5–24–04; 8:45 am]

BILLING CODE 7555–01–M

## NATIONAL SCIENCE FOUNDATION

### Sunshine Act Meeting

*Agency Holding Meeting:* National Science Foundation, National Science Board and its Subdivisions.

**Federal Register** *Citation of Previous Announcement:* Volume 69, Number 84, **Federal Register**, pages 23823–23824, April 30, 2004

*Previously Announced Date and Time:* Monday, May 3, 2004.

**Additional Concurrent Session**

*Open*

National Science Board, *ad hoc* Task Group on High Risk Research (11:00—11:30 a.m.), Room 1295.

Place: The National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230, *www.nsf.gov/nsb.*

*Contact for Information:* National Science Board Office (703) 202–7000

*Status:* Open.

*Changes in the Meeting:* A half-hour open meeting was added to the agenda after the schedule was published in the **Federal Register**. Public announcement of this additional session was made on the National Science Board Web site ahead of the meeting. The following topic was discussed.

*Discussion:* Discussion of Workshop and White Paper.

**Michael P. Crosby,**

*Executive Officer, NSB.*

[FR Doc. 04–11939 Filed 5–21–04; 2:58 pm]

BILLING CODE 7555–01–M

## NUCLEAR REGULATORY COMMISSION

**[Docket No. 50–336 and 50–423 ASLBP No. 04–824–01–LR]**

### Dominion Nuclear Connecticut; Establishment of Atomic Safety and Licensing Board

Pursuant to delegation by the Commission dated December 29, 1972, published in the **Federal Register**, 37 FR 28,710 (1972), and the Commission's regulations, *see* 10 CFR 2.104, 2.300, 2.303, 2.309, 2.311, 2.318, and 2.321, notice is hereby given that an Atomic Safety and Licensing Board is being established to preside over the following proceeding:

**Dominion Nuclear Connecticut (Millstone Nuclear Power Station, Units 2 and 3)**

Pursuant to a March 8, 2004 notice of opportunity for hearing published in the **Federal Register** (69 FR 11,897 (Mar. 12, 2004)), and a May 4, 2004 Commission memorandum and order, CLI–04–12, 59 NRC__(May 4, 2004), a Licensing Board is being established to conduct a proceeding on the March 22, 2004 hearing petition of Connecticut Coalition Against Millstone (CCAM) regarding the January 22, 2004

Dominion Nuclear Connecticut applications for renewal of the Millstone Units 2 and 3 operating licenses.

The Board is comprised of the following administrative judges:

Dr. Paul B. Abramson, Chair, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Ann Marshall Young, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

Dr. Richard F. Cole, Atomic Safety and Licensing Board Panel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

All correspondence, documents, and other materials shall be filed with the administrative judges in accordance with 10 CFR 2.302.

Issued at Rockville, Maryland, this 19th day of May 2004.

**G. Paul Bollwerk, III,**

*Chief Administrative Judge, Atomic Safety and Licensing Board Panel.*

[FR Doc. 04–11755 Filed 5–24–04; 8:45 am]

BILLING CODE 7590–01–P

## NUCLEAR REGULATORY COMMISSION

**[Docket No. 030–34781]**

### Notice of Availability of Environmental Assessment and Finding of No Significant Impact for License Amendment for Message Pharmaceutlcals, Inc.'s Facility in Malvern, PA

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Notice of Availability of Environmental Assessment and Finding of No Significant Impact.

**FOR FURTHER INFORMATION CONTACT:** Sattar Lodhi, Nuclear Materials Safety Branch 2, Division of Nuclear Materials Safety, Region I, 475 Allendale Road, King of Prussia, Pennsylvania, 19406, telephone (610) 337–5364 fax (610) 337–5269; or by e-mail: *asl@nrc.gov.*

**SUPPLEMENTARY INFORMATION:**

#### I. Introduction

The Nuclear Regulatory Commission (NRC) is considering the issuance of a license amendment to Message Pharmaceuticals, Inc.'s Materials License No. 37–30462–01, to authorize release of its facility in Malvern, Pennsylvania for unrestricted use. NRC has prepared an Environmental Assessment (EA) in support of this action in accordance with the requirements of 10 CFR part 51. Based on the EA, the NRC has concluded that a Finding of No Significant Impact (FONSI) is appropriate. The amendment will be issued following the publication of this Notice.

#### II. EA Summary

The purpose of the proposed action is to authorize the release of the licensee's Malvern, Pennsylvania facility for unrestricted use. Message Pharmaceuticals, Inc., was authorized by NRC from July 29, 1998, to use radioactive materials for research and development purposes at the site. On January 5, 2004, Message Pharmaceuticals, Inc., requested that NRC release the facility for unrestricted use. Message Pharmaceuticals, Inc., has conducted surveys of the facility and determined that the facility meets the license termination criteria in Subpart E of 10 CFR part 20. The NRC staff has prepared an EA in support of the proposed license amendment.

#### III. Finding of No Significant Impact

The staff has prepared the EA (summarized above) in support of the proposed license amendment to terminate the license and release the facility for unrestricted use. The NRC staff has evaluated Message Pharmaceuticals, Inc.'s request and the results of the surveys and has concluded that the completed action complies with the criteria in Subpart E of 10 CFR part 20. The staff has found that the environmental impacts from the proposed action are bounded by the impacts evaluated by the "Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Facilities" (NUREG–1496). On the basis of the EA, the NRC has concluded that the environmental impacts from the proposed action are expected to be insignificant and has determined not to prepare an environmental impact statement for the proposed action.

#### IV. Further Information

The EA and the documents related to this proposed action, including the application for the license amendment and supporting documentation, are available for inspection at NRC's Public Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html* (ADAMS Accession Nos. ML040250011 and ML041040862). These documents are also available for inspection and copying for a fee at the Region I Office, 475 Allendale Road, King of Prussia, Pennsylvania, 19406. Persons who do not have access to ADAMS, should contact the NRC PDR Reference staff by telephone at 1–800–397–4209 or (301) 415–4737, of by e-mail to *pdr@nrc.gov.*

For the Nuclear Regulatory Commission.

Dated at King of Prussia, Pennsylvania this 18th day of May, 2004.

**John D. Kinneman,**

*Chief, Nuclear Materials Safety Branch 2, Division of Nuclear Materials Safety Region I*

[FR Doc. 04–11758 Filed 5–24–04; 8:45 am]

BILLING CODE 7590–01–P

## NUCLEAR REGULATORY COMMISSION

**[Docket Nos. 050–00135 (Retired) and 030–01317]**

### Notice of Availability of Environmental Assessment and Finding of No Significant Impact for License Amendement for Department of the Army, Walter Reed Army Medical Center Washington, DC

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Notice of Availability of Environmental Assessment and Finding of No Significant Impact.

**FOR FURTHER INFORMATION CONTACT:** Laurie Peluso, Decommissioning Branch, Division of Nuclear Materials Safety, Region I, 475 Allendale Road, King of Prussia, Pennsylvania, 19406, telephone (610) 337–5323, fax (610) 337–5269; or by email: *LAP@nrc.gov.*

**SUPPLEMENTARY INFORMATION:**

#### I. Introduction

The Nuclear Regulatory Commission (NRC) is considering the issuance of a license amendment to Department of Army, Walter Reed Medical Center for Materials License No. 08–01738–02, to authorize release of Building 40 of the Washington, DC site for unrestricted use. NRC has prepared an Environmental Assessment (EA) in support of this action in accordance with the requirements of 10 CFR part 51. Based on the EA, the NRC has concluded that a Finding of No Significant Impact (FONSI) is appropriate. The amendment will be issued following the publication of this Notice.

#### II. EA Summary

The purpose of the proposed action is to authorize the release of the licensee's Building 40 of the Washington, DC facility for unrestricted use. WRAMC was authorized by the U.S. Atomic Energy Commission (AEC) from February 18, 1959 to use radioactive

materials for medical research, diagnosis, and therapy purposes and on August 17, 1962 to operate a research reactor in Building 40 at the site. On March 9, 2004, WRAMC requested that NRC release the facility for unrestricted use. WRAMC has conducted surveys of the facility and determined that the facility meets the license termination criteria in Subpart E of 10 CFR part 20. The NRC staff has prepared an EA in support of the proposed license amendment.

**III. Finding of No Significant Impact**

The staff has prepared the EA (summarized above) in support of the proposed license amendment to release Building 40 in its entirety of the WRAMC facility at 6900 Georgia Avenue, NW., Washington, DC for unrestricted use. The NRC staff has evaluated WRAMC's request and the results of the surveys, performed independent measurements to confirm the results, and has concluded that the completed action complies with the criteria in Subpart E of 10 CFR part 20. The staff has found that the environmental impacts from the proposed action are bounded by the impacts evaluated by the "Generic Environmental Impact Statement in Support of Rulemaking on Radiological Criteria for License Termination of NRC-Licensed Facilities" (NUREG–1496). On the basis of the EA, the NRC has concluded that the environmental impacts from the proposed action are expected to be insignificant and has determined not to prepare an environmental impact statement for the proposed action.

**IV. Further Information**

The EA and the documents related to this proposed action, including the application for the license amendment and supporting documentation, are available for inspection at NRC's Public Electronic Reading Room at *http://www.nrc.gov/reading-rm/adams.html* (ADAMS Accession No. ML041380084). These documents are also available for inspection and copying for a fee at the Region I Office, 475 Allendale Road, King of Prussia, Pennsylvania, 19406. Persons who do not have access to ADAMS, should contact the NRC PDR Reference staff by telephone at 1–800–397–4209 or (301) 415–4737, or by e-mail to *pdr@nrc.gov*.

Dated at King of Prussia, Pennsylvania this 18th day of May, 2004.

For the Nuclear Regulatory Commission.

**Ronald R. Bellamy,**

*Chief, Decommissioning Branch, Division of Nuclear Materials Safety, Region I.*

[FR Doc. 04–11756 Filed 5–24–04; 8:45 am]

BILLING CODE 7590–01–P

## NUCLEAR REGULATORY COMMISSION

### Sunshine Act Meeting

**AGENCY HOLDING THE MEETING:** Nuclear Regulatory Commission.

**DATE:** Weeks of May 24, 31, June 7, 14, 21, 28, 2004.

**PLACE:** Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

**STATUS:** Public and closed.

**MATTERS TO BE CONSIDERED:**

**Week of May 24, 2004**

Tuesday, May 25, 2004
2 p.m. Discussion of Management Issues (Closed—Ex. 2)
Wednesday, May 26, 2004
10:30 a.m. All Employees Meeting (Public Meeting)
All Employees Meeting (Public Meeting)

**Week of May 31, 2004—Tentative**

Wednesday, June 2, 2004
9:30 a.m. Briefing on Equal Employment Opportunity Program (Public Meeting) (Contact: Corenthis Kelley, 301–415–7380)
This meeting will be webcast live at the Web address—*www.nrc.gov*
1:30 p.m. Meeting with Advisory Committee on Reactor Safeguards (ACRS) (Public Meeting) (Contact: John Larkins, 301–415–7360)
This meting will be webcast live at the Web address—*www.nrc.gov*

**Week of June 7, 2004—Tentative**

Thursday, June 10, 2004
1:30 p.m. Discussion of Security Issues (Closed—Ex. 1)

**Week of June 14, 2004—Tentative**

There are no meetings scheduled for the Week of June 14, 2004.

**Week of June 21, 2004—Tentative**

There are no meetings scheduled for the Week of June 21, 2004.

**Week of June 28, 2004—Tentative**

There are no meetings scheduled for the Week of June 28, 2004.

*The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings call (recording)—(301) 215–1292. Contact person for more information: Dave Gamberoni, (301) 415–1651.

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**Additional Information**

By a vote of 3–0 on May 14 and 18, the Commission determined pursuant to U.S.C. 552b(e) and § 9.107(a) of the Commission's rules that "Discussion of Security Issues (Closed—Ex. 1)" be held May 20, and on less than one week's notice to the public.

By a vote of 3–0 on May 19 and 20, the Commission determined pursuant to U.S.C 552b(e) and § 9.107(a) of the Commission's rules that "Affirmation of (1) Nuclear Fuel Services, Inc. (Erwin, Tennessee); Appeal of LBP–04–05, the Presiding Officer's Ruling on Hearing Requests; (2) Hydro Resources, Inc. (Rio Rancho, New Mexico) Petitions for Review of LBP–04–03 (Financial Assurance); (3) Louisiana Energy Services, L.P. (National Enrichment Center); and (4) Final Rule to amend 10 CFR Part 2, Subpart J, in Regard to the Licensing Support Network" be held on May 20, and on less than one week's notice to the public.

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The NRC Commission Meeting Schedule can be found on the Internet at: *www.nrc.gov/what-we-do/policy-making/schedule.html.*

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This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it, or would like to be added to the distribution, please contact the Office of the Secretary, Washington, DC 20555 (301–415–1969). In addition, distribution of this meeting notice over the Internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to *dkw@nrc.gov*.

Dated: May 20, 2004.

**Dave Gamberoni,**

*Office of the Secretary.*

[FR Doc. 04–11852 Filed 5–21–04; 9:35 am]

BILLING CODE 7590–01–M

## NUCLEAR REGULATORY COMMISSION

### Biweekly Notice; Applications and Amendments To Facility Operating Licenses Involving No Significant Hazards Considerations

**I. Background**

Pursuant to section 189a. (2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (the Commission or NRC staff) is publishing this regular biweekly

notice. The Act requires the Commission publish notice of any amendments issued, or proposed to be issued and grants the Commission the authority to issue and make immediately effective any amendment to an operating license upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued from, April 30, through May 13, 2004. The last biweekly notice was published on May 11, 2004 (69 FR 26184).

*Notice of Consideration of Issuance of Amendments To Facility Operating Licenses, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing*

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination. Within 60 days after the date of publication of this notice, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. Should the Commission make a final No Significant Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room 6D22, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Copies of written comments received may be examined at the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area O1F21, 11555 Rockville Pike (first floor), Rockville, Maryland. The filing of requests for a hearing and petitions for leave to intervene is discussed below.

Within 60 days after the date of publication of this notice, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's "Rules of Practice for Domestic Licensing Proceedings" in 10 CFR Part 2. Interested persons should consult a current copy of 10 CFR 2.309, which is available at the Commission's PDR, located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the Agencywide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/doc-collections/cfr/*. If a request for a hearing or petition for leave to intervene is filed within 60 days, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of a hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements: (1) The name, address and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also set forth the specific contentions which the petitioner/requestor seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner/requestor shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner/requestor intends to rely in proving the contention at the hearing. The petitioner/requestor must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner/requestor intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner/requestor to relief. A petitioner/requestor who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to

participate fully in the conduct of the hearing.

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; (2) courier, express mail, and expedited delivery services: Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff; (3) E-mail addressed to the Office of the Secretary, U.S. Nuclear Regulatory Commission, *Hearingdocket@nrc.gov;* or (4) facsimile transmission addressed to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC, Attention: Rulemakings and Adjudications Staff at (301) 415–1101, verification number is (301) 415–1966. A copy of the request for hearing and petition for leave to intervene should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and it is requested that copies be transmitted either by means of facsimile transmission to 301–415–3725 or by e-mail to *OGCMailCenter@nrc.gov.* A copy of the request for hearing and petition for leave to intervene should also be sent to the attorney for the licensee.

Nontimely requests and/or petitions and contentions will not be entertained absent a determination by the Commission or the presiding officer of the Atomic Safety and Licensing Board that the petition, request and/or the contentions should be granted based on a balancing of the factors specified in 10 CFR 2.309(a)(1)(i)–(viii).

For further details with respect to this action, see the application for amendment which is available for public inspection at the Commission's PDR, located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the Agencywide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html.* If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC PDR Reference staff at 1–800–397–4209, 301–415–4737 or by e-mail to *pdr@nrc.gov.*

*Duke Energy Corporation, et al., Docket Nos. 50–369 and 50–370, McGuire Nuclear Station, Units 1 and 2, Mecklenburg County, North Carolina Docket Nos. 50–413 and 50–414, Catawba Nuclear Station, Units 1 and 2, York County, South Carolina*

*Date of amendment request:* March 23, 2004.

*Description of amendment request:* The amendments would revise Technical Specification 5.5.7, "Reactor Coolant Pump Flywheel Inspection Program," to extend the allowable inspection interval to 20 years.

The NRC staff issued a notice of opportunity for comment in the **Federal Register** on June 24, 2003 (68 FR 37590), on possible amendments to extend the inspection interval for reactor coolant pump (RCP) flywheels, including a model safety evaluation and model no significant hazards consideration (NSHC) determination, using the consolidated line-item improvement process. The NRC staff subsequently issued a notice of availability of the models for referencing in license amendment applications in the **Federal Register** on October 22, 2003 (68 FR 60422). The licensee affirmed the applicability of the model NSHC determination in its application dated March 23, 2004.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), an analysis of the issue of NSHC is presented below:

Criterion 1—The proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed change to the RCP flywheel examination frequency does not change the response of the plant to any accidents. The RCP will remain highly reliable and the proposed change will not result in a significant increase in the risk of plant operation. Given the extremely low failure probabilities for the RCP motor flywheel during normal and accident conditions, the extremely low probability of a loss-of-coolant accident (LOCA) with loss of offsite power (LOOP), and assuming a conditional core damage probability (CCDP) of 1.0 (complete failure of safety systems), the core damage frequency (CDF) and change in risk would still not exceed the NRC's acceptance guidelines [contained] in Regulatory Guide (RG) 1.174 (<1.0E–6 per year). Moreover, considering the uncertainties involved in this evaluation, the risk associated with the postulated failure of an RCP motor flywheel is significantly low. Even if all four RCP motor flywheels are considered in the bounding plant configuration case, the risk is still acceptably low.

The proposed change does not adversely affect accident initiators or precursors, nor alter the design assumptions, conditions, or configuration of the facility, or the manner in which the plant is operated and maintained; alter or prevent the ability of structures, systems, components (SSCs) from performing their intended function to mitigate the consequences of an initiating event within the assumed acceptance limits; or affect the source term, containment isolation, or radiological release assumptions used in evaluating the radiological consequences of an accident previously evaluated. Further, the proposed change does not increase the type or amount of radioactive effluent that may be released offsite, nor significantly increase individual or cumulative occupational/public radiation exposure. The proposed change is consistent with the safety analysis assumptions and resultant consequences. Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

Criterion 2—The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed change in flywheel inspection frequency does not involve any change in the design or operation of the RCP. Nor does the change to examination frequency affect any existing accident scenarios, or create any new or different accident scenarios. Further, the change does not involve a physical alteration of the plant (*i.e.*, no new or different type of equipment will be installed) or alter the methods governing normal plant operation. In addition, the change does not impose any new or different requirements or eliminate any existing requirements, and does not alter any assumptions made in the safety analysis. The proposed change is consistent with the safety analysis assumptions and current plant operating practice. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

Criterion 3—The proposed change does not involve a significant reduction in a margin of safety.

The proposed change does not alter the manner in which safety limits, limiting safety system settings, or limiting conditions for

operation are determined. The safety analysis acceptance criteria are not impacted by this change. The proposed change will not result in plant operation in a configuration outside of the design basis. The calculated impact on risk is insignificant and meets the acceptance criteria contained in RG 1.174. There are no significant mechanisms for inservice degradation of the RCP flywheel. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff proposes to determine that the amendment request involves NSHC.

*Attorney for licensee:* Ms. Lisa F. Vaughn, Legal Department (PB05E), Duke Energy Corporation, 422 South Church Street, Charlotte, North Carolina 28201–1006.

*NRC Section Chief:* Stephanie M. Coffin, Acting.

*Energy Northwest, Docket No. 50–397, Columbia Generating Station, Benton County, Washington*

*Date of amendment request:* April 19, 2004.

*Description of amendment request:* The proposed change revises Limiting Condition for Operation (LCO) 3.7.3, "Control Room Emergency Filtration System," to provide specific conditions and required actions that address degraded control room boundary.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. The proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed Technical Specifications (TS) change involves the Control Room Emergency Filtration (CREF) System and associated control room boundary, which provide a radiological controlled environment from which the plant can be operated following a design basis accident (DBA). The CREF system and the control room boundary are not assumed to be initiators of any analyzed accident and do not affect the probability of accidents. The proposed change adds a Note to LCO 3.7.3 that allows the control room boundary to be opened intermittently under administrative controls. A new Condition B is also added to LCO 3.7.3 to specify a Completion Time of 24 hours to restore an inoperable control room boundary to OPERABLE status before requiring the plant to perform an orderly shutdown. The 24-hour Completion Time is reasonable based on the low probability of a DBA occurring during this time period and Energy Northwest's commitment to implement, via administrative controls, appropriate compensatory measures consistent with the intent of 10 CFR 50, Appendix A, General Design Criteria (GDC) 19. These compensatory measures will serve to minimize the consequences of an open control room boundary and ensure the CREF system can continue to perform its function. As such, these changes will not affect the function or operation of any other systems, structures or components. Therefore, the proposed TS change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. The proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

The proposed change adds a Note to LCO 3.7.3 that allows the control room boundary to be opened intermittently under administrative controls. A new Condition B is also added to LCO 3.7.3 to specify a Completion Time of 24 hours to restore an inoperable control room boundary to OPERABLE status before requiring the plant to perform an orderly shutdown. The CREF system and the control room boundary are designed to protect the habitability of the control room. The CREF system and the control room boundary are not accident initiators and do not affect the probability of accidents. This change is administrative in nature and does not involve any physical changes to the plant. Therefore, the proposed TS change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. The proposed change does not involve a significant reduction in a margin of safety.

The proposed change adds a Note to LCO 3.7.3 that allows the control room boundary to be opened intermittently under administrative controls. A new Condition B is also added to LCO 3.7.3 to specify a Completion Time of 24 hours to restore an inoperable control room boundary to OPERABLE status before requiring the plant to perform an orderly shutdown. The 24-hour Completion Time is reasonable based on the low probability of a DBA occurring during this time period and Energy Northwest's commitment to implement, via administrative controls, appropriate compensatory measures consistent with the intent of 10 CFR 50, Appendix A, GDC 19. These compensatory measures will serve to minimize the consequences of an open control room boundary and assure that the CREF system can continue to perform its function. Therefore, the proposed TS change does not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Thomas C. Poindexter, Esq., Winston & Strawn, 1400 L Street, NW., Washington, DC 20005–3502.

*NRC Section Chief:* Stephen Dembek.

*Entergy Gulf States, Inc., and Entergy Operations, Inc., Docket No. 50–458, River Bend Station (RBS), Unit 1, West Feliciana Parish, Louisiana*

*Date of amendment request:* October 21, 2003, as supplemented February 10, 2004.

*Description of amendment request:* The amendment would modify the Technical Specifications (TSs) to delete TS 3.6.4.4, "Shield Building Annulus Mixing System," in its entirety, revise the Main Steam Isolation Valve (MSIV) leakage limits contained within TS Surveillance Requirement 3.6.1.3.10, and delete reference to TS 3.6.4.4 within TS 3.10.1, "Inservice Leak and Hydrostatic Testing Operation."

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

*Response:* No.

As discussed above, the proposed changes are to delete the annulus mixing function and deletion of the single MSIV leakage rate limit. A review of the safety analysis report indicates that operation (or mis-operation) of the annulus mixing system, or any component of the annulus mixing system is not considered an initiator of any accident evaluated in the Updated Safety Analysis Report. The deletion of the single MSIV leakage limit of 50 scfh in effect establishes a maximum leakage limit of 150 scfh which is the current total MSIV leakage limit. The elimination of the single MSIV acceptable leakage rate limit does not impact any event initiator. As the proposed changes do not involve any accident initiators, there is no increase in the probability of an accident previously evaluated.

The annulus mixing system and the main steam isolation valves operate following an LOCA [loss-of-coolant accident] to mitigate the consequences of an accident. Elimination of the annulus mixing system and the single MSIV leakage limit will lead to some increase in the dose consequences of a LOCA. The current LOCA dose consequences evaluation for RBS was revised to account for the elimination of the annulus mixing system and for increasing the single MSIV leakage to 150 scfh (applying the total MS–PLCS Division limit to the single MSIV). The results of the revised evaluation with the proposed changes show an increase in the calculated dose consequences, however, the calculated doses were still within the acceptance limits of 10 CFR 50.67. Thus, while there is an increase in the dose consequences of an accident previously identified, the increase is not deemed to be significant.

Therefore, the proposed change does not involve a significant increase in the

probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

*Response:* No.

The proposed change does not add any equipment, nor is any equipment replaced with equipment with different performance characteristics. Thus, no new initiators are added, and therefore, no new accident types are created as a result of this change. The proposed changes affect performance characteristics assumed in the LOCA dose consequences evaluation, however, the nature of the accidents evaluated in the safety analysis report are not changed.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

*Response:* No.

With respect to dose consequences for the LOCA event, the margin of safety is considered to be that provided by meeting the 10 CFR 50.67 limits. The revised dose consequences evaluation, which includes the proposed changes, continues to demonstrate that the doses at the exclusion area boundary, the low population zone, and the control room are within the acceptance limits in 10 CFR 50.67. Therefore, there is no reduction in the margin of safety.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Mark Wetterhahn, Esq., Winston & Strawn, 1400 L Street, NW., Washington, DC 20005.

*NRC Section Chief:* Robert A. Gramm.

*Entergy Gulf States, Inc., and Entergy Operations, Inc., Docket No. 50–458, River Bend Station (RBS), Unit 1, West Feliciana Parish, Louisiana*

*Date of amendment request:* February 16, 2004.

*Description of amendment request:* The amendment would change Technical Specification (TS) 3.6.5.1.3, regarding drywell bypass leakage testing (DWBT). The change would allow for a one-time extension of the interval (from 10 to 15 years) for performance of the next DWBT.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

*Response:* No.

The proposed amendment to TS SR 3.6.5.1.3 adds a one-time extension to the current interval for the DWBT. The current interval of ten years, based on past performance, would be extended on a one-time basis to 15-years from the date of the last test. The proposed extension to the DWBT cannot increase the probability of an accident since there are no design or operating changes involved and the test is not an accident initiator. The proposed extension of the test interval does not involve a significant increase in the consequences since analysis has shown that, the proposed extension of the DWBT frequency has a minimal impact on plant risk. Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

*Response:* No.

The proposed extension to the interval for the DWBT does not involve any design or operational changes that could lead to a new or different kind of accident from any accidents previously evaluated. The tests are not being modified, but are only being performed after a longer interval. The proposed change does not involve a physical alteration of the plant (no new or different type of equipment will be installed) or a change in the methods governing normal plant operation. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

*Response:* No.

An evaluation of extending the DWBT surveillance frequency from once in 10 years to once in 15 years has been performed using methodologies based on the ILRT [integrated leak rate testing] methodologies. This evaluation assumed that the DWBT frequency was being adjusted in conjunction with the ILRT frequency. This analysis used realistic, but still conservative, assumptions with regard to developing the frequency of leakage classes associated with the DWBT. The results from this conservative analysis indicates that the proposed extension of the DWBT frequency has a minimal impact on plant risk and therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Mark Wetterhahn, Esq., Winston & Strawn, 1400 L Street, NW., Washington, DC 20005.

*NRC Section Chief:* Robert A. Gramm.

*Entergy Operations Inc., Docket No. 50–382, Waterford Steam Electric Station, Unit 3, (Waterford 3) St. Charles Parish, Louisiana*

*Date of amendment request:* May 7, 2004.

*Description of amendment request:* The proposed changes will revise the Waterford 3 Technical Specifications (TS) to clarify the actions of TS 3.4.5.1, Reactor Coolant System (RCS) Leakage; some of the surveillance requirements (SRs) of TS 3.4.5.2, RCS Operational Leakage; and delete duplication in TS 3.3.3.1, Radiation Monitoring Instrumentation. The proposed change is based on NUREG–1432, "Standard Technical Specifications Combustion Engineering Plants," Revision 2, dated April 30, 2001. Also, the proposed change will delete the containment atmosphere gaseous radioactivity monitoring system from the TS because this monitor does not meet the requirements of Regulatory Guide 1.45, Revision 0, "Reactor Coolant Pressure Boundary Leakage Detection Systems," and Title 10 of the Code of Federal Regulations (10 CFR), Part 50, Appendix A, General Design Criteria 30, "Quality of Reactor Coolant System Pressure Boundary."

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

*Response:* No.

The proposed revisions do not involve any physical change to plant design. The less restrictive changes proposed in this amendment request include relocation of information to the UFSAR [updated final safety analysis report], addition of a TS 3.0.4 exception, utilization of the diversity and redundancy of the Waterford 3 leakage detection instrumentation, allowing diversity in the contingency actions, deletion of SRs, and addition of an allowed outage time when two of three required leakage detection instrumentation is inoperable. The less restrictive changes will not affect the capability of Waterford 3 to detect RCS leakage. At least one RCS leakage detection instrumentation is always required to remain operable, and other leakage detection indication, while not credited specifically for RCS leakage detection, is still available and required to be operable per other TS

requirements (*i.e.*, Containment Temperature and Containment Pressure). Also contingency actions are required (*i.e.*, RCS Inventory Balance, containment grab samples, flow switch verification) when any of the RCS leakage detection instrumentation is inoperable. Performance of the RCS inventory balance is the most accurate method of determining and quantifying leakage. The RCS inventory balance is being added as a contingency and replacement for monitoring instrumentation that has continuous indication and alarms in the control room.

The more restrictive changes proposed by this revision do not adversely affect the capability of Waterford 3 RCS leakage detection instrumentation to detect RCS leakage. The deletion of the containment atmosphere gaseous radioactivity monitor is considered a more restrictive change. This monitor does not meet the leakage detection requirements of Regulatory Guide 1.45 and does not meet the requirements for retention specified in 10 CFR 50.36. Deletion of this monitor will reduce the diversity of the Waterford 3 instrumentation for monitoring the containment atmosphere and require the plant to enter an Action statement when the containment atmosphere particulate monitor is inoperable. Requiring performance of an RCS inventory balance when the containment sump monitor is inoperable provides contingency actions when the plant is in a degraded RCS leakage detection condition.

The administrative changes proposed by this revision do not adversely affect the capability of Waterford 3 RCS leakage detection instrumentation to detect RCS leakage. Relocating the requirements associated with the RCS Leak Detection System from various TS to Specification 3.4.5.1 and adding requirement to shutdown when all required RCS leakage detection instrumentation are inoperable are administrative in nature. The relocation of information from one TS to another consolidates information and causes less contusion in the control room by having all requirements for the leakage detection instrumentation in one TS. The addition of a specific action to shutdown when all three leakage detection instrumentation are inoperable versus an implied requirement to enter TS 3.0.3 is being performed to be similar to the STS [Standard Technical Specifications].

None of the above less restrictive, more restrictive, or administrative changes affects the accident analyses. Since the proposed changes only affect the requirements for the detection of RCS leakage, the probability that an accident previously evaluated will occur remains unchanged. The proposed changes do not prevent nor limit the diversity of acceptable detection of RCS leakage. These changes also do not affect the mitigation capability of any accident previously evaluated. The consequences of an accident previously evaluated are not affected since the mitigation of previously evaluated accidents is not affected and leak rate information will remain available to station personnel.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

*Response:* No.

The aforementioned revisions do not involve any physical change to plant design. None of the proposed changes affect[s] the accident analyses. The RCS water inventory balance is more accurate than normal leak detection methods in regard to actual RCS leak rates, and therefore is an excellent alternative when other leak detection components may become inoperable. The proposed changes do not prevent acceptable detection of RCS leakage by diverse methods. The detection of a RCS leak can not cause an accident. Likewise, detecting a RCS leak, while in its beginning stages, does not create the possibility of a new or different kind of accident than any previously analyzed. Therefore, a new or different kind of accident than that previously analyzed does not result due to the proposed changes of this submittal.

Therefore. the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

*Response:* No.

The aforementioned revisions do not involve any physical change to plant design. The proposed changes do not adversely affect the ability of the RCS leakage detection system to detect RCS leakage. The ability of the RCS leakage detection instrumentation to detect leakage within the requirements of Regulatory Guide 1.45 is actually improved. The containment atmosphere gaseous monitor is being deleted from TS, because, it does not meet the requirements of Regulatory Guide 1.45 to detect a 1.0 gpm [gallon per minute] RCS leakage within 1 hour. Extending the AOT [allowed outage time] when two of three leakage detection systems is inoperable does not decrease the margin of safety because one instrument remains operable, other instrumentation capable of indicating RCS leakage is available, and an RCS inventory balance is required to be performed on an increased frequency. The RCS inventory balance is more accurate than normal leak detection methods in regard to actual RCS leak rates, and therefore is an excellent alternative when other leak detection components may become inoperable. Maintaining diverse and accurate RCS leak detection methods available and capable of prompt leakage detection helps to ensure RCS leaks will be detected within an acceptable period of time and, therefore, the proposed changes do not significantly reduce the margin to safety.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* N. S. Reynolds, Esquire, Winston & Strawn 1400 L Street NW., Washington, DC 20005–3502.

*NRC Section Chief:* Robert A. Gramm.

*FirstEnergy Nuclear Operating Company, Docket No. 50–346, Davis-Besse Nuclear Power Station, Unit 1, Ottawa County, Ohio*

*Date of amendment request:* April 29, 2004.

*Description of amendment request:* The proposed amendment would revise Technical Specification (TS) Section 3/4.4.10, "Reactor Coolant System—Structural Integrity, ASME Code Class 1, 2, and 3 Components," to relocate Surveillance Requirement (SR) 4.4.10.1.b which requires that the reactor vessel internals vent valves be tested and inspected, to the Technical Requirements Manual (TRM). The Davis-Besse Nuclear Power Station (DBNPS) TRM is a licensee-controlled document that is incorporated by reference into the DBNPS Updated Safety Analysis Report (USAR). Changes to the DBNPS TRM are performed in accordance with the regulatory requirements of 10 CFR 50.59.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensees have provided their analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

*Response:* No. The proposed surveillance requirement relocation from the Technical Specifications to the USAR TRM does not alter the design, operation, or testing of any structure, system, or component. No preciously analyzed accident scenario is changed. Initiating conditions and assumptions remain as previously analyzed. Therefore, the proposed changes does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

*Response:* No. The proposed surveillance requirement relocation from the Technical Specifications to the USAR TRM does not alter the design, operation, or testing of any structure, system or component. The proposed change does not introduce any new or different accident initiators. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

*Response:* No. The proposed surveillance requirements relocation from the Technical Specifications to the USAR TRM does not affect the capabilities of the Reactor Vessel Internals Vent Valves. Therefore, the proposed change will not affect a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Mary E. O'Reilly, Attorney, FirstEnergy Corporation, 76 South Main Street, Akron, OH 44308.

*NRC Section Chief:* Anthony J. Mendiola.

*FirstEnergy Nuclear Operating Company, Docket No. 50–346, Davis-Besse Nuclear Power Station, Unit 1, Ottawa County, Ohio*

*Date of amendment request:* May 3, 2004.

*Description of amendment request:* The proposed amendment would change the facility as described in the Updated Safety Analysis Report (USAR) for the emergency diesel generators (EDGs). Specifically, the proposed change would describe a departure from Safety Guide 9, "Selection of Diesel Generator Set Capacity for Standby Power Supplies," for the frequency and voltage transient during the EDG automatic loading sequence.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensees have provided their analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

*Response:* No. The proposed amendment alters the design requirements for the Emergency Diesel Generators (EDGs). Specifically, the proposed amendment affects the requirements for EDG voltage and frequency response following a loss of offsite power. The EDGs function to mitigate the consequences of accidents when offsite power is not available. The EDGs are not an initiator of any analyzed accident.

The effect of this change on the capability of the EDGs, the onsite electric power system, and essentially powered equipment to perform their required safety functions has been evaluated, and the proposed change does not significantly impact the capability of these systems to perform their required accident mitigation functions. No previous analyzed accident scenario is affected by the proposed change.

The proposed change does not affect the initiation of any analyzed accident. The accident mitigation functions for affected equipment are maintained. Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

*Response:* No. The proposed amendment affects the USAR requirements for EDG voltage and frequency response following a loss of offsite power. The effect of this change on the capability of the EDGs, the onsite electric power system, and essentially powered equipment to perform their required safety functions has been evaluated, and the proposed change does not significantly impact the capability of these systems to perform their required safety functions. The assumptions of the current accident analyses are maintained and no new or different accident initiators are created. Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

*Response:* No. The proposed amendment affects the USAR requirements for EDG voltage and frequency response following a loss of offsite power. The effect of this change on the capability of the EDGs, the onsite electric power system, and essentially powered equipment to perform their required safety functions has been evaluated, and it is concluded the proposed change does not impact the capability of these systems to perform their required safety functions. However, since the proposed change does make changes to the controlling values for EDG voltage and frequency transient response that are less restrictive than those presently described in the USAR, this is considered a reduction in a margin of safety.

The magnitude of voltage and frequency drops which would result in failure of the EDGs, the onsite power system, or essentially powered equipment have not been determined due to the limitations of the transient assessment model and the nonlinear phenomena associated with that postulated failure. However, based on (1) a computer model and testing of the diesel engine, engine speed control governor and actuator, the synchronous generator and excitation system that demonstrate the EDGs are capable of starting, accelerating, and carrying the required loads, (2) a comprehensive evaluation of the impact of the transient voltage and frequency response on plant equipment and safety functions, (3) the momentary duration of the voltage and frequency dips, and (4) based on engineering judgement, the proposed change is not considered to have a significant effect on the margin of safety. Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Mary E. O'Reilly, Attorney, FirstEnergy Corporation, 76 South Main Street, Akron, OH 44308.

*NRC Section Chief:* Anthony J. Mendiola.

*Florida Power and Light Company, Docket Nos. 50–250 and 50–251, Turkey Point Plant, Units 3 and 4, Miami-Dade County, Florida*

*Date of amendment request:* April 23, 2004.

*Description of amendment request:* The proposed amendments would revise several Technical Specification (TS) Allowed Outage Times for TS 3.3.3, Accident Monitoring, to be consistent with the Completion Times in the related Specification in NUREG–1431, Revision 2, "Standard Technical Specifications Westinghouse Plants (the Improved Standard Technical Specifications, or ISTS)."

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Operation of the facility in accordance with the proposed amendment would not involve a significant increase in the probability or consequences of an accident previously evaluated.

The proposed changes revise the Actions and allowed outage times of the accident monitoring instrumentation. The accident monitoring instrumentation is not an initiator of any accident previously evaluated. As a result, the probability of any accident previously evaluated is not significantly increased by these proposed changes. The Technical Specifications continue to require the accident monitoring instrumentation to be operable. Therefore, the accident monitoring instrumentation will continue to provide sufficient information on selected plant parameters to monitor and assess these variables following an accident. The consequences of an accident during the extended allowed outage time are the same as the consequences during the current allowed outage time. As a result, the consequences of any accident previously evaluated are not significantly increased by these proposed changes. Therefore, the proposed amendments do not involve a significant increase in the probability or consequences of any accident previously evaluated.

2. Operation of the facility in accordance with the proposed amendments would not create the possibility of a new or different

kind of accident from any previously evaluated.

The proposed changes do not alter the design, physical configuration, or mode of operation of the plant. The accident monitoring instrumentation is not an initiator of any accident previously evaluated. No changes are being made to the plant that would introduce any new accident causal mechanisms. The proposed changes do not affect any other plant equipment. Therefore, operation of the facility in accordance with the proposed amendments does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Operation of the facility in accordance with the proposed amendments would not involve a significant reduction in a margin of safety.

The proposed changes do not change the operation, function, or modes of the plant or equipment operation. The proposed changes do not change the level of assurance that the accident monitoring instrumentation will be available to perform its function. The proposed changes provide a more appropriate time to restore the inoperable channel(s) to operable status, and only apply when one or more channels of a required instrument are inoperable. The additional time to restore an inoperable channel to operable status is appropriate based on the low probability of an event requiring an accident monitoring instrument during the interval, providing a reasonable time for repair, and other means which may be available to obtain the required information. Therefore, operation of the facility in accordance with the proposed amendments would not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* M.S. Ross, Attorney, Florida Power & Light, P.O. Box 14000, Juno Beach, Florida 33408–0420.

*NRC Section Chief:* William F. Burton, Acting.

*Maine Yankee Atomic Power Company, Docket No. 50–309, Maine Yankee Atomic Power Station, Lincoln County, Maine*

*Date of amendment request:* March 15, 2004.

*Description of amendment request:* Maine Yankee Atomic Power Company (Maine Yankee) is requesting that the U.S. Nuclear Regulatory Commission (NRC) release the remaining land under License No. DPR–36, with the exception of land where the Independent Spent Fuel Storage Installation is located. Maine Yankee submitted detailed information on dismantlement activities and final status survey results for the Spray Building and Spray Pipe with the amendment request, and proposes to submit dismantlement and survey information for the remaining land area in four additional submittals. Maine Yankee is seeking review and approval of the amendment; however, Maine Yankee is requesting that the NRC condition the effective date of the license amendment to correspond with the NRC's approval of the final information submittal.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

*Response:* No.

The requested license amendment involves release of land presently considered part of the Maine Yankee plant site under license DPR–36. The release of this land will occur after all demolition activities are completed and final status surveys have been performed to document the final radiological conditions of the land. When the release occurs, the only remaining radiological hazard at the site will be contained in the Independent Spent Fuel Storage Installation (ISFSI). Therefore, the focus of the analysis is on the potential impact on the probability and consequences of accidents associated with the ISFSI.

The accident conditions evaluated for the spent fuel storage casks include the following: accident pressurization, mis-loading of fuel canisters, drop of the vertical concrete casks, explosion, fires, maximum anticipated heat load, earthquakes, floods, lightening strikes, tornado and tornado driven missiles, tip over of vertical concrete cask, and full blockage of vertical concrete cask air inlets and outlets. The release of the non-ISFSI land from the license will not affect the probability of any of these accidents. Maine Yankee will retain sufficient control over activities performed on the Owner Controlled Area through rights granted in the legal land conveyance documents to ensure that there is no impact on consequences from postulated accidents. Therefore, the proposed release of the land will not affect the consequences of any of these postulated accidents.

The proposed action, therefore, does not increase either the probability or the consequences of any accidents that have been considered.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

*Response:* No.

The requested amendment involves release of land presently considered part of the Maine Yankee plant site under license DPR–36. When the amendment becomes effective, demolition activities will be complete and all systems, structures and components will have been removed from the land. The requested release of the land does not create the possibility of a new or different kind of accident that could affect the ISFSI that has not been considered in the design, installation or operation of the ISFSI. As noted above, Maine Yankee will retain control over activities performed in the Owner Controlled Area for the ISFSI to assure that no new hazards are introduced that could create the potential for a new or different kind of accident. Therefore, the proposed amendment does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

*Response:* No.

The margin of safety defined in the statements of consideration for the final rule on the Radiological Criteria for License Termination is described as the margin between the 100 mrem/yr public dose limit established in 10 CFR 20.1301 for licensed operation and the 25 mrem/yr dose limit to the average member of the critical group at a site considered acceptable for unrestricted use. This margin of safety accounts for the potential effect of multiple sources of radiation exposure to the critical group. Additionally, the State of Maine, through legislation, has imposed a 10 mrem/yr all pathways dose limit, with no more than 4 mrem/yr attributable to drinking water sources.

The License Termination Plan (LTP) prepared by Maine Yankee establishes conservative criteria for residual radiation levels following completion of demolition activities at the site. The LTP demonstrates that when these conservative criteria are met, the dose to the average member of the critical group will be below the regulatory criteria established by the State of Maine, and, therefore, well below the dose limits established by the NRC. The proposed release of the site lands, once the criteria established in the LTP have been met will, therefore, not result in any reduction in the margin of safety.

Conclusion

Based on the above, Maine Yankee concludes that the proposed amendment presents no significant hazards consideration under the standards set forth in 10 CFR 50.92(c), and, accordingly, a finding of "no significant hazards consideration" is justified.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the requested amendment involves no significant hazards consideration.

*Attorney for licensee:* Joe Fay, Esquire, Maine Yankee Atomic Power Company, 321 Old Ferry Road, Wiscasset, Maine 04578

*NRC Section Chief:* Claudia M. Craig.

*Nine Mile Point Nuclear Station, LLC, Docket No. 50–220, Nine Mile Point Nuclear Station Unit No. 1, Oswego County, New York*

*Date of amendment request:* April 19, 2004.

*Description of amendment request:* The licensee proposed to revise the Technical Specifications (TSs) to establish an operating cycle (24-month) calibration surveillance frequency for the Intermediate Range Monitor (IRM) instrumentation, which would replace the current "prior to startup and normal shutdown" Surveillance Requirement (SR). The proposed changes also included associated conforming changes. In addition, the licensee proposed to relocate the Limiting Conditions for Operation (LCOs) and SRs for selected control rod withdrawal block instrumentation to the Updated Final Safety Analysis Report (UFSAR), a licensee-controlled document.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

*Response:* No.

The proposed changes are limited to: (1) establishing a 24-month calibration frequency for the IRM instrumentation in lieu of the current "prior to startup and normal shutdown" requirement and incorporating the associated conforming changes, and (2) the relocation of certain instrumentation requirements from the TSs that do not satisfy the screening criteria for retention in the TSs. The proposed changes do not introduce any new modes of plant operation, make any physical changes to the plant, or alter any operational setpoints in a manner which could degrade the performance of, or increase the challenges to, any safety system assumed to function in the accident analysis. In addition, evaluations of the proposed changes pursuant to NRC and industry guidance demonstrate that the availability and reliability of equipment and systems required to prevent or mitigate the radiological consequences of an accident are not significantly affected. Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

*Response:* No.

The proposed changes establish a 24-month IRM calibration frequency in lieu of the current "prior to startup and normal shutdown" requirement and relocate certain instrumentation requirements to the UFSAR. As such, the proposed changes do not eliminate any requirements or impose any new requirements, and adequate controls of existing requirements are maintained. Furthermore, since the proposed changes do not make any physical changes to the plant, no new accident initiators or failure mechanisms are introduced, and the accident assumptions and initial conditions will remain unchanged. Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident [previously] evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

*Response:* No.

The proposed changes establish a 24-month IRM calibration frequency in lieu of the current "prior to startup and normal shutdown" requirement and relocate certain instrumentation requirements to the UFSAR. Although the proposed changes result in changes to surveillance intervals, the impact, if any, on system availability is small based on (1) other more frequent testing that is performed, (2) the existence of redundant equipment, and (3) overall system reliability. Consistent with the findings of previous industry evaluations, the NMP1 [Nine Mile Point Nuclear Station, Unit No. 1] plant-specific analyses have shown no evidence of time-dependent failures that would impact the availability of the affected systems. Furthermore, plant-specific evaluations and the adoption of the calculated IRM setpoint Allowable Values ensure that the setpoint margins are maintained for a 24-month (30-month maximum) calibration frequency. The proposed relocated requirements are consistent with the Improved Standard TSs (NUREG–1433 and NUREG–1434) and 10 CFR 50.36, and will be maintained in accordance with 10 CFR 50.59. Accordingly, the proposed changes will have no significant impact on the condition or performance of structures, systems, and components relied upon for accident mitigation. Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

*Attorney for licensee:* Mark J. Wetterhahn, Esquire, Winston & Strawn, 1400 L Street, NW., Washington, DC 20005–3502.

*NRC Section Chief:* Richard J. Laufer.

*Nuclear Management Company, LLC, Docket Nos. 50–282 and 50–306, Prairie Island Nuclear Generating Plant, Units 1 and 2, Goodhue County, Minnesota*

*Date of amendment request:* January 20, 2004.

*Description of amendment request:* This License Amendment Request (LAR) proposes selective scope application of the alternate source term (AST) for the fuel handling accident (FHA) in accordance with the provisions of 10 CFR 50.67. Nuclear Management Company requests the Nuclear Regulatory Commission (NRC) review and approval of the AST FHA methodology for application to the Prairie Island Nuclear Generating Plant. This LAR also proposes revisions to Technical Specifications (TS) associated with ensuring that safety analyses assumptions are met for a postulated FHA in containment. Based on the AST FHA analyses, this LAR proposes to modify TS 3.9.4, "Containment Penetrations," to apply during the handling of recently irradiated fuel and require all containment penetrations to be closed during handling of recently irradiated fuel; and also proposes to remove the requirements of TS 3.3.5, "Containment Ventilation Isolation Instrumentation" relating to movement of irradiated fuel assemblies.

*Basis for proposed no significant hazards consideration determination:* As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Do the proposed changes involve a significant increase in the probability or consequences of an accident previously evaluated?

*Response:* No.

The proposed Technical Specification changes require containment integrity during movement of recently irradiated fuel. With this change, the Technical Specifications selectively implement 10 CFR 50.67 alternative source term methodologies for a fuel handling accident and implement portions of the approved industry improved Standard Technical Specification traveler, TSTF–51, "Revise containment requirements during handling irradiated fuel and core alterations' as it applies to TS 3.9.4, "Containment Penetrations." This change also removes requirements for containment ventilation isolation instrumentation during handling irradiated fuel from TS 3.3.5, "Containment Ventilation Isolation Instrumentation" since the containment purge and inservice purge system penetrations which are isolated by this instrumentation will be required to be isolated during movement of recently irradiated fuel. With the proposed 10 CFR 50.67 alternative source term methodologies, these filtration systems are not assumed to function during a fuel handling accident involving fuel which is not recently irradiated.

This amendment does not alter the methodology or equipment used directly in fuel handling operations. None of the containment integrity features including the containment equipment hatch, personnel air locks or any other containment penetration

are used to handle fuel. Therefore, containment integrity and ventilation systems, and spent fuel pool ventilation systems are not accident initiators and therefore these changes do not increase the probability of a previously evaluated accident.

The total effective dose equivalent (TEDE) doses from the analysis supporting this amendment request have been compared to equivalent total effective dose equivalent (TEDE) doses estimated with the guidelines of Regulatory Guide 1.183 Footnote 7. The new values are shown to be comparable to the results of the previous analysis.

A fuel handling accident analysis utilizing alternative source term methodologies allowed by 10 CFR 50.67 demonstrated that the dose consequences of a postulated fuel handling accident remain within the limits of 10 CFR 50.67 without taking credit for containment closure or ventilation systems assuming the fuel has not recently been in a critical reactor. The alternative source term fuel handling accident analysis also demonstrated that the more restrictive dose guidelines of Regulatory Guide 1.183 are also met without taking credit for these mitigation features. Since the alternative source term fuel handling accident analysis results are within the regulatory limits and regulatory guidelines without taking credit for these mitigation features, revising this Technical Specification for containment closure does not involve a significant increase in the consequences of a previously evaluated accident.

Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Do the proposed changes create the possibility of a new or different kind of accident from any accident previously evaluated?

*Response:* No.

The proposed Technical Specification changes require containment integrity during movement of recently irradiated fuel. With this change, the Technical Specifications selectively implement 10 CFR 50.67 alternative source term methodologies for a fuel handling accident and implement portions of the approved industry improved Standard Technical Specification traveler, TSTF–51, "Revise containment requirements during handling irradiated fuel and core alterations" as it applies to TS 3.9.4, "Containment Penetrations." This change also removes requirements for containment ventilation isolation instrumentation during handling irradiated fuel from TS 3.3.5, "Containment Ventilation Isolation Instrumentation" since the containment purge and inservice purge system penetrations which are isolated by this instrumentation will be required to be isolated during movement of recently irradiated fuel. With the proposed 10 CFR 50.67 alternative source term methodologies, these filtration systems are not assumed to function during a fuel handling accident involving fuel which is not recently irradiated.

The proposed Technical Specification changes do not involve plant design, hardware, system operation, or procedures involved with actual handling of irradiated fuel. The proposed changes include application of new methodology for fuel handling accident analysis and revises requirements for equipment operability during movement of irradiated fuel assemblies. These changes do not create the possibility for a new or different kind of accident.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any previously evaluated.

3. Do the proposed changes involve a significant reduction in a margin of safety?

*Response:* No.

The proposed Technical Specification changes require containment integrity during movement of recently irradiated fuel. With this change, the Technical Specifications selectively implement 10 CFR 50.67 alternative source term methodologies for a fuel handling accident and implement portions of the approved industry improved Standard Technical Specification traveler, TSTF–51, "Revise containment requirements during handling irradiated fuel and core alterations' as it applies to TS 3.9.4, "Containment Penetrations." This change also removes requirements for containment ventilation isolation instrumentation during handling irradiated fuel from TS 3.3.5, "Containment Ventilation Isolation Instrumentation" since the containment purge and inservice purge system penetrations which are isolated by this instrumentation will be required to be isolated during movement of recently irradiated fuel. With the proposed 10 CFR 50.67 alternative source term methodologies, these filtration systems are not assumed to function during a fuel handling accident involving fuel which is not recently irradiated.

The assumptions and input used in the fuel handling accident analysis are conservative. The design basis fuel handling accident has been defined to identify conservative conditions. The source term and radioactivity releases have been calculated pursuant to Regulatory Guide 1.183, Appendix B and with conservative assumptions concerning prior reactor operations. The control room atmospheric dispersion factor has been calculated with conservative assumptions associated with the release. These conservative assumptions and input ensure that the radiation doses cited in this license amendment request are the upper bounds to radiological consequences of a fuel handling accident in containment or the spent fuel pool. The analysis shows that there is a significant margin between the offsite radiation doses calculated for the postulated fuel handling accident using the alternate source term and the dose limits of 10 CFR 50.67 and acceptance criteria of Regulatory Guide 1.183. The proposed changes will not degrade the plant protective boundaries, will not cause a release of fission products to the public, and will not degrade the performance of any structures, systems, and components important to safety.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment requests involve no significant hazards consideration.

*Attorney for licensee:* Jonathan Rogoff, Esquire, Vice President, Counsel & Secretary, Nuclear Management Company, LLC, 700 First Street, Hudson, WI 54016.

*NRC Section Chief:* L. Raghavan.

**Notice of Issuance of Amendments to Facility Operating Licenses**

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for A Hearing in connection with these actions was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.12(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendment, (2) the amendment, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment as indicated. All of these items are available for public inspection at the Commission's Public Document Room, located at One White Flint North, Public File Area 01F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the Agencywide Documents Access and Management Systems (ADAMS) Public Electronic

Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html*. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC Public Document Room (PDR) Reference staff at 1–800–397–4209, 301–415–4737 or by e-mail to *pdr@nrc.gov*.

*Calvert Cliffs Nuclear Power Plant, Inc., Docket Nos. 50–317 and 50–318, Calvert Cliffs Nuclear Power Plant, Unit Nos. 1 and 2, Calvert County, Maryland*

*Date of application for amendments:* April 17, 2003, as supplemented July 29, 2003.

*Brief description of amendments:* These amendments revise the Required Actions requiring suspension of operations involving positive reactivity additions and various notes that preclude reduction of boron concentration.

*Date of issuance:* May 6, 2004.

*Effective date:* As of the date of issuance to be implemented within 30 days.

*Amendment Nos.:* 266 and 243.

*Renewed Facility Operating License Nos. DPR–53 and DPR–69:* Amendments revised the Technical Specifications.

*Date of initial notice in Federal Register:* May 27, 2003 (68 FR 28841).

The July 29, 2003, letter clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register** on May 27, 2003 (68 FR 28841).

The Commission's related evaluation of these amendments is contained in a Safety Evaluation dated May 6, 2004.

No significant hazards consideration comments received: No.

*Duke Energy Corporation, et al., Docket Nos. 50–413 and 50–414, Catawba Nuclear Station, Units 1 and 2, York County, South Carolina*

*Date of application for amendments:* November 5, 2003.

*Brief description of amendments:* The amendments revised the Technical Specifications to adopt the provisions of Industry/Technical Specification Task Force change TSTF–359, "Increase Flexibility in Mode Restraints."

*Date of issuance:* April 29, 2004.

*Effective date:* As of the date of issuance and shall be implemented within 120 days from the date of issuance.

*Amendment Nos.:* 213, 207.

*Renewed Facility Operating License Nos. NPF–35 and NPF–52:* Amendments revised the Technical Specifications.

*Date of initial notice in Federal Register:* February 17, 2004 (69 FR 7520)

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated April 29, 2004.

No significant hazards consideration comments received: No.

*Duke Energy Corporation, Docket Nos. 50–369 and 50–370, McGuire Nuclear Station, Units 1 and 2, Mecklenburg County, North Carolina*

*Date of application for amendments:* November 5, 2003.

*Brief description of amendments:* The amendments revised the Technical Specifications to adopt the provisions of Industry/Technical Specification Task Force change TSTF–359, "Increase Flexibility in Mode Restraints."

*Date of issuance:* April 29, 2004.

*Effective date:* As of the date of issuance and shall be implemented within 120 days from the date of issuance.

*Amendment Nos.:* 221, 203.

*Renewed Facility Operating License Nos. NPF–9 and NPF–17:* Amendments revised the Technical Specifications.

*Date of initial notice in Federal Register:* February 17, 2004 (69 FR 7520)

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated April 29, 2004.

No significant hazards consideration comments received: No.

*Entergy Operations, Inc., Docket No. 50–368, Arkansas Nuclear One, Unit No. 2, Pope County, Arkansas*

*Date of application for amendment:* February 9, 2004, as supplemented by letter dated March 2, 2004.

*Brief description of amendment:* The amendment removed the pressurizer heatup and cooldown limits, and the associated action and surveillance requirements, from the Technical Specifications and placed them in the Technical Requirements Manual.

*Date of issuance:* May 4, 2004.

*Effective date:* As of the date of issuance to be implemented within 60 days from the date of issuance.

*Amendment No.:* 253.

*Facility Operating License No. NPF–6:* Amendment revised the Technical Specifications.

*Date of initial notice in Federal Register:* March 2, 2004 (69 FR 9860).

The March 2, 2004, supplemental letter provided clarifying information that did not change the scope of the original **Federal Register** notice or the original no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 4, 2004.

No significant hazards consideration comments received: No.

*Florida Power and Light Company, et al., Docket Nos. 50–335 and 50–389, St. Lucie Plant, Units Nos. 1 and 2, St. Lucie County, Florida*

*Date of application for amendments:* July 18, 2002, as supplemented November 14, 2002, and December 11, 2003.

*Brief description of amendments:* The amendments relocate Technical Specification (TS) 3/4 9.7 regarding the Spent Fuel Storage Pool Building cranes and TS 3/4 9.13 (Unit 1) and TS 3/4 9.12 (Unit 2) regarding spent fuel cask cranes to the respective units' Updated Final Safety Analysis Report.

*Date of Issuance:* April 28, 2004

*Effective Date:* As of the date of issuance and shall be implemented within 60 days of issuance.

*Amendment Nos.:* 190 and 134

*Facility Operating License Nos. DPR–67 and NPF–16:* Amendments revised the Technical Specifications.

*Date of initial notice in Federal Register:* August 6, 2002 (67 FR 50954). The November 14, 2002, and December 11, 2003, supplements did not affect the original proposed no significant hazards determination, or expand the scope of the request as noticed in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated April 28, 2004.

No significant hazards consideration comments received: No.

*Florida Power and Light Company, Docket No. 50–335, St. Lucie Plant, Unit No. 1, St. Lucie County, Florida*

*Date of application for amendment:* May 22, 2002, as supplemented by letters dated December 5, 2002, and February 11, 2004.

*Brief description of amendment:* The amendment revised Technical Specification 6.9.1.11.b to add two NRC-approved topical reports to the Core Operating Limits Report methodology list, and delete superseded reports. Also, the method of listing topical reports was revised to be consistent with Technical Specifications Task Force 363, which has been approved by the NRC.

*Date of Issuance:* May 6, 2004.

*Effective Date:* As of the date of issuance and shall be implemented within 60 days of issuance.

*Amendment No.:* 191.

*Facility Operating License No. DPR–67:* Amendment revised the Technical Specifications.

*Date of initial notice in Federal Register:* June 25, 2002 (67 FR 42827).

The supplemental letters provided clarifying information that was within the scope of the initial notice and did not change the initial proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 6, 2004.

No significant hazards consideration comments received: No.

*Nine Mile Point Nuclear Station, LLC, Docket No. 50–410, Nine Mile Point Nuclear Station, Unit 2, Oswego County, New York*

*Date of application for amendment:* August 22, 2003, as supplemented by letters dated January 12 and March 11, 2004.

*Brief description of amendment:* The amendment revised Section 3.7.1, "Service Water (SW) System and Ultimate Heat Sink (UHS)," by adding a new Condition G to allow continued operation with short-term elevated UHS temperatures.

*Date of issuance:* May 7, 2004.

*Effective date:* As of the date of issuance to be implemented within 60 days.

*Amendment No.:* 113.

*Facility Operating License No. NPF–69:* Amendment revises the Technical Specifications.

*Date of initial notice in Federal Register:* September 30, 2003 (68 FR 56344).

The January 12 and March 11, 2004, letters provided clarifying information within the scope of the original application, and did not change the staff's initial proposed no significant hazards consideration determination. The staff's related evaluation of the amendment is contained in a Safety Evaluation dated May 7, 2004.

No significant hazards consideration comments received: No.

*Nuclear Management Company, LLC, Docket No. 50–305, Kewaunee Nuclear Power Plant, Kewaunee County, Wisconsin*

*Date of application for amendment:* January 30, 2004.

*Brief description of amendment:* The amendment relocates the requirements for hydrogen monitors from the Technical Specifications to the Technical Requirements Manual.

*Date of issuance:* May 13, 2004.

*Effective date:* As of the date of issuance and shall be implemented within 120 days.

*Amendment No.:* 174.

*Facility Operating License No. DPR–43:* Amendment revised the Technical Specifications.

*Date of initial notice in Federal Register:* March 2, 2004 (69 FR 9862).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 13, 2004.

No significant hazards consideration comments received: No.

*Omaha Public Power District, Docket No. 50–285, Fort Calhoun Station, Unit No. 1, Washington County, Nebraska*

*Date of amendment request:* July 25, 2003, as supplemented on December 5, 2003

*Brief description of amendment:* The amendment modifies Technical Specification (TS) 2.1.4, "Reactor Coolant System (RCS) Leakage Limits," by (1) adding a requirement for no RCS pressure boundary leakage, (2) combining the existing RCS leakage limits into a format similar to the Improved Standard TS (ISTS), and (3) replacing the existing basis associated with this TS with a basis similar in format and content to the ISTS.

*Date of issuance:* May 7, 2004.

*Effective date:* As of the date of issuance, to be implemented within 90 days from issuance.

*Amendment No.:* 226.

*Renewed Facility Operating License No. DPR–40:* The amendment revised the Technical Specifications.

*Date of initial notice in Federal Register:* August 19, 2003 (68 FR 49818).

The December 5, 2003, supplemental letter provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated May 7, 2004.

No significant hazards consideration comments received: No.

*Pacific Gas and Electric Company, Docket Nos. 50–275 and 50–323, Diablo Canyon Nuclear Power Plant, Unit Nos. 1 and 2, San Luis Obispo County, California*

*Date of application for amendments:* December 30, 2003, and its supplement dated March 11, 2004.

*Brief description of amendments:* The amendments eliminate the requirements in the technical specifications associated with hydrogen recombiners and hydrogen monitors.

*Date of issuance:* May 4, 2004.

*Effective date:* May 4, 2004, and shall be implemented within 60 days from the date of issuance.

*Amendment Nos.:* Unit 1—168; Unit 2—169.

*Facility Operating License Nos. DPR–80 and DPR–82:* The amendments revised the Technical Specifications.

*Date of initial notice in Federal Register:* March 2, 2004 (69 FR 9864).

The March 11, 2004, supplemental letter provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated May 4, 2004.

No significant hazards consideration comments received: No.

Dated at Rockville, Maryland, this 14th May 2004.

For the Nuclear Regulatory Commission.

**Eric J. Leeds,**

*Acting Director, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.*

[FR Doc. 04–11507 Filed 5–24–04; 8:45 am]

BILLING CODE 7590–01–P

## NUCLEAR REGULATORY COMMISSION

### 10 CFR Part 52 Construction Inspection Program Framework Document; Availability of NUREG

**AGENCY:** U.S. Nuclear Regulatory Commission.

**ACTION:** Notice of availability.

**SUMMARY:** The Nuclear Regulatory Commission is announcing the completion and availability of NUREG–1789, "10 CFR Part 52 Construction Inspection Program Framework Document," dated April 2004.

**ADDRESSES:** Copies of NUREG–1789 may be purchased from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402–9328; *http://www.access.gpo.gov/su_docs;* 202–512–1800 or The National Technical Information Service, Springfield, Virginia 22161–0002; *http://www.ntis.gov;* 1–800–533–6847 or, locally, 703–805–6000.

A copy of the document is also available for inspection and/or copying for a fee in the NRC Public Document Room, 11555 Rockville Pike, Rockville, Maryland. As of November 1, 1999, you may also electronically access NUREG-series publications and other NRC records at NRC's Public Electronic Reading Room at *http://www.nrc.gov/reading-rm.html.*

Some publications in the NUREG series that are posted at NRC's Web site address *http://www.nrc.gov* are updated regularly and may differ from the last printed version.

**FOR FURTHER INFORMATION, CONTACT:** Ms. Mary Ann M. Ashley, Inspection Program Branch, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Ms. Ashley may be reached at (301) 415–1073 or by e-mail at *mab@nrc.gov.*

**SUPPLEMENTARY INFORMATION:** On May 30, 2003, the NRC staff issued the "Draft 10 CFR Part 52 Construction Inspection Program Framework Document" for public comment. The framework document set forth the proposed basis for the construction inspection program for reactors built under 10 CFR Part 52. A public workshop was held on August 27, 2003 to discuss the scope and the types of inspections which are planned during the new reactor construction project.

The NRC has considered the comments received from stakeholders and has incorporated them, as appropriate, into a final revision of the construction inspection program framework document and is issuing the framework as NUREG–1789. A detailed resolution of comments submitted about the draft framework document has been incorporated into NUREG–1789. The NUREG details the audits and inspections that will be conducted by the NRC during the Early Site Permit (ESP) and Combined License (COL) phases. The document also discusses how the NRC staff will verify satisfactory completion of the inspections, tests, analyses, and acceptance criteria (ITAAC) and review operational programs. NRC staff will use the inspection program descriptions contained in the framework NUREG to guide the development of internal inspection documents including Inspection Manual Chapters and Inspection Procedures.

Dated at Rockville, Maryland, this 12th day of May 2004.

For the Nuclear Regulatory Commission.

**Stuart A. Richards,**

*Chief, Inspection Program Branch, Division of Inspection Program Management, Office of Nuclear Reactor Regulation.*

[FR Doc. 04–11757 Filed 5–24–04; 8:45 am]

**BILLING CODE 7590–01–P**

## PRESIDIO TRUST

### Public Health Service Hospital, The Presidio of San Francisco (Presidio), CA; Notice of Intent To Prepare a Supplemental Environmental Impact Statement and Conduct Public Scoping

**AGENCY:** The Presidio Trust.

**ACTION:** The Presidio Trust (Trust) announces, in accordance with the provisions of the National Environmental Policy Act (NEPA) (42 U.S.C. 4321 *et seq.*), that it is commencing preparation of a Supplemental Environmental Impact Statement (SEIS) regarding the rehabilitation and reuse of historic buildings in the Public Health Service Hospital (PHSH) district of the Presidio, and that the Trust is inviting the participation of the public and interested agencies in the scoping process. The SEIS tiers from the Final EIS for the Presidio Trust Management Plan, the Trust's comprehensive land use plan and policy framework for Area B of the Presidio, adopted in August 2002.

**SUMMARY:** The Trust prepared and made available to the public an Environmental Assessment (EA) for the PHSH in February 2004 (69 FR 96591). Based on the impact analysis in the EA and a review of public comments received on the document, the Trust has determined that the proposed Federal action has the potential to cause significant effects on the human environment, and that a SEIS would best achieve NEPA's goals. The EA will be used to help facilitate preparation of the SEIS, which will include new substantive environmental analyses and information in response to public comment.

The SEIS will evaluate the following alternatives:

- No-Action Alternative—Continues recent and existing activities in the PHSH district with no building rehabilitation, new construction or demolition.
- PTMP Alternative (Alternative 1)—Rehabilitates existing buildings for educational and residential uses with no new construction or demolition.
- Infill Alternative (Alternative 2)—Rehabilitates the historic buildings as well as the non-historic wings of the hospital for residential use with limited demolition and new construction.
- No Infill Alterative (Alternative 3)—Rehabilitates the historic buildings for residential use and removes the hospital's non-historic wings as well as other non-historic buildings and additions.
- Battery Caulfield Alternative (Alternative 4)—Rehabilitates the historic buildings for residential use, removes the hospital's non-historic wings as well as other non-historic buildings and additions, and provides for new construction on Battery Caulfield.

A complete description of Alternatives 1 through 4 is provided in the EA, which may be viewed at or downloaded from the Trust's Web site at *http://www.presidio.gov* following the link from the home page. A printed copy may be requested at no charge at 415/561–5414 or *phsh@presidiotrust.gov,* or by writing to the Presidio Trust, P.O. Box 29052, San Francisco, CA 94129–0052. The EA may also be reviewed in the Trust's library on the Presidio at 34 Graham Street, San Francisco, CA.

The Trust encourages all interested individuals, organizations and agencies to provide comments on the scope of the SEIS. As part of the scoping process, oral comments will be accepted from the public on the issues and choice of alternatives to be considered in the SEIS at a Trust public meeting on June 29, 2004, beginning at 6 p.m., at the Officers' Club, 50 Moraga Avenue, on the Main Post in the Presidio. Written comments may be submitted to John Pelka, NEPA Compliance Coordinator at 415/561–2790 (fax), *phsh@presidiotrust.gov,* or the Trust Post Office address specified above, and must be received no later than July 7, 2004. Comments previously received regarding the EA need not be repeated; these comments will inform the Trust's preparation of the Supplemental EIS. Please be aware that all written comments and information submitted will be made available to the public, including, without limitation, any postal address, e-mail address, phone number or other information contained in each submission.

The Trust will provide information updates and notices concerning the project through postings on its Web site or through its bi-monthly publication, the Presidio Post. The Trust will announce the release of the SEIS by notice in the **Federal Register** and Presidio Post, as well as via direct mailing and other means.

**FOR FURTHER INFORMATION CONTACT:** John Pelka, NEPA Compliance Coordinator, the Presidio Trust, 34 Graham Street, P.O. Box 29052, San Francisco, CA 94129–0052, 415/561–5300.

Dated: May 19, 2004.
**Karen A. Cook,**
*General Counsel.*
[FR Doc. 04–11753 Filed 5–24–04; 8:45 am]
BILLING CODE 4310–4R–P

## SECURITIES AND EXCHANGE COMMISSION

**[Release No. 34–49732; File No. SR–NASD–2004–069]**

## Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the National Association of Securities Dealers, Inc. To Redesignate Rules 4200A and 4350A

May 19, 2004.

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 April 23, 2004, the National Association of Securities Dealers, Inc. ("NASD"), through its subsidiary, The Nasdaq Stock Market, Inc. ("Nasdaq"), filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by Nasdaq. Pursuant to section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(3) thereunder,[4] Nasdaq has designated this proposal as one concerned solely with the administration of the self-regulatory organization, 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 filing a proposed rule change to redesignate Rules 4200A and 4350A as 4200–1 and 4350–1 respectively, and to make conforming changes.

The text of the proposed rule change is available at Nasdaq and at the Commission.

### 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 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*

1. Purpose

On November 4, 2003, the Commission approved a number of rule changes to the rules relating to the corporate governance of companies listed on Nasdaq,[5] including the adoption of Rules 4200A and 4350A. Nasdaq seeks to redesignate Rules 4200A and 4350A as 4200–1 and 4350–1, respectively, to avoid any confusion with previously existing NASD Rule 4200A. In addition, Nasdaq seeks to conform references to Rules 4200A and 4350A in other rules.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of Section 15A of the Act,[6] in general, and with Section 15A(b)(6) of the Act,[7] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, remove impediments to a free and open market and a national market system, and, in general, to protect investors and the public interest. Nasdaq believes that clarifying the new rules helps investors and issuers.

*B. Self-Regulatory Organization's Statement on Burden on Competition*

Nasdaq does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others*

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 pursuant to section 19(b)(3)(A)(iii) of the Act[8] and Rule 19b–4(f)(3) thereunder[9] in that it is concerned solely with the administration of the self-regulatory organization. At any time within 60 days of the filing of such proposed rule change, 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, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

*Electronic Comments*

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an e-mail to *rule-comments@sec.gov*. Please include File No. SR–NASD–2004–069 on the subject line.

*Paper Comments*

- Send paper comments in triplicate to Jonathan G. Katz, Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549–0609.

All submissions should refer to File No. SR–NASD–2004–069. This file number should be included on the subject line if e-mail is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing also will be available for inspection and copying at the principal office of the NASD. All comments

[1] 15 U.S.C. 78s(b)(1).
[2] 17 CFR 240.19b–4.
[3] 15 U.S.C. 78s(b)(3)(A)(iii).
[4] 17 CFR 240.19b–4(f)(3).
[5] *See* Securities Exchange Act Release No. 48475 (November 4, 2003), 68 FR 64154 (November 12, 2003).
[6] 15 U.S.C. 78o–3.
[7] 15 U.S.C. 78o–3(b)(6).
[8] 15 U.S.C. 78s(b)(3)(A)(iii).
[9] 17 CFR 240.19–4(f)(3).

received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–NASD–2004–069 and should be submitted on or before June 15, 2004.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[10]

**Margaret H. McFarland,**

*Deputy Secretary.*

[FR Doc. 04–11764 Filed 5–24–04; 8:45 am]

BILLING CODE 8010–01–P

## SMALL BUSINESS ADMINISTRATION

### Advisory Committee on Veterans Business Affairs; Public Meeting

The U.S. Small Business Administration (SBA), pursuant to the Veterans Entrepreneurship and Small Business Development Act of 1999 (Pub. L. 106–50), will host its second meeting of the Advisory Committee on Veterans Business Affairs for fiscal year 2004. The meeting will be held on June 1–2, 2004, from 9 a.m.–5 p.m. in the Eisenhower conference room, located on the 2nd floor, side B at the SBA, 409 3rd Street, SW., Washington, DC, 20416. If you have any questions or concerns regarding this meeting, please contact Ms. Cheryl Clark in The Office of Veterans Business Development (OVBD) at (202) 619–1697.

**Matthew K. Becker,**

*Committee Manager Officer, Office of the Administrator.*

[FR Doc. 04–11759 Filed 5–24–04; 8:45 am]

BILLING CODE 8025–01–P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### Notice of Intent To Request Renewal From the Office of Management and Budget (OMB) of Three Current Public Collections of Information

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

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), the FAA invites public comment on three currently approved public information collections which will be submitted to OMB for renewal.

[10] 17 CFR 200.30–3(a)(12).

**DATES:** Comments must be received on or before July 26, 2004.

**ADDRESSES:** Comments may be mailed or delivered to the FAA at the following address: Ms. Judy Street, Room 613, Federal Aviation Administration, Standards and Information Division, APF–100, 800 Independence Ave., SW., Washington, DC 20591.

**FOR FURTHER INFORMATION CONTACT:** Ms. Judy Street at the above address or on (202) 267–9895.

**SUPPLEMENTARY INFORMATION:** In accordance with the Paperwork Reduction Act of 1995, 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. Therefore, the FAA solicits comments on the following current collections of information in order to evaluate the necessity of the collection, the accuracy of the agency's estimate of the burden, the quality, utility, and clarity of the information to be collected, and possible ways to minimize the burden of the collection in preparation for submission to renew the clearances of the following information collections.

1. 2120–0020, Maintenance, Preventive Maintenance, Rebuilding, and Alternation. FAR Part 43 prescribes the rules governing maintenance, rebuilding, and alteration of aircraft and aircraft components, and is necessary to ensure this work is performed by qualified persons, and at proper intervals. This work is done by certified mechanics, repair stations, and air carriers authorized to perform maintenance. The current estimated annual reporting burden is 1,43,784 hours.

2. 2120–0101, Psychological Training. This report is necessary to establish qualifications of eligibility to receive voluntary psychological training and will be used as proper evidence of training. The form is completed by pilots and crewmembers for application to receive voluntary training. The current estimated annual reporting burden is 733 hours.

3. 2120–0524, High Density Airports, Slot Allocation and Transfer Methods. The FAA needs this information to allocate slots and maintain accurate records of slot transfers at the High Density Traffic Airports. The information will be provided by air carriers and commuter operators or other persons holding a slot at High Density Traffic Airports. The current estimated annual reporting burden is 3,064 hours.

Issued in Washington, DC, on May 18, 2004.

**Judith D. Street,**

*FAA Information Collection Clearance Officer, APF–100.*

[FR Doc. 04–11792 Filed 5–24–04; 8:45 am]

BILLING CODE 4910–13–M

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

**[Summary Notice No. PE–2004–33]**

### Petitions for Exemption; Dispositions of Petitions Issued

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

**ACTION:** Notice 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 dispositions of certain petitions previously received. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities.

**FOR FURTHER INFORMATION CONTACT:** Tim Adams (202) 267–8033, or Sandy Buchanan-Sumter (202) 267–7271, 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.

Issued in Washington, DC, on May 19, 2004.

**Donald P. Byrne,**

*Assistant Chief Counsel for Regulations.*

**Dispositions of Petitions**

*Docket No.:* FAA–2002–13275.

*Petitioner:* Frankfort Flight Service, Inc.

*Section of 14 CFR Affected:* 14 CFR 135.143(c)(2).

*Description of Relief Sought/Disposition:* To permit Frankfort Flight Service, Inc., to operate certain aircraft under part 135 without a TSO–C112 (Mode S) transponder installed on those aircraft.

*Grant, 5/5/2004, Exemption No. 7888A*

*Docket No.:* FAA–2001–9502.

*Petitioner:* AMI Jet Charter, Inc./TAG Aviation d/b/a. *Section of 14 CFR Affected:* 14 CFR 135.152(i)(1).

*Description of Relief Sought/Disposition:* To permit AMI Jet Charter, Inc./TAG Aviation d/b/a, to operate a

Dassault Falcon 50–900EX aircraft without meeting the digital flight data recorder requirements established by the Federal Aviation Administration.

*Denial, 5/4/2004, Exemption No. 8310*

*Docket No.:* FAA–2001–10955.

*Petitioner:* LC Busre E.I.R.L.

*Section of 14 CFR Affected:* 14 CFR 135.152.

*Description of Relief Sought/ Disposition:* To permit LC Busre E.I.R.L., to operate a Fairchild Metroliner III SA–227–AC airplane, registration No. N139LC, in a 19-passenger configuration under part 135, without the airplane being equipped with one or more digital flight data recorders.

*Denial, 5/4/2004, Exemption No. 8311*

*Docket No.:* FAA–2004–17409.

*Petitioner:* United Parcel Service.

*Section of 14 CFR Affected:* 14 CFR 121.434(c)(1) and (2).

*Description of Relief Sought/ Disposition:* To permit a United Parcel Service check airman to take a rest period during the cruise portion of a flight leg in which the check airman is observing the operating experience of a qualifying crewmember.

*Denial, 5/4/2004, Exemption No. 8308*

*Docket No.:* FAA–2004–17514.

*Petitioner:* Mr. Adrian A. Eichhorn.

*Section of 14 CFR Affected:* 14 CFR 91.109(a) and (b)(3).

*Description of Relief Sought/ Disposition:* To permit Mr. Adrian A. Eichhorn to conduct certain flight training and to provide simulated instrument flight experience in certain Beech airplanes that are equipped with a functioning throwover control wheel.

*Grant, 5/4/2004, Exemption No. 8307*

*Docket No.:* FAA–2004–17600.

*Petitioner:* Barth's Aviation.

*Section of 14 CFR Affected:* 14 CFR 61.89(a)(5) and 61.111(b).

*Description of Relief Sought/ Disposition:* To permit Mr. Maxime Desouches' student pilots of Barth's Aviation, to conduct solo flights between the French islands of Saint Bathelemy, Saint Martin and Guadeloupe, the Dutch islands of Sint Maarten, Sint Eustatius in the Netherlands Antilles and the islands of the Federation of St. Kitts and Nevis in the eastern Carribbean while fulfilling the cross-country requirements for a private pilot certificate.

*Grant, 5/4/2004, Exemption No. 8309*

*Docket No.:* FAA–2002–12343.

*Petitioner:* Federal Express Corporation.

*Section of 14 CFR Affected:* 14 CFR 121.434(c)(1)(ii).

*Description of Relief Sought/ Disposition:* To permit the Federal Express Corporation to substitute a qualified and authorized check airman in place of a Federal Aviation Administration inspector to observe a qualifying pilot in command who is completing the initial or upgrade training specified in § 121.424 during at least one flight leg that includes a takeoff and a landing, subject to certain conditions and limitations.

*Grant, 5/4/2004, Exemption No. 6473D*

*Docket No.:* FAA–2002–12728.

*Petitioner:* National Business Aviation Association, Inc.

*Section of 14 CFR Affected:* 14 CFR 91.409(e) and 91.501(a).

*Description of Relief Sought/ Disposition:* To permit National Business Aviation Association, Inc., members to operate small civil airplanes and helicopters of U.S. registry under the operating rules of §§ 91.503 through 91.535 and to select an inspection program as described in § 91.409(f), subject to certain conditions and limitations.

*Grant, 5/3/2004, Exemption No. 7897A*

*Docket No.:* FAA–2004–17609.

*Petitioner:* Rugby Aviation, LLC.

*Section of 14 CFR Affected:* 14 CFR 135.143(c)(2).

*Description of Relief Sought/ Disposition:* To permit Rugby Aviation, LLC, to operate certain aircraft under part 135 without a TSO–C112 (Mode S) transponder installed on those aircraft.

*Grant, 5/3/2004, Exemption No. 8305*

*Docket No.:* FAA–2004–17631.

*Petitioner:* JIM Air, Inc.

*Section of 14 CFR Affected:* 14 CFR 135.143(c)(2).

*Description of Relief Sought/ Disposition:* To permit JIM Air, Inc., to operate certain aircraft under part 135 without a TSO–C112 (Mode S) transponder installed on those aircraft.

*Grant, 5/3/2004, Exemption No. 8304*

*Docket No.:* FAA–2004–17663.

*Petitioner:* Excel Aviation, LLC.

*Section of 14 CFR Affected:* 14 CFR 135.143(c)(2).

*Description of Relief Sought/ Disposition:* To permit Excel Aviation, LLC, to operate certain aircraft under part 135 without a TSO–C112 (Mode S) transponder installed on those aircraft.

*Grant, 5/3/2004, Exemption No. 8303*

*Docket No.:* FAA–2004–17633.

*Petitioner:* Moore Quality Flying.

*Section of 14 CFR Affected:* 14 CFR 135.143(c)(2).

*Description of Relief Sought/ Disposition:* To permit Moore Quality Flying to operate certain aircraft under part 135 without a TSO–C112 (Mode S) transponder installed on those aircraft.

*Grant, 5/3/2004, Exemption No. 8302*

*Docket No.:* FAA–2004–17632.

*Petitioner:* Alaska Air Transit.

*Section of 14 CFR Affected:* 14 CFR 135.143(c)(2).

*Description of Relief Sought/ Disposition:* To permit Alaska Air Transit to operate certain aircraft under part 135 without a TSO–C112 (Mode S) transponder installed on those aircraft.

*Grant, 5/3/2004, Exemption No. 8301*

*Docket No.:* FAA–2001–9331.

*Petitioner:* Pratt & Whitney.

*Section of 14 CFR Affected:* 14 CFR 21.325(b)(3).

*Description of Relief Sought/ Disposition:* To permit authorized representatives employed by Pratt & Whitney ODAR to issue export airworthiness approvals for Class II and Class II products manufactured and located at Pratt & Whitney suppliers located in Germany, Italy, Japan, and Sweden.

*Grant, 4/28/2004, Exemption No. 7915A*

*Docket No.:* FAA–2002–11799.

*Petitioner:* Matsushita Avionics Systems Corporation.

*Section of 14 CFR Affected:* 14 CFR 21.325(b)(3).

*Description of Relief Sought/ Disposition:* To permit Matsushita Avionics Systems Corporation (MAS) airworthiness representatives, reporting to an ODAR at MAS Bothell, to issue export airworthiness approvals for Class III products manufactured by MAS Osaka.

*Grant, 4/28/2004, Exemption No. 7925A*

*Docket No.:* FAA–2002–11900.

*Petitioner:* AM–SAFE Aviation, Inc.

*Section of 14 CFR Affected:* 14 CFR 21.325(b)(3).

*Description of Relief Sought/ Disposition:* To permit AM–SAFE Aviation, Inc., (AMSAFE) to issue export airworthiness approvals for Class II and Class III products manufactured by AMSAFE Aviation UK in the United Kingdom under AMSAFE's technical standard order authorizations.

*Grant, 4/28/2004, Exemption No. 7354B*

*Docket No.:* FAA–2004–16911.

*Petitioner:* American Airlines, Inc.

*Section of 14 CFR Affected:* 14 CFR 121.434(c)(1) and (2).

*Description of Relief Sought/ Disposition:* To permit an American Airlines, Inc., (AAL) check airman to take a rest period during the cruise portion of a flight leg in which the check airman is required to supervise the operating experience of a qualifying AAL pilot in command or a qualifying AAL second in command.

*Denial, 5/1/2004, Exemption No. 8300*

*Docket No.:* FAA–2002–13134.
*Petitioner:* Ram Air Freight, Inc.
*Section of 14 CFR Affected:* 14 CFR 135.143(c)(2).
*Description of Relief Sought/ Disposition:* To permit Ram Air Freight, Inc., to operate certain aircraft under part 135 without a TSO–C112 (Mode S) transponder installed on those aircraft.
*Grant, 5/3/2004, Exemption No. 7876A*

*Docket No.:* FAA–2002–13178.
*Petitioner:* Cedar Valley Air Charter.
*Section of 14 CFR Affected:* 14 CFR 135.143(c)(2).
*Description of Relief Sought/ Disposition:* To permit Cedar Valley Air Charter to operate certain aircraft under part 135 without a TSO–C112 (Mode S) transponder installed on those aircraft.
*Grant, 5/3/2004, Exemption No. 7880A*

*Docket No.:* FAA–2001–11080.
*Petitioner:* Experimental Aircraft Association, Small Aircraft Manufacturers Association, and National Association of Flight Instructors.
*Section of 14 CFR Affected:* 14 CFR 91.319(a)(1) and (2).
*Description of Relief Sought/ Disposition:* To permit the members of the Experimental Aircraft Association, Small Aircraft Manufacturers Association, and the National Association of Flight Instructors who own certain amateur-and kit-built aircraft certificated in the experimental category, to receive compensation for the use of the aircraft for the purpose of conducting aircraft-specific flight training and flight reviews under 14 CFR 61.56.
*Grant, 5/2/2004, Exemption No. 7162C*

*Docket No.:* FAA–2002–13346.
*Petitioner:* Westjet Air Center, Inc.
*Section of 14 CFR Affected:* 14 CFR 135.143(c)(2).
*Description of Relief Sought/ Disposition:* To permit Westjet Air Center, Inc., to operate certain aircraft under part 135 without a TSO–C112 (Mode S) transponder installed on those aircraft.
*Grant, 4/30/2004, Exemption No. 7881A*

*Docket No.:* FAA–2003–15969.
*Petitioner:* Northern Air Cargo, Inc.
*Section of 14 CFR Affected:* 14 CFR 121.345(c)(2).
*Description of Relief Sought/ Disposition:* To permit Northern Air Cargo, Inc., to operate certain aircraft under part 121 without a TSO–C112 (Mode S) transponder installed on those aircraft.
*Grant, 4/30/2004, Exemption No. 8121A*

*Docket No.:* FAA–2002–12097.
*Petitioner:* Mirabella Aviation.
*Section of 14 CFR Affected:* 14 CFR 135.143(c)(2).
*Description of Relief Sought/ Disposition:* To permit Mirabella Aviation to operate certain aircraft under part 135 without a TSO–C112 (Mode S) transponder installed on those aircraft.
*Grant, 4/29/2004, Exemption No. 7178B*

*Docket No.:* FAA–2002–11498.
*Petitioner:* Air Tractor, Inc.
*Section of 14 CFR Affected:* 14 CFR 61.31(a)(1).
*Description of Relief Sought/ Disposition:* To permit Air Tractor, Inc., and pilots of Air Tractor AT–802 and AT–802A airplanes to operate those airplanes without holding a type rating, although the maximum gross weight of the airplanes exceeds 12,500 pounds.
*Grant, 4/27/2004, Exemption No. 5651H*

[FR Doc. 04–11785 Filed 5–24–04; 8:45 am]
BILLING CODE 4910–13–P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

**[Summary Notice No. PE–2004–32]**

### Petitions for Exemption; Summary of Petitions Received; Correction

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

**ACTION:** Notice of petitions for exemption received; correction.

**SUMMARY:** This document makes a correction to the summary of petitions received published in the **Federal Register** on March 23, 2004 (69 FR 13615). That notice contained a summary of certain petitions seeking relief from specified requirements of 14 CFR.

**FOR FURTHER INFORMATION CONTACT:** John Linsenmeyer (202) 267–5174, Tim Adams (202) 267–8033, or Sandy Buchanan-Sumter (202) 267–7271, Office of Rulemaking (ARM–1), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591.

**Correction**

In notice of petitions for exemption FR Doc. 04–6384, published on March 23, 2004 (69 FR 13615), make the following correction:

1. On page 13615, in column 2, under the heading "Petition for Exemption," correct "Description of Relief sought: To permit the Eagle 150B–23 aircraft, which will be issued a 14 CFR 21.29 type certificate * * *" to read "Description of Relief sought: To permit the Eagle 150B–23 aircraft, which will be issued a 14 CFR 21.21 type certificate * * *".

Issued in Washington, DC, on May 19, 2004.

**Donald P. Byrne,**

*Assistant Chief Counsel for Regulations.*

[FR Doc. 04–11786 Filed 5–24–04; 8:45 am]
BILLING CODE 4910–13–P

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### RTCA Government/Industry Air Traffic Management Advisory Committee (Successor of RTCA Government/ Industry Free Flight Steering Committee)

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

**ACTION:** Notice of RTCA/Industry Air Traffic Management Advisory Committee.

**SUMMARY:** The FAA is issuing this notice to advise the public of a meeting of the RTCA Government/Industry Air Traffic Management Advisory Committee.

**DATES:** The meeting will be held June 2, 2004, 1–3 p.m.

**ADDRESSES:** The meeting will be held at Aerospace Building, 901 D Street, SW., Andrews/BWI Conference Rooms (Suite 850) Washington, DC, 20024.

**FOR FURTHER INFORMATION CONTACT:** (1) RTCA Secretariat, 1828 L Street, NW., Suite 805, Washington, DC, 20036; telephone (202) 833–9339; fax (202) 833–9434; Web site *http://www.rtca.org.*

**SUPPLEMENTARY INFORMATION:** Pursuant to section 10(a)(2) of the Federal Advisory Committee (Pub. L. 92–463, 5 U.S.C., Appendix 2), notice is hereby given for the Air Traffic Management Advisory Committee meeting.

**Note:** Non-Government attendees to the meeting must go through security and be escorted to and from the conference room.

Issued in Washington, DC, on May 17, 2004.

**Natalie Olgetree,**

*FAA General Engineer, RTCA Advisory Committee.*

[FR Doc. 04–11793 Filed 5–24–04; 8:45 am]
BILLING CODE 4910–13–M

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

### Proposed Policy Statement on Establishing Supplemental Type Certificate (STC) Project Workload Priorities; PS–ACE100–2004–10028

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

**ACTION:** Notice of availability of proposed policy statement and request for comments.

**SUMMARY:** This notice announces the availability of, and requests comments on, proposed policy statement PS–ACE100–2004–10028, which establishes workload priorities for incoming supplemental type certificate projects (STC). When new STC projects arrive, the Aircraft Certification Office engineer or supervisor must prioritize these projects. To avoid devoting excessive FAA resources to incomplete data packages, we are establishing a policy that will minimize delays to applicants who submit complete packages.

**DATES:** Comments must be received on or before July 26, 2004.

**ADDRESSES:** Send all comments on the proposed policy statement to: Federal Aviation Administration, Small Airplane Directorate, Aircraft Certification Service, Regulations and Policy (ACE–111), 901 Locust Street, Kansas City, Missouri 64106.

**FOR FURTHER INFORMATION CONTACT:** Mr. Taylor Martin, Standards Office, Small Airplane Directorate, Aircraft Certification Service, Kansas City, Missouri 64106, telephone (816) 329–4138, fax (816) 329–4090.

**SUPPLEMENTARY INFORMATION:** Any person may obtain a copy of this proposed policy statement by contacting the person named above under **FOR FURTHER INFORMATION CONTACT**. A copy of the policy statement will also be available on the internet at *http://www.airweb.faa.gov* within a few days.

#### Comments Invited

We invite interested parties to submit comments on the proposed policy statement. Commenters must identify PS–ACE100–2004–10028 and submit comments to the address specified above. The FAA will consider all communications received on or before the closing date for comments before issuing the final policy statement. The proposed policy statement and comments received may be inspected at the Standards Office (ACE–110), 901 Locust, Room 301, Kansas City, Missouri, between the hours of 8:30 and 4 p.m. weekdays, except Federal holidays by making an appointment in advance with the person listed under **FOR FURTHER INFORMATION CONTACT**.

#### Background

Policy statement PS–ACE100–2004–10028, Establishing Supplemental Type Certificate (STC) Project Workload Priorities, has been drafted to aid both the applicant and the Aircraft Certification Offices in evaluating the priorities for STC projects. The FAA will give priority to projects that contain an application, a certification plan, and information about the intended use of FAA designees. Further details of the plan are contained in the proposed policy statement.

Issued in Kansas City, Missouri on May 12, 2004.

**David R. Showers,**

*Acting Manager, Small Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 04–11784 Filed 5–24–04; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Highway Administration

### Environmental Impact Statement: Salt Lake County, UT

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

**ACTION:** Withdrawal of Notice of Intent.

**SUMMARY:** The FHWA is issuing this notice to advise the public that the effort to prepare an Environmental Impact Statement (EIS) will be terminated for transportation improvements in the corridor of Redwood Road (SR–68) in Salt Lake County, Utah.

**FOR FURTHER INFORMATION CONTACT:** Sandra Garcia-Aline, Environmental Engineer, FHWA, Utah Division, 2520 West 4700 South, Suite 9A, Salt Lake City, UT 84118, Telephone (801) 963–0182; or Rob Wight, Utah Department of Transportation (UDOT), 2010 South 2760 West, Salt Lake City, UT 84104, Telephone (801) 887–3438.

**SUPPLEMENTARY INFORMATION:** The FHWA is cooperation with the UDOT have elected to terminate efforts to prepare an EIS for transportation improvements in the corridor of Redwood Road (SR–68) from 10400 South in the city of South Jordan to Bangerter Highway (SR–172) in the city of Bluffdale, Salt Lake County, Utah. The original Notice of Intent was published on May 29, 2003, anticipating Utah Department of Transportation (UDOT) would request Federal funding for project construction. The UDOT has recently elected to fully fund the project with State funds. No federal funds or federal action will be required for the project. The UDOT will prepare a State Environmental Study for the project. Comments or questions concerning this action should be directed to FHWA at the address provided above.

(Catalog of Federal and Domestic Assistance Program Number 20.205, Highway Research, Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Issued on: May 19, 2004.

**Gregory S. Punske,**

*Environmental Program Manager, Utah Division, Federal Highway Administration, Salt Lake City, Utah.*

[FR Doc. 04–11813 Filed 5–24–04; 8:45 am]

**BILLING CODE 4910–22–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) has received a request for a waiver of compliance of certain requirements of its safety regulations. 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.

#### Norfolk Southern Corporation

[Docket Number FRA–2003–16203]

Norfolk Southern Corporation (NS) seeks to modify existing waiver FRA–2002–11896, which is a conditional waiver of compliance from certain provisions of the Safety Appliances Standards, 49 CFR part 231, and Power Brakes and Drawbars regulations, 49 CFR part 232, concerning the operation of RoadRailer equipment in Triple Crown Service over their railroad system. Specifically, NS requests that FRA modify the existing waiver to incorporate the use of "Railrunner" equipment in its RoadRailer operations.

The "Railrunner" equipment is essentially a set of highway trailer chassis and intermediate and transition rail bogies that allows the transport of ship containers by both highway and rail modes. The ship containers are placed on a highway "Railrunner" chassis at the shipping terminal where they can be transported by highway to a rail terminal. Upon arrival at a rail terminal, the chassis and container

combinations are coupled to and made an integral part of a "Railrunner" rail bogie combination. Once the highway "Railrunner" chassis has been converted to rail mode by use of the rail bogies, the "Railrunner" units can then be assembled behind a RoadRailer train for shipment to another terminal on the NS system. NS would introduce the "Railrunner" equipment into their service using existing RoadRailer trains and routes on its system network.

Norfolk Southern requests the following amendments to the existing RoadRailer waiver: (1) The waiver will apply to Norfolk Southern rail operations handling RoadRailer and Railrunner equipment; (2) Interchange of RoadRailer-Railrunner equipment will only be permitted with a railroad that has a comparable waiver to operate the RoadRailer-Railrunner equipment; and (3) RoadRailer-Railrunner equipment will not be handled with conventional railroad rolling equipment and will only be operated in trains consisting exclusively of RoadRailer-Railrunner units.

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. I f any interested party desires an opportunity for oral comment, they should notify the 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 FRA–2003–16203) and must be submitted in triplicate to the Docket Clerk, DOT Central Document Management Facility, Room PL–401, Washington, DC 20590–0001. Communications received within 30 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 (9a.m–5p.m) at DOT Central Docket Management Facility, Room PL–401 (Plaza Level), 400 Seventh Street, SW., Washington, DC. 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*.

Anyone is able to search the electronic form of all comments received into any of our dockets by name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, *etc.*). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78). The Statement may also be found at *http://dms.dot.gov*.

Issued in Washington, DC, on May 19, 2004.

**Grady C. Cothen, Jr.,**

*Acting Associate Administrator for Safety.*

[FR Doc. 04–11698 Filed 5–24–04; 8:45 am]

BILLING CODE 4910–06–P

## 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) has received a request for a waiver of compliance from certain requirements of its safety regulations. 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.

**Union Pacific Railroad Company**

[Docket Number FRA–2004–17565]

Union Pacific Railroad Company (UP) seeks to obtain a waiver of certain provisions of the Safety Appliance Standards, 49 CFR part 231, and Power Brakes and Drawbars regulations, 49 CFR part 232, concerning the operation of RoadRailer equipment in Triple Crown Service over their railroad system. Specifically, the UP requests that it be allowed to operate RoadRailer trains from Chicago, IL to Minneapolis, MN and return. The UP requests FRA to grant approval to operate the Roadrailer equipment to include the following conditions:

1. This waiver applies only to the UPRR Roadrailer equipment operation.

2. Interchange will only be permitted with a railroad that has a comparable waiver to operate RoadRailer equipment.

3. RoadRailer equipment shall not be commingled with conventional railroad rolling equipment. RoadRailer units shall only be operated in trains consisting exclusively of RoadRailer units and locomotives.

4. RoadRailer trains shall be limited to a maximum trailing tonnage of 5,200 tons and will be further limited by RoadRailer total gross rail load, track grade and curvatures.

5. At no time shall the train length exceed the equivalent of 150 Mark V RoadRailer units.

6. An adapter unit (couplermate bogie) must be used between the hauling locomotive and the first RoadRailer unit in the train.

7. Each adapter unit (couplermate bogie) shall be equipped with a tool box containing appropriate instructions, job aids, and the necessary tools and equipment required to address problems that may be encountered in route by the train crew.

8. Trains will only be permitted to pick-up or set-out RoadRailer units at locations specifically designed to perform these functions with mechanical personnel that are trained and on duty for the purpose of assembly and disassembly of RoadRailer units unless a defective condition develops in route that would require a RoadRailer unit to be set-out of the train.

9. Hazardous materials are permitted to be hauled in RoadRailer units provided: (1) The particular commodities are limited to those listed in Table 2 of 49 CFR 172.504; (2) the shipment complies with other relevant provisions of the hazardous materials regulations; (3) placarding provisions of 49 CFR subpart F of part 172 shall apply during rail movements; and (4) cargo tanks, multi-unit tank car tanks, portable tanks and intermodal (1M) portable tanks handling hazardous materials are not permitted in this service.

10. Each RoadRailer-43 adapter unit (couplermate bogie) that does not have safety appliances that are compliant with current federal regulations (with the exception of the handbrake), must be stenciled on each side, in clearly legible letters not less than 6 inches high, "NO SAFETY APPLIANCES" and "DO NOT RIDE", at a location that is visible to a person walking at track level beside the unit.

11. UPRR shall have instructions that prohibits anyone from riding RoadRailer equipment unless it is an adapter unit (couplermate bogie) specifically designed to be ridden and is not stenciled as required in condition #10. Strict enforcement of this rule is required.

12. New terminal facilities for RoadRailer equipment shall, to the extent feasible, be designed to limit the frequency and length of reverse movements. Reverse movements of RoadRailer equipment, with personnel riding couplermates equipped with compliant safety appliances, shall not exceed 10 miles per hour.

13. Whenever a shoving move of RoadRailer equipment is required, the

movement shall be protected by either; an individual riding an adapter unit (couplermate bogie) specifically designed to be ridden, or by an individual walking with the movements and the speed of the move shall not exceed that of the individual walking.

14. Maximum speed of a RoadRailer train is 60 MPH, unless the RoadRailer units are equipped with AAR–1 B narrow flange profile (#40 taper) and maintained in that condition whereby the maximum speed shall be 70 MPH.

15. Piston travel at initial terminal shall be 1.25 to 3.5 inches.

16. The air brake shall be considered ineffective at 3–5/8 inches piston travel.

17. UPRR shall ensure that adequate records are maintained to demonstrate all personnel (including contractors) responsible for assembly, inspection, testing, maintenance and operation of RoadRailer equipment have been trained and qualified to perform those duties prior to undertaking them, including instruction in the provisions of this waiver pertinent to their duties. Training for railroad operating and mechanical personnel, who may encounter the equipment, shall specifically include training necessary to provide for their personal safety when working on or in proximity to the equipment. Supervisors shall also possess the knowledge and skills required of employees subject to their direct supervision. Effective coincident with compliance dates established for revisions to 49 CFR part 232, all personnel required to receive training subject to this condition shall have their qualifications for duties, related to RoadRailer equipment, documented in the same manner provided in that part.

18. UPRR shall ensure that adequate records are maintained to demonstrate the current qualification status of all personnel assigned to operate, inspect, test, and maintain RoadRailer equipment.

19. UPRR supervisors or their representatives shall exercise oversight or undertake contractual arrangements to ensure that all tasks and maintenance/repair practices are performed in accordance with the railroad's written procedures, applicable standards and recommended practices of the AAR, current AAR interchange rules, and all applicable Federal Regulatory requirements.

20. UPRR shall immediately report any accident, incident or injury involving this equipment to FRA's Office of Safety Assurance and Compliance in Washington, DC.

21. FRA will reserve the right to modify or rescind this waiver at any time upon receipt of information pertaining to the safety of rail operations or in the event of non-compliance with any of the conditions of this waiver.

22. UPRR requests that this waiver is effective for a five-year period from the date of approval of the requested waiver and FRA will reserve the right to extend the waiver if petition having been made and conditions warrant. UPRR will make a written request for an extension of the five-year period to the FRA's Office of Safety Assurance and compliance within six months of the granted expiration date.

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 FRA–2004–17565) and must be submitted in triplicate to the Docket Clerk, DOT Central Docket Management Facility, Room PL–401, Washington, DC 20590–0001. FRA will consider communications received within 30 days of the date of this notice 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 DOT Central Docket Management Facility, Room PL–401 (Plaza Level), 400 Seventh Street, SW., Washington, DC 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.*

Anyone is able to search th electronics form of all comments received into any of our dockets by name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78). The Statement may also be found at *http://dms.dot.gov.*

Issued in Washington, DC on May 19, 2004.

**Grady C. Cothen, Jr.,**

*Acting Associate Administrator for Safety.*

[FR Doc. 04–11699 Filed 5–24–04; 8:45 am]

BILLING CODE 4910–06–P

## DEPARTMENT OF TRANSPORTATION

### Federal Railroad Administration

### Notice of Application for Approval of Discontinuance or Modification of a Railroad Signal System or Relief From the Requirements of Title 49 Code of Federal Regulations Part 236

Pursuant to title 49 Code of Federal Regulations (CFR) part 235 and 49 U.S.C. 20502(a), the following railroad has petitioned the Federal Railroad Administration (FRA) seeking approval for the discontinuance or modification of the signal system or relief from the requirements of 49 CFR part 236 as detailed below.

[Docket Number FRA–2004–17688]

*Applicant:* Union Pacific Railroad Company, Mr. Phil Abaray, Chief Engineer—Signals, 1416 Dodge Street, Room 1000, Omaha, Nebraska 68179–1000.

The Union Pacific Railroad Company (UP) seeks approval of the proposed modification of the traffic control system, on the two main tracks at Endicott, Nebraska, milepost 180.3, on the Marysville Subdivision, Council Bluffs Area. The proposed changes consist of the following:

1. Removal of three power-operated switches, No's. 1A, 1B, and 2;

2. Removal of five associated controlled signals, No's. 1E, 2E, 1W, 2W, and BNSF 1W;

3. Removal of the Approach "D" signals on the BNSF track;

4. Conversion of the No. 3 power-operated switch to hand operation;

5. Conversion of the eastbound No. 2E signal, to an absolute entrance signal, in lieu of a switch lock; and

6. Installation of eastbound and westbound back-to-back controlled signals on both main tracks.

The reason given for the proposed changes is that the crossover and switches were installed to replace a diamond crossover. The BNSF is taking their north connecting track out of service, so the control point with the crossover is no longer needed.

Any interested party desiring to protest the granting of an application shall set forth specifically the grounds upon which the protest is made, and include a concise statement of the interest of the party in the proceeding.

Additionally, one copy of the protest shall be furnished to the applicant at the address listed above.

All communications concerning this proceeding should be identified by the docket number and must be submitted to the Docket Clerk, DOT Central Docket Management Facility, Room PL–401 (Plaza Level), 400 7th Street, SW., . Washington, DC 20590–0001. Communications received within 45 days of the date of this notice will be considered by the 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.*

FRA wishes to inform all potential commenters that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, *etc.*). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

FRA expects to be able to determine these matters without an oral hearing. However, if a specific request for an oral hearing is accompanied by a showing that the party is unable to adequately present his or her position by written statements, an application may be set for public hearing.

Issued in Washington, DC, on May 19, 2004.

**Grady C. Cothen, Jr.,**

*Acting Associate Administrator for Safety.*

[FR Doc. 04–11697 Filed 5–24–04; 8:45 am]

BILLING CODE 4910–06–P

## DEPARTMENT OF TRANSPORTATION

### Maritime Administration

### Maritime Security Act of 2003, Subtitle D—National Defense Tank Vessel Construction Assistance

**AGENCY:** Maritime Administration, DOT.

**ACTION:** Notice of conference call.

**SUMMARY:** The purpose of the notice is to advise interested parties of a conference call to be hosted by the Maritime Administration to address certain issues regarding the Request for Competitive Proposals (RFP) for the construction of up to five new tank vessels. The RFP is available on the Internet at *http://www.fedbizopps.gov* and *http://www.marad.dot.gov* and hard copies of the RFP are available in the Office of the Secretary, Maritime Administration.

**FOR FURTHER INFORMATION CONTACT:** Gregory V. Sparkman or Edmond J. Fitzgerald, Office of Insurance and Shipping Analysis, Maritime Administration, Room 8117, 400 Seventh Street, SW., Washington, DC 20590; Telephone: (202) 366–2400; Fax: (202) 366–7901.

**SUPPLEMENTARY INFORMATION:** On February 20, 2004, the Maritime Administration formally solicited competitive RFPs for the construction of up to five new product tank vessels necessary to meet the commercial and national security needs of the United States and to be built with assistance under subtitle D of the Maritime Security Act of 2003. In response to certain questions raised by industry representatives, the Maritime Administration has decided to host a public conference call to provide additional information, have further discussion and answer any outstanding questions related to the new tanker program. The conference call is open to all interested parties and will be held on May 26, 2004 in two parts:

- From 3:30 to 4:30 p.m. for vessel owners/operators
- From 4:30 to 5:30 p.m. for shipyards

To participate, contact Edmond Fitzgerald or Greg Sparkman at (202) 366–2400 for specific instructions. Please note that each call is limited to 30 participants.

**Authority:** 49 CFR 1.66

By Order of the Maritime Administrator

Dated: May 19, 2004.

**Joel C. Richard,**

*Secretary, Maritime Administration.*

[FR Doc. 04–11746 Filed 5–24–04; 8:45 am]

BILLING CODE 4910–81–P

## DEPARTMENT OF TRANSPORTATION

### National Highway Traffic Safety Administration

**[Docket No. NHTSA–2004–17903; Notice 1]**

### Kumho Tire Co., Inc., Receipt of Petition for Decision of Inconsequential Noncompliance

Kumho Tire Co., Inc. (Kumho) has determined that certain tires it produced in 2003 and 2004 do not comply with S4.3(d) and S4.3(e) of 49 CFR 571.109, Federal Motor Vehicle Safety Standard (FMVSS) No. 109, "New pneumatic tires." Kumho has filed an appropriate report pursuant to 49 CFR part 573, "Defect and Noncompliance Reports."

Pursuant to 49 U.S.C. 30118(d) and 30120(h), Kumho has petitioned for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety.

This notice of receipt of Kumho's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any agency decision or other exercise of judgment concerning the merits of the petition.

A total of approximately 2656 tires are involved. These include 324 size 255/50R17 tires and 2332 size 255/45R17 tires. The tires are marked "Tread: Rayon 2 + Steel 2 + Nylon 2, Sidewall: Rayon 2," when the correct stamping would be "Tread: Polyester 2 + Steel 2 + Nylon 2, Sidewall: Polyester 2." Paragraph S4.3 of FMVSS No. 109 requires "each tire shall have permanently molded into or onto both sidewalls * * * (d) The generic name of each cord material used in the plies * * * of the tire; and (e) Actual number of plies in the sidewall, and the actual number of plies in the tread area if different."

Kumho states that it uses rayon and polyester body ply construction to meet the preferences of the North American and European markets, and that rayon is popular in the European market while polyester is more popular in the North American market. Kumho explains that for sizes sold in both markets, either material may be used, and the two sizes which are the subject of this petition have North American construction and European stamping.

Kumho states that the tires meet or exceed all performance requirements of FMVSS No. 109 and will have no impact on the operational performance or safety of vehicles on which these tires are mounted. Therefore, Kumho believes that the noncompliance is inconsequential to motor vehicle safety and that no corrective action is warranted.

Interested persons are invited to submit written data, views, and arguments on the petition described above. Comments must refer to the docket and notice number cited at the beginning of this notice and be submitted by any of the following methods. Mail: Docket Management Facility, U.S. Department of Transportation, Nassif Building, Room PL–401, 400 Seventh Street, SW.,

Washington, DC, 20590–0001. Hand Delivery: Room PL–401 on the plaza level of the Nassif Building, 400 Seventh Street, SW., Washington, DC. It is requested, but not required, that two copies of the comments be provided. The Docket Section is open on weekdays from 10 am to 5 pm except Federal Holidays. Comments may be submitted electronically by logging onto the Docket Management System Web site at *http://dms.dot.gov*. Click on "Help" to obtain instructions for filing the document electronically. Comments may be faxed to 1–202–493–2251, or may be submitted to the Federal eRulemaking Portal: go to *http://www.regulations.gov*. Follow the online instructions for submitting comments.

The petition, supporting materials, and all comments received before the close of business on the closing date indicated below will be filed and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the extent possible. When the petition is granted or denied, notice of the decision will be published in the **Federal Register** pursuant to the authority indicated below.

Comment closing date: June 24, 2004.

**Authority:** (49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.50 and 501.)

Issued on: May 19, 2004.

**Kenneth N. Weinstein,**

*Associate Administrator for Enforcement.*

[FR Doc. 04–11791 Filed 5–24–04; 8:45 am]

BILLING CODE 4910–59–P

## DEPARTMENT OF TRANSPORTATION

### Surface Transportation Board

**[STB Docket No AB–6 (Sub–No. 416X)]**

### The Burlington Northern and Santa Fe Railway Company—Abandonment Exemption—in Bottineau County, ND

The Burlington Northern and Santa Fe Railway Company (BNSF) has filed a notice of exemption under 49 CFR part 1152 subpart F—*Exempt Abandonments* to abandon and discontinue service over a 15.50-mile line of railroad between milepost 52.00 near Souris, and milepost 67.50, near Westhope, in Bottineau County, ND. The line traverses United States Postal Service Zip Codes 58783 and 58793.

BNSF has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) there is no overhead traffic to be rerouted; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7 (environmental reports), 49 CFR 1105.8 (historic reports), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication) and 49 CFR 1105.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line R. Co.—Abandonment—Goshen*, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed. Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on June 24, 2004, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[1] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[2] and trail use/rail banking requests under 49 CFR 1152.29[3] must be filed by June 4, 2004. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by June 14, 2004, with: Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to the applicant's representative: Michael Smith, Freeborn & Peters, 311 S. Wacker Dr., Suite 3000, Chicago, IL 60606–6677.

If the verified notice contains false or misleading information, the exemption is void *ab initio*.

BNSF has filed an environmental report which addresses the abandonment's effects, if any, on the environment and historic resources. SEA will issue an environmental assessment (EA) by May 28, 2004. Interested persons may obtain a copy of the EA by writing to SEA (Room 500, Surface Transportation Board, Washington, DC 20423–0001) or by calling SEA, at (202) 565–1539. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.] Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), BNSF shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the line. If consummation has not been effected by BNSF's filing of a notice of consummation by May 25, 2005, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available on our Web site at "*http://www.stb.dot.gov.*"

Decided: May 17, 2004.

By the Board, David M. Konschnik, Director, Office of Proceedings.

**Vernon A. Williams,**

*Secretary.*

[FR Doc. 04–11517 Filed 5–24–04; 8:45 am]

BILLING CODE 4915–01–P

[1] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Section of Environmental Analysis (SEA) in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Service Rail Lines*, 5I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[2] Each OFA must be accompanied by the filing fee, which currently is set at $1,100. *See* 49 CFR 1102.2(f)(25).

[3] Each trail use request must be accompanied by the filing fee, which is set at $200.00 *See* 49 CFR 1002.2(f)(27).

## DEPARTMENT OF TRANSPORTATION

### Surface Transportation Board

**[STB Docket No. AB–6 (Sub–No. 417X)]**

### The Burlington Northern and Santa Fe Railway Company—Abandonment Exemption-in Clay County, MN

The Burlington Northern and Santa Fe Railway Company (BNSF) has filed a notice of exemption under 49 CFR 1152 Subpart F—*Exempt Abandonments* to abandon a 15.91-mile line of railroad between milepost 18.09 near Glyndon and milepost 34.00 near Felton, in Clay County, MN. The line traverses United States Postal Service Zip Codes 56547 and 56536.

BNSF has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) there is no overhead traffic to be rerouted; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Board or with any U.S. District Court or

has been decided in favor of complainant within the 2-year period; and (4) the requirements at 49 CFR 1105.7 (environmental reports), 49 CFR 1105.8 (historic reports), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line R.Co.—Abandonment—Goshen,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on June 24, 2004, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[1] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[2] and trail use/rail banking requests under 49 CFR 1152.29 must be filed by June 4, 2004. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by June 14, 2004, with the Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to BNSF's representative: Michael Smith, Freeborn & Peters, 311 S. Wacker Dr., Suite 3000, Chicago, IL 60606–6677.

If the verified notice contains false or misleading information, the exemption is void *ab initio.*

BNSF has filed an environmental report which addresses the abandonment's effects, if any, on the environment and historic resources. SEA will issue an environmental assessment (EA) by May 28, 2004. Interested persons may obtain a copy of the EA by writing to SEA (Room 500, Surface Transportation Board, Washington, DC 20423–0001) or by calling SEA, at (202) 565–1539. [Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at 1–800–877–8339.] Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), BNSF shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the line. If consummation has not been effected by BNSF's filing of a notice of consummation by May 25, 2005, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available on our website at *"http://www.stb.dot.gov."*

*COM019*Decided: May 18, 2004.

By the Board, David M. Konschnik, Director, Office of Proceedings.

**Vernon A. Williams,**

*Secretary.*

[FR Doc. 04–11660 Filed 5–24–04; 8:45 am]

BILLING CODE 4915–01–P

[1] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Section of Environmental Analysis (SEA) in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Service Rail Lines,* 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[2] Each OFA must be accompanied by the filing fee, which currently is set at $1,100. See 49 CFR 1002.2(f)(25).

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### Proposed Collection; Comment Request for Form 1040A and Schedules 1, 2, 3 and EIC

**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, Pub. L. 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 1040A, U.S. Individual Income Tax Return, and Schedules 1, 2, 3 and EIC.

**DATES:** Written comments should be received on or before July 26, 2004 to be assured of consideration.

**ADDRESSES:** Direct all written comments to Glenn P. Kirkland, Internal Revenue Service, room 6411, 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 at Internal Revenue Service, room 6407, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 622–3945, or through the Internet at *CAROL.A.SAVAGE@irs.gov.*

**SUPPLEMENTARY INFORMATION:** *Title:* U.S. Individual Income Tax Return.

*OMB Number:* 1545–0085.

*Form Number:* 1040A and Schedules 1, 2, 3, and EIC.

*Abstract:* This form is used by individuals to report their income subject to income tax and to compute their correct tax liability. The data are used to verify that the income reported on the form is correct and are also for statistics use.

*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:* 28,826,589.

*Estimated Time Per Respondent:* Varies.

*Estimated Total Annual Burden Hours:* 318,019,338.

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: May 19, 2004.

**Glenn P. Kirkland,**

*IRS Reports Clearance Officer.*

[FR Doc. 04–11810 Filed 5–24–04; 8:45 am]

BILLING CODE 4830–01–P

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### Open meeting of the Wage & Investment Reducing Taxpayer Burden (Notices) Issue Committee of the Taxpayer Advocacy Panel

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice.

**SUMMARY:** An open meeting of the Wage & Investment Reducing Taxpayer Burden (Notices) Issue Committee of the Taxpayer Advocacy Panel will be conducted (via teleconference). The Taxpayer Advocacy Panel is soliciting public comments, ideas and suggestions on improving customer service at the Internal Revenue Service.

**DATES:** The meeting will be held Wednesday, June 23, 2004 from 12 p.m. to 1 p.m. e.d.t.

**FOR FURTHER INFORMATION CONTACT:** Sallie Chavez at 1–888–912–1227, or 954–423–7979.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Wage & Investment Reducing Taxpayer Burden (Notices) Issue Committee of the Taxpayer Advocacy Panel will be held Wednesday, June 23, 2004, from 12 p.m. to 1 p.m. e.d.t. via a telephone conference call. If you would like to have the TAP consider a written statement, please call 1–888–912–1227 or 954–423–7979, or write Sallie Chavez, TAP Office, 1000 South Pine Island Road, Suite 340, Plantation, FL 33324. Due to limited conference lines, notification of intent to participate in the telephone conference call meeting must be made with Sallie Chavez. Ms. Chavez can be reached at 1–888–912–1227 or 954–423–7979, or post comments to the Web site: *http://www.improveirs.org.*

The agenda will include: Various IRS issues.

Dated: May 20, 2004.

**Bernard Coston,**

*Director, Taxpayer Advocacy Panel.*

[FR Doc. 04–11811 Filed 5–24–04; 8:45 am]

BILLING CODE 4830–01–P

## DEPARTMENT OF VETERANS AFFAIRS

### Professional Certification and Licensure Advisory Committee; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under Public Law 92–463 (Federal Advisory Committee Act) that the Professional Certification and Licensure Advisory Committee has scheduled a meeting for Wednesday, June 30, 2004, at the Department of Veterans Affairs, Veterans Benefits Administration, Conference Room 542, 1800 G Street, NW., Washington, DC, from 8:30 a.m. to 4 p.m. The meeting is open to the public.

The purpose of the Committee is to advise the Secretary of Veterans Affairs on the requirements of organizations or entities offering licensing and certification tests to individuals for which payment for such tests may be made under chapters 30, 32, 34, or 35 of title 38, United States Code.

The meeting will begin with opening remarks by Ms. Sandra Winborne, Committee Chair. During the morning session, there will be a discussion about the process of applying for approval of a test, a presentation on the usage of the license and certification test reimbursement benefit, and a discussion of helpful links from the VA Education Service Web site. The afternoon session will include old business, and any new business.

Interested persons may file written statements to the Committee before the meeting, or within 10 days after the meeting, with Mr. Giles Larrabee, Designated Federal Officer, Department of Veterans Affairs, Veterans Benefits Administration (225B), 810 Vermont Avenue, NW., Washington, DC 20420. Oral statements from the public will be heard at 1 p.m. on June 30. Anyone wishing to attend the meeting should contact Mr. Giles Larrabee or Mr. Michael Yunker at (202) 273–7187.

Dated: May 13, 2004.

By Direction of the Secretary.

**E. Philip Riggin,**

*Committee Management Officer.*

[FR Doc. 04–11745 Filed 5–24–04; 8:45 am]

BILLING CODE 8320–01–M

## DEPARTMENT OF VETERANS AFFAIRS

### Advisory Committee on Structural Safety of Department of Veterans Affairs Facilities, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under Public Law 92–463 (Federal Advisory Committee Act) that a meeting of the Advisory Committee on Structural Safety of Department of Veterans Affairs Facilities will be held on Thursday, June 10, 2004, from 10 a.m. until 5 p.m., and on Friday, June 11, 2004, from 8:30 a.m. until 12:30 p.m., in Room 442, Export Import Bank, 811 Vermont Avenue, NW., Washington, DC. The meeting is open to the public.

The purpose of the Committee is to advise the Secretary of Veterans Affairs on matters of structural safety in the construction and remodeling of VA facilities, and to recommend standards for use by VA in the construction and alteration of facilities as prescribed under section 8105 of title 38, United States Code.

On June 10, the Committee will review developments in the field of structural design as they relate to seismic safety of buildings and fire safety issues. On June 11, the Committee will receive briefings/presentations on current fire and seismic safety issues that are particularly relevant to facilities owned and leased by the Department. The Committee will also vote on structural and fire safety recommendations for inclusion in VA's standards.

No time will be allocated for receiving oral presentations from the public. However, the Committee will accept written comments. Comments should be sent to Mr. Krishna K. Banga, Senior Structural Engineer, Facilities Quality Service, Office of Facilities Management (181A), Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420. Those wishing to attend should contact Mr. Banga at (202) 565–9370.

Dated: May 18, 2004.

By Direction of the Secretary.

**E. Philip Riggin,**

*Committee Management Officer.*

[FR Doc. 04–11737 Filed 5–24–04; 8:45 am]

BILLING CODE 8320–01–M


Federal Register

Tuesday,
May 25, 2004

Part II

# Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 210, 211, 820, and 1271
Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products; Final Rule and Notice

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 210, 211, 820, and 1271**

**[Docket No. 1997N–0484S]**

**[RIN 0910–AB27]**

# Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is requiring human cell, tissue, and cellular and tissue-based product (HCT/P) establishments to screen and test cell and tissue donors for risk factors for, and clinical evidence of, relevant communicable disease agents and diseases. The agency is amending the current good manufacturing practice (CGMP) and quality system (QS) regulations that apply to HCT/Ps regulated as drugs, medical devices, and/or biological products to clarify the role of the new donor-eligibility regulations in relation to existing CGMP regulations. By preventing the transmission of communicable disease by the wide spectrum of HCT/Ps that are marketed now or may be marketed in the future, the agency's action will improve protection of the public health and increase public confidence in new technologies.

**DATES:** This rule is effective May 25, 2005. This rule is applicable to cells and tissues recovered on or after May 25, 2005.

**FOR FURTHER INFORMATION CONTACT:** Paula S. McKeever, 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:**

**Table of Contents**



## I. Introduction

This final rule is part of a comprehensive new system of regulation for HCT/Ps. The goal of the new approach is to improve protection of the public health without imposing unnecessary restrictions on research, development, or the availability of new products. Consolidating the regulation of HCT/Ps into one regulatory program is expected to lead to increased consistency and greater efficiency. Together, these planned improvements will increase the safety of HCT/Ps, and public confidence in their safety. We intend to make the good tissue practice final rule, which has not yet published but which FDA intends to issue soon, effective 1 year after publication of this rule. Once both this rule and the good tissue practice regulations are in effect, FDA's comprehensive regulatory framework will be complete.

### *A. Background*

In 1997, FDA proposed a new approach to the regulation of HCT/Ps (62 FR 9721, March 4, 1997). (The term "HCT/P" is defined at § 1271.3(d) (21 CFR 1271.3(d).) To improve the regulation of HCT/Ps, we announced our intention to establish a comprehensive regulatory program for HCT/Ps, contained in part 1271 (21 CFR part 1271). In accordance with the tiered, risk-based approach that we proposed, some HCT/Ps would be regulated only under these new regulations, while others would also be regulated as drugs, devices, and/or biological products.

To implement the proposed approach, we issued three proposed rules:

- Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products (the registration proposed rule) (63 FR 26744, May 14, 1998);
- Suitability Determination for Donors of Human Cellular and Tissue-Based Products (the donor-suitability proposed rule) (64 FR 52696, September 30, 1999); and
- Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement (the CGTP proposed rule) (66 FR 1508, January 8, 2001).

We published a final rule entitled "Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing," in the **Federal Register** on January 19, 2001 (the registration final rule) (66 FR 5447). The registration final rule put into place general provisions pertaining to the scope and applicability of part 1271. These provisions are contained in subpart A of part 1271, along with a section that contains definitions applicable to all of part 1271 (§ 1271.3). The registration final rule requires cell and tissue establishments to register with us and submit a list of their HCT/Ps; the procedures for registration and listing are contained in subpart B of part 1271.

Some sections of the registration final rule became effective on April 4, 2001. Under those provisions, we now receive registration and listing information from establishments that engage in the recovery, screening, testing, processing, storage, or distribution of human tissue intended for transplantation (as described in § 1271.3(d)(1)). The effective date for the remaining sections was January 21, 2003, by which time we expected to have completed rulemaking for all of part 1271 (66 FR 5447 at 5448). At that time, the registration and listing requirements would have become effective for all other HCT/Ps (as described in § 1271.3(d)(2)). However, we recognized that unanticipated delays in completing the rulemaking for the remainder of part 1271 could occur, and we noted that, should the rulemaking proceedings be delayed past the 2-year timeframe, we would consider whether to maintain the 2-year effective date for the HCT/Ps described in § 1271.3(d)(2) or whether to extend that date for some or all of these HCT/Ps (66 FR 5447 at 5449). Since the rulemaking proceedings were delayed past the original 2-year effective date of January 21, 2003, we delayed the effective date of § 1271.3(d)(2) until January 21, 2004 (68 FR 2690, January 21, 2003). After the definition became final on January 21, 2004, we issued an interim final rule excepting human dura mater and human heart valve allografts from the scope of the definition of "human cells, tissues, or cellular or tissue-based products (HCT/Ps)" (69 FR 3823, January 27, 2004). We took this action to assure that these products, which were subject to the Federal Food, Drug, and Cosmetic Act (the act) and therefore regulated under the current good

manufacturing practice regulations set out in the quality system regulations in part 820 (21 CFR part 820), were not released from the scope of those regulations before a more comprehensive regulatory framework applicable to HCT/Ps, including donor eligibility requirements, good tissue practice regulations, and appropriate enforcement provisions, is fully in place. When that comprehensive framework is in place, we intend that human dura mater and human heart valve allografts will be subject to it. We intend to revoke the interim final rule at that time.

We are now making final the donor-suitability proposed rule that was proposed on September 30, 1999. (For reasons discussed in comment 26 of this document, we refer in this final rule to donor "eligibility" rather than "suitability.") The comment period for that proposed rule closed on December 29, 1999. On April 18, 2000, we reopened the comment period for an additional 90 days. We took this step in response to requests for an extension of the comment period as well as to provide sufficient time for State officials to participate in the rulemaking (65 FR 20774, April 18, 2000).

Because of their nature as derivatives of the human body, HCT/Ps pose a risk of transmitting communicable diseases. For this reason, this final rule requires that most cell and tissue donors be tested and screened for evidence of relevant communicable disease infection. It also contains other related requirements (e.g., on records, quarantine, storage, and labeling). These donor-eligibility requirements, which locate in subpart C of part 1271, are part of the core requirements applicable both to HCT/Ps regulated solely under these regulations and section 361 (the 361 HCT/Ps) of the Public Health Service Act (the PHS Act) and to those HCT/Ps also subject to regulation as drugs, devices, and/or biological products. As part of this rulemaking, we are also amending the drug CGMP regulations and the device QS regulations to clarify the role of the donor-eligibility requirements in the manufacture of HCT/Ps subject to regulation as drugs, devices, and/or biological products.

Since the publication of the donor-suitability proposed rule, we have continued to obtain current and accurate information on the risks of communicable-disease transmission by HCT/Ps and the most appropriate testing and screening measures. To this end, we have met with FDA's Transmissible Spongiform Encephalopathies Advisory Committee (TSEAC) (January 18 to 19, 2001, and June 26 to 27, 2002); the Blood Products Advisory Committee (BPAC) (December 13 to 14, 2001, and March 14 to 15, 2002); and the Centers for Disease Control and Prevention (CDC) (June 26 to 27, 2000). We have placed information on these meetings in the docket for this rulemaking.

We have used the information obtained at those meetings to develop a draft guidance document on determining donor eligibility entitled "Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products" (the donor-eligibility draft guidance). Elsewhere in this issue of the **Federal Register**, we announce the availability of that draft guidance, and solicit comments on its contents. We have also developed draft guidance on screening for Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) entitled "Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" (the CJD draft guidance) (67 FR 42789, June 25, 2002). We intend to combine the donor-eligibility draft guidance with the CJD draft guidance, and to issue a single final guidance document.

*B. Legal Authority*

We are issuing these new regulations under the authority of section 361 of the PHS Act (42 U.S.C. 264). Under that section, by delegation from the Surgeon General and the Secretary of Health and Human Services, FDA may make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States or from foreign countries into the States. Intrastate transactions affecting communicable disease transmission may also be regulated under section 361 of the PHS Act. (See *Louisiana* v. *Mathews*, 427 F. supp. 174, 176 (E.D. La. 1977).)

It is especially important to recognize that HCT/P manufacturing inevitably has interstate effects. HCT/Ps recovered in one State may be sent to another for processing, then shipped for use throughout the United States, or beyond. FDA has been involved in many recalls where HCT/Ps processed in a single establishment have been distributed in many States.

Section 361 of the PHS Act authorizes FDA to issue regulations necessary to prevent the introduction, transmission, or spread of communicable diseases. Communicable diseases include, but are not limited to, those transmitted by viruses, bacteria, fungi, parasites, and transmissible spongiform encephalopathy agents.

Certain diseases are transmissible through the implantation, transplantation, infusion, or transfer of HCT/Ps derived from donors infected with those diseases. To prevent the introduction, transmission, or spread of such diseases, we consider it necessary to take appropriate measures to prevent the use of cells or tissues from infected donors. Thus, these regulations require that, before the use of most HCT/Ps, the cell or tissue donor must be determined to be eligible to donate, based on the results of screening and testing for relevant communicable diseases. In most cases, a donor who tests reactive for a particular disease, or who possesses clinical evidence of or risk factors for such a disease, would be considered ineligible, and cells and tissues from that donor would not ordinarily be used.

In addition to regulations governing the testing and screening of donors for relevant communicable disease and quarantine and storage of HCT/Ps, FDA has also determined that regulations requiring establishments to maintain certain records related to HCT/Ps and to establish standard operating procedures are necessary to prevent the introduction, transmission, or spread interstate of communicable disease. A single donor may be the source of a large number of HCT/Ps. For example, it may be discovered, long after the donation and transplantations have been completed, that a donor of HCT/Ps transplanted into a large number of recipients had a relevant communicable disease. Although it might be too late to prevent the recipients' infections, it would not be too late to for the recipient to obtain treatment and take steps to avoid infecting others, such as close family members. However, unless adequate records were maintained, and maintained for the period of time throughout which infections may be identified, it would be impossible to identify the recipients potentially infected by the donor's HCTPs. This would be a critical breakdown in the prevention of disease transmission. Accordingly, FDA determined that the maintenance and retention of records are necessary to prevent the interstate introduction, transmission, and spread of communicable disease. Since some diseases, such as transmissible spongiform encephalopathies (TSEs), appear to have a long latency period, FDA has determined that a 10-year record retention period is necessary.

Similarly, it is necessary for establishments to establish, maintain,

and follow procedures related to the prevention of communicable disease. The agency has determined that these provisions are necessary to ensure that the important protections created by these regulations are actually effected and are not simply empty promises. Only manufacturing conducted in accordance with established procedures can assure that HCT/Ps meet the standards in these rules. If standardized processes are not developed and used, mistakes, inevitably, are made. Moreover, review of procedures can be critical to determining the cause of a disease transmission. Without that analysis, it would be impossible to prevent a future occurrence, with possibly fatal consequences.

These regulations are intended to prevent the transmission of communicable disease through the implantation, transplantation, infusion, or transfer of HCT/Ps. However, as noted in the registration and donor-suitability proposed rules, all HCT/Ps pose some risk of carrying pathogens that could cause disease in health-care personnel, other handlers of tissue, recipients, and family members or other contacts of recipients (63 FR 26744 and 64 FR 52696 at 52698). This broader concern for the spread of communicable disease is reflected in certain labeling requirements in these regulations and in the criteria for identifying a relevant communicable disease. We recognize that regulations exist that are specifically designed to protect employees who may come in contact with infectious materials (see 29 CFR 1910.1030, 42 CFR 72.6, and 49 CFR 173.196), and we do not consider these regulations to be in conflict with those other regulations currently in effect. However, we have made an effort to be consistent with the terminology used in these other regulations; e.g., "Infectious Substances" and the Biohazard legend.

Under section 361 of the PHS Act, FDA is authorized to enforce the regulations it issues to prevent the introduction, transmission, or spread of communicable diseases interstate through such means as inspection, disinfection, sanitation, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection in human beings, and other measures that may be necessary. In addition, under section 368(a) of the PHS Act, any person who violates a regulation prescribed under section 361 of the PHS Act may be punished by imprisonment for up to 1 year. Individuals may also be punished for violating such a regulation by a fine of up to $100,000 if death has not resulted from the violation or up to $250,000 if death has resulted. For organizational defendants, fines range up to $200,000 and $500,000. Individuals and organizations also face possible alternative fines based on the amount of gain or loss (18 U.S.C. 3559 and 3571(b) through (d)). Federal District Courts also have jurisdiction to enjoin individuals and organizations from violating regulations implementing section 361 of the PHS Act. (See *Califano* v. *Yamasaki*, 442 U.S. 682, 704–05 (1979); *United States* v. *Beatrice Foods Co.*, 493 F.2d 1259, 1271–72 (8th Cir. 1974), *cert. denied*, 420 U.S. 961 (1975).) Under sections 501(a)(2)(B) and (h), and 520(f)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351(a)(2)(B) and (h), and 21 U.S.C. 360j(f)(1)), drugs (including biological products) and devices (including biological products) are subject to CGMP requirements designed to ensure, among other things, product safety (21 U.S.C. 351(a)(2)(B) and (h), and 21 U.S.C. 360j(f)(1)). The authorities supporting the CGMP and QS regulations are also applicable when the CGMP and QS regulations apply to an HCT/P regulated as a drug, biological product, or device. Currently, the CGMP and QS regulations applicable to HCT/Ps regulated as drugs or devices do not delineate testing and screening procedures for communicable diseases. (See parts 210, 211, and 820 (21 CFR parts 210, 211, and 820).) Nevertheless, we consider communicable-disease testing and screening to be steps in the manufacturing process that are crucial to the safety of such products. As a result, we are amending the existing CGMP regulations for drugs in parts 210 and 211 and the QS regulations for devices in part 820, which include CGMP requirements, to make clear that the testing and screening provisions of part 1271 subpart C apply to HCT/Ps regulated as drugs, devices, and/or biological products.

Under § 210.1(c), the manufacturer of an HCT/P regulated as a drug, including a biological product that is a drug under the act, must comply with the donor-eligibility procedures in part 1271, subpart C. Failure to follow the CGMP requirements, including the testing and screening procedures in part 1271, would make the product adulterated under the act. In issuing this regulation, FDA is relying on the drug CGMP authorities (in particular, section 501(a)(2)(B) of the act (21 U.S.C. 351(a)(2)(B)), as well as section 361 of the PHS Act. Under § 820.1(a)(1), the manufacturer of an HCT/P regulated as a device, including a biological product that is a device under the act, must comply with the same procedures.

Section 375 of the PHS Act provides for Federal oversight of the nation's Organ Procurement and Transplantation Network, and section 379 of the PHS Act authorizes the National Bone Marrow Donor Registry (42 U.S.C. 274c and 274k). The Health Resources and Services Administration (HRSA) currently administers both of these programs. Given HRSA oversight in these areas, vascularized human organs (to include vascularized subparts of human organs) and minimally manipulated bone marrow (as defined in § 1271.3(d)(2)) for unrelated allogeneic use are specifically excluded from these final regulations.

## II. Highlights of the Final Rule

This final rule requires establishments to make donor-eligibility determinations for cell and tissue donors, based on donor screening and testing for relevant communicable disease agents and diseases (§ 1271.45). The regulations cover how to screen and test donors (§§ 1271.75, 1271.80, and 1271.85), as well as how to make the donor-eligibility determination (§ 1271.50). The term "relevant communicable disease agent or disease" is defined at § 1271.3(r). The rule also contains related requirements pertaining to procedures (§ 1271.47); records (§ 1271.55); quarantine (§ 1271.60); and storage of HCT/Ps from ineligible donors (§ 1271.65). Two of these provisions describe situations where it is not prohibited to use an HCT/P from an ineligible donor or a donor who has not yet been determined eligible (§§ 1271.60 and 1271.65). Exceptions from the requirement for making a donor-eligibility determination appear in § 1271.90.

The donor-eligibility draft guidance that may be found elsewhere in this **Federal Register** is intended to assist establishments in complying with the requirements of this final rule and contains details that are not in the regulation. Although not binding, the draft guidance presents the agency's current thinking on the topics covered. For example, whereas the regulation requires an establishment to screen donors for risk factors, the draft guidance specifies what we consider those risk factors to be. Similarly, the draft guidance contains recommendations on which tests to use to comply with the testing requirements in §§ 1271.80 and 1271.85. The draft guidance also identifies several additional disease agents or diseases that we believe meet the definition of relevant communicable disease agent or

disease. We welcome comments on the draft guidance. As scientific knowledge is developed, new tests are introduced, and additional relevant communicable disease agents and diseases are identified, we intend to follow the good guidance practices set out in § 10.115 to modify the donor-eligibility guidance so that it remains current.

*A. Plain Language*

In the **Federal Register** of June 10, 1998 (63 FR 31885), the Presidential Memorandum on Plain Language in Government Writing was issued. The goal of the plain language initiative is to publish government documents that are easier to understand.

In response to this initiative, we have written the donor-eligibility regulation in plain language. We have taken the following actions:

- Written the regulation in question-and-answer format;
- Reorganized some regulatory sections for greater clarity; and
- Followed other plain-language conventions, such as using "must" instead of "shall."

The resulting codified language is easier to read and understand than the proposed regulation. These editorial changes are for clarity only and do not change the substance of the requirements.

*B. New Terminology and Definitions*

In the registration final rule, we discussed our decision to replace the term "human cellular or tissue-based products" with "human cells, tissues, and cellular and tissue-based products" (abbreviated HCT/Ps) (66 FR 5447 at 5455). For consistency, we have made the same change in this final rule.

In response to comments, we have changed the term "donor suitability" to "donor eligibility."

In addition, we have made several changes to the definition of "relevant communicable disease agent or disease" with respect to prevalence. We intend the new language to cover both intentional and unintentional release of infectious agents.

We have also modified the definition of "directed donor" and changed the term to "directed reproductive donor."

We have deleted the definitions of "xenotransplantation" and "close contacts."

*C. Other Highlights*

This final rule contains other changes from the proposed rule. These changes are listed as follows:

- Provisions in § 1271.47, originally proposed in the CGTP proposed rule, require that HCT/P establishments establish and maintain procedures for the steps they perform in determining donor eligibility, including testing and screening;
- The requirement for donor retesting 6 months after donation now applies only to anonymous semen donors. In addition, you do not have to obtain a specimen for testing at each donation from a repeat anonymous donor, so long as you do not release the donation unless the donor has been retested (at least 6 months post donation). Directed donations of semen are excepted from the retesting requirement;
- Physical separation between HCT/Ps from ineligible and eligible donors is no longer required;
- We have removed the requirement that a physician must consent to the use of an HCT/P from an ineligible donor;
- You must screen all donors for *Treponema pallidum* and some donors for Human T-lymphotropic virus (HTLV) (in addition to testing);
- You must screen donors for "communicable disease risks associated with xenotransplantation." Under the proposed rule, receipt of a xenotransplantation product would have made a donor ineligible under all circumstances. Now, receipt of a xenotransplantation product no longer overrides the special circumstances, listed in § 1271.65(b)(1), under which use of an HCT/P from an ineligible donor is not prohibited;
- We have modified the requirements applicable to testing for Cytomegalovirus (CMV);
- If the donor is one month of age or younger, you must test a specimen from the birth mother;
- The requirements on timing of specimen collection allow 7 days before or after recovery, or for donors of peripheral blood stem progenitor cells only, up to 30 days before recovery, if specimen collection at the time of recovery is not feasible; and
- Required testing can be performed by a laboratory that has met requirements equivalent to those imposed by the Clinical Laboratory Improvement Amendments of 1988 (CLIA), as determined by the Centers for Medicare and Medicaid Services (CMS).

## III. Comments on the Proposed Rule and FDA's Responses

We received over 500 comments on the proposed rule.

Some comments raised issues relating to the general provisions in subpart A of part 1271 or the registration and listing procedures in subpart B, and we considered those comments in drafting the registration final rule (66 FR 5447 at 5450, January 19, 2001). For example, in that final rule we discussed comments on dispute resolution (66 FR 5447 at 5451); homologous use (66 FR 5447 at 5458); the practice of medicine (66 FR 5447 at 5452); minimal manipulation (66 FR 5447 at 5457); the definition of "family-related allogeneic use" (66 FR 5447 at 5454); the terms "human cellular or tissue-based product" and "manufacture" (66 FR 5447 at 5455 and 5456); the regulation of bone allografts (66 FR 5447 at 5457); establishments not required to comply with part 1271 (66 FR 5447 at 5460); and the frequency of updates (66 FR 5447 at 5460 and 5461). If we considered an issue in the registration final rule, we are not reiterating our response here.

Several comments submitted to the docket for the CGTP proposed rule raised issues that are appropriately addressed in this final rule. We respond to those comments in comments 32, 48, 49, and 59, and in the discussion of § 1271.47 in section III.D.3 of this document.

We received two requests for an extension of the comment period. On April 18, 2000, a document was published in the **Federal Register** reopening the comment period for an additional 90 days (65 FR 20774).

*A. General*

(Comment 1) We received various comments expressing general approval of the proposed rule. One comment applauded us for addressing concerns of vital interest to the protection of the public health. Another comment expressed continued support for our efforts to design a comprehensive regulatory program for HCT/Ps, and agreed that screening and testing of donors constitutes a vital component of such a program. Other comments supported our goal of preventing the transmission of communicable diseases through donor screening and testing. One comment supported requiring semen banks to comply with the proposed screening and testing regulations.

We also received comments voicing general criticism of the proposed rule and of our comprehensive regulatory approach to cells and tissues. Some comments described the proposed rule as unnecessary or burdensome. One comment asserted that the regulations were inconsistent with the Congressionally supported "least burdensome" practice of regulation.

(Response) We acknowledge and appreciate the supportive comments. This rule contains important requirements that will help prevent the transmission of communicable diseases by HCT/Ps. Moreover, it forms a vital

component of the new tiered, risk-based regulatory program, which will be superior to the patchwork of requirements that it replaces. As discussed in greater detail in section IV of this document, this rule is consistent with Executive Order 12866, which, in its eleventh Principle of Regulation applicable to Federal rulemaking, requires FDA to "* * * tailor its regulations to impose the least burden on society * * * consistent with obtaining the regulatory objectives." FDA has designed this regulatory program to impose only appropriate, and appropriately limited, burdens.

For example, the compliance expectations for a small medical practice that provides artificial insemination are commensurate with the communicable disease risks associated with its activities. If the practice is limited to artificial insemination using either semen from an anonymous or directed reproductive donor obtained from a semen bank (§ 1271.15(d)), or semen recovered at the practice and immediately used to inseminate the donor's sexually intimate partner (§ 1271.15(e)), then the risks are minimal and the practice is not required to comply with part 1271. If the semen is not immediately transferred to a donor's sexually intimate partner but instead is stored (raising concerns about possible cross-contamination during storage), the practice would not be eligible for the exception under § 1271.15(e) and would need to comply with the requirements in part 1271 subpart B (registration and listing) and in applicable sections of subpart C (minimal standard operating procedures, minimal recordkeeping, and specific labeling for stored reproductive cells or tissue from sexually intimate partners if not screened or tested). Additional risks are associated with the recovery of semen from an anonymous or directed reproductive donor for artificial insemination; practitioners who perform these services are not eligible for the exception under § 1271.15(d) and must comply with both subpart B (registration and listing) and all of subpart C (donor screening and testing, standard operating procedures, recordkeeping, and labeling) in part 1271. FDA intends to provide further detailed guidance regarding these risk-based approaches.

We have striven to establish regulations that provide public health protection without imposing an undue burden on regulated industry. In this sense, they are also entirely consistent with the requirement for "least burdensome" regulation of devices set out in section 205(a) and (b) of the Food and Drug Administration Modernization Act of 1997.

(Comment 2) Several comments asked that provisions be made for HCT/Ps collected before the effective date of this regulation and opposed retrospective application of the new regulations.

(Response) This regulation will apply to cells and tissues recovered on or after the effective date of the regulation.

(Comment 3) One comment urged us to coordinate our donor screening requirements with those of other countries.

(Response) We support the long-term goal of international harmonization. In the process of developing this final rule, we have reviewed standards from other countries and met with representatives from the European Union, Australia, Japan, and other nations. The requirements in place in other countries are diverse and rarely static, reflecting the fact that other countries may have screening needs different from those in the United States and different tests available to them. The challenge of achieving consistency is underscored by the European Commission's announcement of the need for a new directive on human tissue, intended to replace the current myriad of 15 differing—and sometimes nonexistent—national laws on the subject. On June 19, 2002, the Commission of European Communities put forth a "Proposal for a Directive of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, storage, and distribution of human tissues and cells." Completion of this directive is expected to take several years. We applaud this effort and will continue to follow developments in tissue regulation throughout the world. However, at this time, our primary goal is to put into place the basic safeguards set out in this rule, an effort that may provide a starting point for further harmonization efforts.

(Comment 4) Several comments stated that the rule would conflict with the rule concerning privacy of health care information proposed by the Department of Health and Human Services (HHS) on November 3, 1999. The privacy rule was subsequently finalized on December 28, 2000 (65 FR 82462), and amended on August 14, 2002 (67 FR 53182).

(Response) The Department regulations on privacy of health care information (the Privacy Rule) were codified at 45 CFR parts 160 and 164. The Privacy Rule does not include the procurement or banking of organs, blood (including autologous), sperm, eyes or any other tissue or human product within the definition of health care and the establishments that perform such activities are not considered health care providers when conducting these functions (65 FR 82462 at 82477, December 28, 2000). In addition, the Privacy Rule authorizes health care providers who are subject to the Privacy Rule to "disclose protected health information to organ procurement organizations or other entities engaged in the procurement, banking or transplantation of cadaveric organs, eyes, or tissue for the purpose of facilitating organ, eye or tissue donation and transplantation" (45 CFR 164.512(h)). The preamble to the Privacy Rule notes that, when an individual has not previously authorized release of protected health information, this provision of the Privacy Rule "* * * is intended to allow covered entities [those subject to the privacy rule] to initiate contact with organ and tissue donation and transplantation organizations to facilitate transplantation of cadaveric organs, eyes, and tissues" (65 FR 82464 at 82534). The Privacy Rule further authorizes covered entities to disclose protected health information to persons subject to the jurisdiction of FDA with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity (45 CFR 164.512(b)(1)(iii)). Finally, we further note that in the event that one of the previously mentioned provisions is not applicable, covered entities may disclose protected health information pursuant to an authorization from the individual or the individual's personal representative (45 CFR 164.502(a)(1)(iv) and (g)(1), and 164.508). For these reasons, we do not believe that the Privacy Rule conflicts with this final rule.

However, FDA has considered the impact of this donor-eligibility final rule on patient privacy. We have deleted the requirement that relevant patient records accompany an HCT/P, requiring instead a summary of records. We made this change in response to concerns about privacy.

(Comment 5) One comment stated that, in the proposed rule, FDA improperly "relied" on provisions of the registration proposed rule. Another comment objected to the rulemaking process, asserting that we circumvented the usual departmental review process before publishing the proposed rule.

(Response) We disagree with both comments. In the proposed rule, the agency did not "rely" on the registration

proposed rule, but merely described another ongoing, related, rulemaking. Moreover, we made clear that the provisions of the registration proposed rule we referenced in the preamble to the donor-suitability proposed rule were merely proposals. The agency received comments related to those proposals in the donor suitability docket. When we finalized those provisions in the registration final rule, we considered comments received in the donor suitability docket, as well as in the registration docket (66 FR 5447 at 5450). With respect to the second comment, we disagree that we followed anything other than our usual review process; however, we note that these procedures constitute department practice and are not required by regulation by law or regulation.

(Comment 6) One comment cited a potential conflict with the regulation issued by CMS requiring hospitals to notify organ procurement organizations (OPOs) upon patients' death or imminent death (42 CFR 482.45). The comment pointed out that OPOs might, in some instances, determine donor eligibility for tissue donors. The comment asserted that FDA does not regulate OPOs and questioned who would be accountable for compliance with FDA regulations.

(Response) We disagree that there is a conflict between the regulations in part 1271 and CMS's regulation of OPOs; we also disagree that OPOs are exempt from FDA regulations. The determination of donor eligibility is a key function of an HCT/P manufacturing establishment. Therefore, although human organs are excluded from the definition of HCT/P, and thus not covered by the regulations in part 1271, any OPO that performs any part of any HCT/P manufacturing function, is subject to the regulations in part 1271. Such an OPO must register with the agency and comply with all applicable regulations in part 1271; thus, an OPO that screens tissue donors must do so in compliance with the regulations in part 1271 on donor screening. If an OPO performs no tissue manufacturing functions, it would not be subject to these regulations.

(Comment 7) One comment recommended that we set allowable limits for additives to allograft tissues, such as glycerol.

(Response) We decline to set a specific limit on such additives in these regulations. We point out, however, that one of the criteria in § 1271.10 for regulation of an HCT/P solely under section 361 of the PHS Act and part 1271 is that the manufacture of the HCT/P does not involve the combination of the cell or tissue component with a drug or a device, except for a sterilizing, preserving, or storage agent, and then only if the addition of the agent does not raise new clinical safety concerns with respect to the HCT/P. Should an additive raise new safety concerns or, as in the case of glycerol, be for any purpose other than sterilizing, preserving, or storage, the HCT/P would be subject to regulation under the act and/or section 351 of the PHS Act, and FDA would consider allowable limits of chemical additives in the context of the premarket review process.

(Comment 8) One comment asserted that tissue banks should audit their domestic and international tissue recovery and distribution intermediaries to assure accountability to the same standards that they themselves uphold.

(Response) We agree that documentation of these audits would help assure our goals of protecting the public health. Audits and other ways of ensuring accountability are addressed in the CGTP proposed rule.

(Comment 9) One comment supported the establishment of a central registry for tracking all reproductive tissue donors to locate donors and recipients in an emergency.

(Response) We encourage interested parties to explore methods of tracking donors, donations, and recipients, including the establishment of such a central registry. However, we do not propose to require such a registry at this time.

(Comment 10) One comment asked that the regulations clarify the responsibilities of reproductive tissue banks and client depositors with respect to length of storage of tissue and the right of a bank to destroy tissue of noncompliant depositors.

(Response) The requested clarification is beyond the scope of these regulations, which concern communicable disease transmission and not provisions of agreements between HCT/P establishments and individual clients that are unrelated to communicable disease transmission.

(Comment 11) One comment questioned why these regulations do not address the use of cellular material other than from the patient in in-vitro fertilization. Another comment supported restrictions on gene, ooplasm, and nuclear transfer.

(Response) We recognize the comments' concerns and are addressing these issues in contexts outside of this rulemaking.

*B. Amendments to 21 CFR Parts 210, 211, and 820*

We proposed amending §§ 210.1 and 820.1 to require manufacturers of HCT/Ps regulated as drugs, medical devices, and/or biological products to comply with the donor-eligibility procedures in subpart C and the current good tissue practice (CGTP) procedures in subpart D of part 1271. (We also proposed minor amendments, for consistency, to §§ 210.2 and 211.1.) The donor-eligibility and CGTP procedures would be considered part of CGMP requirements for drugs and the QS requirements for devices.

The proposed amendment to § 210.1 stated that failure to comply with the donor-eligibility, CGTP, or other CGMP regulations would render adulterated, under section 501(a)(2)(B) of the act, an HCT/P regulated as a drug and/or biological product, and the HCT/P, as well as the person responsible for the failure to comply, would be subject to regulatory action. The proposed amendments to § 820.1 were comparable, stating in part that the failure to comply with any applicable donor-eligibility, CGTP, or QS regulation would render a device adulterated under section 501(h) of the act.

We received no comments on the proposed amendments.

We are finalizing the proposed modifications to §§ 211.1(b) and 820.1(a), which add a cross-reference to the regulations in part 1271. As finalized, § 211.1(b) applies to HCT/Ps that are also regulated as drugs or biological products subject to the drug current good manufacturing practice (CGMP) regulations in parts 210 and 211, and § 820.1(a) applies to HCT/Ps that are also regulated as devices subject to the QS regulations in part 820.

In response to a comment submitted on the CGTP proposed rule that asserted that the "impossible to comply" language in proposed § 1271.150(c) did not provide useful guidance, we have modified this provision by replacing the "impossible to comply" language with more specific wording referring to a conflict between applicable regulations in different parts. In the event of a conflict between applicable regulations in part 1271 and regulations in parts 210, 211, or 820, the regulations specifically applicable to the product in question will supersede the more general regulations. Because the "impossible to comply" language is contained in related provisions in other parts we have made the same change to these provisions to ensure consistency. This new language is intended for

purposes of clarity. The "impossible to comply" language in our current regulations was not the subject of complaints by regulated establishments. With the revised language, FDA intends to continue to interpret the standard reasonably and does not intend to impose unreasonable burdens on establishments.

We note that the phrase "impossible to comply" has been used for products other than HCT/Ps since FDA first issued the device CGMP regulations in 1978 (43 FR 31508, July 21, 1978). Two months later, FDA used the phrase in the drug CGMP regulations (43 FR 45014, September 29, 1978). FDA explained in the preamble to the drug regulations that "impossible to comply" encompasses situations where regulations contradict or conflict each other (43 FR 45014 at 45029).

The new language on a conflict between applicable regulations replaces the phrase "impossible to comply" in §§ 210.2(a), 211.1(b), 820.1(a), and 820.1(b). (Although a revision to § 820.1(b) was not proposed, it is now necessary to revise that paragraph for consistency with § 820.1(a).) The new language pertains only to conflicts that occur between applicable regulations in one part (e.g., part 211) and applicable regulations in another part (e.g., part 1271) and not between regulations within one part (e.g., between two regulations in part 211). FDA believes that, in the event of such a conflict, the more specifically applicable regulation would be found in part 1271.

We are also finalizing proposed § 210.1(c), which would provide that the failure to comply with any applicable provision in part 1271, subparts C and D, would render a drug adulterated under section 501(a)(2)(B) of the act.

We have made minor revisions to the wording of the proposed amendments to §§ 210.1(c), 210.2, 211.1(b), and 820.1(a). These changes include the addition of a reference to section 361 of the PHS Act in §§ 210.1(c) and 820.1(a). We have also clarified in § 210.1(c) that screening refers to donor screening and that testing includes donor testing.

However, we are not finalizing proposed § 820.1(c) in this rule, which would have provided that the failure to comply with any applicable provision in part 1271, subparts C and D, would render a device adulterated under section 501(h) of the act. The act requires FDA to follow special procedures when issuing regulations under the device good manufacturing practice (GMP) authority; those procedures are not applicable to regulations issued under the CGMP authority for drugs. Before issuing regulations establishing requirements under section 520(f) of the act, the act requires FDA to submit the proposed regulations for review by an advisory committee meeting the criteria established in section 520(f)(3). However, FDA's advisory committee for device GMP regulations has not met since April 29, 1997, and only six of the required nine seats are currently filled. Although the agency believes it would be desirable to include a provision such as proposed § 820.1(c), we believe it is not absolutely necessary to the regulatory scheme. When the device GMP advisory committee has been fully reconstituted, FDA may consider submitting proposed § 820.1(c) for its consideration. In the meantime, FDA intends to enforce violations of part 1271, subparts C and D, under the enforcement provisions contained in section 368 of the PHS act (42 U.S.C. 271), and the general equitable powers of the Federal courts.

Finally, we note that the references to part 1271 in these sections (§§ 210.1, 210.2, 211.1, and 820.1) refer to "applicable" provisions of part 1271. In the event that the final CGTP rule provides that any or all provisions in that rule are not being implemented for certain HCT/Ps, those CGTP provisions would not be "applicable" for those HCT/Ps.

### *C. Definitions (§ 1271.3)*

We have grouped all definitions pertinent to part 1271 in a single definitions section (§ 1271.3), among the general provisions of subpart A.

We received no comments on the proposed definitions of the following terms, and those definitions appear in the final rule either unchanged or with only minor changes for consistency in terminology (i.e., references to HCT/Ps): Biohazard legend (§ 1271.3(h)), blood component (§ 1271.3(i)), donor (§ 1271.3(m)), plasma dilution (§ 1271.3(p)), responsible person (§ 1271.3(t)), act (§ 1271.3(v)); PHS Act (§ 1271.3(w)); and FDA (§ 1271.3(x)). For clarity, we have added the phrase "of a cadaveric donor" to the term "physical assessment," but have made no other change to that definition (§ 1271.3(o)).

We received no comments on the proposed definitions of the terms "embryo" and "gamete," but have deleted those definitions from this final rule as unnecessary; "gamete" is not used in the codified provisions and "embryo" is generally understood. We received no comments on the term "reconstituted blood," but have deleted the term from the final rule because of its potential to cause confusion. We have incorporated the substance of the proposed definition of "summary of records" into § 1271.55 and so have deleted the definition of that term from the final rule. We received no comments on that definition. We also received no comments on the proposed definition of "quarantine," and it remains unchanged in this final rule (§ 1271.3(q)); however, comments on the quarantine provisions in § 1271.60 are addressed in section III.D.6 of this document.

#### 1. Colloid (§ 1271.3(j)) and Crystalloid (§ 1271.3(k))

Proposed § 1271.3(k) defined "colloid," and proposed § 1271.3(l) defined "crystalloid." Both are terms used in § 1271.80 with respect to plasma dilution. Although we specifically requested comments on the appropriateness of these definitions, no comments were submitted.

For greater accuracy, we have made minor changes to the language of each definition. The final rule contains a two-part definition of "colloid" in § 1271.3(j). Under the first part, a colloid is a protein or polysaccharide solution, such as albumin, dextran, or hetastarch, that can be used to increase or maintain osmotic (oncotic) pressure in the intravascular compartment. We have deleted the word "certain" from the second part of the definition, so that it now reads: "Blood components such as plasma and platelets."

The final rule replaces the word "balanced" in the proposed definition of crystalloid with "isotonic," so that the definition now refers to an isotonic salt and/or glucose solution used for electrolyte replacement or to increase intravascular volume, such as saline solution, Ringer's lactate solution, or 5 percent dextrose in water.

#### 2. Directed Reproductive Donor (§ 1271.3(l))

The proposed rule contained a definition of "directed donor," a term used in proposed § 1271.65(b) to describe a situation in which the use of reproductive cells or tissue from an ineligible donor would not be prohibited. In considering the comments on § 1271.65(b), discussed in greater detail in section III.C.5 of this document, we concluded that, for clarity, we should limit the definition of "directed donor" to donors of reproductive cells and tissue and change the term to "directed reproductive donor." Because the term "directed reproductive donor" is used only in the context of the donation of reproductive cells and tissue, these changes do not affect the scope of the exception.

As proposed, a directed donation involved the designation of a specific potential recipient. We have maintained this part of the definition in the final rule.

(Comment 12) Our review of comments indicated that there was some confusion about whether the designation of a specific recipient could take place in the context of anonymous semen donation (i.e., a situation in which the donor and recipient do not know each other).

(Response) We did not intend for the term "directed donor" to refer to anonymous donations. Rather, our intention was to respect the existence of relationships between people. To recognize existing relationships between donors and recipients, we have added language to the definition of "directed reproductive donor" to indicate that, in a directed donation, the donor knows and is known by the recipient before donation.

We have also clarified the definition by noting that directed reproductive donors do not include sexually intimate donors, who are excepted from screening and testing requirements under § 1271.90. This change is intended to make clear that, for the purpose of this rule, there are three categories of reproductive donors, subject to three different sets of requirements listed as follows: (1) The anonymous donor, to whom all the donor-eligibility requirements apply; (2) the directed reproductive donor, whose reproductive cells and tissue may be used even if the donor is determined ineligible; and (3) the sexually intimate partner, for whom testing and screening are not required (discussed in section III.D.11 of this document).

(Comment 13) One comment requested that we define an additional category of anonymous semen donor, the "Identification Revealed Donor." Under this kind of donation, the identity of an anonymous semen donor may be revealed to the child and/or mother at some point after birth. (We also received comments supporting this type of arrangement.) The comment suggested a related change to proposed § 1271.75 so that screening for risk factors for relevant communicable diseases would not be required for donors whose identities may be revealed later.

(Response) Donor identification is outside our jurisdiction and unrelated to the purpose of this rule, which is to prevent the transmission of communicable disease. For these reasons, this rule does not address any agreements that might be entered into for revealing a donor's identity at a future time.

We note that the suggested change to the screening requirement in § 1271.75 would exempt the anonymous donors described in the comment from screening for risk factors for human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), human transmissible spongiform encephalopathy (TSE), including CJD and vCJD, *Treponema pallidum*, HTLV, *Chlamydia trachomatis*, and *Neisseria gonorrhea*. We cannot justify this exception on public health grounds. Whether or not the identity of an anonymous donor may be revealed later has no bearing on the appropriate screening and testing of that donor. For the prevention of the transmission of communicable disease, the same requirements should apply to all anonymous donors.

We have distinguished between directed reproductive donors and anonymous donors to respect the existence of relationships between people who know each other and have made a joint decision for the recipient to conceive a child. In contrast to the directed reproductive donor who has an existing relationship with the recipient, only the potential for a future relationship exists for the anonymous donors described in the comment. Under the identification-revealed donation arrangement described in the comment, there is no relationship between donor and recipient at the time of donation. The recipient does not even know the name of the donor at the time of the donation, and may never learn the donor's identity at all. For these reasons, we decline to add a new definition for "identification revealed donor."

3. Donor Medical History Interview (§ 1271.3(n))

The donor medical history interview is one of the relevant medical records that are reviewed in the donor screening process. We proposed to define "donor medical history interview" as a documented dialog with the donor, if living, or, if the donor is not living or is unable to participate in the interview, with an individual knowledgeable about the donor's medical history and relevant social behavior (proposed § 1271.3(o)). The proposed definition provided examples of possible interviewees and described the questions to be asked about relevant social behavior

(Comment 14) Several comments asserted that the proposed definition of donor medical history interview implies that an in-person, face-to-face interview would be required. One comment assumed that the definition includes communications with friends and life partners.

(Response) A donor medical history interview means a "documented dialog." You may conduct such a dialog in person, by telephone, or through written or other forms of communication that allow the exchange of information between interviewer and interviewee. The interview method should allow the interviewer to ask followup questions to collect necessary information or to clarify responses. In the case of a living donor, a face-to-face interview is generally the most effective way to conduct a dialog.

We agree that the definition may include communications with friends and life partners, if they are knowledgeable about the donor's medical history and relevant social behavior.

We note that the definition of "donor medical history interview" is among the provisions of this final rule that we have redrafted for clarity and plain language reasons. The meaning of the definition remains unchanged.

4. Relevant Communicable Disease Agent or Disease (§ 1271.3(r))

Proposed § 1271.3(y) contained a 2-part definition of "relevant communicable disease or disease agent." The first part listed those disease agents and diseases that are specifically identified in §§ 1271.75 and 1271.85 as relevant communicable diseases for which screening and testing would be required. These are as follows: HIV, types 1 and 2; HBV; HCV; TSE, including CJD and vCJD; *Treponema pallidum*; HTLV, types I and II; CMV; *Chlamydia trachomatis* and *Neisseria gonorrhea*. The proposed rule noted that in some instances, FDA had identified a disease agent or disease as relevant for a particular type of HCT/P and that this distinction was reflected in the proposed testing and screening requirements in §§ 1271.75 and 1271.85 (64 FR 52696 at 52701). For clarity, we have reorganized the list of identified relevant communicable disease agents and diseases in the first part of the definition (§ 1271.3(r)(1)) according to tissue type. Thus, for example, HIV, types 1 and 2, is listed as relevant for all cells and tissues; HTLV, types I and II, is listed as a cell-associated disease agent or disease relevant for viable, leukocyte-rich cells and tissues; and *Chlamydia trachomatis* is listed as a disease agent or disease of the genitourinary tract relevant for reproductive cells and tissues. This is an organizational change and not substantive.

The second part of the proposed definition described criteria for other communicable diseases or disease agents to be considered "relevant." The proposed criteria related to prevalence, transmission risk, significance of health risk, and the availability of appropriate screening and/or testing methods. We have made changes to several aspects of this part of the definition, discussed in comments 16 through 19 of this document.

"Relevant communicable disease agent or disease" is defined in the final rule at § 1271.3(r)

(Comment 15) One comment stated that we had not sufficiently demonstrated the need to expand agency oversight to include diseases in addition to HIV and hepatitis. Another comment asserted that transmission of CJD and syphilis (*Treponema pallidum*) via cornea transplants is rare or nonexistent.

(Response) When we issued part 1270 as an interim rule in 1993, among other reasons, we were acting swiftly to counter the transmission of three serious disease agents, HIV, HBV, and HCV (64 FR 52696 at 52698). One reason for the inclusion of more diseases and disease agents in the proposed rule and this final rule is that the new rules cover more types of cells and tissues than were subject to part 1270. These additional cells and tissues pose additional risks of transmitting communicable disease. For example, we are now requiring you to test donors of viable, leukocyte-rich tissue for HTLV and CMV; this requirement did not previously exist, because part 1270 did not cover such viable, leukocyte-rich HCT/Ps as semen and hematopoietic stem/progenitor cells. Similarly, we are now requiring that you test donors of reproductive tissue for *Neisseria gonorrhea* and *Chlamydia trachomatis*, a requirement that did not exist under part 1270, which did not cover reproductive tissue.

We proposed to add TSE (including CJD and vCJD) and syphilis to the list of disease agents and diseases for which donors of all types of cells and tissues would be required to undergo screening and/or testing, because these two diseases present significant health risks. We disagree with the assertion that testing is unnecessary due to the infrequency of transmission. With respect to CJD, there have been over 100 transmissions of CJD from dura mater worldwide (including 3 in the United States) and 1 transmission from cornea (in addition to 2 possible transmissions), and the number of cases of vCJD is rising. With respect to syphilis, several factors could be responsible for the lack of reports of syphilis transmission via organs, tissues, or cells, including the use of antibiotics during tissue processing and the storage of tissues at low temperature. (*Treponema pallidum* does not survive when stored at 4 °C for more than 48 to 72 hours.) However, these factors might not always be in place; i.e., antibiotics might not be used, and fresh bone grafts might not be stored under time and temperature conditions that would kill the organism, if present. Because of the potential for transmission by cells and tissue, including cornea, of both CJD and syphilis, we are maintaining the screening and testing requirements in the final rule.

(Comment 16) Several comments asked about the procedure we would use to identify additional relevant communicable disease agents and diseases under the second part of the definition. Two comments asserted that we should specify that procedure, and that, except in cases of real urgency, the agency must afford interested parties prior notice and an opportunity to comment before adding a new disease agent or disease to the list. According to these comments, providing for such input would provide the following results: (1) Reveal scientific complexities otherwise unknown to FDA, (2) allow us to avoid imposing an additional testing obligation where no test is available, and (3) help avert the unnecessary destruction of tissues in inventory. Some comments stated that tissue establishments would have a difficult time identifying a new relevant communicable disease agent or disease under the four factors set out in the proposed rule. In the absence of guidance by the agency, establishments might feel forced to conduct testing that was not supported by the risk, due to liability concerns.

(Response) We agree that public participation in these issues is important. We intend to issue guidance in accordance with the good guidance practices set out in § 10.115 to advise you when, in the agency's view, a new relevant communicable disease agent or disease exists. Good guidance practices provide the public with an opportunity to comment on guidance before its implementation, except when the agency determines that prior public participation is not feasible or appropriate (e.g., in a public health emergency). When FDA issues guidance for immediate implementation, the public is invited to comment after publication. In suitable situations, we will hold public meetings or consult with advisory committees to help us identify communicable disease agents or diseases for which donor screening and testing should be performed.

We also believe that, by issuing guidance, the agency will assist small tissue establishments, which may not be in a position to track the prevalence of emerging diseases and disease agents in a timely manner. Through guidance, FDA will perform an important communications function and assist small tissue establishments in meeting their regulatory obligations to test and screen for relevant communicable diseases and disease agents.

Under the final rule, whether or not a disease or disease agent is "relevant" under the rule will still be measured by the factors set out in § 1271.3(r)(2)(i), (r)(2)(ii), and (r)(2)(iii), taken together. We recognize that, due to a variety of circumstances, you may not be aware of every instance when a disease or disease agent meets these factors. We therefore intend to clarify the application of these criteria in guidance. FDA's role in issuing guidance is to provide notice that the definitional elements appear to be met. FDA's notification will take the form of guidance and will not constitute a rule. In an enforcement action involving testing and screening for a new relevant communicable disease or disease agent, FDA's identification in guidance of the disease or disease agent would not be dispositive of the issue of whether it meets the factors set out in § 1271.3(r)(2)(i), (r)(2)(ii), and (r)(2)(iii). In such an action, FDA would have to establish that the disease met those factors.

(Comment 17) One comment asserted that the application of "relevant" is subject to FDA's sole determination, which is further complicated by FDA's interpretation of terms such as "risk" and "appropriate screening." The comment asserted that these terms are not sufficiently defined, and that relevant risk is broadly applied and does not sufficiently address risk by specific tissue. Another comment stated that "relevant disease risk" is overly broad and would subject all tissue entities to unfair malpractice claims, leaving the system vulnerable and subject to unnecessary costs. The comment further opined that the mere hypothetical threat of a disease or agent would make it eligible for required screening and testing.

(Response) The rule establishes factors that must be met before a disease agent or disease is "relevant" under this rule. As explained in comment 16 of this document, we intend to follow good guidance practices to notify you that the agency believes additional relevant communicable disease agents or

diseases exist. This will provide the opportunity for public participation in the process.

We disagree with those comments that question the terms "relevant disease risk" and "relevant risk." These are not terms that we used in the proposed definition of relevant communicable disease agent or disease, and they do not appear in the final definition.

With respect to the comment on requiring testing and screening for a disease that poses a "mere hypothetical threat," screening and testing would be required only when supported by a sound scientific basis. Identifying a relevant communicable disease agent or disease will entail an evaluation of the risk of the disease based on the criteria in § 1271.3(r)(2). Establishments would not be required to determine independently which disease agents and diseases meet the definition of "relevant communicable disease agent or disease," and could simply follow FDA guidance concerning communicable diseases or disease agents newly identified as relevant. Establishments could also participate in FDA's identification process, for example by commenting on draft and final guidances. Such FDA guidances would identify disease agents or diseases which, in the agency's view, meet the standards for "relevant communicable disease or disease agent." Each guidance would describe effective, and thus "appropriate," screening practices, and would list recommended tests, if there are available and effective tests that have been licensed, approved, or cleared by FDA.

(Comment 18) One comment asserted that the term "prevalent" is not sufficiently defined. Another comment asked at which point and by whom a disease would be designated sufficiently prevalent among potential donors.

(Response) We have made several changes to the definition of "relevant communicable disease agent or disease" with respect to prevalence.

First, we have made the question of prevalence and/or incidence part of the evaluation of the risk of transmissibility of a communicable disease agent or disease. We have implemented this change by dividing the question of risk of transmissibility into the following two parts: (1) Is the disease or disease agent potentially transmissible by an HCT/P? and (2) does the disease or disease agent have sufficient incidence and/or prevalence to affect the potential donor population? This change is reflected in § 1271.3(r)(2)(i). Both questions are important in considering whether to require testing and/or screening for a communicable disease or disease agent; grouping them will ensure that both factors are considered together.

We believe that the factors set out in § 1271.3(r)(2)(i), (r)(2)(ii), and (r)(2)(iii) should be considered as a whole. This approach is useful in explaining the concept of prevalence/incidence. On the one hand, a highly prevalent but relatively harmless disease agent might not be considered relevant. For example, some communicable diseases (e.g., Ureaplasma urealyticum, a disease of the genitourinary tract) are prevalent, but their pathogenicity to cell and tissue recipients is of questionable clinical significance. For this reason, we do not currently consider Ureaplasma urealyticum to be a relevant communicable disease agent. On the other hand, testing or screening might be required for a less prevalent but particularly virulent agent. Examples of communicable diseases that are less prevalent, yet pose extremely significant health risks, are TSE and HIV–2.

The second change we have made is to modify the proposed language on prevalence so that it now refers to "sufficient incidence and/or prevalence to affect the potential donor population." Whereas prevalence refers to the number of existing cases over a period of time, incidence refers to the number of new cases. Both prevalence and incidence are important indicators of the risk that a potential HCT/P donor could be infected with a particular disease or disease agent, and that HCT/Ps from that donor could transmit the disease.

The third change we have made is to identify an alternative to prevalence. Under § 1271.3(r)(2)(i)(B), a relevant communicable disease or disease agent is one that "* * * either (1) has sufficient incidence and/or prevalence to affect the potential donor population, or (2) may have been released accidentally or intentionally in a manner that could place donors at risk of infection."

We intend this new language to cover both intentional and unintentional release of infectious agents. Although prevalence/incidence remains an important consideration in determining whether a communicable disease or disease agent should be considered relevant, we recognize that when an infectious agent is released, whether by accident or purposefully (e.g., to inflict harm), we may not immediately have adequate information to assess the prevalence of the disease or disease agent. In this instance, where we have information about the release of an infectious agent, and the other prongs of the definition are met, it is important for the agency to be able to respond promptly by issuing guidance on testing and screening without awaiting the accumulation of data on prevalence.

In response to the second comment, which asked at which point and by whom would a disease be designated sufficiently prevalent among potential donors, we discuss in comment 16 of this document, the procedures we will follow to communicate the agency's conclusions concerning when a disease or disease agent meets the definition of relevant communicable disease or disease agent.

(Comment 19) One comment asked us to define "significant" health risk. This comment asserted that the term is vague and subject to misinterpretation.

(Response) In response to this comment, we have replaced the phrase with more specific language in § 1271.3(r)(2)(ii). The definition now states that a relevant communicable disease agent or disease is one that could be fatal or life-threatening, could result in permanent impairment of a body function or permanent damage to body structure, or could necessitate medical or surgical intervention to preclude permanent impairment of body function or permanent damage to a body structure. This more specific description is modeled on language used in the agency's regulations on medical device reporting (see 21 CFR 803.3(bb)).

5. Relevant Medical Records (§ 1271.3(s))

Donor screening involves the review of relevant medical records for risk factors for, and clinical evidence of, a relevant communicable disease agents and diseases. Proposed § 1271.3(v) would define "relevant medical records" as a collection of documents that includes a current donor medical history interview and a current report of the physical assessment of a cadaveric donor or the physical examination of a living donor. The proposed definition listed additional records that would be considered relevant medical records if they were available.

(Comment 20) One comment opposed including, in the definition of "relevant medical records," a current report of a physical assessment or examination. The comment asserted that these evaluations are of minimal utility, particularly if the available exam was not performed to look for evidence of specific disease, and suggested that the requirement be moved to the "if available" part of the definition.

(Response) We disagree with this comment. There are clear physical findings that could indicate that a donor either has a relevant communicable

disease or exhibits signs of risk factors for such a disease. Examples include jaundice, lymphadenopathy, or needle marks. The donor-eligibility draft guidance that accompanies this final rule lists physical findings that would suggest if a cadaveric or living donor could have a relevant communicable disease and that should be looked for in the physical assessment or examination.

(Comment 21) Five comments questioned the need for a physical examination of a cord blood donor. Three of these recommended that the requirement not apply to cord blood donors, but only to HCT/Ps for which the physical examination is relevant to the safety of the donor or the HCT/P. Two comments proposed requiring only a limited physical examination.

(Response) We disagree with the suggestion that it is unnecessary to conduct a physical examination of a cord blood donor. A physical examination could reveal risk factors for or the presence of a relevant communicable disease.

We note that the purpose of the physical examination is to assess for signs of a relevant communicable disease and for signs suggestive of any risk factor for a relevant communicable disease. The donor-eligibility draft guidance announced elsewhere in this **Federal Register** provides further information on physical evidence of relevant communicable diseases that may be observed during the physical examination of a living donor.

(Comment 22) One comment asserted that the scope of medical records should be limited to information pertaining to relevant communicable diseases. The comment expressed concern that a potentially significant finding would be lost in the minutiae. The comment cited autopsy results as an example of a record that does not add significant value to the donor screening process, noting also that certain products need to be released before coroner and autopsy reports are available.

(Response) We agree that the scope of medical records that you review in donor screening is limited to information pertaining to relevant communicable diseases. We disagree, however, with the assertion that autopsy results do not provide significant information. On the contrary, an autopsy can lead to the discovery of subclinical evidence of relevant communicable diseases (e.g., liver disease may indicate hepatitis). We understand that certain HCT/Ps need to be released before autopsy results are available (e.g., corneas). However, autopsy results are an important component of a donor's relevant medical records, and you must review them if they are available at the time of the donor-eligibility determination.

(Comment 23) Other comments recommended that the definition of "relevant medical records" be limited to processing records, health histories, and the infectious disease test results of the donor. These comments expressed concern that the definition includes the donor's medical records "if available." This comment urged us to make the summary of records the sole set of documents required to accompany the product.

(Response) We agree that the summary of records should be the sole set of documents required to accompany an HCT/P, and we have modified § 1271.55, as discussed in greater detail in comment 29 of this document. However, for the purposes of donor screening, we continue to believe that a larger range of information should be considered, including the donor's medical records, if available. For that reason, we have not changed the list of documents that make up the relevant medical records.

6. Urgent Medical Need (§ 1271.3(u))

Under proposed § 1271.65(b) and (c), an HCT/P from an ineligible donor could be used in cases of urgent medical need. We proposed to define "urgent medical need" as meaning that no comparable HCT/P is available and the recipient is likely to suffer serious morbidity without the product.

(Comment 24) One comment requested that we add to the definition of "urgent medical need" the requirement that the risk of morbidity with use of the product be considerably less than without the product.

(Response) We decline to make this change. We expect that doctors will use their professional judgment to balance the risk of using an HCT/P against the risk of not using it.

We have, however, modified the definition of "urgent medical need" to include the risk of death, in addition to the risk of serious morbidity. The risk of death is clearly more urgent than the risk of serious morbidity and should have been included in the proposed definition.

7. Xenotransplantation Product Recipient and Intimate Contact of a Xenotransplantation Product Recipient

Proposed § 1271.75(a)(2) would require you to determine whether a potential donor has received a xenotransplant (now called a xenotransplantation product) or has been a close contact of such a recipient. We proposed to define "xenotransplantation" and "close contact" in proposed § 1271.3(aa) and (bb).

(Comment 25) Several comments requested clarification of the definitions of "xenotransplantation" and "close contacts," including the meaning of "live cells" and "ex vivo," two terms used to define xenotransplantation. One comment preferred the term "intimate contact" to "close contact." We were also asked to provide examples of activities that could result in exchanges of bodily fluids, a factor in the proposed definition of close contact.

(Response) The final rule does not contain definitions of "xenotransplantation" or "close contact." These terms are relevant to the determination under § 1271.50, concerning whether the donor presents communicable disease risks associated with xenotransplantation. We now explain our current understanding of "xenotransplantation," "xenotransplantation product," "xenotransplantation product recipient," and "intimate contact of a xenotransplantation product recipient" in the donor-eligibility draft guidance announced elsewhere in this issue of the **Federal Register**.

The terminology used in the accompanying guidance, and the definitions provided, are consistent with guidance on xenotransplantation developed by the Public Health Service (PHS) and by FDA (PHS Guideline on Infectious Disease Issues in Xenotransplantation; Availability (66 FR 8120, January 29, 2001); Draft Guidance for Industry: Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Product Recipients and Their Intimate Contacts (67 FR 6266, February 11, 2002). In the accompanying guidance, we describe "xenotransplantation" as any procedure that involves the transplantation, implantation, or infusion into a human recipient of either of the following: (1) Live cells, tissue, or organs from a nonhuman animal source; or (2) Human body fluids, cells, tissues, or organs that have had ex vivo contact with live nonhuman animal cells, tissues, or organs. By "live cells" we mean cells that have the ability to metabolize or divide. By "ex vivo" we mean outside of an individual's body.

We agree with the comment that the term "intimate contact" is preferable to "close contact," because it is more specific. The donor-eligibility draft guidance describes "intimate contact of a xenotransplantation product recipient" as a person who has engaged

in activities that could result in the intimate exchange of body fluids with a xenotransplantation product recipient. Examples of intimate contacts include, but are not limited to, sexual partners, household members who share razors or toothbrushes, and health care workers or laboratory personnel with repeated percutaneous, mucosal, or other direct exposures. Mere sharing of domicile or casual contact, such as hugging or kissing without the exchange of saliva, would not be interpreted as intimate contact.

*D. Part 1271, Subpart C—Donor Eligibility*

Subpart C of part 1271 contains the donor-eligibility requirements for HCT/Ps, including donor screening and testing.

1. General

(Comment 26) We received comments urging the use of a term other than "unsuitable" to describe a reproductive tissue donor with risk factors for relevant communicable disease.

(Response) "Suitability" is a term with wide usage in tissue and blood establishments. We understand, however, that when the term "unsuitable" is applied to a donor, it may take on an unintended meaning. For that reason, we have decided to substitute the more neutral terms "donor eligibility," "eligible donor," and "ineligible donor" throughout this final rule. Like the donor-suitability determination in the proposed rule, the donor-eligibility determination will be based on both screening and testing. A donor is "ineligible" if either screening or testing indicates the presence of a communicable disease or risk factor for a communicable disease. Throughout this rule, we refer to the "donor-suitability proposed rule," but in all other instances, even references to the provisions of that rule, we now refer to "donor eligibility."

2. What Requirements Does This Subpart Contain? (§ 1271.45)

In this final rule, we have added § 1271.45 ("What requirements does this subpart contain?"). Section 1271.45(a) states that subpart C sets out requirements for determining donor eligibility, and points out that the requirements in subpart C are a component of CGTP requirements.

Section 1271.45(b) requires a determination of eligibility, based on donor screening and testing for relevant communicable disease agents and diseases, for all donors of cells or tissue used in HCT/Ps, except as provided under § 1271.90. Section 1271.45(b) also states that, in the case of an embryo or of cells derived from an embryo, a donor-eligibility determination is required for both the oocyte donor and the semen donor. We have moved this requirement from proposed § 1271.50(a). We have also extended the proposed requirement, which referred only to embryos, to cells derived from an embryo. Although this meaning was implicit in the proposed language, we have made this change for greater clarity.

Section 1271.45(c) prohibits the implantation, transplantation, infusion, or transfer of an HCT/P unless the cell or tissue donor has been determined to be eligible, except as provided under §§ 1271.60(d), 1271.65(b), and 1271.90. This was originally proposed in § 1271.50(a).

Section 1271.45(d) states that, if you are an establishment that performs any function described in subpart C, you must comply with the requirements that are applicable to that function.

3. What Procedures Must I Establish and Maintain? (§ 1271.47)

In this final rule, we have added § 1271.47 ("What procedures must I establish and maintain?"). This reflects an organizational change, but is not substantive. General requirements for establishing and maintaining procedures were proposed as part of the GTP proposed rule (§ 1271.180). These proposed requirements would apply to all significant steps in the manufacture of HCT/Ps, including donor screening and testing. However, in finalizing the donor-eligibility rule, we have decided that a separate provision on procedures specific to the donor-eligibility requirements of subpart C is warranted. To consolidate procedural requirements within the donor-eligibility requirements, and to remind you that you must develop procedures for testing and screening, we have added § 1271.47. Final section § 1271.47 is based on proposed § 1271.180, but tailored to be specific to donor-eligibility requirements. (In this final rule, we sometimes refer to procedures as standard operating procedures (SOPs).)

For greater clarity and ease of reading, we have divided the proposed language into paragraphs. Paragraph (a) of § 1271.47 requires that you establish and maintain written procedures for all steps that you perform in testing, screening, determining donor eligibility, and complying with all other requirements in subpart C. Paragraph (a) of § 1271.47 incorporates an explanation of the phrase "establish and maintain." This definition was proposed in the GTP proposed rule under § 1271.3(ll); we received no comments on the proposed definition. Paragraph (b) of § 1271.47 requires that a responsible person must review and approve all procedures before implementation. Under paragraph (c) of § 1271.47, written procedures must be readily available to personnel. Paragraph (d) of § 1271.47 contains requirements relating to departures from established procedures. Paragraph (e) of § 1271.47 states that an establishment may adopt current standard procedures, provided that certain conditions are met.

Section 1271.47 reflects the following changes to proposed § 1271.180, made in response to comments submitted to the GTP proposed rule docket:

*All steps.* Proposed § 1271.180 would require procedures for "all significant steps" that an establishment performs. One comment asked for examples of what constitutes a "significant step" and asked how it differs from "any step."

A "significant" step is not considered different from "any or all steps," as the latter term is used in the definition of "manufacture" in § 1271.3(e). For this reason, we have removed the word "significant," and § 1271.47(a) refers instead to "all steps."

*Periodic review.* Proposed § 1271.180 would require establishments to review and, if necessary, revise all procedures at least once in a 12-month period. One comment objected to the specificity of this requirement, citing the more flexible requirements in the CGMP and QS regulations.

We agree with this comment and note that the comparable requirements in the CGMP and QS regulations (§§ 211.100 and 820.40) do not require an annual review of procedures. For this reason, we are deleting the proposed requirement, § 1271.47 does not contain a requirement for an annual review of procedures.

*Departures from procedures.* We have replaced the term "deviation" with "departure" in this final rule to prevent confusion with HCT/P deviation reporting in the CGTP proposed rule. Several comments objected to the proposed requirement that departures from procedures be authorized in advance, because departures are not foreseeable and cannot be authorized before they occur. One comment suggested requiring a justification for the departures to be recorded at the time of the occurrence, and requiring approval of the departures by a responsible person before release of the tissue.

We agree with these comments and have modified the requirement in

accordance with the suggestion. Section 1271.47(d) now requires an establishment to record and justify any departure from a procedure relevent to preventing risks of communicable disease transmission at the time of its occurrence, rather than before. The provision further states that the establishment must not make available for distribution any HCT/P from a donor whose eligibility is determined under such a deviation unless a responsible person has determined that the departure does not increase the risk of communicable disease transmission through the use of the HCT/P.

*Archiving of obsolete procedures.* Proposed § 1271.180 would require obsolete procedures to be archived for at least 10 years. One comment suggested that a longer retention period of 10 years after transplantation would be more appropriate and consistent with record retention requirements in § 1271.270 (which also appear in proposed § 1271.55).

We have deleted archiving obsolete procedures as a requirement, but we recommend that establishments archive their obsolete procedures so that they may reference at any time and as needed a specific procedure used for manufacturing a specific HCT/P that is still available for use and in storage.

4. How Do I Determine Whether a Donor Is Eligible? (§ 1271.50)

Proposed § 1271.50 sets out basic requirements with respect to the donor-eligibility determination. Under proposed § 1271.50(b), the determination would be required to be performed by a responsible person. Under proposed § 1271.50(b), the responsible person would determine a donor to be eligible if the following requirements are met: (1) The results of donor screening indicated that the donor was free from risk factors for, and clinical evidence of, infection due to relevant communicable disease agents and diseases and is neither a xenotransplant recipient nor a close contact of a xenotransplant recipient, and (2) the results of donor testing for relevant communicable disease agents are negative or nonreactive.

Final § 1271.50 reflects changes in screening for xenotransplantation made in § 1271.75, discussed in comment 48 of this document.

(Comment 27) Two comments supported the provision in proposed § 1271.50 that required a determination of eligibility to be based on both screening and testing. These comments further asserted that requiring both screening and testing for all prospective donors would assure that a prospective donor who is deemed unsuitable, and who is covered by proposed § 1271.65, nevertheless, would be subject to mandatory testing.

(Response) We agree that you must base a donor-eligibility determination on both screening and testing. If the screening shows the presence of a risk factor, the donor becomes ineligible and there is no reason to conduct the testing. Thus, we disagree that testing is mandatory where screening indicates a risk factor for a relevant communicable disease and use under § 1271.65 is not sought. To require testing in the case of a donor already determined ineligible based on screening would impose an unnecessary expense.

If the screening does not reveal any risk factors, the testing should be conducted to determine the donor's eligibility. We also agree that, if donor screening indicates a risk factor, and you wish to use the HCT/P from the ineligible donor under the provisions of § 1271.65(b), you must complete all required testing.

(Comment 28) One comment asked whether a person who has tested positive for a treatable communicable disease could donate reproductive tissue.

(Response) A living donor who tests positive for a relevant communicable disease is ineligible to donate, but could become eligible to donate reproductive tissue in the future after successful treatment of the disease. In the donor-eligibility draft guidance, we make recommendations concerning the length of time following treatment of various communicable diseases after which a donor could become eligible to donate.

5. What Records Must Accompany an HCT/P After the Donor-Eligibility Determination Is Complete? (§ 1271.55)

Proposed § 1271.55(a) would require documentation of the donor-eligibility determination to accompany the HCT/P. This documentation would include a copy of the donor's relevant medical records, results of required testing, and the name and address of the establishment that made the determination. Alternatively, the HCT/P could be accompanied by a summary of records (defined in proposed § 1271.3(x)). In both instances, the donor's name must be deleted from the documentation. Proposed § 1271.55(b) would require that the establishment that generated the records used in the eligibility determination, and the establishment that made the determination, maintain the records for 10 years and make them available for FDA inspection.

(Comment 29) Several comments described as burdensome the requirement in proposed § 1271.55(a) that a copy of the donor's relevant medical records accompany an HCT/P. One comment questioned the confidentiality of information in these records, even with the donor's name redacted. Other comments urged us to require only that a summary of records accompany an HCT/P, to ensure patient privacy and the appropriate use of a patient's medical records. Another comment supported our decision to require deletion of the donor's name.

(Response) To increase confidentiality protections, we have removed the provision in § 1271.55 for relevant medical records to accompany an HCT/P. The regulation now requires only that the summary of records accompany the HCT/P. We note that this change affects only the documentation that accompanies the HCT/P; it does not affect the requirement in § 1271.75(a) to review relevant medical records.

As redrafted, § 1271.55(a) requires that, once a donor-eligibility determination has been made, the HCT/P must be accompanied by: (1) A distinct identification code affixed to the HCT/P container, e.g., alphanumeric, that relates the HCT/P to the donor and to all records pertaining to the HCT/P and, except in the case of autologous or directed reproductive donations, does not include an individual's name, social security number, or medical record number; (2) a statement whether, based on the results of screening and testing, the donor has been determined to be eligible or ineligible; and (3) a summary of the records used to make the donor-eligibility determination. We have specified that the distinct identification code must be affixed to the HCT/P container (rather than attached by a tie-tag) because it is crucial that this information never become separated from the HCT/P. Instead of defining "summary of records" in § 1271.3, as proposed, we describe in § 1271.55(b) that the summary of records must contain the following components: (1) A statement that the testing was performed by a laboratory certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 or that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services; (2) a listing and interpretation of the results of all communicable disease tests performed; and (3) the name and address of the establishment that made the donor-eligibility determination. We have

removed the requirement for a statement describing the types of records, which may have been reviewed as part of the relevant medical records, because it did not add useful information about the particular HCT/P. We note that the requirement to list and interpret all communicable disease tests refers not just to those tests required under this rule, but would also include any nonrequired communicable disease tests that have been performed.

We have added one item to the list of information in the summary of records, in the case of an HCT/P from a donor, ineligible based on screening, that is released under the provisions of § 1271.65(b), the summary of records must contain a statement noting the reason or reasons for the determination of ineligibility. This information will greatly assist practitioners in weighing the risks of using an HCT/P from an ineligible donor and in explaining risks to the recipient.

The final regulation, at § 1271.55(c), states that the records that accompany the HCT/P must not include the donor's name and other personal information that might identify the donor.

(Comment 30) One comment asked whether separate records would be required for all batches of HCT/Ps made from a single cell bank.

(Response) If you make multiple batches from a single cell bank, you may maintain a single set of donor-eligibility records for the cell bank. However, each HCT/P from that cell bank must be accompanied by a copy of the summary of records.

(Comment 31) One comment asserted that it is important to permit a tissue bank to qualify a donor as eligible and then to certify that eligibility to the establishment that further processes the cells or tissue without providing specific donor information. This comment also asserted that a mechanism should provide traceability through use of a donor number that can be used to trace the cells or tissue to the tissue bank if necessary.

(Response) Under § 1271.55, an HCT/P must be accompanied by a summary of records that indicates the conclusions of the donor-eligibility determination and that does not contain information that could identify the donor. We have added the requirement for a distinct identification code, e.g., alphanumeric, that relates the HCT/P to the donor and to all records pertaining to the HCT/P and, except in the case of autologous or directed reproductive donation, does not include an individual's name, social security number, or medical record number. This requirement is consistent with the tracking requirements of the CGTP proposed rule.

(Comment 32) One comment supported the requirement in proposed § 1271.55(b) that records regarding gamete donation be kept 10 years.

(Response) We appreciate this comment and have maintained the requirement, in § 1271.55(d), that donor-eligibility records must be maintained for 10 years.

The record retention requirements in § 1271.55(d) have been reorganized and clarified. In several instances, we have modified the requirements for consistency with the more general records requirements of the GTP rule. For example, proposed § 1271.55(b) would require records to be retained: "* * * at least 10 years after the date of implantation, transplantation, infusion, or transfer of the product, or if the date of implantation, transplantation, infusion, or transfer is not known, then * * * at least 10 years after the date of the product's distribution, disposition, or expiration, whichever is latest." Three comments submitted to the GTP docket pointed out that similar language in proposed § 1271.270(e) is confusing.

Accordingly, we have revised the relevant language in proposed § 1271.55(b) by replacing the words "implantation, transplantation, infusion, or transfer" with "administration." Section 1271.55(d) now reads "You must retain the records pertaining to a particular HCT/P at least 10 years after the date of its administration, or if the date of administration is not known, then at least 10 years after the date of the HCT/P's distribution, disposition, or expiration, whichever is latest."

We have made several other changes to the record retention requirements that both improve the language and also increase consistency with the proposed GTP rule. Final § 1271.55(d) requires that all records must be accurate, indelible, and legible; this language is consistent with the proposed GTP rule (proposed § 1271.270(a)). Similarly, § 1271.55(d) sets out a more specific list of required documentation than appeared in the proposed rule; as in proposed § 1271.270(c), § 1271.55(d) specifies that you must maintain documentation of the results and interpretation of all testing and screening for relevant communicable disease and disease agents; the name and address of the testing laboratory or laboratories; documentation of the donor-eligibility determination; the name of the responsible person who made the determination; and the date of the determination. (No comments were received on either of these issues.)

We have also incorporated into § 1271.55(d) the requirement that information on the identity and relevant medical records of the donor must be in English, or, if in another language, must be translated into English. We received two comments on the docket for the GTP rule about the English language requirement in proposed § 1271.270(c). One comment stated that the proposed language implied that the original non-English record may be destroyed, and suggested revising the regulation to indicate that the original may be in any language and should be retained, but that a copy translated into English should also be kept. Another comment asserted that we should stipulate that the English translation requirement applies to products distributed within the United States.

We disagree that the proposed regulation implies that an original record that is not in English can be destroyed, and for this reason we have added the codified language that the information on the identity and relevant medical records of the donor must be retained. You must maintain the original documentation, whether or not the documentation is in English. These requirements apply to all HCT/Ps that are imported into the United States, for distribution within the United States, and that are shipped under § 1271.60(c) into the United States for processing or other manufacture before distribution in another country.

(Comment 33) One comment requested that we change proposed § 1271.55(b) to require that any party involved in the collection, processing, or transplantation of an HCT/P be allowed access to the donor's medical records.

(Response) The purpose of the language, as proposed, was to ensure FDA's access to records supporting a donor-eligibility determination. Because of concerns about maintaining the confidentiality of patient information, we decline to expand the provision to require an establishment to make medical records available to any party involved in the collection, processing, or transplantation of the HCT/P.

6. What Quarantine and Other Requirements Apply Before the Donor-Eligibility Determination Is Complete? (§ 1271.60)

Proposed § 1271.60 contained provisions for quarantine of HCT/Ps pending the donor-eligibility determination. Proposed § 1271.60(a) stated that, "* * * [f]or reproductive cells and tissues that can reliably be

stored, quarantine shall last until completion of the testing required under § 1271.85(d)." (In § 1271.85(d), we proposed to require retesting of the donor of such reproductive cells or tissue at least 6 months after the date of donation.)

(Comment 34) One comment supported the provision in § 1271.60 that permits, under certain safeguards, shipping of material that is in quarantine.

(Response) We have maintained this provision in the final rule.

(Comment 35) Many comments opposed any quarantine requirement for embryos. These comments disputed the communicable disease risks associated with embryos. They also cited increased costs from a quarantine; decreased success rates through use of frozen embryos; adverse effects on patients from a quarantine requirement; logistical concerns associated with retesting; and other possible consequences of a quarantine requirement, including loss of embryos.

Some comments asserted that current screening practices are adequate. Others asserted that FDA was interfering with the practice of medicine or criticized our approach as having a potentially negative effect on the field of reproductive medicine. Many comments suggested alternative approaches, such as optional quarantine, mandatory insurance coverage for infertility, and creation of an embryo bank. One comment described a clinically effective program using frozen embryos that was instituted to help ensure patient confidentiality.

(Response) We also received comments opposed to quarantining oocytes. Some comments distinguished between oocytes and semen based on differences in communicable disease risk, cryopreservation success, availability, cost, and other factors.

We have considered the many comments received on the retesting and quarantine requirements and have decided to clarify our intentions with respect to embryos and oocytes. In the preamble to the proposed rule, we stated that reproductive cells and tissues that can reliably be stored are those that maintain function and integrity during storage. As examples, we listed spermatozoa and sperm progenitor cells (64 FR 52696 at 52706). Given technologies at the time, we did not assert that embryos or oocytes could reliably be stored. Thus, we did not intend the quarantine and retesting requirement to apply to embryos or oocytes.

To clarify the provisions for quarantine and retesting of reproductive HCT/Ps, we have deleted the phrase "reproductive cells and tissue that can reliably be stored." The 6-month quarantine requirement in § 1271.60(a) and the retesting requirement in § 1271.85(d) applies only to anonymous semen donors.

We disagree with comments that minimize the communicable disease risks associated with reproductive cells and tissue. Among other things, these comments assert that there have been no known transmissions of disease by ova or embryos or that there is no compelling evidence to indicate that human gametes or embryos are capable of transmitting infectious disease

Each cell in the human body has receptors for viruses and bacteria and is thus capable of transmitting communicable disease. Even avascular tissue has been known to transmit disease (e.g., corneas have transmitted HBV). Semen is known to have transmitted HBV and HIV. Because embryos are a result of the combining of sperm and ova, they have the potential of being contaminated by communicable disease agents transmitted by the sperm. Moreover, bacterial contamination and transmission of HCV has occurred in assisted reproduction procedures. Two cases have been reported of women in France who were HCV antibody negative, but seroconverted after undergoing assisted reproductive technology (ART) procedures. The cause of transmission was theorized to be cross-contamination by health care workers (Lesourd, F., et al., "Transmissions of Hepatitis C Virus During the Ancillary Procedures for Assisted Conception," *Human Reproduction*, vol. 15, no. 5 pp. 1083–1085, (2000)).

Because there is a risk that ova and embryos could transmit disease, this risk should not be ignored. Given the lack of oversight and reporting requirements to date, it is difficult to know whether incidents of transmission of disease by ova or embryos have occurred.

(Comment 36) Many comments objected to the application of the quarantine and retesting requirements to directed semen donations. These comments pointed out that, under the proposed regulation, semen from a directed donor would have to be quarantined for 6 months pending retesting of the donor. Comments asserted that this would effectively bar the use of fresh semen in directed donations. Some comments cited problems with sperm cryopreservation and noted a higher conception rate with fresh semen than with frozen semen. Other comments pointed out the delay in conception that would result from quarantine. Some comments asserted that the proposed provisions would encourage people to perform inseminations without medical assistance and safety screening.

(Response) On December 14, 2001, we asked the BPAC whether, compared with fresh semen, the use of cryopreserved semen for artificial insemination reduces pregnancy rates per cycle. After a presentation of data, the committee agreed that the practice of cryopreserving semen for artificial insemination does reduce pregnancy rates.

In light of the comments and the opinion of the BPAC, we have reconsidered whether to require quarantine and retesting in directed semen donation. The requirement to retest the donor was intended to provide an important added measure of protection by addressing the "window period" between the time of infection and the presence of detectable levels of antigens and/or antibodies to communicable diseases and agents such as HIV. However, we recognize that semen from different donors varies in its ability to withstand cryopreservation. Because of the variability in whether a particular donor's sperm will survive the freeze/thaw process, a requirement for quarantine could defeat the intentions of the directed reproductive donor and intended recipient who have made a joint decision for the recipient to conceive a child. Accordingly, we have modified the regulation to except directed semen donors from the 6-month retesting requirement in § 1271.85(d). Because of this change, the requirement in § 1271.60(a) that semen be quarantined until the completion of retesting under § 1271.85(a) no longer applies to directed semen donations.

7. How Do I Store an HCT/P From a Donor Determined to Be Ineligible, and What Uses of the HCT/P Are Not Prohibited? (§ 1271.65)

Proposed § 1271.65(a) would require HCT/Ps from ineligible donors to be kept in quarantine and physically separate from other HCT/Ps until destruction or other permissible disposition was accomplished. Proposed § 1271.65(b) described three situations in which these regulations would not prohibit the use of an HCT/P from an ineligible donor, and additional requirements that would apply in those instances. The three cases were as follows: (1) Family-related, allogeneic use; (2) directed donation of reproductive cells or tissue; and (3) urgent medical need. Under proposed § 1271.65(c), the use of an HCT/P from a donor for whom the donor-eligibility

determination had not yet been completed would not have been prohibited in cases of urgent medical need. (For organizational consistency, we have moved that provision to § 1271.60 of this final regulation, which deals with HCT/Ps pending the donor-eligibility determination.) Finally, proposed § 1271.65(d) would impose special labeling requirements on HCT/Ps used under § 1271.65(b).

Proposed § 1271.65(b)(4) would prohibit making available an HCT/P from a xenotransplantation product recipient or an intimate contact of a xenotransplantation product recipient for use in the special circumstances set out elsewhere in paragraph (b) (family-related, allogeneic use; directed donation of reproductive cells or tissue; and urgent medical need). Throughout this final rule, we have adopted a more flexible approach to screening for xenotransplantation than proposed. This new approach is intended to recognize that different kinds of xenotransplantation may present different degrees of risk and to provide us with the ability to respond appropriately to these differences as the field of xenotransplantation develops. The absolute prohibition in proposed paragraph (b)(4) is not consistent with this new flexibility in approach, and so we have deleted it from § 1271.65.

(Comment 37) Several comments questioned how to comply with the requirement that HCT/Ps from ineligible donors be kept physically separate from other HCT/Ps. Some comments asserted that physical separation would require additional refrigerator storage units, presenting an unnecessary cost and space burden. These comments questioned the benefit of physically separate storage, suggested that quarantine alone should be sufficient, or requested that we delete the physical separation requirement. One comment asked whether storing in vapor phase nitrogen or encasing units in plastic bags is sufficient to prevent cross-contamination.

(Response) We have revised § 1271.65(a) to delete the requirement for physical separation. Section 1271.65(a) now incorporates language from the definition of quarantine; however, the term "quarantine" is no longer used in paragraph (a), because we believe it is more appropriately reserved for HCT/Ps awaiting the outcome of the donor-eligibility determination. Section 1271.65(a) now requires you either to store or identify HCT/Ps from ineligible donors in a physically separate area clearly identified for such use or to follow other procedures that prevent improper release, such as automated designation, until destruction of the HCT/P or other disposition in accordance with § 1271.65(b) or (c).

As revised, § 1271.65(a) now provides establishments with flexibility in achieving the goal of preventing the improper release of HCT/Ps from ineligible donors. You may choose to keep HCT/Ps from ineligible donors in a physically separate area clearly identified for such use. Such physical separation may include storage on a separate shelf in a refrigerator or freezer that also contains other shelves storing HCT/Ps in quarantine pending the donor-eligibility determination and shelves storing HCT/Ps from eligible donors. A separate refrigerator or freezer may not be necessary.

Alternatively, § 1271.65(a) allows you to use other procedures that prevent improper release. Such procedures could include automated designation to prevent improper release. For example, some establishments label HCT/Ps with bar codes and store the HCT/Ps in freezers that maintain a constant temperature. Moving the products to a separate storage area would risk transient warming. Instead, the HCT/Ps remain in the original storage area and are tracked by a validated computer system that maintains information on the results of screening and testing. At the time of release of the HCT/P, the establishment activates the computer system to assure identification and retrieval of the specific HCT/P for the intended recipient. This is an example of a system of automated designation that could satisfy the requirements of § 1271.65(a).

The provisions of the CGTP proposed rule would require you to establish and maintain procedures for the control of storage areas to prevent such problems as cross-contamination and improper release (proposed § 1271.260(a)).

As for the comment regarding vapor phase nitrogen and plastic bags, limited scientific evidence exists to show the effectiveness of measures such as overwrap bags or storage in the vapor phase of liquid nitrogen to reduce the likelihood of cross-contamination. Such measures could be used if sufficient evidence exists of their ability to minimize the risk of cross-contamination.

(Comment 38) One comment urged us to delete the exception for family-related, allogeneic use, arguing that the urgent medical need exception would apply for both related and unrelated stem/progenitor cell donors. Another comment supported the concept that hematopoietic stem/progenitor cell donors who are related to the recipient should be held to the same standards as unrelated donors with respect to screening and testing for communicable disease.

(Response) Although we recognize that the urgent medical need exception might apply in some instances of donations between family members, we decline to make the change requested by the first comment. Our intention in crafting the exception was to recognize that, in some situations, a recipient and his or her physician might weigh the risks of using an HCT/P from an ineligible family member in the absence of an urgent medical need, if such an action were in keeping with the family's wishes; this exception, with its added safeguards, would allow them to do so.

We agree with the second comment that the same screening and testing requirements should apply to donors of hematopoietic stem/progenitor cells who are related to the recipient as to unrelated donors, and the final rule is consistent with this view. However, we have chosen to defer to the family and physician the decision of whether or not to use an HCT/P from a related donor who has been determined to be ineligible. For this reason, the regulations do not prohibit such use.

We have rewritten proposed § 1271.65(b)(1) to reflect changes made in the registration final rule (66 FR 5447 at 5454). The proposed exception for "family-related, allogeneic use" extended only to first-degree blood relatives; as modified, the exception now extends to "allogeneic use in a first-degree or second-degree blood relative." Our decision, expressed in the registration final rule, to broaden the scope of related donors was based on several factors, which also apply here. The likelihood of finding a donor with a haplotype identical to that of the recipient is greater among blood-related individuals than among unrelated individuals. In addition, for certain ethnic groups, it is extremely difficult to find an appropriate unrelated donor. Finally, registry outcome data for some hematologic malignancies suggest that peripheral blood and bone marrow transplant recipients may have a better survival rate when transplanted with hematopoietic stem/progenitor cells from related donors (66 FR 5447 at 5454).

Parents, children, and siblings are considered first-degree relatives. Aunts, uncles, nieces, nephews, first cousins, grandparents, and grandchildren are second-degree relatives. Relations by adoption or marriage are excluded from § 1271.65(b)(1), because they are not in the same genetic pool as blood relatives.

(Comment 39) We received comments on the proposed provision for directed

donation of HCT/Ps from ineligible donors. Elsewhere in this rule, we respond to comments on the definition of directed reproductive donor and on the applicability of retesting requirements to directed donations of reproductive cells and tissues.

One comment on proposed § 1271.65 praised the directed donor provision as appropriate. This comment stated that the directed donor provisions should also apply when a woman seeks a second child by the same anonymous donor with known high-risk behavior.

(Response) We disagree that the directed reproductive donor provisions of § 1271.65(b) extend to anonymous donation. As discussed in comment 13 of this document, the term "directed reproductive donor" does not apply to anonymous donations, but to situations where the donor knows, and is known by, the recipient. Moreover, under this final rule, all potential anonymous semen donors must be screened for risk factors for relevant communicable disease, including high-risk behavior; potential donors with a high-risk behavior will be determined ineligible.

(Comment 40) One comment expressed concern about allowing patients and physicians to decide whether to use donated gametes from a directed reproductive donor who is found to be ineligible. This comment asserted that it is essential that patients be fully informed, and that written contracts be signed indicating the possible risks to recipient and baby, so that there is complete understanding for the risks involved.

(Response) It is essential that the patient who chooses to use a directed donation from an ineligible donor be fully informed of the risks involved. For any use under § 1271.65(b)(1), the establishment must notify the physician using the HCT/P from the ineligible donor of the results of testing and screening. Under § 1271.65(b), the HCT/P must be labeled prominently with the Biohazard legend and must bear the statement "WARNING: Advise patient of communicable disease risks," and, in the case of reactive test results, "WARNING: Reactive test results for (name of disease agent or disease)." In the case of reproductive HCT/Ps, this includes risk to the baby. We have removed the proposed requirement for the establishment to document that the physician agreed to explain the communicable disease risks associated with the use of the HCT/P to the recipient or the recipient's legally authorized representative and that the physician agreed to obtain from the recipient or the recipient's legally authorized representative consent to use the HCT/P. We decline to require a written contract between physician and patient. We know that physicians are under legal and ethical restrictions, requiring them to discuss the risks of communicable disease transmission stemming from the use of HCT/Ps. We rely on physicians to meet these obligations when obtaining consent to procedures involving HCT/Ps from patients and their legal representatives.

(Comment 41) One comment on directed donations of reproductive cells or tissue praised FDA for adding clarity to a process that has created confusion for donors and patients. This comment endorsed the procedures in proposed § 1271.65(b), but objected to the proposed requirement for physician consent. The comment asserted that the patient has the right to make his or her own decisions about medical treatment, that physician consent is unnecessary because of other standards of physician conduct, and that some physicians may withhold consent for invalid reasons.

(Response) In light of this comment, we have reconsidered the necessity of requiring documentation of the physician's authorization of the use of an HCT/P from an ineligible donor in the directed reproductive donor situation, as well as in cases of urgent medical need or use in a first- or second-degree blood relative. Our decision is not based on an evaluation of patients' rights, but on the observation that, in each of these situations, a physician will be closely involved in the decision to use the HCT/P from the ineligible donor. For this reason, no additional requirement to obtain physician consent is necessary.

For the same reasons, we have also removed the requirement for physician authorization from the provisions governing use of an HCT/P for urgent medical need before completion of the donor-eligibility determination (§ 1271.60(d)).

(Comment 42) Several comments strongly supported the urgent medical need provision in proposed § 1271.65(b) and (c). Some comments commended the structuring of the proposed regulations, noting that the transplanting physician and the informed patient may deem appropriate a tissue that is positive for infectious disease when comparing alternatives, particularly in a matter of life or death or other emergency medical situations. One comment asserted that the transplant physician must be the ultimate authority for the use of tissues from all donors and noted that the prevalence of CMV positivity in the normal donor population will make this exception widely used.

(Response) We have maintained the provisions for urgent medical need, although, as noted, the provisions governing use pending the donor-eligibility determination have been moved to § 1271.60. (To ensure that the physician receives sufficient information about the risks of the HCT/P, § 1271.60(d)(2) requires that an HCT/P from a donor for whom the eligibility determination is not complete be accompanied by results of donor screening and testing that have been completed, as well as a list of any screening or testing that has not yet been completed.)

We also note that, under the final regulation, you are not required to determine a donor ineligible on the basis of a reactive CMV test, but under § 1271.85(b)(2) you must establish and maintain an SOP governing the release of an HCT/P from a donor whose specimen tests reactive for CMV. Thus, it will be unnecessary to invoke the urgent medical need provisions to use an HCT/P from a donor who has tested positive for CMV. (See the discussion in comment 60 of this document.)

(Comment 43) One comment asserted that labeling tissue "untested for Biohazard" might cause transportation issues, because commercial carriers are reluctant to transport a container labeled "Biohazard." The comment recommended that the proposed regulations clarify that the tissue container, not necessarily the tissue transport container, be labeled "untested for Biohazard."

(Response) The labeling requirements in this final regulation apply to the labeling of the HCT/P. (An HCT/P made available under § 1271.60(d) must be labeled "NOT EVALUATED FOR INFECTIOUS SUBSTANCES," and an HCT/P made available under § 1271.65(b) must bear the Biohazard legend; in both instances, the label must state: "WARNING: Advise patient of communicable disease risks.") Other regulations, e.g., those issued by the Department of Transportation, may apply to the shipping container.

8. How Do I Screen a Donor? (§ 1271.75)

Proposed § 1271.75(a) would require screening of all donors, except as provided in § 1271.90, for risk factors for, and clinical evidence of, relevant communicable disease agents and diseases, including, at a minimum, HIV, HBV, HCV, and TSE, including CJD and vCJD. Under proposed § 1271.75(b), donors of reproductive cells or tissue would be screened for genitourinary diseases that can be transmitted with

the recovery of reproductive cells or tissues, including at a minimum *Chlamydia trachomatis* and *Neisseria gonorrhea*. Under proposed § 1271.75(c), donors would also be screened for xenotransplantation or close contact with a xenotransplantation product recipient. And proposed § 1271.75(d) would allow establishments to follow an abbreviated donor screening procedure when a complete donor screening had been performed within the previous 6 months.

We have deleted the phrase "at a minimum" from § 1271.75(a) and (b), because it might give the impression that screening is required only for those relevant communicable diseases listed in § 1271.75. Although at this time we only require screening for those listed diseases, additional diseases may be identified as relevant in the future. As discussed in comment 16 of this document, we intend to issue guidance that notifies you when we have identified additional relevant communicable diseases that appear to meet the definition in § 1271.3(r)(2).

Section 1271.75, as finalized, requires the establishment that performs donor screening to review the donor's relevant medical records for risk factors for, and clinical evidence of, relevant communicable disease agents and diseases. For consistency with testing requirements, we have added the requirements that you screen all donors for *Treponema pallidum* (§ 1271.75(a)(1)) and that you screen donors of viable, leukocyte-rich cells or tissue for relevant cell-associated communicable diseases, including HTLV (§ 1271.75(b)). These additional screening requirements impose only a minimal burden. We describe screening factors for these relevant communicable diseases in the donor-eligibility draft guidance.

(Comment 44) Proposed § 1271.75(a)(1) would require screening of all donors for human TSE, including CJD. We received several comments on this provision. One comment supported the proposed screening requirements as written. Another comment stated that the agency should make clear whether it intends procurers of human tissue to apply the policies in the draft guidance for blood donors issued on November 23, 1999. Other comments argued that semen and oocytes should be exempt from screening for TSE, or questioned why the screening is applied to all donors, not just donors of dura mater or cornea. One comment expressed concern that particular symptoms of TSE, such as changes in speech or gait, are not specific to TSE.

(Response) Given the severity of TSE, the lack of an approved test, and the lack of information about the tissue distribution of the vCJD agent in humans, we continue to believe that it is necessary to screen all prospective donors for risk factors. In January 2001, we asked the TSEAC to evaluate the risk of transmission of vCJD through the transplantation, implantation, infusion, or transfer of HCT/Ps. The committee agreed that, compared to the risk of transmission of vCJD by blood transfusion, there is a significant risk of transmission of vCJD from HCT/Ps.

We recognize that the potential for transmission appears to differ between different types of HCT/Ps, with the greatest risk associated with corneas and dura mater. Nevertheless, you must screen all donors for TSE, for the previously listed reasons. This screening would include questions about risk factors for sporadic CJD and vCJD, and donors would be subject to exclusion based on those factors. We also recognize that some TSE symptoms are not specific to TSE. The specific symptoms to watch for are discussed in the CJD draft guidance.

(Comment 45) The proposed regulations did not contain an exception from the donor medical history interview for corneas procured under legislative consent; i.e., in accordance with a State law that allows the medical examiner or coroner to procure corneal tissue without the consent of the donor's next of kin. The preamble to the proposed rule stated that requiring a donor medical history interview for corneas obtained under legislative consent is necessary to ensure that the risk of communicable disease transmission is appropriately assessed. We noted that the necessity of adequate screening for TSE illustrates the importance of the donor medical history interview (64 FR 52696 at 52703).

We also noted that the proposed definition of donor medical history interview would permit the interview to be conducted with an individual knowledgeable about the donor's medical history and relevant social behavior (e.g., primary treating physician) and would not require an interview with the next of kin. For this reason, we considered that the proposed regulation and State laws on legislative consent may coexist and stated that we did not intend to preempt those laws. We specifically requested comments on any potential conflicts that might make it impossible to comply with both this regulation and State laws on legislative consent.

We received many comments about the proposed requirement for a donor medical history interview. Most of these comments came from eye banks.

Comments from eye banks that supported the proposal described their positive experiences performing medical history interviews. One comment described a next-of-kin interview that revealed the information that the potential donor's sister had died from CJD, information that would not have otherwise been obtained. Another comment supported the interview as a means of detecting high-risk behavior for diseases other than CJD, such as hepatitis and HIV, and said that FDA should carefully consider any interview questions relating to TSE with input from transplant practitioners and other experts. Several comments cited the risk to patients if donors are not screened with an interview. One comment from the medical director of an Italian eye bank described a positive experience with a recently implemented Italian requirement to obtain medical and social information through an interview.

Some comments criticized the recovery of corneas under legislative consent, asserting that autopsy reports are insufficient for assessing high-risk behaviors and that donors from medical examiner's or coroner's offices have an increased likelihood of high risk behavior. One comment asserted that, although part of the justification for legislative consent has been that there is a cornea shortage in this country, current donation rates have enabled most eye banks to become exporters.

Most comments on this issue opposed a requirement for a donor medical history interview for all cornea donors. One comment opposed the requirement but appreciated FDA's efforts to help ensure a safe supply of donor corneal tissues. Another comment asserted that the government should stay out of eye banking.

Many comments cited benefits of medical examiner laws, and some comments expressed the view that the proposed requirement would eliminate the procurement of corneas under legislative consent. Some expressed concern about diminished cornea supplies. Others asserted that the time required for screening would detract from cornea viability and quality, and some comments expressed concern about decreased access to healthy young corneal material from the medical examiner donor pool. Numerous comments cited the added expense of performing a medical history interview.

Many comments asserted that additional screening is unnecessary, or disputed the usefulness of an interview. Two comments asserted that the medical/social histories performed on

all cases obtained under legislative consent are just as comprehensive as those obtained with a next-of-kin consent and a medical/social history questionnaire. Other comments expressed doubt that the interview would be effective in screening for CJD or would increase the safety of corneal tissue.

Many comments disputed the risk of CJD transmission via corneas. One comment asserted that TSE cases are not brought to the medical examiner's office for determination of cause of death. Another comment asserted that there is no evidence of any increased risk of disease transmission through corneas obtained under legislative consent absent a medical history interview and that mandating an interview does not appear to have adequate scientific substantiation. Another comment stated that CJD is not sufficiently prevalent to warrant testing and screening.

The Eye Bank Association of America (EBAA) commissioned a report, which it submitted to the docket, on the occurrence and transmissibility of CJD as it relates to cornea transplantation. The report concluded, in part, that screening for symptoms of CJD would have minimal impact on safety but would reduce the supply of donor corneas. One comment objected to the report's conclusion and supported a medical/social history interview. On the other hand, one comment indicated that, based on the EBAA report, it now recommended that the regulation permit corneal donation under legislative consent without a donor medical history interview.

(Response) We have carefully considered the many comments on this difficult issue. Since the publication of the proposed rule, our concerns about preventing the spread of TSE, including vCJD, have increased. We have taken steps to address those concerns by developing an agency action plan and issuing new guidance documents, including guidance specific to HCT/Ps. In August 2001, HHS also announced a TSE action plan. One of FDA's responsibilities under the departmental action plan is to review and upgrade our policies designed to prevent potential exposure to TSE through blood transfusion or tissue transplantation or transmission of TSE through FDA-regulated products. (You can find information about the departmental action plan on the Internet at *http://www.hhs.gov/news/press/2001pres/20010823.html.*)

We developed our action plan for TSE in April 2001. The plan has several focus areas, including prevention of exposure to TSE through human and animal products, blood transfusion, tissue transplantation, and other FDA-regulated products. FDA also wants to establish a coordinated education and outreach program to the community, and to expand research in TSE. The plan will enhance regulatory tools, and help enforce regulations concerning cattle feeding and import restrictions. The action plan is posted on the Internet at *http://www.fda.gov/oc/oca/roundtable/bse/FDA_actionplan.html.*

Another example of FDA's heightened concern with potential TSE transmission is the publication of the guidance entitled "Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products (January 2002)," available on the Internet at *http://www.fda.gov/cber/gdlns/cjdvcjd.pdf.* This guidance recommends blood donor deferrals for travel to the UK and the rest of Europe, for military personnel who resided in U.S. military bases in Europe, and for receipt of blood in the UK.

In January 2001, we asked the TSEAC to evaluate the risk of transmission of vCJD through the transplantation, implantation, infusion, or transfer of HCT/Ps and to compare this risk to that of the transfusion of blood and blood products, for which precautionary measures have already been adopted. We specifically requested advice on how information about residence/travel history could best be obtained and noted the relevance of this question to corneas procured under legislative consent. The committee agreed that, compared with blood transfusion, there is a significant risk of transmission of vCJD from HCT/Ps, and noted that dura mater and cornea have the greatest risk. A majority of the committee supported deferral for donors of dura mater and cornea who had possibly been exposed to the bovine spongiform encephalopathy agent, but the committee did not vote on the question of whether an interview should be required of all donors.

Since that meeting of the TSEAC, we have issued a draft guidance document entitled "Draft Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" dated June 2002, available on the Internet at *http://www.fda.gov/cber/gdlns/cjdvcjd0602.pdf.* This draft guidance document contains our current recommendations on appropriate donor screening measures for CJD and vCJD. This draft guidance was discussed at the TSEAC meeting in June 2002.

It would be inconsistent with our level of concern about TSE to fail to require a donor medical history interview for some corneas, when it is generally agreed that corneas are among the tissues most likely to transmit TSE. The information needed to screen for TSE (e.g., cognitive changes; travel history) is not the sort that can be obtained through an autopsy or through a review of investigators' reports or hospital charts.

Moreover, although the preamble to the proposed rule used TSE to illustrate the need for a medical history interview for all cornea donors, questions pertaining to other relevant communicable diseases would also go unanswered without an interview. We agree with the comment that supported the interview as a way of screening for diseases other than CJD, such as hepatitis and HIV.

The EBAA report focused on CJD, and not on other diseases that might be screened for, including HIV. The report recommended against requiring a donor medical history interview in cases of legislative consent. In reaching this conclusion, the report's authors made certain assumptions about the diagnosis, course, and prevalence of CJD in the cornea donor population, including the frequency of misdiagnosis of CJD. As we discuss in this document, varying these assumptions can lead to very different conclusions. Moreover, the report analyzed the possible effect of supplemental screening applicable to all cornea donors, assuming a new screening requirement where none currently exists. However, the requirement for a donor medical history interview is currently in place with respect to all cornea donations except for the small percentage obtained under legislative consent. (The actual percentage of cornea donations obtained under legislative consent is unknown. The EBAA report used an unsupported value of 10 percent.)

In evaluating the proposed regulation, the EBAA report considered the number of potential cornea donors who might be deferred for CJD risk because of the results of supplemental screening but who in fact do not have CJD (i.e., the number of all cornea donors who might be erroneously excluded). Depending on the assumptions made, the estimated number of cornea donors with CJD and the number of donors erroneously excluded by screening could vary tremendously. For instance, the authors of the report assumed that 1 percent of actual CJD cases would be missed, and

diagnosed as some other neurological disease. They calculated that it would take 8.1 years of screening to exclude one actual case of CJD, and the numbers of otherwise eligible donors incorrectly excluded by screening would range from 18,415 to 73,362 (depending upon the specificity of the screening questions). If, instead of 1 percent, we make the assumption that 10 percent of cases of CJD would be misdiagnosed, then it would take 1.4 years of screening to exclude 1 actual case of CJD, with 3,219 to 12,876 donors incorrectly excluded. Thus, the assumption made by the authors resulted in a calculation of approximately six times the number of donors incorrectly excluded as under another possible scenario. Furthermore, the EBAA model estimates the numbers of incorrectly excluded donors that would result assuming that the additional screening would apply to all cornea donors. However, the additional screening required under this rule would affect only the subset of donors from whom an interview is not currently obtained (e.g., corneas obtained under legislative consent).

Because the report failed to explicitly consider a variety of uncertainties in the model assumptions, did not consider the effect of the donor medical history interview requirement on the appropriate subset of potential donors, and did not include diseases other than CJD in the risk assessment, we decline to follow any recommendation based on the results.

We disagree with comments that predict a shortage of corneas resulting from this rule. At present, approximately 30 percent of corneas recovered in the United States are exported (2002 Eye Banking Statistical Report, Eye Bank Association of America). Because any estimates of potential reductions in donations under legislative consent are quite speculative, we have not included such estimates in this response. Even if this final rule led to a reduction in donations under legislative consent, we do not anticipate that a shortage would result.

(Comment 46) Although comments expressed concern about the effect of the proposed requirement for a donor medical history interview on medical examiner laws, we received only a few responses to our request for comments on any potential conflicts that might make it impossible to comply with both this regulation and State laws on legislative consent. One comment agreed with requiring a donor medical history interview, but noted that, given privacy considerations, an interview with a primary treating physician may be difficult to obtain without permission of the deceased and/or the deceased's family. Another comment asserted that, for the proposed rule not to conflict with State laws on legislative consent, it would have to allow the medical examiner or pathologist who performs the autopsy to qualify as an "individual knowledgeable about the donor's medical history and relevant social behavior" and to respond to a modified set of history questions appropriate to the medical examination. According to the comment, other medical and social history would be obtained through the case file containing investigator's reports, hospital charts, or other sources of donor history.

(Response) As discussed in section VI of this document, we contacted the States to give them the opportunity to comment on any possible preemption issues. No States replied to our request.

In this final rule, we have defined "donor medical history interview" as a documented dialog about the donor's medical history and relevant social behavior, including activities, behaviors, and descriptions considered to increase the donor's relevant communicable disease risk. If the donor is not living or able to participate in the interview, the interview must take place with an individual or individuals who are able to provide the information sought in the interview. (This language replaces "individual knowledgeable about the donor's medical history and relevant social behavior" from the proposed rule. This change is for purposes of clarity and plain language, and it does not affect the definition's meaning.) Examples of these individuals who could possibly provide the appropriate information include the donor's next-of-kin, the nearest available relative, a member of the donor's household, an individual with an affinity relationship, or the primary treating physician.

We continue to believe that the definition of "donor medical history interview" provides sufficient flexibility to allow for the continued recovery of corneas under legislative consent. However, we recognize that there may be some difficulty in communicating with the primary treating physician without obtaining permission from the deceased and/or the family of the deceased, and that therefore this final rule may have an effect on the ability of medical examiners and coroners to recover corneas under State legislative consent laws. But, given the known transmission by corneas of HBV and CJD, and the potential for corneas to transmit other communicable diseases, including TSE, we have concluded that making an exception from the requirement for a donor medical history interview in the case of corneas obtained under legislative consent is not justified.

We disagree with the comment that urged us to interpret the definition to include an interview with the medical examiner or pathologist who performs the autopsy. Although the medical examiner or pathologist will have useful clinical information that should bear on the donor-eligibility determination, it is unlikely that this person will know the donor well enough to answer questions about his or her medical history, travel history, and/or social behavior. Therefore, an interview with the medical examiner or pathologist would be inadequate to fulfill the interview requirements.

(Comment 47) In the preamble to the proposed rule, we noted that, together with CDC, we were reviewing the risk factors for transmission of relevant communicable diseases in light of current scientific knowledge. Based on that review, we planned to specifically describe, in a guidance document, risk factors and screening information to assist establishments in complying with the regulations (64 FR 52696 at 52703). Although the proposed rule did not specify risk factors, we received many comments opposed to a screening factor that would prevent men who have had sex with men from donating semen anonymously. (Many comments also focused on the proposed requirement to quarantine directed donations of reproductive cells and tissue. As discussed in comment 36 of this document, we have deleted this requirement from this final rule. The final regulations allow the use of fresh semen from directed reproductive donors.)

Some comments disagreed with considering homosexual men to be "high risk donors" and disputed the scientific basis for excluding these men as donors. Many comments cited the efficacy of the blood test for HIV, with retesting after a 6-month quarantine, although one comment noted that HIV antibody testing is imperfect. Many comments disputed the public health benefits of the rule, although some applauded the agency for trying to craft safeguards to protect the public.

Other comments asserted that the regulations would abridge the reproductive, civil, or constitutional rights of both donor and recipient, but did not provide an explanation of the scope of those rights or a legal analysis of how this rule would affect them. Many comments argued that the proposed regulations were discriminatory. Some comments

suggested language for the donor-eligibility draft guidance.

(Response) In response to the comments suggesting that FDA should allow establishments to rely on HIV test results alone, or on quarantine and retesting, without screening for risk factors, FDA rejects that approach at this time. Although it is reasonable to expect that more sensitive nucleic acid amplification testing (NAT) will be available soon for reproductive tissue donors, even that testing may fail to detect early stage HIV and other infections, particularly because the level of viremia may be extremely low in the early stages of infection (Refs. 1, 2, and 3). Moreover, even the best test may fail to provide an accurate test result due to human error in running the test or in linking the test result to the correct donor. Accordingly, FDA believes that, based on the current state of testing and current knowledge about disease transmission, it is necessary to screen for risk factors as well as to test for diseases such as HIV.

Like the proposed rule, this final rule does not specify risk factors. Risk factors and other information about screening are contained in the donor-eligibility draft guidance announced elsewhere in this **Federal Register**. We welcome comments on the guidance document.

In developing the guidance, we have seriously considered the comments. To obtain up-to-date information on risk factors, we have worked with CDC. CDC performed a literature search and then, on June 26 and 27, 2000, held a donor suitability consultation to consider whether the 1994 "Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs" (*Morbidity and Mortality Weekly Report* 1994; 43(RR–8)), should be revised with respect to men who have sex with men.

Approximately 50 persons were invited as consultants. They represented transfusion and transplant professional organizations, public health experts, donor families, persons receiving transplants, ethicists, and donor rights advocates. Representatives of the Department of Health and Human Services and its component agencies also participated. Observers at the meeting were also encouraged to contribute.

Representatives of CDC presented the scientific literature search prepared as a background for the consultation. Presenters compared the transmissibility of infection through blood, organs, tissues, and reproductive tissues. Data were presented on the incidence and prevalence on HIV, HBV, and HCV for specific groups and risk behaviors; these data were derived primarily from the literature published between 1995 and 2000 and from unpublished sources. Data indicated that, compared to the general population, the incidence and prevalence rates for HIV, HBV, and HCV were substantially higher for heterosexuals attending sexually transmitted disease clinics, men who have sex with men, commercial sex workers, and injection drug users.

After the consultation, it was concluded that there is no new data that would warrant revising the 1994 guidelines. CDC and others also concluded that current data are not sufficient to allow the identification of lower-risk subsets of currently excluded population groups, and thus, to refine the exclusionary criteria. At the consultation, representatives of CDC encouraged the development of new data.

On December 14, 2001, we asked the Center for Biologics Evaluation and Research's (CBER) BPAC, whether there are existing data that identify subsets of men who have had sex with other men in which the incidence and prevalence rates for HIV, HBV, and HCV of the subsets are similar to the population at large. By a 10 to 0 vote, the committee advised that these data do not exist.

We have reviewed relevant legal authorities and disagree that these regulations discriminate or improperly abridge donor or recipient rights. We further note that, since FDA has tailored the rule's requirements to take into account an existing relationship between a donor and recipient (for example, FDA has not required quarantine and retesting for directed reproductive donors, permits the use of reproductive tissue from ineligible directed reproductive donors, and requires no testing for sexually intimate partners), the comments' remaining objections relate almost exclusively to anonymous donations of reproductive tissue. We will continue to examine the data on risk factors and, as new data are developed that justify changes to our guidance, we will make those changes in accordance with good guidance practice.

(Comment 48) Proposed § 1271.75(a)(2) would require screening a potential donor to determine if he or she had received a "xenotransplant" or was a "close contact" of a xenotransplant recipient. Two comments agreed that xenotransplantation recipients should be deferred as tissue donors, but asserted that close contacts do not need to be deferred. One comment asserted that there have been no reports of the spread of zoonoses to close contacts or household members. The comment further recommended use of a simplified question in donor screening.

(Response) This final rule adopts a different approach to screening for xenotransplantation than proposed. The rule is intended to permit the agency added flexibility in responding appropriately to the risks presented by different kinds of xenotransplantation as this field develops and changes. To this end, we have modified several provisions of the final rule with respect to xenotransplantation, including the screening requirements set out in § 1271.75. (Changes to the definitions and to § 1271.65 are discussed in comment 25 and the text before comment 37 of this document.)

The final rule requires screening for "communicable disease risks associated with xenotransplantation." The donor-eligibility draft guidance that accompanies this final rule describes those risks. Because, at this time, so few xenotransplantations have been performed, and much is unknown about the actual risks of xenotransplantation, the risks for which you must screen may be potential or hypothetical risks. We currently consider both the xenotransplantation product recipient and the intimate contact of a xenotransplantation product recipient to be at risk for acquiring zoonoses, and, as in the proposed rule, these individuals would be ineligible to donate HCT/Ps. However, if requested to do so through a request for an exemption from or alternative to the regulations under proposed § 1271.155 when finalized, we will consider exceptions for certain ex vivo exposures (e.g., exposure to a well-characterized cell line, or exposure across a physical barrier).

We have considered the comments' assertion that intimate contacts should be eligible for donation, based on the lack of reports of zoonosis spread, and we disagree. Given the potential risks associated with the spread of diseases from live animal cells, tissues, and organs, we believe that the most prudent course at this time is to defer intimate contacts, and the donor-eligibility draft guidance follows this course. As with hepatitis and HIV, those individuals most likely to be infected by a xenotransplantation product recipient with a zoonosis are the recipient's intimate contacts. Should that individual become infected with a zoonosis, then an HCT/P from that intimate contact could transmit the zoonosis to the recipient of that HCT/P.

The donor-eligibility draft guidance describes the types of questions that can

elicit information on communicable disease risks associated with xenotransplantation. We welcome comments on the draft guidance.

(Comment 49) One comment said that, instead of questioning at the time of donation, FDA should require that past xenotransplantation product recipients and their next of kin be notified by the medical institution performing the clinical trials that they are deferred from donating blood and tissues.

(Response) We agree that a transplant institution should tell a xenotransplantation product recipient not to donate blood and tissues (e.g., as part of informed consent). The PHS Guideline on Infectious Disease Issues in Xenotransplantation (January 19, 2001) recommends that xenotransplantation product recipients be instructed not to donate blood, blood components, tissues, breast milk, ova, sperm, or any other body parts for use in humans. This document further recommends that the recipient inform his contacts (now referred to as "intimate contacts") not to donate.

However, as an added precaution, an HCT/P donor, or other person interviewed in the donor medical history interview, should be questioned at the time of HCT/P donation. Unless prodded by the question, the donor may not remember that he or she is not supposed to donate HCT/Ps. Moreover, another person interviewed in the donor medical history interview may not remember the warning against donation unless specifically asked about xenotransplantation.

(Comment 50) Proposed § 1271.75(d) would allow an abbreviated donor screening procedure for living donors, as long as complete donor screening is performed every 6 months. One comment asserted that it is impractical to conduct abbreviated screening at each donation for anonymous semen donors and that a complete donor-eligibility determination every 6 months is unnecessary. Another comment recommended that a complete screening be recorded with each donation event. A third comment asked us to revise the regulation to indicate that an abbreviated donor screening would not be acceptable if there has been a change in screening requirements since the last complete screening procedure was performed on the donor.

(Response) We decline to make the changes suggested by the comments. We believe that the requirement for a complete screening procedure (i.e., a donor medical history interview), review of medical records and physical examination, every 6 months is appropriate because in this timeframe a potential donor may develop physical signs of a communicable disease that can be detected by examination.

With an abbreviated screening procedure, a full review of records is not necessary, but you must make sure that there have been no changes in a donor's risk factors, including high risk behavior, since the previous donation. You may accomplish this by having the donor read a written list of risk behaviors and asking whether he or she has participated in these behaviors.

With respect to changes in screening requirements, we agree with the intent of the comment but disagree that the requested change is necessary. Information on screening (e.g., risk factors) is contained in guidance that, although not binding, represents our current thinking on the topic. If FDA guidance on screening has changed since the last donation (for example, if a new risk factor has been added), we recommend that you screen in accordance with the new guidance at the next scheduled donation following the implementation date of the guidance (for example, by screening for the new risk factor).

We have made several changes to the regulation for clarity. We have replaced the phrase "on subsequent donations" with "on repeat donations" to clarify that we intend this abbreviated procedure to apply in repeat donation situations (e.g., semen).

We note that while § 1271.75(d) addresses abbreviated screening procedures for repeat donors, the requirements for quarantine, testing, and retesting applicable to repeat donations are contained in §§ 1271.60, 1271.80, and 1271.85. In comment 53 of this document, we discuss changes to the testing requirements applicable in the repeat donor situation.

9. What Are the General Requirements for Donor Testing? (§ 1271.80)

Proposed § 1271.80 would require an establishment to test donor specimens for relevant communicable disease agents, to adequately and appropriately reduce the risk of transmission of relevant communicable diseases. Among other things, proposed § 1271.80 sets out requirements for the timing of specimen collection; the use of FDA-licensed, approved, or cleared tests; which laboratories could perform the required tests; exceptions applicable to certain test results for CMV or syphilis; and determining the adequacy of a specimen where the donor has received a transfusion or infusion.

a. *Testing of mother.* Proposed § 1271.80(a) stated that, in the case of a fetal or neonatal donor, a specimen from the mother is generally acceptable for testing.

(Comment 51) One comment emphasized the importance of permitting testing of an appropriate specimen from the mother of a fetal or neonatal donor. Another comment requested that we require maternal tests to be validated as predictive of transmissibility of infection in the fetal or neonatal tissue.

(Response) We have reexamined the proposed language on maternal testing and now believe that testing of the mother is preferable to testing of the fetal or neonatal donor. We are particularly concerned about the possibility that HBV might be transmitted at or around the time of birth, or possibly in utero. In such cases, HBV testing of the fetus or neonate could lead to a false negative result, but testing of the mother would be positive. We have therefore revised § 1271.80(a) to require that, in the case of a donor 1 month of age or younger, you must test a specimen from the birth mother instead of from the donor. We note that requiring testing of the mother is consistent with the standards of several professional organizations (see, e.g., American Association of Blood Banks (AABB) Standards for Hematopoietic Progenitor Cell and Cellular Product Services, 3rd edition, 2002; NMDP Standards, 17th edition, Sept. 1999; Foundation for the Accreditation of Cellular Therapy (FACT)/Netcord International Standards for Cord Blood, 2002; FACT Standards for Hematopoietic Progenitor Cell Collection, Processing and Transplantation, 2nd edition, 2002). Because it is generally accepted that, in most cases, until a month of age the same IgG antibodies are present in the mother's blood as in the neonate's, we decline to add the requested validation requirement.

b. *Timing of specimen collection.* Proposed § 1271.80(b) would require collection of the donor specimen at the time of recovery of cells or tissue from the donor or within 48 hours after recovery, although proposed § 1271.80(b)(1) through (b)(3) would allow specimen collection from a living donor up to 7 days before recovery in certain situations.

We received many comments on this provision.

(Comment 52) One comment recommended that time constraints for specimen storage before testing be consistent with test kit instructions.

(Response) We agree. Section 1271.80(c) requires that you follow the manufacturer's instructions in

performing testing. This includes instructions with respect to storage time before testing.

(Comment 53) Numerous comments asserted that the proposed rule was too restrictive and requested that we allow more time between collection of the specimen and recovery of the cells or tissue. Comments concerned with the recovery of peripheral blood stem/progenitor cells, where recipient conditioning is performed, suggested a timeframe of 30 days before recovery of the HCT/P. Other comments requested that, for cord blood donors, specimen collection be permitted at any time following the donation; another comment requested 7 days. One comment requested from 30 to 90 days post-donation for specimen collection from a sperm donor, citing expense and natural fluctuations in semen sample parameters. Another comment asserted that the proposed time limits were too restrictive for oocyte donors. Some comments expressed concern that, in the case of cadaveric donors, the regulations would not allow testing of specimens collected before death (premortem specimens). Other comments asserted that the requirements on timing of specimen collection would prohibit the use of pretransfusion samples.

(Response) We agree that more time should be allowed between collection of specimens for testing and HCT/P recovery. The final rule requires a sample at the time of recovery, when feasible. However, if specimen collection at the time of cell or tissue recovery is not feasible, you may collect the specimen up to 7 days before or after recovery. We decline to rely on testing for communicable diseases performed later than 7 days before donation, because the test results would not accurately reflect the donor's actual disease exposure at the time of donation. Moreover, as the time period between donation and specimen collection increases, the chances of mix-ups or difficulties with followup also increase. An establishment may choose to perform testing before initiating preparatory regimens on the donor (e.g., oocyte donors require hormone stimulation), but that earlier testing would not replace the testing required by this regulation.

However, we are making an exception for testing donors of peripheral blood stem/progenitor cells. Since the recipient undergoes a myeloablative treatment regiment, i.e., high dose chemotherapy and total body irradiation, it is important to determine the eligibility of the donor before the recipient's treatments begin. At 7 days prior to recovery, the treatment of the recipient has already started and the decision to proceed is irreversible. Therefore, under § 1271.80(b), for donors of peripheral blood stem/progenitor cells only, the establishment may collect the donor specimen up to 30 days before recovery of the stem/progenitor cells. We understand that the current practice of peripheral blood stem/progenitor cell establishments is to take a donor specimen on the day of recovery for additional testing, and we encourage these establishments to continue this practice, in order to permit appropriate followup and treatment if test results are positive.

In response to the comment on semen donation, we have added an exception to § 1271.85(d) that will provide flexibility for the testing of anonymous, repeat semen donors. We understand that, under current practices, establishments do not collect a specimen for testing at each donation by a repeat semen donor. As long as a specimen has been taken and tested, and the donated semen is quarantined pending the results of retesting at least 6 months after donation, it is not necessary for us to restrict this practice through these regulations. For this reason, we have added an exception to § 1271.85(d) for repeat semen donors from whom a specimen has already been collected and tested, and for whom retesting is required under § 1271.85(d). We reiterate that you must collect a new specimen and test it under § 1271.85(d) at least 6 months after the donation, and pending the completion of that retesting you must quarantine the donated semen under § 1271.60(a).

Under the new regulatory language in § 1271.80(b), which permits the collection of a specimen up to 7 days before recovery of cells or tissue, you may use a premortem specimen to test a cadaveric donor, as long as the specimen is collected within that timeframe. The use of specimens taken pretransfusion or preinfusion will continue to be allowed, subject to the same 7-day timeframe; use of these specimens is discussed in section III.C.8.g of this document.

c. *Approved tests.* Proposed § 1271.80(c) would require the use of appropriate FDA-licensed, approved, or cleared donor screening tests in accordance with the manufacturer's instructions (except that, for *Chlamydia trachomatis* and *Neisseria gonorrhea*, tests labeled for the detection of those organisms in an asymptomatic, low-prevalence population must be used until screening tests are available). In addition, proposed § 1271.80(c) would require the use of tests specifically labeled for cadaveric specimens, when applicable and available, instead of more generally labeled donor screening tests.

(Comment 54) Two comments suggested that § 1271.80(c) describe the circumstances in which tissue establishments may use tests that are not licensed, cleared, or approved.

(Response) We decline to make this change. This section requires the use of FDA licensed, approved, or cleared screening tests. The use of unapproved tests would not meet the requirements of this regulation.

(Comment 55) One comment urged FDA to work with laboratories and manufacturers of diagnostic tests to approve tests for cadaveric specimens. Other comments noted that there were no FDA-licensed screening kits for cadaveric blood samples. Another comment expressed doubts that cadaveric blood tests for corneas would be approved.

(Response) FDA has encouraged manufacturers of in vitro diagnostic products to develop products intended for use with cadaveric specimens. Since the publication of the proposed rule, we have licensed test kits specifically labeled for use with cadaveric blood specimens. These test kits must be used, if applicable, when testing all cadaveric HCT/P donors, including cornea donors. A list of licensed test kits for use with cadaveric specimens may be found at *http://www.fda.gov/cber/products/testkits.htm*.

d. *CLIA certification.* Proposed § 1271.80(c) stated, in part, that testing must be performed by a laboratory certified to perform testing on human specimens under the CLIA.

(Comment 56) Two comments asserted that we should permit testing by laboratories that are exempt from CLIA certification.

(Response) We agree with the comment that not all laboratories that comply with CLIA are certified under CLIA. We have revised § 1271.80(c) to require that required testing must be performed by a laboratory that either is certified to perform such testing on human specimens under CLIA and 42 CFR part 493, or has met equivalent requirements as determined by the CMS. Examples of the latter are Veterans Administration hospital laboratories, laboratories in states that have received an exemption from CMS, and laboratories accredited by certain approved accrediting organizations.

(Comment 57) Comments also urged us to permit testing by foreign laboratories subject to requirements equivalent to or more stringent than those imposed by CLIA. One comment

requested that we consider allowing U.S. citizens access to cord blood units from foreign tissue banks, which would not follow CLIA standards but would have similarly regulated clinical laboratory testing.

(Response) We decline to make the change requested because it is not feasible for us to identify and assess the equivalence of other countries' requirements, keep track of any changes to those requirements, and then to ascertain that each foreign tissue bank meets those requirements. In contrast, CLIA certification provides a uniform, workable mechanism for determining laboratory proficiency. Foreign establishments are not prohibited from using domestic CLIA-certified laboratories for performing the required testing, and some firms operating under part 1270 send samples ahead to the United States for testing in CLIA-certified laboratories.

When we first issued regulations on human tissue, one major concern was the distribution in the United States of imported tissue from donors who had not been adequately screened and tested to prevent the transmission of infectious disease (62 FR 40429 at 40435, July 29, 1997). The proficiency of the laboratory performing the required testing is a key element in assuring the safety of HCT/Ps. Certification under CLIA helps to ensure that the laboratory is proficient and competent to perform the required tests accurately. Moreover, any laboratory, foreign or domestic, may apply for certification under CLIA. At this time, we are aware of 21 foreign CLIA-certified laboratories.

e. *Ineligible donors.* Proposed § 1271.80(d)(1) stated that a donor whose specimen tests repeatedly reactive or positive must be determined unsuitable.

We have made several changes to the wording of this paragraph. As discussed earlier in this document, "unsuitable" is now "ineligible."

In addition, for consistency with other FDA regulations, we have changed "repeatedly reactive" to "reactive." As noted in the preamble to the proposed rule, repeatedly reactive means initially reactive, and then reactive in at least one of two duplicate tests with the same manufacturer's test kit (64 FR 52696 at 52705). Deleting the word "repeatedly" from the regulation should allow for future advancements in testing, when the process of repeating an initial reactive result in duplicate would no longer be appropriate. This modification does not affect the requirement that you follow the testing protocol set out in the test kit instructions (§ 1271.80(c)). In other words, if the test kit instructions direct you to repeat an initial reactive test result in duplicate, you must do so. In such cases, the term "reactive" should be understood to mean repeatedly reactive.

Proposed § 1271.80(d)(1) contained two exceptions to the general rule that a donor whose specimen tests reactive or positive must be determined ineligible. Under the first exception, a reactive test for CMV would not make a donor unsuitable unless additional testing showed the presence of an active infection. The second exception was for a donor whose specimen tested repeatedly reactive on a nontreponemal screening test for syphilis and negative on a specific treponemal confirmatory test.

(Comment 58) One comment asserted that FDA should permit confirmatory tests to prevail in all cases, arguing that this is consistent with medical practice and would prevent discarding transplantable tissue. Another comment noted that proposed § 1271.80(d)(1) contained no exception for HBV, although tests for HBV recognize the validity of confirmatory testing in the manufacturer's instructions.

(Response) We disagree that the results of confirmatory tests rather than the results of screening tests should determine donor eligibility. Confirmatory tests may not be as sensitive as screening tests in detecting early infection. Our decision is consistent with the agency's policy in blood regulation: For blood donors, supplemental testing is used for donor reentry or for donor notification and counseling.

Confirmatory testing for HBV, such as the hepatitis B surface antigen (HBsAg) neutralization assay, is valuable for confirming the presence of HBsAg in specimens found to be reactive by a screening assay, and so can be helpful for donor counseling. However, the neutralization assay may not always detect all potentially infectious HCT/Ps. Therefore, we are not making an exception in this section that would permit a donor-eligibility determination based on HBV confirmatory testing.

(Comment 59) One comment, submitted to the CGTP docket, asked us to allow tissue banks to use the results of triplicate testing, performed by laboratories for OPOs, when all three tests are negative.

(Response) If you are using test results of an enzyme immunoassay obtained by an OPO, and the test was initially run in triplicate, you may interpret three nonreactive results in a single run as a negative test result.

f. *Testing for CMV.* Proposed § 1271.85(b)(3) would require that donors of viable, leukocyte-rich cells or tissue be tested for CMV. Proposed § 1271.80(d)(1)(i) would require you to determine ineligible a donor whose specimen tests reactive for CMV, unless additional testing does not show the presence of an active infection. We proposed the exception in § 1271.80(d)(1)(i) because, although a donor with active CMV poses a risk of CMV transmission, a donor's past infection with the virus does not necessarily present such a risk (64 FR at 52705). We noted that the results of CMV testing would accompany the HCT/P, and we specifically requested comments on this approach (64 FR 52705).

(Comment 60) One comment noted that the proposed rule did not specify a means for assuring that CMV viral shedding is not occurring, and suggested that we specify the type of tests to use to determine the presence or absence of viral shedding.

(Response) Considering this comment has led us to conclude that it would be difficult to comply with the terms of the exception in proposed § 1271.80(d)(1)(i). Therefore, we have made several modifications to the final rule with respect to CMV testing. The effect of these changes is to require CMV testing of donors of leukocyte-rich cells or tissue, while allowing the use of HCT/Ps from CMV-reactive donors in some instances.

First, we have deleted proposed § 1271.80(d)(1)(i) from the final rule, and we have removed CMV from the list of relevant communicable disease agents and diseases in § 1271.3(r)(1), as well as from § 1271.85(b)(3). We have made this change because we believe that, as proposed, the rule may have led all donors who test reactive for CMV to be disqualified, an undesirable result.

Second, although we have removed CMV from the list of relevant communicable disease agents and diseases in § 1271.3(r)(1), we have not removed the requirement for CMV testing from the final rule altogether. An HCT/P from a CMV-antibody-reactive donor is capable of transmitting CMV to a recipient who tests negative for CMV antibody, and in some recipients this can have serious consequences. To prevent these consequences, the final rule, at § 1271.85(b)(2), requires you to test donors of viable leukocyte-rich cells and tissue for evidence of infection due to CMV. Under § 1271.55(b), results of testing (including testing for CMV) must accompany an HCT/P.

The third change we have made in the final rule is to require, in § 1271.85(b)(2), that you establish and maintain an SOP governing the release

of an HCT/P from a donor whose specimen tests reactive for CMV. This approach will permit the development of procedures that are specific to different situations. SOPs might, for example, permit the release of an HCT/P from a donor with a CMV-antibody reactive test, depending on the CMV status of the recipient. We address the issue of the use of HCT/Ps from CMV-reactive donors in the donor-eligibility draft guidance, announced elsewhere in this **Federal Register**.

(Comment 61) Another comment asked whether a semen bank would be able to use a semen donor who tested positive for CMV (IgG) in a CMV positive (IgG) recipient.

(Response) Section 1271.85(b)(2), in part, requires you to establish and maintain an SOP governing the release of an HCT/P from a donor whose specimen tests reactive for CMV. Thus, your SOP would need to address this situation. We discuss the use of semen from a donor who tests reactive to CMV (IgG) in the donor-eligibility draft guidance announced elsewhere in this **Federal Register**.

(Comment 62) One comment suggested that we used the term "repeatedly positive" instead of "repeatedly reactive" when describing results of CMV testing, because the term "repeatedly reactive" is not recognized as a CMV screening test result.

(Response) As discussed, we have changed the wording from "repeatedly reactive" to "reactive." Although the labeling of the devices used to perform CMV testing describes results as positive or negative, the terms "positive" and "reactive" are synonymous in this context for the purposes of this rule.

(Comment 63) One comment asserted that, for reproductive cells, it is unnecessary to require the CMV status to accompany the product, because approximately 40 percent of semen donors are CMV antibody (IgG) positive. The comment noted that it is rare for the physician conducting the insemination to review this information, and that, for this reason, the information is provided only upon request.

(Response) We disagree. CMV is the most commonly identified cause of congenital infection (Krugman S., et al., Infectious Diseases in Children, St. Louis, CV Mosby, pp. 8–21, 1985). If a CMV negative pregnant woman contracts CMV, the fetus may acquire congenital CMV infection. We continue to believe that information about the semen donor's CMV status should appear in materials accompanying the HCT/P, so that physicians may rely on this information to make informed decisions about the use of an HCT/P in a particular patient's situation.

g. *Plasma dilution.* The transfusion or infusion of blood, colloids, or crystalloids may result in plasma dilution, which can affect the results of communicable disease testing. Section 1271.3(p) defines plasma dilution as a decrease in the concentration of the donor's plasma proteins and circulating antigens or antibodies.

Proposed § 1271.80(d)(2) and (d)(3) would set out requirements relating to plasma dilution. We have reorganized those provisions in this final rule, and they now appear in paragraph (d)(2).

The final rule requires you to determine ineligible any donor in whom plasma dilution sufficient to affect the results of communicable disease testing is suspected, unless you: (1) Test a specimen taken before transfusion or infusion (and up to 7 days before recovery of cells or tissue), or (2) analyze the extent of plasma dilution, using an established procedure called an algorithm. If that analysis rules out plasma dilution sufficient to affect test results, then you can perform required testing on a specimen taken after transfusion or infusion. However, if plasma dilution is sufficient to affect results, and no specimen taken before transfusion or infusion is available, then the donor is ineligible to donate.

The final rule gives examples of clinical situations in which you must suspect plasma dilution sufficient to affect test results. Under § 1271.80(d)(2)(ii)(A), if you know of or suspect blood loss in a donor over 12 years of age, transfusions and infusions totaling more than 2,000 milliliters (mL) must be suspected of affecting test results. Under § 2171.80(d)(2)(ii)(B), any transfusion or infusion in a donor 12 years of age or younger must be suspected of affecting test results, whether or not blood loss has occurred. These clinical situations were set out in the proposed regulation and were based closely on § 1270.20(h)(2) and (h)(3).

However, whereas the proposed rule specified the timeframe for these transfusions or infusions as within 48 hours of specimen collection (or within 1 hour in the case of crystalloids), the final rule sets the timeframe as within 48 hours (or one hour, for crystalloids) before death or specimen collection, whichever occurred earlier. We have inserted the reference to death to take into account those situations where the specimen is collected after death. For example, if the specimen is collected 3 days after death, it does not make sense to consider transfusions within the 48 hours before specimen collection, when the donor would already be dead and would not be receiving transfusions. What is relevant in this instance is any transfusion or infusion within 48 hours of the donor's death (or one hour, for crystalloids).

As we noted in the guidance document that accompanied part 1270, every possible clinical situation cannot be predicted, and there may be additional circumstances where plasma dilution sufficient to affect test results should be suspected. As restructured, § 1271.80(d)(2) recognizes that these other situations exist. In the donor-eligibility draft guidance announced elsewhere in this issue of the **Federal Register**, we list additional circumstances in which it may be necessary to employ an algorithm.

A discussion of plasma dilution and algorithms appeared in the final rule "Human Tissue Intended for Transplantation" issued in the **Federal Register** of July 29, 1997 (see 62 FR 40429 at 40435 through 40436), and also in a guidance document entitled "Guidance for Screening and Testing of Donors of Human Tissue Intended for Transplantation" dated July 1997. We now refer to those documents. We also note that the donor-eligibility draft guidance announced elsewhere in this issue of the **Federal Register** contains information on appropriate algorithms.

(Comment 64) One comment requested clarification of the term "blood loss."

(Response) By blood loss, we mean bleeding, including internal bleeding. Thus, in considering whether blood loss has occurred in a potential donor, you should consider both blood lost within the body cavity and blood lost outside of the body.

(Comment 65) One comment questioned how to determine whether to use an algorithm due to the 2000 mL limit without actually performing the tabulation.

(Response) You may need to review medical records to make a rough determination of the total amount of blood, colloids, or crystalloids administered to a potential donor. This threshold determination will allow you to decide whether further analysis, using an algorithm, is necessary. In an adult with blood loss, if the total exceeds 2,000 mL, and administration took place within the timeframes set out in § 1271.80(d), then you must suspect plasma dilution sufficient to affect test results. Section 1271.80(d)(2) would then require you either to test a specimen taken before infusion or transfusion or to use an appropriate algorithm to analyze further the possibility of plasma dilution.

(Comment 66) One comment asserted that including the total volume of whole blood in calculations does not meet scientific principles, because the volume of the red blood cells does not contribute to plasma dilution.

(Response) The calculations that are made to determine if plasma dilution has occurred depend upon the category of fluids transfused or infused. The three categories are blood (e.g., whole blood, red blood cells); colloids (e.g., dextran, plasma, platelets, albumin, hetastarch); and crystalloids (e.g., saline, dextrose in water, Ringer's lactate). If the donor has received colloids in the 48 hours before death or specimen collection, and/or crystalloids in the one hour before death or specimen collection, then a comparison of the total volume of these fluids with the donor's plasma volume would be sufficient to determine if plasma dilution has occurred. However, when the fluids transfused are in the "blood" category (alone, or in combination with colloids and/or crystalloids), a comparison of the total volume of these fluids with the donor's blood volume should be performed, in addition to a comparison of the total volume of colloids and/or crystalloids with the donor's plasma volume.

In the situation described in the comment, a comparison of the estimated volume of plasma contained in whole blood with the donor's plasma volume only (without a comparison of the volume of whole blood with the donor's blood volume) would underestimate the amount of plasma dilution. Thus, a donor might be inappropriately determined to be eligible even though plasma dilution sufficient to affect viral marker testing had occurred.

The draft guidance that accompanies this final rule explains which calculations should be performed for each category of fluids transfused or infused.

The proposed rule referred to "reconstituted blood" under the category of fluids called "blood." We have removed the reference to "reconstituted blood," because we believe it is unnecessary and could lead to confusion in performing the necessary calculations (e.g., in which one of the three categories should reconstituted blood be included?). You should consider reconstituted blood to be whole blood for the purpose of § 1271.80(d)(2), and you should include whole blood in the category of "blood" transfused in the 48 hours before death or specimen collection.

10. What Testing Is Required for Different Types of Cells and Tissues? (§ 1271.85)

Proposed § 1271.85(a) would require you to test donors of all types of cells and tissues for relevant communicable disease agents including, at a minimum, HIV, HBV, HCV, and *Treponema pallidum*. Proposed § 1271.85(b) would apply to viable, leukocyte-rich cells and tissue and would require testing for relevant cell-associated communicable diseases including, at a minimum, HTLV and CMV. Proposed § 1271.85(c) would apply to donors of reproductive cells and tissues and would require testing for relevant genitourinary disease agents, including, at a minimum, *Chlamydia trachomatis* and *Neisseria gonorrhea*. Proposed § 1271.85(d) would require retesting for semen donors. Proposed § 1271.85(e) would require an assessment to detect evidence of TSE for donors of dura mater.

Under the proposed rule, cells or tissues could be subject to more than one testing requirement. For example, you would test a donor of leukocyte-rich reproductive tissue (e.g., semen) for the diseases listed in proposed § 1271.85 (a), (b), and (c).

The preamble to the proposed rule listed the tests that, according to our current thinking, are appropriate to use to test for the disease agents and diseases listed in § 1271.85 (64 FR 52696 at 52705 and 52706). Those testing recommendations are now contained in the donor-eligibility draft guidance.

We have deleted the phrase "at a minimum" from § 1271.85(a), (b), and (c), because it might give the impression that testing is required only for those communicable diseases listed in § 1271.85. Although at this time we only require testing for these diseases, in the future additional diseases may be identified as relevant. As discussed in comment 16 of this document, we will issue guidance that notifies you when we believe additional relevant communicable diseases meet the definition in § 1271.3(r)(2).

a. *Viable and nonviable cells and tissue (§ 1271.85(a))*. Proposed § 1271.85(a) would require donors of all types of cells and tissues to be tested for HIV type 1, HIV type 2, HBV, HCV, and *Treponema pallidum*.

(Comment 67) One comment noted that FDA did not require use of the HIV p24 antigen test for HIV screening. The comment described the test as easily accessible and inexpensive.

(Response) We recommend the particular tests to assess HIV infection in the donor-eligibility draft guidance, and discuss the HIV p24 antigen test.

(Comment 68) One comment discussed the use of core antibody and hepatitis B surface antibody tests to clarify donor HBV infectivity when the donor is HBsAg negative and core antibody positive. The comment asserted that if the IgM core antibody test is negative, and the surface antibody test is positive, this indicates that the donor had a past HBV infection that has resolved. The comment also asserted that the core antibody (IgG) is not a screening test for HBV infectivity, but is a historical test indicating previous infection with HBV.

(Response) Although we agree that, in most cases, a negative IgM core antibody test with a reactive surface antibody test indicates a past infection, we disagree that this combination of results always indicates that the infection has resolved. Rather, this combination of results does not indicate whether the donor is infectious.

In the donor-eligibility draft guidance that accompanies this final rule, we recommend that you use the total core antibody (IgG and IgM) test to test for HBV in addition to the HBsAg test.

(Comment 69) One comment noted that the standard screening test for HCV in Europe is different from the test FDA listed in the preamble to the proposed rule.

(Response) This comment referred to the use of NAT, which has not yet been licensed in this country for the purpose of screening cadaveric tissue donors. FDA encourages manufacturers of NAT kits licensed for blood donor screening to validate NAT for use with cadaveric blood specimens, and to submit the data to FDA to obtain a labeling change, to include this intended use. (Recommended tests are listed in the donor-eligibility draft guidance.)

(Comment 70) We received several comments on the requirement for syphilis testing (*Treponema pallidum*). One comment requested that, if the agency eliminates syphilis testing for blood donors, it should consider eliminating the requirement for tissue donors. Several comments opposed requiring syphilis testing for cornea donors, asserting that transmission is unlikely or that there is no significant health risk to the corneal transplant recipient. One comment supported the requirement for cornea donors.

(Response) We disagree that syphilis testing should not be required for cell and tissue donors, including cornea donors, and note that we have not eliminated syphilis testing of blood donors. In the final rule on testing of blood donors, we noted that comments

did not provide sufficient supporting data to justify eliminating the requirements to test blood and blood components with a serological test for syphilis. Moreover, preliminary results from ongoing studies indicate that the infectivity of seroreactive donors remains the subject of scientific debate. For this reason, we maintained the syphilis testing requirement for blood donors (Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents, Final rule (66 FR 31146, June 11, 2001)).

One comment cited a scientific paper, which we have reviewed (Macsai MS, Norris SJ, "OptiSol Corneal Storage Medium and Transmission of *Treponema pallidum*," *Cornea*, vol. 14(6), pp. 595–600, November 1995). The paper reports the results of a rabbit study on the effects of storage media on the probability of syphilis transmission. Although the media prevented the transmission of syphilis by contaminated corneas, transmission occurred when the media was not used. This paper does not support the lack of syphilis transmissibility by corneas; indeed, it shows the opposite. For this reason, we do not believe this study provides sufficient evidence to support eliminating the proposed syphilis testing requirement. Moreover, we disagree with the comment's assertion that there is no significant health risk to the corneal transplant recipient. Although treatable, syphilis remains a serious disease.

b. *Leukocyte-rich cells and tissues (§ 1271.85(b))*. Proposed § 1271.85(b) would require testing for HTLV, type I; HTLV, type II; and Cytomegalovirus for donors of viable, leukocyte-rich cells and tissue.

(Comment 71) We received several comments on our proposal to distinguish between leukocyte-rich cells and tissue and other cells and tissue, and on our preamble discussion of which cells and tissues we consider leukocyte-rich (64 FR 52696 at 52705). One comment noted that the differentiation was helpful. The comment suggested adding cultures of certain cell types, such as fibroblasts, to the list of materials that are not considered to be leukocyte-rich. Two comments asserted that oocytes and embryos are not leukocyte-rich. One comment noted that the term "stem cells," listed in the preamble as an example of leukocyte-rich cells or tissue, is too broad, and would apply to corneal epithelial stem cells, which are not leukocyte-rich. Another comment agreed that semen can be characterized as leukocyte-rich tissue but asserted that treated or "washed" sperm do not pose the same disease risks.

(Response) We agree with the comment requesting a more precise description of those stem cells that are rich in leukocytes, and we will refer to those cells as hematopoietic stem/progenitor cells. We also agree with the comments asserting that oocytes and embryos are not leukocyte-rich.

However, we disagree that sperm that has been treated or washed should be treated differently, for the purposes of these testing requirements, from semen. The HCT/P initially donated is semen, which is leukocyte-rich; thus, the donor must be tested for HTLV–I and –II and CMV. The donated semen poses risks; for example, it could transmit communicable disease to those handling it, or it could be released improperly before further processing. Later processing may decrease or remove the leukocytes from the donated semen, but would not affect the testing that must be performed on the donor at the time of donation. These testing requirements apply at the time of donation, regardless of how the HCT/P might later be processed.

For the same reason, we decline to state whether or not cultures of certain cell types, such as fibroblasts, are rich in leukocytes. As with semen, the HCT/P initially donated is not the fibroblast, but some other tissue from which fibroblasts are isolated. Thus, the applicable testing requirements depend on whether or not the donated cells or tissue are leukocyte-rich.

(Comment 72) One comment asserted that HTLV–I/II and CMV testing is not relevant to corneal transplants.

(Response) We agree. As noted in the preamble to the proposed rule (64 FR 52696 at 52705), corneas are not rich in leukocytes, so § 1271.85(b) does not apply to them. The donor-eligibility draft guidance contains our current thinking about which cells and tissues are leukocyte-rich.

(Comment 73) One comment asked how to counsel donors of reproductive tissue who test positive for HTLV. Another comment noted that diagnosis of some infections, such as HTLV, would lead to serious consequences for those individuals who test positive.

(Response) We recognize that it may be difficult to counsel patients about the results of HTLV testing; however, the scope of this rule does not extend to issues of donor notification.

(Comment 74) One comment asserted that, because leukocyte-rich, nonviable lymphocytes may transmit latent HTLV and CMV, they should be tested.

(Response) We agree that these lymphocytes must be tested. However, we do not consider them to be nonviable. Although they do not proliferate, they are live cells, which means cells that have the ability to metabolize or divide, and thus "are viable."

(Comment 75) One comment asserted that CMV testing is not necessary for oocyte donors because the virus does not appear to infect oocytes or surrounding cells.

(Response) We agree that CMV testing is not necessary for oocyte donors. Oocytes and embryos are not considered leukocyte-rich.

c. *Reproductive cells and tissues (§ 1271.85(c))*. Proposed § 1271.85(c) would list relevant communicable disease agents and diseases of the genitourinary tract for which you would test a donor of reproductive cells or tissue. The proposal would exclude reproductive cells or tissues procured by a method that ensures freedom from contamination of the cells or tissue by infectious disease organisms that may be present in the genitourinary tract.

(Comment 76) One comment asserted that most oocytes are retrieved through vaginal ultrasound techniques, so the exception to testing for chlamydia and gonorrhea would not apply in most cases.

(Response) We agree with this comment that, in most instances, oocytes are removed transvaginally, and so the exception in § 1271.85(c) would not apply; thus, testing would be required. However, if you use vaginal ultrasound for visualization only, and retrieve the oocytes in a way that ensures freedom from contamination with infectious disease organisms (e.g., nonvaginal laparoscopy), then the exception would apply.

d. *Retesting (§ 1271.85(d))*. Proposed § 1271.85(d) would require retesting of donors of "reproductive cells or tissue that can be reliably stored."

We have rewritten this provision to apply only to anonymous donors of semen. We discuss the reasons for this change elsewhere in this final rule in comment 35 of this document.

(Comment 77) Several comments expressed concern that retesting would be required for all tissues that can be reliably stored, not simply reproductive cells and tissue.

(Response) This was not our intention. As noted previously, § 1271.85(d) requires retesting only for semen from anonymous donors.

(Comment 78) The preamble to the proposal recommended that, where appropriate and feasible, all living donors of banked tissue be retested 6 months after donation (64 FR 52696 at 52706). Several comments objected to

the recommendation and asserted that retesting donors of nonreproductive cells and tissue would be onerous, costly, and inefficient.

(Response) At the time of initial testing, a donor may test negative but still be in the infectious window period. For this reason, retesting living donors of banked tissue 6 months after donation is an added safeguard for the prevention and spread of communicable diseases. However, in response to the comments, we are not adopting this requirement in this final rule.

e. *Dura mater (§ 1271.85(e))*. Proposed § 1271.85(e) would require, for donors of dura mater, an assessment designed to detect evidence of TSE. The preamble to the proposed rule described procedures for complying with the assessment requirement (see 64 FR 52696 at 52706). These procedures included, after removal of the dura mater, a full brain autopsy of the donor, including gross and histological examination, performed by a qualified neuropathologist, to identify evidence of TSE changes. The preamble also noted that, although there is no FDA-approved or validated test for screening TSE in brain tissue, a negative test to detect protease-resistant prion protein (PrP-RES), either by immunohistochemistry or Western Blot, is considered significant in increasing the level of confidence that the brain and the dura mater are free of TSE.

(Comment 79) Several comments supported the proposed requirement and the procedures set out in the preamble. One comment noted that the precautions of a full brain autopsy in addition to donor screening and medical history are a necessary step until there is an approved screening test. One comment asserted that a brain autopsy for dura donors is not feasible and recommended a brain biopsy instead. Two comments suggested that we change our recommendation that the autopsy be performed by a qualified neuropathologist to a qualified pathologist.

(Response) We based the recommendations in the preamble to the proposed rule on conclusions reached by FDA's TSEAC at meetings held on October 6, 1997, and April 16, 1998. The committee reiterated these recommendations at a meeting on January 18, 2001. The committee recommended a full brain autopsy of the donor, including gross and histological examination, to identify evidence of TSE changes. We agree with comments that a brain autopsy is necessary in the absence of an appropriate test, and will consider changing the requirement in the future if a sufficiently sensitive test is approved. A brain biopsy, although less expensive and intrusive, may not provide adequate information on TSE changes, because these changes may occur focally in the brain. Moreover, it has not been validated as a predictor of TSE. For these reasons, we decline to change that aspect of our recommendation.

However, we have reconsidered our proposal that the assessment be performed by a qualified neuropathologist. We recognize that many institutions do not have a neuropathologist on staff, and that many pathologists are qualified to do this assessment. For this reason, we now recommend that a qualified pathologist perform the assessment. To be qualified, the pathologist needs to have the appropriate training or experience to perform the appropriate neuropathologic examination.

We have modified the regulation slightly to require that the assessment performed on donors of dura mater be "adequate." The previous discussion provides our current understanding of what would constitute an adequate assessment.

(Comment 80) The preamble to the proposed rule noted that the type of TSE testing required for donors of dura mater did not appear feasible for cornea donors, and we requested comments on this issue (64 FR 52696 at 52706).

Several comments agreed that TSE testing for corneal tissue donors is not a feasible option because of the time required for brain autopsy or biopsy. The comments also cited concerns about costs and a potential decrease in donation rates. One comment noted that the use of all available screening components, including the medical screening interview, would satisfactorily substitute for TSE testing.

(Response) Under present conditions of storage in the United States, corneas must be transplanted within days of procurement to maintain their utility. For this reason, it is not feasible to test cornea donors for TSE using current methodologies, and we are not imposing a testing requirement at this time. However, under § 1271.75(a), screening for TSE is required for donors of all types of tissues.

11. Are There Exceptions From the Requirement of Determining Donor Eligibility, and What Labeling Requirements Apply? (§ 1271.90)

Proposed § 1271.90 would recommend, but not require, screening and testing for banked cells and tissues for autologous use and reproductive cells or tissue donated by a sexually intimate partner of the recipient for reproductive use. Proposed § 1271.90 would require special labeling for these HCT/Ps. We have added appropriate warning label requirements to § 1271.90.

(Comment 81) Several comments supported our proposal to recommend that the requirements for infectious disease testing be applied to HCT/Ps designated for autologous use. Two comments expressed concern that the recommendations in proposed § 1271.90(a) pertaining to reproductive tissue would have the same effect as requirements.

We recognize that a codified recommendation may carry more force than we intended. For this reason, although we recognize that many establishments will screen and test donors of autologous and reproductive HCT/Ps that fall within the exceptions in § 1271.90, and we believe there are valid reasons for doing so, we have deleted the recommendation from the codified section.

(Comment 82) One comment pointed out that the rules of safe laboratory operation dictate that laboratory personnel be informed of the risks in handling autologous donations. Another comment requested that we add to § 1271.90(b) the requirement that these HCT/Ps be handled as untested in accordance with § 1271.60.

Although we agree with the concerns expressed in the comments, we decline to amend § 1271.90(b) as suggested by the comments. The labeling required in § 1271.90(b) (e.g., "NOT EVALUATED FOR INFECTIOUS SUBSTANCES") should alert personnel to the risks of these HCT/Ps.

(Comment 83) One comment questioned whether proposed § 1271.90(a)(2) referred to semen, ova, and embryos.

(Response) Semen, ova, and embryos are examples of reproductive cells and tissues included in § 1271.90(a)(2).

(Comment 84) Two comments questioned how § 1271.90 would apply to individual semen donors who wish to cryopreserve their semen (e.g., cancer patients).

(Response) If the semen donor intends that the cryopreserved sperm be used with a sexually intimate partner, then § 1271.90 applies.

After reviewing these comments, we also realized that cryopreserved reproductive cells or tissue for autologous use or for use by a sexually intimate partner, originally exempted from the donor screening and testing requirements, could be subsequently used for directed donation. Therefore, we have added an exception to the rule to accommodate individuals whose reproductive options have been restricted due to health or infertility.

These individuals may not have undergone testing at the time of donation, because their intention at that time was autologous use or use in a sexually intimate partner. For various reasons, the donor(s) cannot make additional donations (e.g., the woman is post-menopausal or has her ovaries and uterus removed; the man has undergone chemotherapy, which renders him infertile.) To permit use of such cryopreserved cells or tissue for directed donation in situations where subsequent screening and testing is available, we have added § 1271.90(a)(3).

Section 1271.90(a)(3) states that cryopreserved cells or tissue for reproductive use, which were originally intended for autologous use, or use in a sexually intimate partner (and therefore the donor(s) were not tested at the time of donation) may subsequently be used for directed donation, provided that a donor cannot make additional donations of HCT/Ps due to infertility, or health; and appropriate measures are taken to screen and test the donor(s) before transfer to the recipient. The agency intends to address, in guidance, the appropriate methods for screening and testing donors in such circumstances to determine whether the HCT/Ps may carry communicable diseases.

An example is the situation in which a sexually intimate couple create embryos, some of which are cryopreserved. The donors were not screened and tested at the time of the donation. The woman subsequently has her ovaries and uterus surgically removed, due to cancer. The donor couple wishes to make a directed donation of the cryopreserved embryos to a recipient who is known to one or both of the donors prior to the donation. Under § 1271.90(a)(3), the embryos would be eligible for directed donation provided the couple can now be screened and tested.

(Comment 85) One comment opposed the exception in proposed § 1271.90 for sexually intimate reproductive tissue donors. The comment asserted that all reproductive tissue donors should be screened, because sexually intimate partners may have escaped exposure to each other's bodily fluids.

(Response) Although we agree that screening and testing may be appropriate for sexually intimate partners, and encourage establishments to perform screening and testing, we believe that this should be the responsibility of the attending physician, the donor, and the recipient.

*E. Economic Impacts*

(Comment 86) Five comments suggested that we significantly underestimated the rule's economic impact and that significant changes in the SOPs of all eye banks would be required.

(Response) We do not agree. Current industry standards meet or exceed most of the specifications of this final rule and industry consultants have indicated that compliance with these standards is nearly 100 percent. Based on this information, we do not believe that SOPs will need to be substantively changed as a result of this final rule. Furthermore, these comments did not provide any data that refute or would cause us to adjust our estimates of the economic impacts.

(Comment 87) One comment suggested that cost increases are not easily absorbed by the not-for-profit eye banking community, and that a rule could negatively affect the availability of and/or access to services.

(Response) We do not agree. Many similarities exist between the provisions of this final rule and current industry standards. Furthermore, our Analysis of Economic Impacts suggests only a minor compliance cost burden, which will not significantly affect the availability of and/or access to services.

(Comment 88) One comment suggested that user fees could potentially add to the rule's economic impact.

(Response) A user fee is not a component of this final rule.

(Comment 89) Two comments stated that the rule will impose compliance costs of $10,000 to $20,000 per average tissue and eye bank, and that the effects of the regulation on hospitals may push this figure higher.

We do not agree with these estimates of compliance costs. Furthermore, we are not able to address their validity as no information or data were provided to support them. We are also unable to address the rule's effects on hospitals as alluded to by the comments, because the comments did not provide any data that would allow us to evaluate the alleged effects.

(Comment 90) One comment objected to our $1.23 million estimate of average annual eye bank establishment income and noted that "* * * many U.S. eye banks operate within budgets that are <50% of that figure."

(Response) We realize that these figures may vary. Our average annual income estimate was intended to provide insight as to the financial burden of this rule for a representative establishment. Some establishments would be expected to have income greater than $1.23 million and others less than $1.23 million. While we recognize that the financial impact of regulations on small business entities is an important consideration under The Regulatory Flexibility Act, our analysis suggests this final rule will not have a significant economic impact.

(Comment 91) One comment objected to our estimate of the cost of testing tissue donors for syphilis, suggesting that such testing will cost $15 per donor and that testing 650 donors will increase costs by approximately $10,000.

(Response) We do not dispute these figures. However, there is no indication given in the comment as to whether this is a significant cost impact, and/or for which types of establishments (i.e., small versus large). These figures are accurate, but would be of greater value if presented in context, e.g., as a percentage of establishment revenues.

(Comment 92) One comment noted that there was no discussion of the costs of the forthcoming "good manufacturing practices" rule.

(Response) We believe the comment is referring to the compliance costs associated with the forthcoming CGTP rules, which are not a part of this final rule. We will include a full economic analysis of the forthcoming CGTPs when that final rule is published.

(Comment 93) Four comments objected to a quarantine requirement for donated oocytes and embryos. These comments suggested that this requirement is unnecessary and unacceptable due to the excessive burden placed on reproductive clinics, physicians, and patients.

(Response) The 6-month quarantine requirement for reproductive tissues now applies only to semen from anonymous donors, and not to oocytes or embryos.

(Comment 94) One comment suggested that testing and screening of oocyte and embryo donors would need to be repeated after a 6-month quarantine, resulting in additional costs.

(Response) This final rule does not require retesting of oocyte and embryo donors. Therefore, there is no need to include these costs in the economic analysis.

(Comment 95) One comment suggested that the private sector would have to spend more than $100 million per year to comply with this final rule, requiring a cost-benefit analysis.

(Response) We do not agree. Based on our analysis, the costs of complying with this final rule are far less than $100 million per year, and therefore a cost-benefit analysis is not required. Furthermore, no data were provided in the comment to support its estimate of compliance costs.

(Comment 96) Three comments objected to our estimate of the cost of

screening and testing oocyte donors and suggested that the actual cost is much higher.

(Response) We agree that this cost may be higher, and have revised our Analysis of Economic Impacts to reflect the most recent cost data available.

(Comment 97) One comment suggested that our estimate of the cost of a donor oocyte cycle is too low.

(Response) We realize that these figures may vary. However, comments from another ART facility indicate that our cost estimate for a donor oocyte cycle (originally obtained from a study published in the journal Fertility and Sterility) is reasonable (Ref. 26).

(Comment 98) One comment suggested that our estimate of the average revenue of ART centers was too high.

(Response) We do not agree. The comment assumes the cost of an IVF cycle is $10,000, whereas we assume the average cost of an ART cycle is $11,868, a more general and somewhat larger number. Furthermore, the comment presents a net average revenue estimate for ART facilities, after subtracting drug costs and oocyte retrieval fees. In the proposed rule, we present a gross average revenue estimate. It is therefore unclear that these estimates of average revenue can be meaningfully compared.

## IV. Analysis of Economic Impacts

FDA has examined the impacts of this final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and 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 Unfunded Mandates Reform Act requires that agencies prepare a written statement under section 202(a) 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 (adjusted annually for inflation) in any one year. The Regulatory Flexibility Act requires agencies to analyze whether a rule may have a significant economic impact on a substantial number of small entities and, if it does, to analyze regulatory options that would minimize the impact.

The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866. The Office of Management and Budget (OMB) has determined that this final rule is a significant regulatory action as defined by the Executive order, and so, is subject to review. Because the rule does not impose mandates on State, local, or tribal governments, or the private sector, that will result in an expenditure in any one year of $100 million or more, FDA is not required to perform a cost-benefit analysis according to the Unfunded Mandates Reform Act.

The Regulatory Flexibility Act requires agencies to prepare a Regulatory Flexibility Analysis for each rule unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. As explained in section IV.C of this document, the agency believes that most facilities would not be significantly affected by this final rule because they are already performing the infectious disease screening and testing and recordkeeping that is being required. However, FDA does not have sufficient data to fully characterize the size distribution and other relevant features of small entities, particularly those involved with reproductive HCT/Ps, and the impact on these entities is uncertain. The following analysis, along with this preamble, represents FDA's Final Regulatory Flexibility Analysis.

Based on the following economic analysis, FDA estimates that the total one-time costs to comply with this final rule will be between $0.4 and $2.1 million, and the annual or recurring costs will be between $1.8 and $3.5 million. These figures imply a total annualized cost estimate of between $1.9 and $3.8 million. The average annualized cost per affected entity, expressed as a percentage of average annual revenue, ranges from 0.003 to 0.35 percent. FDA has provided ranges of cost estimates to account for uncertainty with respect to both the number of entities affected, and the degree to which affected entities are already performing the activities required by this final rule.

### *A. Objectives and Basis of the Proposed Action*

FDA is publishing this final rule as the next step in establishing regulations for the rapidly evolving HCT/P industry. This final rule is needed to prevent unwitting use of contaminated tissues with the potential for transmitting infectious diseases, including HIV and hepatitis.

While acting to increase the safety of the nation's supply of HCT/Ps, FDA is implementing regulations in a way that will avoid unnecessary requirements. To minimize burdens while maintaining safety, the agency has designed the screening and testing provisions to vary with the specific type and use of each HCT/P. This regulatory action is focused on the prevention of disease transmission through implantation, transplantation, infusion, or transfer of any HCT/P. For example, FDA will now require cell and tissue donors to be tested for syphilis and screened for TSE. Donors of viable, leukocyte-rich cells or tissue will also be tested for HTLV types I and II, and CMV. Because communicable disease agents can be transmitted by semen and other genitourinary secretions, FDA is requiring that certain donors of reproductive cells and tissue be screened and tested for sexually transmitted diseases. FDA is also amending the existing CGMP regulations for drugs and QS regulations for medical devices to clarify the scope of the screening and testing requirements in part 1271, subpart C.

FDA's objectives and authority for issuing this final rule are described in detail in section II of this document. FDA is relying on the authority provided by section 361 of the PHS Act to issue regulations to prevent the spread of communicable disease, as well as its authority under the act to issue CGMP regulations for drugs (21 U.S.C. 351(a)(2)(B)). FDA has reviewed related Federal rules and has not identified any rules that duplicate, overlap, or conflict with this final rule.

This final rule provides oversight for the full spectrum of HCT/Ps that are now marketed and may be marketed in the future. This action will improve protection of the public health and increase public confidence in new technologies, while imposing a minimal regulatory burden. An important benefit of this final rule is that it will establish a consistent standard of safety for marginal firms not currently following voluntary industry standards and guidelines and help to ensure equivalent protection from transmissible diseases for all recipients of therapy involving HCT/Ps, regardless of the health condition for which they are being treated. This final rule will help minimize the risk to all HCT/P recipients of exposure to several life-threatening, in some cases incurable, diseases, including HIV, HBV, HCV, CJD, HTLV, CMV, and others. These risks will be minimized through validated screening procedures, lab tests, recordkeeping and adequate product labeling to avoid unwitting use of unsafe HCT/Ps.

*B. The Type and Number of Entities Affected*

This final rule requires manufacturers of HCT/Ps to screen and test the donors of cells and tissue used in those products. The rule requires that donors be screened and tested for risk factors for, and clinical evidence of, a relevant communicable disease agents and diseases. This final rule applies to a range of activities conducted at facilities such as conventional tissue banks, eye banks, semen banks, infertility treatment centers, and facilities processing hematopoietic stem/progenitor cells.

Information obtained under the registration final rule forms the basis for FDA's estimates of the number of affected eye banks and conventional tissue banks. The agency has not yet received all registration and listing information from reproductive tissue and hematopoietic stem/progenitor cells establishments, because registration and listing requirements for such establishments and products have not yet gone into effect. The agency's estimates of the number of affected eye banks, hematopoietic stem/progenitor cell facilities, semen banks and ART facilities rely heavily on information obtained from various professional organizations associated with the HCT/P industry. Where good statistical data are not available, FDA's estimates have incorporated the quantitative judgments of individual experts identified through contacts with HCT/P industry professional associations.

As presented in table 1 of this document, FDA has a record of 134 registered facilities listing eye tissue including 96 eye banks, 93 of which are currently accredited by EBAA. FDA also has a record of 166 registered tissue banks involved in the manufacture of other conventional HCT/Ps, e.g., pericardium, dura mater, heart valves, skin and bone allografts, fascia, tendons and ligaments (hereafter referred to as "conventional tissue banks"). The American Association of Tissue Banks (AATB) lists approximately 75 accredited tissue banks and projects an additional 40 to 60 members not accredited.

Facilities that produce hematopoietic stem/progenitor cell products from peripheral blood or umbilical cord blood will also be affected by this final rule. FDA finds that available data with which to estimate the number of peripheral blood stem/progenitor cell (PBSC) facilities and evaluate current practices are quite limited, and the actual number of PBSC facilities may range from 200 to 400. As of April 2002, CBER has a record of 178 voluntarily registered facilities listing "stem cell" as a type of product or establishment. The National Marrow Donor Program (NMDP), which includes establishments that recover PBSCs, lists approximately 92 donor centers and 113 collection centers. Approximately 150 facilities involved with PBSC production are currently accredited by AABB and an estimated 107 are accredited by the Foundation FACT. Industry sources estimate that approximately 80 of these facilities have or are seeking dual AABB/FACT accreditation, suggesting an unduplicated count of approximately 200 PBSC facilities assumed to be accredited by the AABB and/or FACT. However, the number and donor screening and testing practices of nonaccredited facilities are unknown. The International Bone Marrow Transplant Registry/Autologous Blood and Marrow Transplant Registry (IBMTR/ABMTR) estimates that the total number of blood or bone marrow facilities may be as high as 400 (e.g., 200 more than the number estimated to be accredited by AABB and/or FACT), but the number of IBMTR/ABMTR-estimated facilities that actually process peripheral blood (as opposed to bone marrow) is uncertain. For the purposes of this analysis, FDA has assumed that 400 peripheral blood stem/progenitor cell facilities will be affected by this final rule.

Although there is no single national organization that keeps track of the number of facilities for umbilical cord blood banking, FDA estimates that there are approximately 25 umbilical cord blood banks currently operating in the United States. These facilities may also seek accreditation through AABB or FACT. Based on this information, the agency estimates that a total of 425 establishments involved in manufacturing hematopoetic stem/progenitor cells would be affected by this rule.

In addition, 67 establishments produce licensed biological products or approved medical devices that are currently required to register under parts 207 and 807 (21 CFR parts 207 and 807) but would also be subject to the provisions of this final rule.

Finally, this final rule also applies to facilities involved with reproductive tissue, primarily semen banks and ART facilities that collect and process donor semen or donor oocytes. The American Society of Reproductive Medicine (ASRM) has a membership of approximately 400 fertility centers, 370 of which have provided reports to the 1999 Society for Assisted Reproductive Technology (SART) registry. The ASRM also has a 1996 list of approximately 110 semen banks operating in the United States. Although ASRM has published guidelines for donor screening and other aspects of oocyte donation, and for therapeutic donor insemination (TDI), ASRM does not exercise oversight or provide accreditation of facilities that collect donor reproductive tissue or use these tissue products in infertility treatment.

*C. Nature of the Impact*

This final rule includes requirements for donor screening, donor testing, recordkeeping, and quarantine of cells and tissue. Donor screening will involve the review of relevant medical records to include a medical history interview (particularly pertaining to communicable disease risk), a current report of a physical assessment for cadaveric donors, and a physical examination for living donors. For living, repeat anonymous semen donors, a complete donor-eligibility determination procedure will be required at least once every 6 months. This final rule requires that a donor specimen be tested for evidence of infection due to relevant communicable disease agents and diseases, with testing conducted within a specified time of recovery of cells or tissue. In general, a donor may be determined eligible if free from risk factors for, and clinical evidence of, infection due to relevant communicable disease agents and diseases, and if the required testing is negative or nonreactive.

This final rule also requires recordkeeping for donor-eligibility determinations. Manufacturers must ship HCT/Ps accompanied by documentation of donor eligibility status, including a summary of records that includes the results of the required testing and the name and address of the establishment that made the eligibility determination. This final rule also requires that HCT/Ps be quarantined until a donor-eligibility determination is made, and that products be clearly labeled as under quarantine during that period. Manufacturers are responsible for the appropriate labeling and documentation of HCT/Ps from a donor who is found to be ineligible.

The economic impact of these requirements is expected to be minor because the leading industry associations have already established standards for screening, testing and recordkeeping that, in most cases, meet or exceed the criteria specified in this final rule, and because existing FDA regulations already apply to certain HCT/Ps intended for transplantation (see part 1270). Table 1 of this

document lists the types of HCT/Ps that will be affected by this final rule and the associated establishments that manufacture these products. Table 1 also provides estimates of the number of establishments affected by this final rule and the estimated percentage of establishments believed to be following current industry standards for donor screening and testing. The lists of specific donor screening and testing requirements proposed by FDA can be compared with those currently required by the industry associations.

TABLE 1.—TYPE AND NUMBER OF ESTABLISHMENTS AFFECTED AND PERCENTAGE ALREADY IN COMPLIANCE WITH INDUSTRY STANDARDS FOR DONOR ELIGIBILITY SCREENING AND TESTING

| Type of Human Tissue | Type of Entities Affected (and Estimated Total Number) | FDA Regulatory Requirements Compared to Industry Standards | | Estimated Percent of Entities in Compliance With Industry Standards |
|---|---|---|---|---|
| | | FDA | Industry Standards | |
| NonreproductiveTissue | | | | |
| Eye tissue | 134 FDA registered eye tissue facilities, including 93 EBAA accredited eye banks (134 total) | 21 CFR part 1270 and (s1,s2,s3)[1] and (t1, t2, t3, t5)[2] | EBAA (s1 through s3)[1] and (t1 through t3)[2] | 100% |
| Pericardium, dura-mater, heart valves, skin allograft, bone allograft, other viable | 166 FDA registered tissue banks, including 75 AATB accredited tissue banks (166 total) | 21 CFR part 1270 and (s1 through s3)[1] and (t1, t2, t3, t5)[2] | AATB (s1 through s3)[1] and (t1 through t5)[2] | 100% |
| Stem progenitor cells; peripheral blood | 178 FDA registered facilities, 92 NMDP donor centers, and 113 NMDP collection centers (400 total) | (s1 through s3)[1] and (t1 through t6)[2] | AABB/FACT (s1 through s3)[1] and (t1 through t6)[2] | 100% |
| Stem progenitor cells; umbilical cord blood | Cord blood banks (25 total) | (s1 through s3)[1] and (t1 through t6)[2] | AABB/FACT (s1 through s3)[1] and (t1 through t6)[2] | 100% |
| Licensed biological products and approved medical devices | 67 FDA registered establishments (67 total) | Currently regulated under sections 351 and 361 of the PHS Act, 21 CFR parts 207 and 807 | | 100% compliance with 21 CFR parts 207 and 807 |
| Total | 792 Facilities | | | |
| ReproductiveTissue | | | | |
| Donor oocytes, embryos | 370 ART facilities and associate labsin the 1999 SART report (400 total) | (s1 through s3)[1] and (t1, t2, t3, t5)[2] | ASRM/CAP (s1)[1] and (t1,t2,t3,t5)[2] | Unknown |
| Donor semen | 4 Semen banks in 1996 AATB survey (110 total) | (s1 through s3)[1] and (t1 through t8)[2] | AATB (s1 through s3)[1] and (t1 through t8)[2] and ASRM (s1)[1] and (t1, t2, t3, t5, t7, t8)[2] | Unknown |
| Total | 510 Facilities | | | |

[1] Screening for: s1: HIV, s2: hepatitis, s3: CJD
[2] Laboratory Tests: t1: anti-HIV-1-2, t2: anti-HCV, t3: HBsAg, t4: anti-HTLV-I, t5: syphilis, t6: CMV, t7: *Neisseria gonorrhea*, t8: *Chlamydia trachomatis*

Based on communications with representatives of several industry associations and facility managers, FDA estimates that the number of facilities currently in compliance with industry standards for donor screening and testing approaches 100 percent for several affected types of HCT/Ps. Facilities handling reproductive tissue are the primary exception to this finding, and also represent the greatest area of uncertainty for this analysis. There is currently no single reliable source of information on fertility center or semen bank adherence to AATB standards or ASRM guidelines. A small percentage of semen banks are members of the AATB and are known to follow that organization's requirements for screening and testing, but little is known about the standards used at other facilities.

In addition to the required donor screening and testing, this final rule will require facility staff time to align current quarantine, labeling, and recordkeeping systems with the new requirements. As shown in table 2 of this document, all of the industry associations already specify requirements for these procedures. With the exception of facilities handling reproductive tissue, the current industry standards adopted by most facilities are at least as stringent as those included in this final rule.

TABLE 2.—CORRESPONDENCE OF FDA REQUIREMENTS TO CURRENT INDUSTRY STANDARDS FOR SPECIMEN QUARANTINE, LABELING, AND RECORD RETENTION

| FDA | AATB | EBAA | AABB | FACT | ASRM |
|---|---|---|---|---|---|
| Quarantine | X1 | X1 | X1 | X1 | X1 |
| Labeling | X1 | X1 | X1 | X1 | X1 |
| Record Retention | X1 | X1 | X1 | X1 | Recommended; not required |

[1] X means corresponds.

Due to the disparity in the amount of available information and the potential impact of the rule on nonreproductive versus reproductive tissue establishments, these two broad categories of tissue establishments are treated separately in the cost impact analysis that follows.

1. Impact on Nonreproductive Tissue Establishments

a. *Impact of donor screening and testing.* As summarized in table 1 of this document, most nonreproductive tissue establishments are believed to be already in compliance with FDA's new donor screening and testing requirements, as a result of following their own industry association standards and current FDA regulations. Therefore, the cost of compliance with these provisions will be minimal for these establishments.

b. *Impact of recordkeeping and tissue quarantine.* The burden of recordkeeping and tissue quarantine requirements will reflect the staff time needed to compare current recordkeeping and facility procedures with those required under the new standards and to make modifications where needed in current facility SOPs related to these activities. Such changes are expected to be minor for most nonreproductive tissue establishments.

In the proposed rule, FDA estimated that it would take approximately 8 to 40 hours to compare the new regulations against a facility's current SOPs and make any necessary modifications. Since we received no comments from affected entities, we have retained this assumption. This process will be performed by a staff person who acts as a regulatory reviewer, a supervisor, or a manager of quality assurance. Assuming a labor cost of $40 per hour (Ref. 23), this standards reconciliation effort will result in a one-time cost per facility ranging from $320 to $1,600. Applying this range of cost per facility to the approximately 792 nonreproductive tissue facilities yields an impact that ranges from $253,440 (= $320 x 792) to $1,267,200 (= $1,600 x 792).

2. Impact on Reproductive Tissue Establishments

a. *Impact of donor screening and testing.* As indicated in table 1 of this document, the number of reproductive tissue facilities currently following industry standards is unknown. Thus, FDA cannot develop a precise estimate of regulatory costs. To generate an upper bound cost estimate, however, FDA assumed that 100 percent of facilities involved with oocyte donation and 80 percent of semen banks would need to perform additional screening and testing. Although semen banks not currently following voluntary industry standards constitute a majority of the firms in that industry, they are primarily small operations that are estimated to serve only 5 percent of all semen donors.

i. *Oocyte donor screening and testing.* The estimated impact of this final rule on establishments involved in oocyte donation is based on 1999 data reported by SART, an organization of assisted reproductive technology providers affiliated with ASRM. In 1999, donor oocytes were used in approximately 10.4 percent of the 86,822 ART cycles reported, or 9,066 cycles (Ref. 4). FDA believes that all infertility treatment centers already conduct medical exams and history taking and perform some laboratory testing before oocyte retrieval for any potential donor. Compliance with this final rule, however, may entail further blood testing and adding some additional screening questions to the interview.

The cost of additional blood work (including HIV 2, HTLV I and II, and CMV IgG and IgM) is estimated at approximately $238.40 per donor (Ref. 22). The additional time to interview and record information in donor screening is estimated to cost about $37, based on the assumption that approximately half of the required screening is already being done, and that the estimated cost of a full health history interview is $75 ($37 = $75/2) (Ref. 6). Thus, the additional cost per oocyte donation is estimated at $275.40 ($238.40 + $37). Based on a reported (average) cost estimate of $13,500 (Ref. 22) per donor oocyte cycle, this translates into a 2.04 percent increase ($275.40/$13,500) in the average cost of therapy per cycle.

The cost of screening and testing oocyte donors will depend on the number of donor cycles attributable to each screened donor. If each donor contributes oocytes for only one cycle, and the rejection rate is low (assumed to be 0.57 percent, which is the estimated prevalence rate of HBsAg positivity among parturient women) (Ref. 7), the number of donors to be tested would be 9,118 (9,066/(1–0.0057)). If each donor contributes oocytes for two donor cycles, the number of donors to be screened would be 4,559. These alternative assumptions imply a total cost to U.S. facilities involved in oocyte donation of from $1,255,549 to $2,511,097 per year, as shown in table 3 of this document.

TABLE 3.—ALTERNATIVE OOCYTE DONATION SCENARIOS AND ASSOCIATED DONOR SCREENING AND TESTING COSTS

| Screening and Testing Cost per Donor | 2 ART Cycles per Donor = 4,559 Donors | 1 ART Cycle per Donor = 9,118 Donors |
|---|---|---|
| $275.40 | $1.26 million[1] | $2.5 million[2] |

[1] $275.40 x 4,559 = $1,255,549
[2] $275.40 x 9,118 = $2,511,097

FDA believes that much of the additional screening and testing identified in table 3 of this document is already being performed by ART clinics. Therefore, these estimates should be viewed as maximum expected cost burdens. Furthermore, certain methods of donor oocyte recovery, e.g., laparoscopy, are not directly connected with the transmission of sexually transmitted and genitourinary diseases and, therefore, testing for *Neisseria gonorrhea* and *Chlamydia trachomatis* would not be required under this final rule. Use of such methods would be

expected to lower the estimated testing costs by approximately $40 per oocyte donor.

ii. *Semen donor screening and testing.* The agency has conducted an extensive search for current information on the extent of infectious disease screening for semen donors, but has found little information available. The Congressional Office of Technology Assessment (OTA) conducted a survey of establishments involved in semen donation in 1987, and found that all commercial banks surveyed performed routine screening and testing for HIV, but only 45 percent of private physicians included this screening. The most recent available data includes a list of approximately 110 commercial semen banks developed by ASRM in 1996, and a 1996 registration survey of the AATB that includes data for 4 semen banks. Some semen banks that have applied, but are not yet accredited members of AATB, are nonetheless following AATB standards. It is also likely that some other facilities have informally adopted AATB standards. This analysis assumes that all semen banks currently perform HIV screening and testing, as reported by OTA in 1987, and that a smaller percentage of facilities additionally follow all AATB screening and testing standards.

Based on conversations with semen banking industry experts, FDA estimates that the 20 largest semen banks account for approximately 95 percent of the commercial production of donor semen, and are following AATB standards for donor screening and testing. The agency analysis therefore assumes that the 20 largest facilities will experience minimal impact, while the remaining 90 facilities, which account for approximately 5 percent of total industry production, will be more significantly affected. These very small semen banks are described by an industry expert as typically functioning within a physician office practice (e.g., that of an obstetrician or gynecologist). The semen banking in these facilities is generally offered as an additional service to patients receiving fertility treatment, and is not the primary line of business within these establishments.

The total estimated cost of the proposed screening and testing requirements for semen banking facilities is based on the number of semen donors who would require screening and testing, and their respective unit costs. Due to the lack of data on the actual number of semen donors, the agency estimated the number based on projected TDI demand. The level of TDI demand has likely decreased over time, with advances in treatment for male factor infertility. For example, the development of intracytoplasmic sperm injection (ICSI) used in conjunction with in vitro fertilization (IVF) has enabled some couples to forego TDI in favor of ICSI using the male partner's sperm (Ref. 8). In 1985, an estimated 70,000 women per year received TDI (Ref. 9), compared to an estimated 171,000 women who reported ever receiving artificial insemination with donor semen in the National Survey of Family Growth (NSFG) conducted in 1995. If the NSFG respondents referred only to experience over the past 5 years, this would translate to approximately 34,200 women receiving TDI per year. Assuming an average of three cycles of therapy per patient per year, these data yield an estimated demand for TDI donor units of approximately 102,600 units per year. This figure is consistent with an industry expert estimate of current U.S. TDI production of 100,000 units per year.

The clinical literature indicates that most semen donor attrition occurs before the blood testing stage of the donor-eligibility determination. For example, in one study of donor recruitment in which the clinic followed AATB and ASRM standards, of the total of 199 potential donors initially recruited, 174 were rejected; 172 of whom were rejected before blood testing, with only 2 (1 percent) rejected based on the blood test results (Ref. 10). For the purposes of this analysis, the agency assumes that the number of donors who will require infectious disease testing is approximately equal to the number of donors needed to supply the level of demand for TDI. Thus, FDA's estimate is based on the previous TDI unit demand combined with the maximum number of births per donor suggested in ASRM guidelines (Ref. 11), the average delivery rate per cycle of intrauterine insemination, an assumed 10 donated specimens per donor per year, and 4 donation units per donor specimen (Ref. 12). These factors yield an estimated 2,565 donors required per year. Assuming that the number of donors already screened and tested is proportionate to the volume of production accounted for by facilities compliant with AATB standards, FDA estimates that approximately 5 percent of all donors, or 128 donors per year (128 = 0.05 x 2,565), may need to be newly screened and tested to meet the requirements of this final rule.

The screening cost per semen donor is assumed to include an initial medical history and physical, a 6-month followup exam, and an abbreviated screening at the time of each donation. Based on rates published on the Internet (Ref. 6), the agency estimates that a full medical exam costs $175, a less extensive followup exam will cost approximately $75 (a published fee for a health history review), and the abbreviated screening at the time of each donation will cost approximately $15 (i.e., one-fifth of the time required for a full history review). One repeat donor visit per year is assumed. Thus, the total cost of this screening is estimated to be $265 per year per donor.

The lab tests for prospective semen donors include those listed in table 1 of this document, with 6-month followup blood tests. The cost of additional testing, based on screening test fees published on the Internet (Ref. 5), is $230.16 for initial complete blood testing, plus $123.40 for followup blood testing after a 6-month quarantine period, plus $113.30 for bacterial testing. Thus, the total cost of the additional lab work is estimated to be $467 per donor per year ($230.16 + $123.40 + $113.30 = $466.86). Because these estimates are based on charges to facility clients, they are likely to represent an upper bound on actual facility costs. Using these figures, the estimated total industry cost per year is approximately $94,000 (128 x ($265 + $467) = $93,696).

b. *Impact of donor recordkeeping and tissue quarantine.* The impact of recordkeeping and tissue quarantine requirements for reproductive tissue establishments will reflect the staff time required for the following: (1) A one-time review and modification of current SOPs to bring them into alignment with the new standards, and (2) ongoing, expanded practices for each donor who undergoes screening and testing to meet the requirements of this final rule.

In the proposed rule, FDA estimated that the one-time review and alignment of current facility SOPs will require approximately 8 to 40 hours at each facility. Since we received no comments from affected entities, we have retained this assumption. As with nonreproductive tissue facilities, this process would be performed by a regulatory affairs analyst, a supervisor, or a manager of quality assurance. Assuming a labor cost of $40 per hour (Ref. 23), this standards reconciliation effort would result in a one-time cost per facility ranging from $320 to $1,600. Applying this range of cost per facility to the 400 ART clinics and 110 semen banks yields a potential one-time cost for all reproductive tissue facilities that ranges from $163,200 ($320 x (400 + 110)) to $816,000 ($1,600 x (400 + 110)).

The estimated cost of the recurring requirements for tissue quarantine,

labeling, recordkeeping and record retention at reproductive tissue facilities are based on the estimated staff time needed to create and retain records of medical history, screening information and lab testing for each prospective donor from whom specimens are collected. These records must comply with the requirements of this final rule and are estimated to require approximately 4 hours per donor per year of clerical staff time. Assuming a labor cost of $24 per hour (Ref. 24) for clerical staff time implies a cost of $96 per donor per year. Table 4 of this document summarizes the potential range of recurring costs for all reproductive tissue facilities. As shown in table 4 of this document, the estimated costs range from approximately $450,000 to $888,000, depending on the assumed number of oocyte donors.

TABLE 4.—RANGE OF RECURRING COSTS FOR REPRODUCTIVE TISSUE

| | |
|---|---|
| 128 semen donors and 4,559 oocyte donors (2 ART cycles per donor) | $449,952[1] |
| 128 semen donors and 9,118 oocyte donors (1 ART cycle per donor) | $887,616[2] |

[1] $449,952 = (128 + 4,559) x $96
[2] $887,616 = (128 + 9,118) x $96

The range of these estimates reflects the agency's current lack of information about typical donor practices for ART facilities. If a higher rate of donation per donor is typically achieved by facilities compared to that assumed in this analysis, the cost burden may be much lower than these estimates would indicate. More generally, if the current level of facility donor screening, testing and recordkeeping is more stringent among reproductive tissue facilities than assumed in this analysis, the overall cost of compliance with this final rule will also be lower than these estimates suggest.

Uncertainty about current practices results in range estimates of the cost impact of this final rule. However, because facilities in most HCT/P industry sectors already follow voluntary industry standards requiring donor screening and testing, the overall impact is expected to be minor. Tables 5 and 6 of this document provide a summary of the expected cost impacts across the different industry sectors included in the analysis. Table 5 of this document presents costs annualized at 7 percent interest over 10 years, whereas table 6 of this document presents annualized costs for the same time period using a 3 percent interest rate. The total annualized cost for the 792 nonreproductive tissue facilities is estimated to range from $30,000 to $180,000, reflecting agency uncertainty about the extent of effort necessary for a one-time review and alignment of existing SOPs with the donor screening and testing provisions of this final rule. This translates into an average annualized cost of $38 ($30,000/792) to $228 (180,000/792) per facility.

The total annualized cost of compliance for the ART industry ranges from approximately $1.71 to $3.5 million, reflecting uncertainty about the number of oocyte donors, the number of ART cycles per donor per year and current screening, testing and recordkeeping practices. These costs translate into an average annualized cost of approximately $4,270 ($1.708 million/400) to $8,693 ($3.5 million/400) per facility. In general, assumed higher rates of donation per donor, or a lower number of total donor cycles per year, will result in lower industry costs. Similarly, lower rates of donation per donor, or a greater number of total donor cycles per year, will result in higher industry compliance costs.

The total annualized cost impact on the semen banking industry is based on an estimated TDI demand of approximately 103 thousand units per year, and assumed current compliance of the top 20 commercial banks which account for approximately 95 percent of industry production. The total annualized costs range from approximately $110,000 to $131,000. These industry totals yield an average annualized cost range of $1,222 ($110,000/(110–20)) to $1,456 ($131,000/(110–20)) per facility currently noncompliant with this final rule.

TABLE 5.—SUMMARY TABLE OF DONOR ELIGIBILITY COST ANALYSIS AT 7 PERCENT INTEREST OVER 10 YEARS[1]

| Type of Facility | Total One-time Cost | Total Recurring Cost | Total Annualized Cost |
|---|---|---|---|
| NonreproductiveTissue | | | |
| (a) Donor screening and testing | Minimal | Minimal | Minimal |
| (b) Recordkeeping and quarantine | $253 to $1,267 | Minimal | $36 to $180 |
| Reproductive Tissue, ART Facilities | | | |
| (a) Donor screening and testing | Minimal | $1,255 to $2,511 | $1,255 to $2,511 |
| (b) Recordkeeping and quarantine | $128 to $640 | $438 to $875 | $456 to $966 |
| ART subtotal | $128 to $640 | $1,693 to $3,386 | $1,711 to $3,477 |
| Reproductive Tissue, Semen banks | | | |
| (a) Donor screening and testing | Minimal | $94 | $94 |
| (b) Recordkeeping and quarantine | $35 to $176 | $12 | $17 to $37 |
| Semen subtotal | $35 to $176 | $106 | $111 to $131 |
| Total Tissue Industry | $416 to $2,083 | $1,799 to $3,492 | $1,858 to $3,788 |

[1] All figures in thousands of dollars.

TABLE 6.—SUMMARY TABLE OF DONOR ELIGIBILITY COST ANALYSIS AT 3 PERCENT INTEREST OVER 10 YEARS[1]

| Type of Facility | Total One-Time Cost | Total Recurring Cost | Total Annualized Cost |
|---|---|---|---|
| Nonreproductive Tissue | | | |
| (a) Donor screening and testing<br>(b) Recordkeeping and quarantine | Minimal<br>$253 to $1,267 | Minimal<br>Minimal | Minimal<br>$30 to $149 |
| Reproductive Tissue, ART Facilities | | | |
| (a) Donor screening and testing<br>(b) Recordkeeping and quarantine | Minimal<br>$128 to $640 | $1,255 to $2,511<br>$438 to $875 | $1,255 to $2,511<br>$453 to $950 |
| ART subtotal | $128 to $640 | $1,693 to $3,386 | $1,708 to $3,461 |
| Reproductive Tissue, Semen banks | | | |
| (a) Donor screening and testing<br>(b) Recordkeeping and quarantine | Minimal<br>$35 to $176 | $94<br>$12 | $94<br>$16 to $33 |
| Semen subtotal | $35 to $176 | $106 | $110 to $127 |
| Total Tissue Industry | $416 to $2,083 | $1,799 to $3,492 | $1,848 to $3,737 |

[1] All figures in thousands of dollars.

*D. Benefits of the Final Rule*

The risks of disease transmission vary by type of HCT/P. Thus donor screening, testing, and other measures to reduce the risks of transmission for various types of tissue will correspondingly yield a different relative reduction in disease risk. For example, expansion of blood donor screening and improved laboratory testing has dramatically reduced the risk of blood transfusion-transmitted disease. The risk of HIV infection has dropped from a reported 1 in 100 units in some U.S. cities to approximately 1 in 1,930,000 units. The risk of transmission of HBV has been reduced from 1 in 2,100 to 1 in 137,000 units, and the transmission risk for HCV has been lowered from 1 in 200 units in the early 1980s to the current level of 1 in 1,000,000 units (Ref. 25). The levels of risk reduction associated with blood donation offer an illustration of the kind of improvements in safety that might be achieved through improved and expanded screening and testing of HCT/P donors.

As described earlier in this document, most nonreproductive tissue establishments are assumed to be already compliant with this final rule and, therefore, have already achieved much of the potential risk reduction. However, some reduction in communicable disease transmission risk may still be realized under this final rule for firms that are not currently in compliance with the voluntary standards established by their respective professional associations. The discussion of benefits resulting from this final rule will focus on some key areas of risk and the potential benefit of the new requirements for reproductive tissue recipients. The discussion that follows will consider the risks of transmission of disease that will be reduced through expanded screening and testing among reproductive tissue donors, focusing on two life threatening chronic diseases that can be transmitted through donor tissue: HBV and HCV.

The expansion of screening among reproductive tissue donors is expected to produce important reductions in the risk of disease transmission, as evidenced by the apparent reductions in HIV risk that have already been achieved through screening. The risk of HIV transmission through TDI appears to be very low since screening for HIV was recommended by CDC in 1985. A total of six documented and two possible cases have been reported to the CDC as of December 1996 (Ref. 9).

The risks of transmitting HBV and HCV through reproductive tissue might also be substantially reduced as a result of donor screening, based on the significance of self-reported risk factors as predictors of the findings of blood screening for HBV and HCV (Refs. 13 and 14). Compared to HCV, HBV presents a greater risk of sexual transmission. In 1991, heterosexual activity was reported to account for 41 percent of all cases of HBV (Ref. 15). HBV transmission has also been reported by way of TDI. In 1982, a physician used semen from an unscreened donor (later found to be carrying HBsAg) to inseminate several women, one of whom later developed HBV (Ref. 16).

HBV-infected mothers can transmit the disease to their infants. Forty-two percent of infants born to women with HBsAg positivity (adjusted for HBeAg status) are at risk of HBV infection, and an additional 30 percent of infants born to HBsAg positive mothers become infected between 1 and 5 years of age. Prospective studies of infected infants and young children indicate that 25 percent will die from primary hepatocellular carcinoma (PHC) or cirrhosis as adults. The lifetime medical cost per case of PHC and cirrhosis is estimated to be $96,500 (Ref. 17). An analysis of the cost-effectiveness of prenatal screening and testing of mothers, with vaccination for positive screens, estimates that such screening and intervention would prevent 69 percent of the chronic HBV infections acquired perinatally or later in life (Ref. 18). This rate of effectiveness may provide an indication of the potential benefit of HBV screening required by this final rule.

The risk of transmission is estimated to be lower for HCV, compared to HBV. The CDC estimates the rate of sexual transmission between female to male partners, and the rate of transmission from mother to child, to each be approximately 5 percent. However, there is no vaccine intervention available for HCV, although interferon-alpha therapy has been found effective in eliminating the virus for at least some patients, and drug combinations (e.g.,

Interferon and Ribavirin) have been found to be even more effective. Although most patients infected with HCV are relatively healthy during most of their lives, an estimated 30 percent of those infected will eventually die of liver-related causes; an estimated 8,000 patients per year (Ref. 17). The average cost of care per year for persons with liver disease from chronic HCV is estimated to range from $24,600 for patients without interferon-alpha therapy to $26,500 per year for those receiving a 12-month course of therapy. The latter is estimated to provide patients with an additional 0.37 quality-adjusted life-years (QALYs) (Ref. 18).

Screening reproductive tissue donors is expected to significantly reduce the excess morbidity and mortality associated with HBV and HCV. As noted previously in this document, there are an estimated 4,559 to 9,118 oocyte donors and 2,565 semen donors per year. If these populations experience recently reported prevalence rates for HCV (1.8 percent) and HBV (4.9 percent) (Refs. 13 and 14), then screening for significant risk factors and disease markers will result in reduced HBV and HCV exposures for the patient population at risk. The population at risk each year is estimated to include 3,022 to 9,066 women undergoing IVF with donor eggs, and 2,285 newborns delivered as a result of this therapy[1]; and 34,200 to 70,000 women receiving TDI, and 8,800 newborns delivered as a result of that therapy.

*E. Small Entity Impacts and Analysis of Alternatives*

Based on its analysis, FDA found that a substantial number of the establishments required to comply with this final rule may be small business entities. The Small Business Administration defines a small business in this industry sector (NAICS code 621991, Blood and Organ Banks) to be an establishment with $8.5 million or less in annual receipts (Ref. 19). The economic impact analysis presented in section IV.C of this document includes estimates of the number of entities to which this final rule will apply. Each sector of the tissue banking industry includes some facilities that would be classified as small business entities.

A 1995 study of conventional tissue banks (Ref. 20) reports average annual revenues of $1.23 million per facility, which translates into $1.45 million per facility (in 2002 dollars) based on inflation data reported by the Bureau of Labor Statistics. Most nonreproductive tissue facilities are assumed to have a comparable level of average revenues. Reproductive tissue industry experts estimate that 65 percent of ART facilities have average revenues of approximately $2.5 million per year and the remaining 35 percent have average revenues of $11.5 million per year. Industry experts also estimate that 19 of the 20 largest semen banks have average annual revenues of approximately $2 million per year, and 1 of the 20 largest facilities has annual revenues greater than $8.5 million. Thus, the vast majority of facilities in each HCT/P industry sector are small entities. Nevertheless, as noted in the preceding cost analysis, most of these facilities will not be significantly impacted by this final rule because they are already meeting the infectious disease screening and testing and recordkeeping requirements.

Table 7 of this document presents estimates of the average annualized cost per affected small facility expressed as a percentage of average annual revenues. In addition to facility revenues, table 7 presents the estimated annual revenue for physician-owned obstetrician/gynecologist (ob/gyn) practices, because some operate a small donor semen bank as an additional service to patients, but may not currently comply with all of the requirements of this final rule. The average annual practice revenue per self-employed physician in the ob/gyn specialty category was reported as $627,000 in 1998 (Ref. 21). This translates into $692,000 (in 2002 dollars) based on inflation data reported by the Bureau of Labor Statistics.

TABLE 7.—ESTIMATED ANNUALIZED COST PER FACILITY AS A PERCENTAGE OF ESTIMATED ANNUAL REVENUE

| Number of Facilities That May Be Classified as Small Entities | Average Annualized Cost per Facility | Average Annual Revenue per Facility | Annualized Cost as Percentage of Annual Revenue |
|---|---|---|---|
| Nonreproductive Tissue | | | |
| 792 (all potentially small entities) | $38 to $228 | $1.45 million | 0.003 to 0.016% |
| Reproductive Tissue, ART Facilities | | | |
| 260 (65% of 400 facilities) | $4,270 to $8,694 | $2.5 million | 0.17 to 0.35% |
| Reproductive Tissue, Semen banks | | | |
| 19 small commercial banks | $1,222 to $1,456 | $2.0 million | 0.06 to 0.07% |
| 90 small physician practice-based banks | $1,222 to $1,456 | $692,000 | 0.18 to 0.21% |

As noted in table 7 of this document, the greatest expected cost will be incurred by facilities involved with reproductive tissue. Nevertheless, the estimated impact on most small facilities does not appear to be significant. The expected cost burden per facility ranges up to 0.35 percent of average annual revenues. However, if current practices actually involve a much lower level of infectious disease screening and testing than assumed in this analysis, the impact of the new requirements would be greater than expected.

Although this final rule will impose some costs on small entities involved in the manufacture of HCT/Ps, the agency believes that this approach represents an effective means of protecting patient safety and public health. The less burdensome alternatives to this final rule involve fewer requirements for small entities (the vast majority of facilities in the HCT/P industry), but fail to provide fundamental assurances of product safety. For example, reliance on

[1] The range of 3,022 to 9,066 patients is based on a reported 9,066 ART cycles using donor oocytes reported for 1999, varying the assumed number of cycles per patient. The number of newborns is based on an average success rate of 25.2 percent (live births per ART cycle).

published FDA guidance for donor eligibility determination, rather than establishing a regulatory requirement, would provide the agency with no basis for ensuring compliance. Thus, agency guidance may have no greater influence than current voluntary industry standards, which have similar provisions, but have failed to persuade all facilities to adopt comprehensive screening and testing practices. FDA's guidance, alone, therefore, would not be expected to provide adequate protection from the public health risks associated with infected donor-derived HCT/Ps.

Another alternative would involve waiving some of the donor screening and testing requirements for small facilities. However, as noted previously, the vast majority of facilities in this industry are small. Moreover, this alternative would increase the safety risks associated with HCT/Ps if small facilities that currently screen and test donors on a voluntary basis choose to discontinue this practice due to an FDA-granted waiver. For example, waiving a requirement for donor screening would eliminate an extremely cost-effective first-tier level of safety protection because prospective donors deferred or disqualified at this stage need not undergo further testing. Similarly, waiving the requirements for blood testing would expose patients, as well as tissue facility medical staff, to avoidable risks of infectious disease that may be undocumented in a patient's medical history, or be unknown to, or not mentioned by the living donor or cadaveric donor's family during screening.

We also considered waiving the requirement for semen quarantine and anonymous donor retesting to detect infections during the window period, when a donor's infection may not yet be detectable by blood tests. However, this alternative would expose recipients and the public to risks from infectious disease agents that cannot be immediately detected after exposure through most currently available blood tests (e.g., tests for HIV and HCV). Recordkeeping for donor screening and testing is also critical to protecting product recipient and public safety. Adequate documentation and record retention ensure that HCT/Ps can be tracked to their source in the event of infection or other adverse reactions that result from donor tissue characteristics.

In summary, the agency believes that abridged requirements for donor screening and testing, based on voluntary standards or facility size criteria, would provide inadequate protection against the risk of infectious disease transmission through HCT/Ps. Most notably, the absence of regulation allows reproductive tissue facilities to omit the screening and testing of donors that is routinely performed for other types of HCT/Ps, thus exposing patients undergoing infertility treatment to a disproportionate risk of exposure to several life-threatening infectious disease agents.

To help alleviate the impact on small entities while still protecting public health, the agency is not requiring that manufacturers follow screening and testing procedures when an HCT/P is used in the same person from whom it is obtained, or in a sexually intimate partner of a reproductive tissue donor. The agency believes the risk of disease transmission from such activities is minimal. Further, in the case of reproductive HCT/Ps, the 6-month quarantine requirement applies only to semen from anonymous donors and not to oocytes and embryos.

As part of the development process for this final rule, FDA conducted an extensive outreach program in an effort to inform affected small entities and to request input regarding the potential economic impact. Representatives from CBER have given presentations on HCT/P donor eligibility related issues at the annual conferences of many of the professional associations representing affected entities including ASRM, AATB, EBAA, and others. The agency has also engaged in outreach activities directed toward interested consumer groups such as RESOLVE and the American Infertility Association. At their request, FDA also held individual meetings with groups such as ASRM, EBAA and AATB to discuss specific concerns regarding the impact of the donor eligibility rule. Some of these presentation materials and meeting minutes are available on the CBER Web page at *http://www.fda.gov/cber/tissue/min.htm*. Additional materials associated with the donor eligibility rule are available on the Internet at *http://www.fda.gov/cber/tissue/docs.htm*. Finally, in the proposed rule, FDA requested industry comment regarding the assumptions upon which this analysis of economic impacts was based. In particular, we requested detailed industry comment regarding our estimates of the number and type of entities affected, current donor screening and testing practices, and expected compliance costs. To the extent possible and appropriate, we have incorporated these comments and our responses into the preamble and analysis of economic impacts of this final rule.

Under this final rule, small entities involved with reproductive tissue must meet the same safety and quality standards as large reproductive tissue facilities and other HCT/P manufacturers. The specific requirements for donor screening and testing, the required recordkeeping, and the required types of professional skills are described in the economic analysis provided previously. This analysis includes an accounting of all major cost factors, with the exception of the reduced potential liability currently encountered by those reproductive tissue facilities that fail to provide the level of protection from infectious disease that is considered a standard of good practice in other sectors of the HCT/P industry. The relevant Federal rules that are related to this final rule are discussed in section II of this document. This economic analysis provides a summary of the voluntary industry standards that overlap this final Federal standard, but as discussed, there is no current regulation of HCT/Ps that will duplicate this final rule. Consequently, FDA finds that this final rule will enhance both public health and public confidence in the safety and utility of HCT/Ps, while imposing only a minimum burden on the affected industry sectors.

### V. Environmental Impact

The agency has determined under 21 CFR 25.30(h) and (j) that this action is of a type that is categorically excluded from the preparation of an environmental assessment because these actions, as a class, will not result in the production or distribution of any substance and therefore will not result in the production of any substance into the environment.

### VI. Federalism Assessment

Executive Order 13132, dated August 4, 1999, establishes the procedure that Federal agencies must follow when formulating and implementing policies that have federalism implications. The Executive order described nine fundamental federalism principles, stressing the importance and sovereignty of State and local governments, and the contributions of individual States and communities to the development of enlightened public policy. Principles of federalism are inherent in the very structure of the Constitution and formalized in and protected by the Tenth Amendment. Regulations have federalism implications whenever they 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. Whenever a regulation has this result, the agency must prepare a federalism assessment.

The Executive order directs Federal agencies to:

1. Encourage States to develop their own policies to achieve program objectives and to work with appropriate officials in other States;

2. Where possible, defer to the States to establish standards;

3. In determining whether to establish uniform national standards, consult with appropriate State and local officials as to the need for national standards and any alternatives that would limit the scope of national standards or otherwise preserve State prerogatives and authority; and

4. Where national standards are required by Federal statutes, consult with appropriate State and local officials in developing those standards.

This final rule establishes donor-eligibility and other related requirements for HCT/P establishments. In issuing this rule, we rely on the authority of section 361 of the PHS Act (42 U.S.C. 264), under which we may make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States or from foreign countries into the States. (We also rely on our authority to issue CGMP regulations to amend the existing CGMP regulations for drugs in 21 CFR parts 210 and 211, which include CGMP requirements, to incorporate the testing and screening provisions of part 1271 subpart C for HCT/Ps regulated as drugs, and/or biological products (see e.g., 21 U.S.C. 351(a)(2)(B)).

The donor-eligibility proposed rule was published after Executive Order 13132 was issued, but before it went into effect. Nevertheless, we made a considerable effort after the publication of the proposed rule to ensure that States had the opportunity to review the proposed rule and submit comments on it. We directed a mailing of the proposed rule to State health officials to encourage their comments on the proposed rule. We also sent copies of the rule to each State attorney general. To provide additional time to the States to comment on the proposed rule, we reopened the comment period.

In the **Federal Register** document reopening the comment period, we noted that we had learned that several States had enacted legislation and issued regulations governing tissue donor suitability (65 FR 20774, April 18, 2000). Because those laws might conflict with provisions in the proposed rule, we invited State officials to participate in the rulemaking. We specifically noted that we would appreciate comment on the following topics: (1) The need for uniform national standards for donor suitability determinations to prevent communicable disease transmission through human cellular and tissue-based products, (2) the scope of such proposed national requirements and their impact upon State laws, (3) FDA's proposal not to preempt State laws on legislative consent for cornea transplants, and (4) any issues raised by this proposed rule possibly affecting State laws and authorities.

We received only one comment from a State official. This comment addressed abbreviated screening, which is discussed in comment 50 of this document. The comment also asked that we require deferral records for donors determined to be unsuitable. Reviewing deferral records before each donation would only be necessary in the case of living donors who could donate more than once, such as semen donors. As part of the screening process in § 1271.75, establishments determining donor eligibility are required to review the donor's relevant medical records, which would identify the donor as an unsuitable donor. Therefore, we believe that requiring deferral records would be burdensome. We received no comments from State officials on federalism issues.

To the extent that these final regulations cover areas that are already subject to Federal regulation, rather than regulation by the States, we believe the federalism implications of this final rule are minimal or nonexistent, because national standards are already in place. Since 1993, there have been Federal regulations on human tissue intended for transplantation. These regulations, contained in part 1270 (21 CFR part 1270), govern donor screening, testing, and other related issues. The regulations now being made final replace the regulations in part 1270. Although the new donor-eligibility regulations are more extensive in their requirements, and apply to a greater range of HCT/Ps, many of the establishments that will be required to comply with this final rule have been subject to the regulations in part 1270 or to drug or device regulations.

However, we acknowledge that this final rule will have an effect in those areas where there has been no uniform Federal regulation. For example, this rule sets out testing and screening requirements for donors of reproductive cells and tissue, an area where there is a range of State regulation. Some of the State statutes and regulations that have come to our attention focus on the risk of HIV transmission through semen donation and are thus more limited in their requirements than this final rule, which requires testing and screening for additional communicable disease agents and diseases and does not apply only to semen (see e.g., Ind. Code 16–41–14–7; Md. Code Ann., Health-Gen. 18–334(e); 12 Va. Admin. Code 5–90–240, 5–90–250).

Directed donation of reproductive cells or tissue is another area of potential differences between State laws and regulations and this final rule, which permits the use of fresh semen from directed reproductive donors without retesting of the donor 6 months after donation. The final rule is consistent with the California Health and Safety Code with respect to directed reproductive donors, but may be inconsistent with Indiana law, which appears to require quarantine of all semen donations pending retesting 6 months after donation (see Cal. Health & Safety Code § 1644.5(c); Ind. Code 16–41–14–7). We note that Indiana's more stringent statute may coexist with this final rule.

To the extent that additional differences may exist between State statutes and regulations and this final rule with respect to reproductive cells and tissues and other areas where there has not previously been Federal regulation, we recognize that there may be a federalism impact. However, to the extent there is such an impact, it is a necessary part of our effort to institute uniform screening and testing requirements, to prevent the introduction, transmission, or spread of communicable disease.

In the proposed rule, we identified a particular area where we believed concerns about Federal preemption of State laws could arise: Legislative consent, or the recovery of corneas in accordance with State laws that allow the medical examiner or coroner to procure corneal tissue without the consent of the donor's next of kin (64 FR 52696 at 52703). The proposed rule did not contain an exception from the donor medical history interview for corneas procured under legislative consent. We recognized that, when corneal tissue is procured without the consent of the donor's next of kin, a donor medical history interview with the donor's next of kin does not necessarily occur. We noted, however, that the proposed definition of donor medical history interview would permit the interview to be conducted with an individual knowledgeable about the donor's medical history and relevant social behavior and would not require an interview with the next of kin. For that reason, we considered that the proposed

rule and State laws on legislative consent may coexist, and we stated that we did not intend at that time to preempt those laws. We requested that affected parties submit specific, detailed comments on any potential conflicts that might make it impossible to comply with both this regulation and State laws on legislative consent.

Many comments from industry opposed our proposal to require a donor medical history interview for all HCT/P donors, including donors of corneas recovered under legislative consent, and some disputed our assertion that the regulation and State laws could coexist. We address those comments in comments 45 and 46 of this document. After considering the comments, we continue to consider the donor medical history interview necessary for all donors to prevent the introduction, transmission, or spread of communicable diseases, and decline to make an exception for corneas donated under legislative consent.

Although we believe the final rule provides sufficient flexibility to allow for the continued recovery of corneas under legislative consent, we recognize that there may be some difficulty in communicating with the primary treating physician without obtaining permission from the deceased and/or the family of the deceased, and that, therefore, this final rule may have a negative effect on the ability of medical examiners and coroners to recover corneas under State legislative consent laws. However, given the potential for corneas to transmit communicable disease, including TSE, we have concluded that making an exception from the requirement for a donor medical history interview in the case of corneas obtained under legislative consent is not justified.

This final rule represents the exercise of a core Federal function: "* * * prevent[ing] the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession" (section 361(a) of the PHS Act; 42 U.S.C. 264). To prevent the transmission of communicable disease in the United States, including the interstate transmission of disease, uniform national standards on donor testing and screening are necessary. No State official commented otherwise. For these reasons, and for the reasons discussed previously in this document, this rule is consistent with the federalism principles expressed in Executive Order 13132.

## VII. The Paperwork Reduction Act of 1995

This final rule contains information collection provisions that have been reviewed by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). (OMB control number 0910–0543 expires May 31, 2007.) A description of these provisions is shown as follows with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

*Title*: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products.

*Description*: Under the authority of section 361 of the PHS Act, FDA is requiring HCT/P establishments to screen and test the donors of cells and tissue used in those products for risk factors for and clinical evidence of relevant communicable disease agents and diseases. FDA is requiring that donor-eligibility determination regulations apply to all establishments described in § 1271.1(b). The documented determination of whether a donor is eligible or ineligible is made by a responsible person and is based on the results of required donor screening, which includes a donor medical history interview (§ 1271.3(n)), and testing (§ 1271.50(a)). HCT/P establishments are permitted to ship an HCT/P only if it is accompanied by documentation of the donor-eligibility determination (§ 1271.55(a)). This requirement applies to an HCT/P from a donor determined to be eligible as well as to a product from a donor who is determined to be ineligible and made available for use under certain provisions. The accompanying documentation must contain a summary of records used to determine donor eligibility, and a statement whether, based on the results of the screening and testing of the donor, the donor is determined to be eligible or ineligible.

Records used in determining the eligibility of a donor, i.e., results and interpretations of screening and testing, the donor eligibility determination, the name and address of the testing laboratory or laboratories, and the name of the responsible person who made the determination and the date, must be maintained (§ 1271.55(d)(1)). If any information on the donor is not in English, the HCT/P establishment must retain the original record and the statement of authenticity from the translator (§ 1271.55(d)(2)). HCT/P establishments must retain the records pertaining to HCT/Ps at least 10 years after the date of administration, distribution, disposition, or expiration, whichever is latest (§ 1271.55(d)(4)).

When a product is shipped in quarantine, before completion of screening and testing, the HCT/P establishment must provide the donor identification, a statement that the donor-eligibility determination is not completed and that the product is not to be used until eligibility determination is completed (§ 1271.60(c)). With the use of a product from an ineligible or incompletely tested donor the following information must accompany the HCT/P: The results of any completed donor screening and testing, and a list of any required screening and testing not completed. When using an HCT/P from an ineligible donor, documentation by the HCT/P establishment is required showing that the recipient's physician received notification of the screening and testing results (§§ 1271.60(d)(3) and 1271.65(b)(3)).

An HCT/P establishment also is required to establish and maintain procedures for all steps that are performed in determining eligibility (§ 1271.47(a)), including the use of a product from a donor testing positive for CMV (§ 1271.85(b)(2)). The HCT/P establishment must record any departure from the procedures (§ 1271.47(d)).

These provisions are intended as safeguards to prevent the transmission of communicable diseases that may occur with the use of cells and tissue from infected donors. Through this action FDA will improve its ability to protect public health by controlling the spread of communicable diseases.

*Description of Respondents*: HCT/P establishments.

As required by section 3506(c)(2)(B) of the PRA, we provided an opportunity for public comment on the information collection requirements of the proposed rule (64 FR at 52715). Under the PRA, OMB reserved approval of the information collection burden in the proposed rule stating that they will make an assessment in light of public comments received on the proposed rule. One comment on the information collection burden was submitted to the docket.

(Comment 99) One comment states that, although FDA invites comments on whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility, there are no data supporting any practical utility of the information collection, and that the

estimated burden of the proposed collection of information is extremely low compared to the actual cost.

(Response) The reporting and recordkeeping information collection burdens are necessary to help ensure that the objective of the regulations (i.e., to prevent the transmission of communicable disease), is fulfilled. This provides information to the consignee or user of the product that the donor of the product was adequately and appropriately screened and tested for evidence of specific disease agents. In addition, this information allows FDA to monitor the compliance of HCT/P establishments with the regulations.

The data described in section V of the proposed rule is not for the purpose of supporting the practical utility of the information collection, but for demonstrating how the burden is calculated. Although the comment states that the calculated burden is low, the comment did not offer additional data in support of the comment.

We estimate the burden of this collection of information as follows:

TABLE 8.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 1271.3(n) | 1,302 | 60 | 78,136 | 1.0 | 78,136.0 |
| 1271.55(a) | 1,235 | 787 | 972,417 | 0.5 | 486,208.5 |
| 1271.60(c) | 1,069 | 208 | 222,417 | 0.5 | 111,208.5 |
| Total | | | | | 675,553.0 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 9.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

| 21 CFR Section | No. of Recordkeepers | Annual Frequency per Record-keeping | Total Annual Records | Hours per Record | Total Hours |
|---|---|---|---|---|---|
| One-Time Burden (Creation of SOPs) 1271.47(a) and 1271.85(b)(2) | 510 | 5 | 2,550 | 16 | 40,800 |
| One-time Burden (Review of existing SOPs for compliance) | 792 | 5 | 3,960 | 8 | 31,680 |
| SOP Update | 1,302 | 5 | 6,510 | 2 | 13,020 |
| 1271.47(d) | 1,102 | 1 | 1,102 | 1 | 1,102 |
| 1271.55(d)(4) | 195 | 1 | 195 | 120 | 23,400 |
| 1271.50(a) | 510 | 9 | 4,640 | 5 | 23,200 |
| 1271.55(d)(1) | 329 | 162.85 | 53,579 | 1 | 53,579 |
| 1271.55(d)(2) | 1,302 | 1 | 1,302 | 1 | 1,302 |
| 1271.60(d)(3) and 1271.65(b)(3) | 1,302 | 1 | 1,302 | 2 | 2,604 |
| Total | | | | | 190,687 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In the proposed rule, we underestimated the number of respondents. Based on updated information from FDA's registration data and trade organizations, we have revised our estimate of establishments to approximately 1,302 (i.e., approximately 166 conventional tissue establishments, 134 eye tissue establishments, 425 peripheral and cord blood stem/progenitor cell establishments, 510 reproductive tissue establishments, and 67 manufacturers of products regulated under the act and section 351 of the PHS Act).

We also have adjusted our estimates for the number of HCT/Ps annually produced based on updated information from industry provided to us at the time we prepared the final rule.

Our burden estimates for the annual frequency per response and average hours per response are based on institutional experience with comparable reporting and recordkeeping provisions for biological products. These burden estimates have not changed. Also, we are adding burden estimates for §§ 1271.3(n) and 1271.47.

In estimating the burden, we compared the regulations with the current voluntary standards of a number of industry organizations, such as, AATB, EBAA, AABB, FACT, NMDP, and the College of American Pathologists, and the guidelines provided by ASRM. In those cases where a voluntary industry standard appears to be equivalent to a regulation, we assumed that any reporting or recordkeeping burden is a customary and usual business practice of HCT/P establishments who are members of those organizations and no additional burden is calculated here.

Under § 1271.3(n), approximately 1,302 establishments (166 conventional

tissue establishments, 134 eye tissue establishments, 425 peripheral and cord blood stem/progenitor cell establishments, 510 reproductive tissue establishments, and 67 manufacturers of products regulated under the act and section 351 of the PHS Act) are required to have a documented medical history interview about the donor's medical history and relevant social behavior as part of the donor's relevant medical records for each of the estimated 78,136 donors (approximately 20,000 conventional tissue donors, 47,796 eye tissue donors, 5,700 peripheral and cord blood stem/progenitor cell donors, and 4,640 reproductive cell and tissue donors). We estimate that the time to conduct the interview with the donor, if living, or with an individual able to provide the information sought in the interview, is 1 hour.

Under § 1271.55(a), 972,417 HCT/Ps (approximately 750,000 conventional tissues, 94,186 eye tissues, 6,031 hematopoetic stem/progenitor cells, and 122,200 reproductive cells and tissues) are distributed per year. The agency estimates that, for each HCT/P, 1,235 establishments (1,302–67 establishments with approved applications) will expend approximately 0.5 hours to prepare the summary of records. Conventional and eye tissue establishment are currently required to provide a summary of records under § 1270.33(d), which § 1271.55 replaces.

Under § 1271.60(c), a record consisting of donor identification and a statement that the donor-eligibility determination is not completed and that the HCT/P is not to be used until the determination is completed, must accompany each HCT/P shipped under quarantine. We estimate that approximately 1,069 establishments may ship an estimated 222,417 HCT/P under quarantine and that the preparation of the record would take approximately 0.5 hours.

We assume that approximately 510 reproductive HCT/P establishments would create 5 SOPs under §§ 1271.47(a) and 1271.85(b)(2) for a total of 2,550 records, and we estimate that it would take 16 hours per new SOP for a total of 40,800 hours as a 1-time burden. We estimate that up to 5 SOPs would already exist for 792 HCT/P establishments as a result of complying with current applicable regulations or following industry organizational standards, and that it would take each establishment approximately 8 hours per SOP to complete the review for compliance with the requirements for a total of 31,600 hours as a 1-time burden.

Once the SOPs are created, annual SOP maintenance of existing SOPs is estimated to involve 2 hours annually per SOP for all HCT/P establishments. Annual total hours for maintaining the SOPs is estimated at 13,020.

Under § 1271.47(d), an estimated 1,102 HCT/P establishments would take approximately 1 hour to annually document one departure from an SOP.

Under § 1271.55(d)(4), we estimate that 195 HCT/P establishments not currently following existing industry standards will expend 120 hours (10 hours per month) annually to maintain records for 10 years.

Under § 1271.50(a), documentation of donor eligibility is required for the first time for approximately 510 reproductive tissue establishments. Out of a total of 1,302 establishments of HCT/Ps, there would be no added burden for approximately 792 other establishments who document donor eligibility as usual and customary business practice under the trade organization standards. FDA estimates that § 1271.50(a) would impose a new collection of information requirement on 510 establishments of reproductive HCT/Ps, each of which would document the eligibility of an estimated 9 donors per year, or 4,640 donors, expending approximately 5 hours per document.

Approximately 329 HCT/P establishments would maintain screening and testing records under § 1271.55(d)(1) for an estimated 53,579 donors, which would take approximately one hour per donor.

For documents originally not in English, approximately 1,302 HCT/P establishments would maintain a record of translation with an authenticity statement by the translator and the original documents. We estimate that it would take one hour for each establishment to maintain one such document annually.

Under §§ 1271.60(d)(3) and 1271.65(b)(3), when an HCT/P that is ineligible or not fully screened or tested is used, approximately 1,302 establishments of HCT/Ps are required to document the reason for using the product, and notice of the results of testing and screening to the physician. The agency estimates that such documentation would occur approximately once annually per establishments and that each establishment would expend approximately 2.0 hours to create such document.

Under section 1320.3(c)(2) of the PRA, the labeling requirements in proposed §§ 1271.60(d)(2), 1271.65(b)(2), 1271.65(c)(1) and (c)(2), 1271.80(b)(1), (b)(2), and (b)(3) and 1271.90(b), do not constitute collection of information because information required to be on the labeling is originally supplied by FDA to the establishments for the purpose of disclosure to the public to help ensure a safe supply of HCT/Ps and protect public health.

The reporting of screening and testing results to the physician in § 1271.60(d)(4) does not constitute additional reporting burden because it is calculated under the requirement for § 1271.55(a).

The information collection requirements of the final rule have been submitted to OMB for review. Before the effective date of this final rule, we will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. 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.

## VIII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

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2. Stramer, S. L., "US NAT Yield: Where Are We After Two Years?" *Transfusion Medicine*, vol. 12, issue 4, pp. 243–253, 2002.

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estimates that 11 percent of the ART therapy performed included ICSI.

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12. Government Accounting Office, "Human Tissue Banks: FDA Taking Steps to Improve Safety, but Some Concerns Remain," GAO/HEHS–98–25.

13. Alter, M. J., D. Kruszon-Moran, O. V. Nainan, et al., "The Prevalence of Hepatitis C Virus Infection in the United States, 1988 Through 1994," *New England Journal of Medicine*, vol. 341(8), pp. 556–562, 1999.

14. McQuillan, G. M., P. J. Coleman, D. Kruszon-Moran, et al., "Prevalence of Hepatitis B Virus Infection in the United States: The National Health and Nutrition Examination Surveys, 1976 Through 1994," *American Journal of Public Health*, vol. 89(1), pp. 14–8, 1999.

15. Kane, M., "Epidemiology of Hepatitis B Infection in North America," *Vaccine*, vol. 13, suppl. 1, pp. s16–s17, 1995.

16. Guinan, M. E., "Artificial Insemination by Donor: Safety and Secrecy," *Journal of the American Medical Association*, vol. 173, no. 11, pp. 890–891, March 1995.

17. U.S. Centers for Disease Control and Prevention, 1997.

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19. U.S. Small Business Administration, Office of Size Standards, Table of Size Standards, Sector 62—Health Care and Social Assistance, February 22, 2002.

20. Prottas, J., "A Study of the Tissue Procurement and Distribution System of the United States," Brandeis University, FDA/HRSA contract no. 240–090–0048, October 1995.

21. American Medical Association, Center for Health Policy Research, *Physician Socioeconomic Statistics*, 2000–2002 ed., table 41, p. 83.

22. Based on information provided by Dr. David Hoffman, NW Center for Infertility and Reproductive Endocrinology, August 2001.

23. U.S. Department of Labor, Bureau of Labor Statistics, Table 20, Private Industry, Health Services by Occupational Group: Employer Costs per Hour Worked for Employee Compensation, Professional Specialty Occupations (*http://www.bls.gov/ncs/ect/sp/ecechist.pdf*), 1994–2001.

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**List of Subjects**

*21 CFR Part 210*

Drugs, Packaging and containers.

*21 CFR Part 211*

Drugs, Labeling, Laboratories, Packaging and containers, Prescription drugs, Reporting and recordkeeping requirements, Warehouses.

*21 CFR Part 820*

Medical devices, Reporting and recordkeeping requirements.

*21 CFR Part 1271*

Communicable diseases, HIV/AIDS, Human cells, tissues, and cellular and tissue-based products, 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, chapter I of title 21 of the Code of Federal Regulations is amended as follows:

## PART 210—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS; GENERAL

■ 1. The authority citation for 21 CFR part 210 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 355, 360b, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

■ 2. Section 210.1 is amended by adding paragraph (c) to read as follows:

**§ 210.1 Status of current good manufacturing practice regulations.**

* * * * *

(c) Owners and operators of establishments engaged in the recovery, donor screening, testing (including donor testing), processing, storage, labeling, packaging, or distribution of human cells, tissues, and cellular and tissue-based products (HCT/Ps), as defined in § 1271.3(d) of this chapter, that are drugs (subject to review under an application submitted under section 505 of the act or under a biological product license application under section 351 of the Public Health Service Act), are subject to the donor-eligibility and applicable current good tissue practice procedures set forth in part 1271 subparts C and D of this chapter, in addition to the regulations in this part and in parts 211 through 226 of this chapter. Failure to comply with any applicable regulation set forth in this part, in parts 211 through 226 of this chapter, in part 1271 subpart C of this chapter, or in part 1271 subpart D of this chapter with respect to the manufacture, processing, packing or holding of a drug, renders an HCT/P adulterated under section 501(a)(2)(B) of the act. Such HCT/P, as well as the person who is responsible for the failure to comply, is subject to regulatory action.

■ 3. Section 210.2 is revised to read as follows:

**§ 210.2 Applicability of current good manufacturing practice regulations.**

(a) The regulations in this part and in parts 211 through 226 of this chapter as they may pertain to a drug; in parts 600 through 680 of this chapter as they may pertain to a biological product for human use; and in part 1271 of this chapter as they are applicable to a human cell, tissue, or cellular or tissue-based product (HCT/P) that is a drug (subject to review under an application submitted under section 505 of the act or under a biological product license application under section 351 of the Public Health Service Act); shall be considered to supplement, not supersede, each other, unless the regulations explicitly provide otherwise. In the event of a conflict between applicable regulations in this part and in other parts of this chapter, the regulation specifically applicable to the drug product in question shall supersede the more general.

(b) If a person engages in only some operations subject to the regulations in this part, in parts 211 through 226 of this chapter, in parts 600 through 680 of this chapter, and in part 1271 of this chapter, and not in others, that person need only comply with those regulations applicable to the operations in which he or she is engaged.

## PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

■ 4. The authority citation for 21 CFR part 211 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 355, 360b, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

■ 5. Section 211.1 is amended by revising paragraph (b) to read as follows:

**§ 211.1 Scope.**

* * * * *

(b) The current good manufacturing practice regulations in this chapter as they pertain to drug products; in parts

600 through 680 of this chapter, as they pertain to drugs that are also biological products for human use; and in part 1271 of this chapter, as they are applicable to drugs that are also human cells, tissues, and cellular and tissue-based products (HCT/Ps) and that are drugs (subject to review under an application submitted under section 505 of the act or under a biological product license application under section 351 of the Public Health Service Act); supplement and do not supersede the regulations in this part unless the regulations explicitly provide otherwise. In the event of a conflict between applicable regulations in this part and in other parts of this chapter, or in parts 600 through 680 of this chapter, or in part 1271 of this chapter, the regulation specifically applicable to the drug product in question shall supersede the more general.

* * * * *

## PART 820—QUALITY SYSTEM REGULATION

■ 6. The authority citation for 21 CFR part 820 is revised to read as follows:

**Authority:** 21 U.S.C. 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 360l, 371, 374, 381, 383; 42 U.S.C. 216, 262, 263a, 264.

■ 7. Section 820.1 is amended by adding two sentences to the end of paragraph (a)(1), and by revising paragraph (b) to read as follows:

### § 820.1 Scope.

(a) *Applicability.* (1) * * * Manufacturers of human cells, tissues, and cellular and tissue-based products (HCT/Ps), as defined in § 1271.3(d) of this chapter, that are medical devices (subject to premarket review or notification, or exempt from notification, under an application submitted under the device provisions of the act or under a biological product license application under section 351 of the Public Health Service Act) are subject to this part and are also subject to the donor-eligibility procedures set forth in part 1271 subpart C of this chapter and applicable current good tissue practice procedures in part 1271 subpart D of this chapter. In the event of a conflict between applicable regulations in part 1271 and in other parts of this chapter, the regulation specifically applicable to the device in question shall supersede the more general.

* * * * *

(b) The quality system regulation in this part supplements regulations in other parts of this chapter except where explicitly stated otherwise. In the event of a conflict between applicable regulations in this part and in other parts of this chapter, the regulations specifically applicable to the device in question shall supersede any other generally applicable requirements.

* * * * *

## PART 1271—HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS

■ 8. The authority citation for 21 CFR part 1271 is revised to read as follows:

**Authority:** 42 U.S.C. 216, 243, 263a, 264, 271.

### § 1271.1 [Amended]

■ 9. Section 1271.1 *What are the purpose and scope for this part?* is amended by removing the phrase "donor-suitability" and adding in its place the phrase "donor-eligibility" wherever it appears.

■ 10. Section 1271.3 is amended by adding paragraphs (h) through (x) to read as follows:

### § 1271.3 How does FDA define important terms in this part?

* * * * *

(h) *Biohazard legend* appears on the label as follows and is used to mark HCT/Ps that present a known or suspected relevant communicable disease risk.

BIOHAZARD

(i) *Blood component* means a product containing a part of human blood separated by physical or mechanical means.

(j) *Colloid* means:

(1) A protein or polysaccharide solution, such as albumin, dextran, or hetastarch, that can be used to increase or maintain osmotic (oncotic) pressure in the intravascular compartment; or

(2) Blood components such as plasma and platelets.

(k) *Crystalloid* means an isotonic salt and/or glucose solution used for electrolyte replacement or to increase intravascular volume, such as saline solution, Ringer's lactate solution, or 5 percent dextrose in water.

(l) *Directed reproductive donor* means a donor of reproductive cells or tissue (including semen, oocytes, and embryos to which the donor contributed the spermatozoa or oocyte) to a specific recipient, and who knows and is known by the recipient before donation. The term directed reproductive donor does not include a sexually intimate partner under § 1271.90.

(m) *Donor* means a person, living or dead, who is the source of cells or tissue for an HCT/P.

(n) *Donor medical history interview means* a documented dialog about the donor's medical history and relevant social behavior, including activities, behaviors, and descriptions considered to increase the donor's relevant communicable disease risk:

(1) With the donor, if the donor is living and able to participate in the interview, or

(2) If not, with an individual or individuals able to provide the information sought in the interview (e.g., the donor's next-of-kin, the nearest available relative, a member of the donor's household, an individual with an affinity relationship, and/or the primary treating physician).

(o) *Physical assessment of a cadaveric donor* means a limited autopsy or recent antemortem or postmortem physical examination of the donor to assess for signs of a relevant communicable disease and for signs suggestive of any risk factor for a relevant communicable disease.

(p) *Plasma dilution* means a decrease in the concentration of the donor's plasma proteins and circulating antigens or antibodies resulting from the transfusion of blood or blood components and/or infusion of fluids.

(q) *Quarantine* means the storage or identification of an HCT/P, to prevent improper release, in a physically separate area clearly identified for such use, or through use of other procedures, such as automated designation.

(r) *Relevant communicable disease agent or disease* means:

(1)(i) For all human cells and tissues, a communicable disease or disease agent listed as follows:

(A) Human immunodeficiency virus, types 1 and 2;

(B) Hepatitis B virus;

(C) Hepatitis C virus;

(D) Human transmissible spongiform encephalopathy, including Creutzfeldt-Jakob disease; and

(E) *Treponema pallidum.*

(ii) For viable, leukocyte-rich cells and tissues, a cell-associated disease agent or disease listed as follows:

(A) Human T-lymphotropic virus, type I; and

(B) Human T-lymphotropic virus, type II.

(iii) For reproductive cells or tissues, a disease agent or disease of the genitourinary tract listed as follows:

(A) *Chlamydia trachomatis*; and

(B) *Neisseria gonorrhea.*

(2) A disease agent or disease not listed in paragraph (r)(1) of this section:

(i) For which there may be a risk of transmission by an HCT/P, either to the recipient of the HCT/P or to those people who may handle or otherwise come in contact with it, such as medical personnel, because the disease agent or disease:

(A) Is potentially transmissible by an HCT/P and

(B) Either of the following applies:

(*1*) The disease agent or disease has sufficient incidence and/or prevalence to affect the potential donor population, or

(*2*) The disease agent or disease may have been released accidentally or intentionally in a manner that could place potential donors at risk of infection;

(ii) That could be fatal or life-threatening, could result in permanent impairment of a body function or permanent damage to body structure, or could necessitate medical or surgical intervention to preclude permanent impairment of body function or permanent damage to a body structure; and

(iii) For which appropriate screening measures have been developed and/or an appropriate screening test for donor specimens has been licensed, approved, or cleared for such use by FDA and is available.

(s) *Relevant medical records* means a collection of documents that includes a current donor medical history interview; a current report of the physical assessment of a cadaveric donor or the physical examination of a living donor; and, if available, the following:

(1) Laboratory test results (other than results of testing for relevant communicable disease agents required under this subpart);

(2) Medical records;

(3) Coroner and autopsy reports; and

(4) Records or other information received from any source pertaining to risk factors for relevant communicable disease (e.g., social behavior, clinical signs and symptoms of relevant communicable disease, and treatments related to medical conditions suggestive of risk for relevant communicable disease).

(t) *Responsible person* means a person who is authorized to perform designated functions for which he or she is trained and qualified.

(u) *Urgent medical need* means that no comparable HCT/P is available and the recipient is likely to suffer death or serious morbidity without the HCT/P.

(v) *Act* means the Federal Food, Drug, and Cosmetic Act.

(w) *PHS Act* means the Public Health Service Act.

(x) *FDA* means the Food and Drug Administration.

■ 11. Part 1271 is amended by adding subpart C, consisting of §§ 1271.45 through 1271.90, to read as follows:

## Subpart C—Donor Eligibility

Sec.



## Subpart C—Donor Eligibility

### § 1271.45 What requirements does this subpart contain?

(a) *General.* This subpart sets out requirements for determining donor eligibility, including donor screening and testing. The requirements contained in this subpart are a component of current good tissue practice (CGTP) requirements.

(b) *Donor-eligibility determination required.* A donor-eligibility determination, based on donor screening and testing for relevant communicable disease agents and diseases, is required for all donors of cells or tissue used in HCT/Ps, except as provided under § 1271.90. In the case of an embryo or of cells derived from an embryo, a donor-eligibility determination is required for both the oocyte donor and the semen donor.

(c) *Prohibition on use.* An HCT/P must not be implanted, transplanted, infused, or transferred until the donor has been determined to be eligible, except as provided under §§ 1271.60(d), 1271.65(b), and 1271.90 of this subpart.

(d) *Applicability of requirements.* If you are an establishment that performs any function described in this subpart, you must comply with the requirements contained in this subpart that are applicable to that function.

### § 1271.47 What procedures must I establish and maintain?

(a) *General.* You must establish and maintain procedures for all steps that you perform in testing, screening, determining donor eligibility, and complying with all other requirements of this subpart. Establish and maintain means define, document (in writing or electronically), and implement; then follow, review, and as needed, revise on an ongoing basis. You must design these procedures to ensure compliance with the requirements of this subpart.

(b) *Review and approval.* Before implementation, a responsible person must review and approve all procedures.

(c) *Availability.* Procedures must be readily available to the personnel in the area where the operations to which they relate are performed, or in a nearby area if such availability is impractical.

(d) *Departures from procedures.* You must record and justify any departure from a procedure relevant to preventing risks of communicable disease transmission at the time of its occurrence. You must not make available for distribution any HCT/P from a donor whose eligibility is determined under such a departure unless a responsible person has determined that the departure does not increase the risks of communicable disease transmission through the use of the HCT/P.

(e) *Standard procedures.* You may adopt current standard procedures, such as those in a technical manual prepared by another organization, provided that you have verified that the procedures are consistent with and at least as stringent as the requirements of this part and appropriate for your operations.

### § 1271.50 How do I determine whether a donor is eligible?

(a) *Determination based on screening and testing.* If you are the establishment responsible for making the donor-eligibility determination, you must determine whether a donor is eligible based upon the results of donor screening in accordance with § 1271.75 and donor testing in accordance with §§ 1271.80 and 1271.85. A responsible person, as defined in § 1271.3(t), must determine and document the eligibility of a cell or tissue donor.

(b) *Eligible donor.* A donor is eligible under these provisions only if:

(1) Donor screening in accordance with § 1271.75 indicates that the donor:

(i) Is free from risk factors for, and clinical evidence of, infection due to relevant communicable disease agents and diseases; and

(ii) Is free from communicable disease risks associated with xenotransplantation; and

(2) The results of donor testing for relevant communicable disease agents in accordance with §§ 1271.80 and 1271.85 are negative or nonreactive, except as provided in § 1271.80(d)(1).

**§ 1271.55 What records must accompany an HCT/P after the donor-eligibility determination is complete; and what records must I retain?**

(a) *Accompanying records.* Once a donor-eligibility determination has been made, the following must accompany the HCT/P at all times:

(1) A distinct identification code affixed to the HCT/P container, e.g., alphanumeric, that relates the HCT/P to the donor and to all records pertaining to the HCT/P and, except in the case of autologous or directed reproductive donations, does not include an individual's name, social security number, or medical record number;

(2) A statement whether, based on the results of screening and testing, the donor has been determined to be eligible or ineligible; and

(3) A summary of the records used to make the donor-eligibility determination.

(b) *Summary of records.* The summary of records required by paragraph (a)(3) of this section must contain the following information:

(1) A statement that the communicable disease testing was performed by a laboratory:

(i) Certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493; or

(ii) That has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services in accordance with those provisions;

(2) A listing and interpretation of the results of all communicable disease tests performed;

(3) The name and address of the establishment that made the donor-eligibility determination; and

(4) In the case of an HCT/P from a donor who is ineligible based on screening and released under paragraph (b) of § 1271.65, a statement noting the reason(s) for the determination of ineligibility.

(c) *Deletion of personal information.* The accompanying records required by this section must not contain the donor's name or other personal information that might identify the donor.

(d) *Record retention requirements.*

(1) You must maintain documentation of:

(i) Results and interpretation of all testing for relevant communicable disease agents in compliance with §§ 1271.80 and 1271.85, as well as the name and address of the testing laboratory or laboratories;

(ii) Results and interpretation of all donor screening for communicable diseases in compliance with § 1271.75; and

(iii) The donor-eligibility determination, including the name of the responsible person who made the determination and the date of the determination.

(2) All records must be accurate, indelible, and legible. Information on the identity and relevant medical records of the donor, as defined in § 1271.3(s), must be in English or, if in another language, must be retained and translated to English and accompanied by a statement of authenticity by the translator that specifically identifies the translated document.

(3) You must retain required records and make them available for authorized inspection by or upon request from FDA. Records that can be readily retrieved from another location by electronic means are considered "retained."

(4) You must retain the records pertaining to a particular HCT/P at least 10 years after the date of its administration, or if the date of administration is not known, then at least 10 years after the date of the HCT/P's distribution, disposition, or expiration, whichever is latest.

**§ 1271.60 What quarantine and other requirements apply before the donor-eligibility determination is complete?**

(a) *Quarantine.* You must keep an HCT/P in quarantine, as defined in § 1271.3(q), until completion of the donor-eligibility determination required by § 1271.50. You must quarantine semen from anonymous donors until the retesting required under § 1271.85(d) is complete.

(b) *Identification of HCT/Ps in quarantine.* You must clearly identify as quarantined an HCT/P that is in quarantine pending completion of a donor-eligibility determination. The quarantined HCT/P must be easily distinguishable from HCT/Ps that are available for release and distribution.

(c) *Shipping of HCT/Ps in quarantine.* If you ship an HCT/P before completion of the donor-eligibility determination, you must keep it in quarantine during shipment. The HCT/P must be accompanied by records:

(1) Identifying the donor (e.g., by a distinct identification code affixed to the HCT/P container);

(2) Stating that the donor-eligibility determination has not been completed; and

(3) Stating that the product must not be implanted, transplanted, infused, or transferred until completion of the donor-eligibility determination, except under the terms of paragraph (d) of this section.

(d) *Use in cases of urgent medical need.*

(1) This subpart C does not prohibit the implantation, transplantation, infusion, or transfer of an HCT/P from a donor for whom the donor-eligibility determination is not complete if there is a documented urgent medical need for the HCT/P, as defined in § 1271.3(u).

(2) If you make an HCT/P available for use under the provisions of paragraph (d)(1) of this section, you must prominently label it "NOT EVALUATED FOR INFECTIOUS SUBSTANCES," and "WARNING: Advise patient of communicable disease risks." The following information must accompany the HCT/P:

(i) The results of any donor screening required under § 1271.75 that has been completed;

(ii) The results of any testing required under § 1271.80 or 1271.85 that has been completed; and

(iii) A list of any screening or testing required under § 1271.75, 1271.80 or 1271.85 that has not yet been completed.

(3) If you are the establishment that manufactured an HCT/P used under the provisions of paragraph (d)(1) of this section, you must document that you notified the physician using the HCT/P that the testing and screening were not complete.

(4) In the case of an HCT/P used for an urgent medical need under the provisions of paragraph (d)(1) of this section, you must complete the donor-eligibility determination during or after the use of the HCT/P, and you must inform the physician of the results of the determination.

**§ 1271.65 How do I store an HCT/P from a donor determined to be ineligible, and what uses of the HCT/P are not prohibited?**

(a) *Storage.* If you are the establishment that stores the HCT/P, you must store or identify HCT/Ps from donors who have been determined to be ineligible in a physically separate area clearly identified for such use, or follow other procedures, such as automated

designation, that are adequate to prevent improper release until destruction or other disposition of the HCT/P in accordance with paragraph (b) or (c) of this section.

(b) *Limited uses of HCT/P from ineligible donor.*

(1) An HCT/P from a donor who has been determined to be ineligible, based on the results of required testing and/or screening, is not prohibited by subpart C of this part from use for implantation, transplantation, infusion, or transfer under the following circumstances:

(i) The HCT/P is for allogeneic use in a first-degree or second-degree blood relative;

(ii) The HCT/P consists of reproductive cells or tissue from a directed reproductive donor, as defined in § 1271.3(l); or

(iii) There is a documented urgent medical need as defined in § 1271.3(u).

(2) You must prominently label an HCT/P made available for use under the provisions of paragraph (b)(1) of this section with the Biohazard legend shown in § 1271.3(h) with the statement "WARNING: Advise patient of communicable disease risks," and, in the case of reactive test results, "WARNING: Reactive test results for (name of disease agent or disease)." The HCT/P must be accompanied by the records required under § 1271.55.

(3) If you are the establishment that manufactured an HCT/P used under the provisions of paragraph (b)(1) of this section, you must document that you notified the physician using the HCT/P of the results of testing and screening.

(c) *Nonclinical use.* You may make available for nonclinical purposes an HCT/P from a donor who has been determined to be ineligible, based on the results of required testing and/or screening, provided that it is labeled:

(1) "For Nonclinical Use Only" and

(2) With the Biohazard legend shown in § 1271.3(h).

### § 1271.75 How do I screen a donor?

(a) *All donors.* Except as provided under § 1271.90, if you are the establishment that performs donor screening, you must screen a donor of cells or tissue by reviewing the donor's relevant medical records for:

(1) Risk factors for, and clinical evidence of, relevant communicable disease agents and diseases, including:

(i) Human immunodeficiency virus;

(ii) Hepatitis B virus;

(iii) Hepatitis C virus;

(iv) Human transmissible spongiform encephalopathy, including Creutzfeldt-Jakob disease;

(v) *Treponema pallidum*; and

(2) Communicable disease risks associated with xenotransplantation.

(b) *Donors of viable, leukocyte-rich cells or tissue.* In addition to the relevant communicable disease agents and diseases for which screening is required under paragraph (a) of this section, and except as provided under § 1271.90, you must screen the donor of viable, leukocyte-rich cells or tissue by reviewing the donor's relevant medical records for risk factors for and clinical evidence of relevant cell-associated communicable disease agents and diseases, including Human T-lymphotropic virus.

(c) *Donors of reproductive cells or tissue.* In addition to the relevant communicable disease agents and diseases for which screening is required under paragraphs (a) and (b) of this section, as applicable, and except as provided under § 1271.90, you must screen the donor of reproductive cells or tissue by reviewing the donor's relevant medical records for risk factors for and clinical evidence of infection due to relevant communicable diseases of the genitourinary tract. Such screening must include screening for the communicable disease agents listed in paragraphs (c)(1) and (c)(2) of this section. However, if the reproductive cells or tissues are recovered by a method that ensures freedom from contamination of the cells or tissue by infectious disease organisms that may be present in the genitourinary tract, then screening for the communicable disease agents listed in paragraphs (c)(1) and (c)(2) of this section is not required. Communicable disease agents of the genitourinary tract for which you must screen include:

(1) *Chlamydia trachomatis*; and

(2) *Neisseria gonorrhea.*

(d) *Ineligible donors.* You must determine ineligible a donor who is identified as having either of the following:

(1) A risk factor for or clinical evidence of any of the relevant communicable disease agents or diseases for which screening is required under paragraphs (a)(1)(i), (b), or (c) of this section; or

(2) Any communicable disease risk associated with xenotransplantation.

(e) *Abbreviated procedure for repeat donors.* If you have performed a complete donor screening procedure on a living donor within the previous 6 months, you may use an abbreviated donor screening procedure on repeat donations. The abbreviated procedure must determine and document any changes in the donor's medical history since the previous donation that would make the donor ineligible, including relevant social behavior.

### § 1271.80 What are the general requirements for donor testing?

(a) *Testing for relevant communicable diseases is required.* To adequately and appropriately reduce the risk of transmission of relevant communicable diseases, and except as provided under § 1271.90, if you are the establishment that performs donor testing, you must test a donor specimen for evidence of infection due to communicable disease agents in accordance with paragraph (c) of this section. You must test for those communicable disease agents specified in § 1271.85. In the case of a donor 1 month of age or younger, you must test a specimen from the birth mother instead of a specimen from the donor.

(b) *Timing of specimen collection.* You must collect the donor specimen at the time of recovery of cells or tissue from the donor. However, if collection at the time of recovery is not feasible, then you may collect the donor specimen up to 7 days before or after recovery or, for donors of peripheral blood stem/progenitor cells only, up to 30 days before recovery. In the case of a repeat semen donor from whom a specimen has already been collected and tested, and for whom retesting is required under § 1271.85(d), you are not required to collect a donor specimen at the time of each donation.

(c) *Tests.* You must test using appropriate FDA-licensed, approved, or cleared donor screening tests, in accordance with the manufacturer's instructions, to adequately and appropriately reduce the risk of transmission of relevant communicable disease agents or diseases; however, until such time as appropriate FDA-licensed, approved, or cleared donor screening tests for *Chlamydia trachomatis* and for *Neisseria gonorrhea* are available, you must use FDA-licensed, approved, or cleared tests labeled for the detection of those organisms in an asymptomatic, low-prevalence population. You must use a test specifically labeled for cadaveric specimens instead of a more generally labeled test when applicable and when available. Required testing under this section must be performed by a laboratory that either is certified to perform such testing on human specimens under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) and 42 CFR part 493, or has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services.

(d) *Ineligible donors.* You must determine the following donors to be ineligible:

(1) A donor whose specimen tests reactive on a screening test for a

communicable disease agent in accordance with § 1271.85, except for a donor whose specimen tests reactive on a non-treponemal screening test for syphilis and negative on a specific treponemal confirmatory test;

(2)(i) A donor in whom plasma dilution sufficient to affect the results of communicable disease testing is suspected, unless:

(A) You test a specimen taken from the donor before transfusion or infusion and up to 7 days before recovery of cells or tissue; or

(B) You use an appropriate algorithm designed to evaluate volumes administered in the 48 hours before specimen collection, and the algorithm shows that plasma dilution sufficient to affect the results of communicable disease testing has not occurred.

(ii) Clinical situations in which you must suspect plasma dilution sufficient to affect the results of communicable disease testing include but are not limited to the following:

(A) Blood loss is known or suspected in a donor over 12 years of age, and the donor has received a transfusion or infusion of any of the following, alone or in combination:

(*1*) More than 2,000 milliliters (mL) of blood (e.g., whole blood, red blood cells) or colloids within 48 hours before death or specimen collection, whichever occurred earlier, or

(*2*) More than 2,000 mL of crystalloids within 1 hour before death or specimen collection, whichever occurred earlier.

(B) Regardless of the presence or absence of blood loss, the donor is 12 years of age or younger and has received a transfusion or infusion of any amount of any of the following, alone or in combination:

(*1*) Blood (e.g., whole blood, red blood cells) or colloids within 48 hours before death or specimen collection, whichever occurred earlier, or

(*2*) Crystalloids within 1 hour before death or specimen collection, whichever occurred earlier.

**§ 1271.85 What donor testing is required for different types of cells and tissues?**

(a) *All donors.* To adequately and appropriately reduce the risk of transmission of relevant communicable diseases, and except as provided under § 1271.90, you must test a specimen from the donor of cells or tissue, whether viable or nonviable, for evidence of infection due to relevant communicable disease agents, including:

(1) Human immunodeficiency virus, type 1;

(2) Human immunodeficiency virus, type 2;

(3) Hepatitis B virus;

(4) Hepatitis C virus; and

(5) *Treponema pallidum.*

(b) *Donors of viable, leukocyte-rich cells or tissue.* In addition to the relevant communicable disease agents for which testing is required under paragraph (a) of this section, and except as provided under § 1271.90,

(1) You must test a specimen from the donor of viable, leukocyte-rich cells or tissue to adequately and appropriately reduce the risk of transmission of relevant cell-associated communicable diseases, including:

(i) Human T-lymphotropic virus, type I; and

(ii) Human T-lymphotropic virus, type II.

(2) You must test a specimen from the donor of viable, leukocyte-rich cells or tissue for evidence of infection due to cytomegalovirus (CMV), to adequately and appropriately reduce the risk of transmission. You must establish and maintain a standard operating procedure governing the release of an HCT/P from a donor whose specimen tests reactive for CMV.

(c) *Donors of reproductive cells or tissue.* In addition to the communicable disease agents for which testing is required under paragraphs (a) and (b) of this section, as applicable, and except as provided under § 1271.90, you must test a specimen from the donor of reproductive cells or tissue to adequately and appropriately reduce the risk of transmission of relevant communicable disease agents of the genitourinary tract. Such testing must include testing for the communicable disease agents listed in paragraphs (c)(1) and (c)(2) of this section. However, if the reproductive cells or tissues are recovered by a method that ensures freedom from contamination of the cells or tissue by infectious disease organisms that may be present in the genitourinary tract, then testing for the communicable disease agents listed in paragraphs (c)(1) and (c)(2) of this section is not required. Communicable disease agents of the genitourinary tract for which you must test include:

(1) *Chlamydia trachomatis*; and

(2) *Neisseria gonorrhea.*

(d) *Retesting anonymous semen donors.* Except as provided under § 1271.90 and except for directed reproductive donors as defined in § 1271.3(l), at least 6 months after the date of donation of semen from anonymous donors, you must collect a new specimen from the donor and test it for evidence of infection due to the communicable disease agents for which testing is required under paragraphs (a), (b), and (c) of this section.

(e) *Dura mater.* For donors of dura mater, you must perform an adequate assessment designed to detect evidence of transmissible spongiform encephalopathy.

**§ 1271.90 Are there exceptions from the requirement of determining donor eligibility, and what labeling requirements apply?**

(a) *Donor-eligibility determination not required.* You are not required to make a donor-eligibility determination under § 1271.50 or to perform donor screening or testing under §§ 1271.75, 1271.80 and 1271.85 for:

(1) Cells and tissues for autologous use; or

(2) Reproductive cells or tissue donated by a sexually intimate partner of the recipient for reproductive use; or

(3) Cryopreserved cells or tissue for reproductive use, originally exempt under paragraph (a)(1) or (a)(2) at the time of donation, that are subsequently intended for directed donation, provided that

(i) Additional donations are unavailable, for example, due to the infertility or health of a donor of the cryopreserved reproductive cells or tissue; and

(ii) Appropriate measures are taken to screen and test the donor(s) before transfer to the recipient.

(b) *Required labeling.* You must prominently label an HCT/P listed in paragraph (a) of this section:

(1) "FOR AUTOLOGOUS USE ONLY," if it is stored for autologous use;

(2) "NOT EVALUATED FOR INFECTIOUS SUBSTANCES" and "WARNING: Advise patient of communicable disease risks," unless you have performed all otherwise applicable screening and testing under §§ 1271.75, 1271.80, and 1271.85; and

(3) With the Biohazard legend shown in § 1271.3(h), with the statement "WARNING: Advise patient of communicable disease risks," and, in the case of reactive test results, "WARNING: Reactive test results for (name of disease agent or disease)" if the results of any screening or testing performed indicate:

(i) The presence of relevant communicable disease agents and/or

(ii) Risk factors for or clinical evidence of relevant communicable disease agents or diseases.

Dated: March 10, 2004.
**Lester M. Crawford,**
*Acting Commissioner for Food and Drugs.*

Dated: March 10, 2004.
**Tommy G. Thompson,**
*Secretary of Health and Human Services.*
[FR Doc. 04–11245 Filed 5–20–04; 8:45 am]
BILLING CODE 4160–01–S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 2004D–0193]**

### Draft "Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products" Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" dated May 2004. The draft guidance provides to HCT/P establishments recommendations for the appropriate screening and testing of cell and tissue donors for evidence of relevant communicable diseases. These recommendations would assist HCT/P establishments in complying with the requirements for the eligibility determination for donors of HCT/Ps.

**DATES:** Submit written or electronic comments on the draft guidance by August 23, 2004, to ensure their adequate consideration in preparation of the final guidance. General omments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling the Center for Biologics and Research Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

**FOR FURTHER INFORMATION CONTACT:** Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

FDA is announcing the availability of a draft guidance entitled "Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-based Products (HCT/Ps)" dated May 2004. Because of their nature as derivatives of the human body, HCT/Ps pose a risk of transmitting communicable diseases. For this reason, FDA is publishing a final rule "Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" elsewhere in this issue of the **Federal Register**. These donor-eligibility requirements, which are contained in part 1271 (21 CFR part 1271), subpart C, are part of the minimum requirements applicable both to HCT/Ps regulated solely under these regulations and section 361 of the Public Health Service Act and to those HCT/Ps also subject to regulation as drugs, devices, and/or biological products.

In the draft guidance, FDA is providing recommendations to HCT/P establishments on how to comply with the requirements in 21 CFR part 1271, subpart C. The recommendations address the following topics:

- Elements of the donor eligibility determination, including procedures and recordkeeping;
- Donor screening, including review of risk factors for, and clinical and physical evidence of, relevant communicable diseases;
- Donor testing, including general testing for all HCT/Ps and testing specific for some types of HCT/Ps (e.g., reproductive cells and tissues); and
- Exceptions to donor screening and testing.

The draft guidance would apply to cells and tissues recovered on or after the effective date of the final rule published elsewhere in this issue of the **Federal Register**. Part 1271 also contains other requirements applicable to HCT/Ps (e.g., current good tissue practice requirements), which are not addressed in the draft guidance.

We previously have issued a separate draft guidance document entitled "Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" dated June 2002. We intend to issue a single final guidance document that incorporates our guidance on CJD and vCJD with the substance of this document into a final guidance on donor eligibility.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance document, when finalized, will represent the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

#### II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 USC 3501–3520). The collection(s) of information addressed in the guidance document has been submitted to OMB for review in accordance with the PRA under the regulations governing donor-eligibility determination for donors of HCT/Ps (part 1271).

#### III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

#### IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.fda.gov/ohrms/dockets/default.htm.*

Dated: April 27, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–11246 Filed 5–20–04; 8:45 am]

**BILLING CODE 4160–01–S**


Federal Register

Tuesday,
May 25, 2004

Part III

# Department of Defense
# General Services Administration
# National Aeronautics and Space Administration

48 CFR Parts 14, 32, and 52
Federal Acquisition Regulation; Payment Withholding; Proposed Rule

**DEPARTMENT OF DEFENSE**

**GENERAL SERVICES ADMINISTRATION**

**NATIONAL AERONAUTICS AND SPACE ADMINISTRATION**

**48 CFR Parts 14, 32, and 52**

**[FAR Case 2004–003]**

**RIN 9000–AJ94**

## Federal Acquisition Regulation; Payment Withholding

**AGENCIES:** Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

**ACTION:** Proposed rule with request for comments.

**SUMMARY:** The Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (Councils) are proposing to amend the Federal Acquisition Regulation (FAR) by removing the requirement that a contracting officer withhold 5 percent of the payments due under a time-and materials or labor-hour contract, unless otherwise prescribed in the contract Schedule. The proposed rule would permit, but not require, the contracting officer to withhold payment amounts if the contracting officer determines the withholding to be necessary to protect the Government's interests.

**DATES:** Interested parties should submit comments in writing on or before July 26, 2004 to be considered in the formulation of a final rule.

**ADDRESSES:** Submit printed comments to General Services Administration, FAR Secretariat (MVA), 1800 F Street, NW., Room 4035, ATTN: Laurie Duarte, Washington, DC 20405. Submit electronic comments via the Internet to the U.S. Government's rulemaking website at *http://www.regulations.gov*, or to GSA's e-mailbox at *farcase.2004–003@gsa.gov*.

Please submit comments only and cite FAR case 2004–003 in all correspondence related to this case.

**FOR FURTHER INFORMATION CONTACT:** The FAR Secretariat at (202) 501–4755 for information pertaining to status or publication schedules. For clarification of content, contact Mr. Edward Loeb, Policy Advisor, at (202) 501–0650. Please cite FAR case 2004–003.

**SUPPLEMENTARY INFORMATION:**

### A. Background

Federal Acquisition Regulation (FAR) 52.232–7, Payments under Time-and Materials and Labor-Hour Contracts, currently requires the contracting officer to withhold 5 percent of the amounts due, up to a maximum of $50,000, unless otherwise specified in the contract Schedule. The Government retains the withhold amount until the contractor executes and delivers, at the time of final payment, a release discharging the Government from all liabilities, obligations, and claims arising under the contract.

The rule proposes to add FAR 32.111(a)(7)(iii) to permit contracting officers to use their judgment regarding whether to withhold payments under time-and-materials and labor-hour contracts so that the withhold would be applied only when necessary to protect the Government's interests. The proposed rule makes it clear that, normally, there should be no need to withhold payments when dealing with contractors that typically comply with contractual release requirements in a timely manner. This is in contrast to the current requirement in time-and-materials and labor-hour contracts that contracting officers must withhold payments unless other direction is provided in the contract.

The rule also proposes to revise paragraph (a)(2) of the contract clause at FAR 52.232–7, to state that the contracting officer may (rather than shall) withhold 5 percent of the amounts due. The rule also makes several related editorial changes to improve clarity and structure.

The Councils are considering revising its policy because the current withholding provisions are administratively burdensome and may, in some situations, result in the withholding of amounts that exceed reasonable amounts needed to protect the Government's interests. In addition, the contractor is already incentivized to execute and deliver the release discharging the Government from all liabilities, obligations, and claims under the contract, since this release is a condition of final payment.

This is not a significant regulatory action and, therefore, was not subject to review under Section 6(b) of Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

### B. Regulatory Flexibility Act

The Councils do not expect this proposed rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because the rule applies only to time and material and labor-hour contracts with small business, representing approximately 2 percent of all contracting. In addition, the rule eases the impact of the current FAR by permitting the contracting officer to use judgment in deciding whether to withhold payments, thus the number of contracts affected is a subset of the 2 percent figure. This change is expected to have a small but beneficial impact on small businesses. An Initial Regulatory Flexibility Analysis has, therefore, not been performed. We invite comments from small businesses and other interested parties. The Councils will consider comments from small entities concerning the affected FAR parts in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 601, *et seq.* (FAR case 2004–003), in correspondence.

### C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the proposed changes to the FAR do not impose information collection requirements that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

### List of Subjects in 48 CFR Parts 14, 32, and 52

Government procurement.

Dated: May, 19, 2004.

**Ralph De Stefano,**

*Acting Director, Acquisition Policy Division.*

Therefore, DoD, GSA, and NASA propose amending 48 CFR parts 14, 32, and 52 as set forth below:

1. The authority citation for 48 CFR parts 14, 32, and 52 is revised to read as follows:

**Authority:** 40 U.S.C. 121(c); 10 U.S.C. chapter 137; and 42 U.S.C. 2473(c).

## PART 14—SEALED BIDDING

**14.408–3 [Amended]**

2. Amend section 14.408–3 in paragraph (b) by removing "See 32.111(c)(1)," and adding "See 32.111(b)(1)," in its place.

## PART 32—CONTRACT FINANCING

3. Amend section 32.111 by—

a. Removing "and" at the end of paragraph (a)(5);

b. Removing the period at the end of paragraph (a)(6) and adding "; and" in its place;

c. Redesignating paragraph (b) as paragraph (a)(7);

d. Redesignating paragraphs (c) and (d) as (b) and (c), respectively; and

e. Revising newly designated paragraph (a)(7) to read as follows:

**32.111 Contract clauses for non-commercial purchases.**

(a) * * *

(7) The clause at 52.232–7, Payments under Time-and-Materials and Labor-Hour Contracts, in solicitations and contracts when a time-and-materials or labor-hour contract is contemplated.

(i) If the nature of the work to be performed requires the contractor to furnish material that is regularly sold to the general public in the normal course of business by the contractor and the price is under the limitations prescribed in 16.601(b)(3), the contracting officer shall use the clause with its Alternate I.

(ii) If a labor-hour contract is contemplated, and if no specific reimbursement for materials furnished is intended, the contracting officer may use the clause with its Alternate II.

(iii) If the contracting officer determines that it is necessary to withhold payment to protect the Government's interests, paragraph (a)(2) of the clause permits the contracting officer to withhold 5 percent of the amounts due until a reserve is set aside in an amount the contracting officer considers to be necessary, but not to exceed $50,000. Normally, there should be no need to withhold payment for a contractor with a record of timely submittal of the release discharging the Government from all liabilities, obligations, and claims, as required by paragraph (f) of the clause.

* * * * *

## PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

**52.232–7 [Amended]**

4. Amend section 52.232–7 by—

a. Removing "32.111(b)" and adding "32.111(a)(7)" in its place in the introductory text of section 52.232–7.

b. Revising the date of the clause to read "(XXX 2004)".

c. Revising paragraph (a)(2) to read as follows:

**52.232–7 Payments under Time-and-Materials and Labor-Hour Contracts.**

(a) * * *

(2) Unless otherwise prescribed in the Schedule, the Contracting Officer may withhold 5 percent of the amounts due under this paragraph (a), but the total amount withheld shall not exceed $50,000. The amounts withheld shall be retained until the Contractor executes and delivers the release required by paragraph (f) of this clause.

* * * * *

5. In the introductory text of section 52.232–8, remove "32.111(c)(1)" and add "32.111(b)(1)" in its place.

6. In the introductory text of section 52.232–9, remove "32.111(c)(2)" and add "32.111(b)(2)" in its place.

7. In the introductory text of section 52.232–10, remove "32.111(d)(1)" and add "32.111(c)(1)" in its place.

8. In the introductory text of section 52.232–11, remove "32.111(d)(2)" and add "32.111(c)(2)" in its place.

[FR Doc. 04–11736 Filed 5–24–04; 8:45 am]

BILLING CODE 6820–EP–S

Federal Register

Tuesday,
May 25, 2004

Part IV

# The President

**Executive Order 13341—Further Amendment to Executive Order 11023, Providing for the Performance by the Secretary of Commerce of Certain Functions Relating to the National Oceanic and Atmospheric Administration**

Federal Register
Vol. 69, No. 101
Tuesday, May 25, 2004

# Presidential Documents

Title 3—

The President

Executive Order 13341 of May 20, 2004

## Further Amendment to Executive Order 11023, Providing for the Performance by the Secretary of Commerce of Certain Functions Relating to the National Oceanic and Atmospheric Administration

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, it is hereby ordered as follows:

**Section 1.** As a result of the enactment of the National Oceanic and Atmospheric Administration Commissioned Officer Corps Act of 2002 (Public Law 107–372), the following conforming amendments are made to Executive Order 11023 of May 28, 1962, as amended:

(a) In section 1(a), delete "section 6(b) of the Coast and Geodetic Survey Commissioned Officers Act of 1948 (62 Stat. 298; 33 U.S.C. 853e(b))" and insert in lieu thereof: "section 223(b) of the National Oceanic and Atmospheric Administration Commissioned Officer Corps Act of 2002 (Public Law 107–372; 33 U.S.C. 3023(b))".

(b) In section 1(b), delete "section 12(a) of the Coast and Geodetic Survey Commissioned Officers Act of 1948, as amended (75 Stat. 506; 33 U.S.C. 853j–1(a))" and insert in lieu thereof: "section 229(a) of the National Oceanic and Atmospheric Administration Commissioned Officer Corps Act of 2002 (Public Law 107–372; 33 U.S.C. 3029(a))".

(c) In section 1(c), delete "section 12(b) of the Coast and Geodetic Survey Commissioned Officers Act of 1948, as amended (75 Stat. 506; 33 U.S.C. 853j–1(b))" and insert in lieu thereof: "section 229(b) of the National Oceanic and Atmospheric Administration Commissioned Officer Corps Act of 2002 (Public Law 107–372; 33 U.S.C. 3029(b))".

(d) In section 1(d), delete "section 12(c) of the Coast and Geodetic Survey Commissioned Officers Act of 1948, as amended (75 Stat. 506; 33 U.S.C. 853j–1(c))" and insert in lieu thereof: "section 229(c) of the National Oceanic and Atmospheric Administration Commissioned Officer Corps Act of 2002 (Public Law 107–372; 33 U.S.C. 3029(c))".

(e) Section 1(e) shall be revised to read as follows: "The authority vested in the President by section 243(b) of the National Oceanic and Atmospheric Administration Commissioned Officer Corps Act of 2002 (Public Law 107–372; 33 U.S.C. 3043(b)), to defer the retirement of an officer of the National Oceanic and Atmospheric Administration serving in a rank above that of captain who has attained 62 years of age, but such a deferment may not extend beyond the first day of the month in which the officer becomes 64 years of age."

(f) Section 1(f) shall be revised to read as follows: "The authority vested in the President by section 244 of the National Oceanic and Atmospheric Administration Commissioned Officer Corps Act of 2002 (Public Law 107–372; 33 U.S.C. 3044), to retire from the active service any commissioned officer of the National Oceanic and Atmospheric Administration, upon his own application, who has completed 20 years of active service, of which at least 10 years was service as a commissioned officer."

(g) In section 1(g), delete "section 23(a) of the Coast and Geodetic Survey Commissioned Officers Act of 1948, as amended (75 Stat. 506; 33 U.S.C.

853t(a))" and insert in lieu thereof: "section 221(a)(4) of the National Oceanic and Atmospheric Administration Commissioned Officer Corps Act of 2002 (Public Law 107–372; 33 U.S.C. 3021(a)(4))".

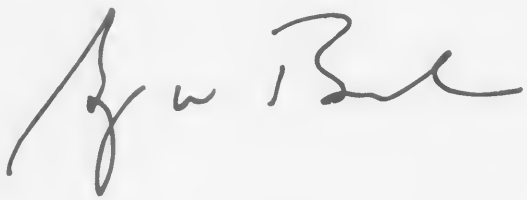
(h) In section 1(h), delete "section 1(1) of the Act of December 3, 1942 (56 Stat. 1038; 33 U.S.C. 854a–1(1))" and insert in lieu thereof: "section 230(b)(1) of the National Oceanic and Atmospheric Administration Commissioned Officer Corps Act of 2002 (Public Law 107–372; 33 U.S.C. 3030(b)(1))".

(i) In section 1(i), delete "section 1(2) of the Act of December 3, 1942 (56 Stat. 1038; 33 U.S.C. 854a–1(2))" and insert in lieu thereof: "section 230(b)(2) of the National Oceanic and Atmospheric Administration Commissioned Officer Corps Act of 2002 (Public Law 107–372; 33 U.S.C. 3030(b)(2))".

(j) Section 1(j) shall be revised to read as follows: "The authority contained in section 230(b)(3) of the National Oceanic and Atmospheric Administration Commissioned Officer Corps Act of 2002 (Public Law 107–372; 33 U.S.C. 3030(b)(3)), to appoint temporarily in all grades to which original appointments in the National Oceanic and Atmospheric Administration are authorized to fill vacancies caused by transfer of officers to the military departments."

(k) In section 1(k), delete "section 16 of the Act of May 22, 1917 (40 Stat. 87; 33 U.S.C. 855)" and insert in lieu thereof: "section 251 of the National Oceanic and Atmospheric Administration Commissioned Officer Corps Act of 2002 (Public Law 107–372; 33 U.S.C. 3061)", and delete the word "personnel" in the two places in which it appears and insert in lieu thereof: "officers".

**Sec. 2.** Section 1(m) is added to Executive Order 11023 to read as follows: "(m) The authority vested in the President by Public Law 96–215, as amended (10 U.S.C. 716(a)), to transfer any commissioned officer with his consent from his uniformed service to, and appoint him in, the National Oceanic and Atmospheric Administration, provided consent for the transfer is given by the Secretary of Defense, the Secretary of Homeland Security, or the Secretary of Health and Human Services, as applicable, in accordance with joint regulations issued under that statute establishing the policies and procedures for such transfers and appointments."



THE WHITE HOUSE,
*May 20, 2004.*

[FR Doc. 04–11991
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Billing code 3195–01–P

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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 "PLUS" (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal_register/public_laws/public_laws.html.*

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**S. 2315/P.L. 108–228**
To amend the Communications Satellite Act of 1962 to extend the deadline for the INTELSAT initial public offering. (May 18, 2004; 118 Stat. 644)
**Last List May 10, 2004**

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